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DEPARTMENT OF HOMELAND SECURITY

8 CFR Part 100

[CBP Dec. 25–17; Docket No. USCBP–2026–0133]

RIN 1651–AB64

Establishing the Gordie Howe International Bridge as a Port of Entry in Detroit, MI

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Final rule.

SUMMARY: This rule establishes the Gordie Howe International Bridge border crossing as a Class A port of entry for immigration purposes and as part of the port of Detroit for customs purposes. Establishing the Gordie Howe International Bridge border crossing is part of U.S. Customs and Border Protection's (CBP) continuing program to use its personnel, facilities, and resources more efficiently and to provide better service to carriers, importers, and the general public.

DATES: This final rule is effective March 2, 2026. CBP will notify the public when the Gordie Howe International Bridge border crossing is fully operational and open to the public for use through a notice published on the CBP website.

FOR FURTHER INFORMATION CONTACT: Joshua Serian, Office of Field Operations, U.S. Customs and Border Protection, (202) 713–8649, or by email at joshua.serian@cbp.dhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

As part of its continuing efforts to use personnel, facilities, and resources more efficiently, and to provide better service to carriers, importers, and the general public, U.S. Customs and Border Protection (CBP) is establishing the Gordie Howe International Bridge

border crossing as a Class A port of entry for immigration purposes and as part of the port of entry of Detroit for customs purposes. CBP ports of entry are locations where CBP officers and employees are assigned to accept entries of merchandise, clear passengers, collect duties, and enforce the various provisions of customs, immigration, agriculture, and related U.S. laws at the border. The term “port of entry” is used in the Code of Federal Regulations (CFR) in title 8 for immigration purposes and in title 19 for customs purposes.

For immigration purposes, 8 CFR 100.4(a) lists ports of entry for aliens arriving by vessel or by land transportation. These ports are listed according to location by district and are designated as Class A, B, or C, which designates which aliens may use the port. This rule establishes the Gordie Howe International Bridge border crossing as a Class A port of entry for immigration purposes in title 8 and makes that change at 8 CFR 100.4(a). Class A means the port is a designated port of entry for all aliens.

For customs purposes, CBP operates Customs ports of entry,¹ Customs service ports,² and Customs stations³ listed and described in part 101 of the CBP regulations (19 CFR part 101). See 19 CFR 101.3(b)(1), 101.3(b)(2), and 101.4(c). The Gordie Howe International Bridge border crossing is situated entirely within the corporate limits of

¹ A port of entry is defined in 19 CFR 101.1 as “any place designated by Executive Order of the President, by order of the Secretary of the Treasury, or by Act of Congress, at which a U.S. Customs and Border Protection (“CBP”) officer is authorized to accept entries of merchandise to collect duties, and to enforce the various provisions of the customs and navigation laws.” The authority of the Secretary of the Treasury referred to in this definition has been transferred to the Secretary of Homeland Security. Sections 403(l) and 411 of the Homeland Security Act of 2002 (“the Act,” Pub. L. 107–296, 6 U.S.C. 203(l), 211) transferred the United States Customs Service and its functions from the Department of the Treasury to the Department of Homeland Security.

² A service port is defined in 19 CFR 101.1 as “a Customs location having a full range of cargo processing functions, including inspections, entry, collections, and verification.”

³ A Customs station is defined in 19 CFR 101.1 as “any place, other than a port of entry, at which Customs officers or employees are stationed, under the authority contained in article IX of the President's Message of March 3, 1913 (T.D. 33249), to enter and clear vessels, accept entries of merchandise, collect duties, and enforce the various provisions of the Customs and navigation laws of the United States.”

the city of Detroit, Michigan, which is included in the port limits of Detroit. See 19 CFR 101.3(b)(1). Therefore, the Gordie Howe International Bridge border crossing will operate as a part of the port of entry of Detroit and will not be specifically listed in 19 CFR part 101.

II. The Gordie Howe International Bridge Project

In 2001, Transport Canada, the United States Federal Highway Administration, the Ontario Ministry of Transportation, and the Michigan Department of Transportation formed the Canada-United States-Ontario-Michigan Border Transportation Partnership (the Partnership) to identify and evaluate border infrastructure improvements in the Detroit, Michigan—Windsor, Ontario trade corridor, with a focus on the long-term studies needed to support this work. The study was completed in 2004 and included a broad range of recommendations, including the recommendation that a new or expanded international crossing be constructed and connected to highway networks on both sides of the border.

Following the completion of the study, the formal environmental assessment process was launched to develop a new or expanded Detroit-Windsor crossing. A coordinated environmental study process was developed to meet the legislative requirements of each jurisdiction. Through the environmental assessment process, the location for a new Detroit-Windsor crossing, associated border inspection facilities, and freeway connections were selected in both Canada and the United States.

In February 2015, Transport Canada, the Windsor-Detroit Bridge Authority, the General Services Administration, CBP, and the State of Michigan signed a non-binding arrangement which identified the roles and responsibilities of the Federal Government in areas of project requirements delivery, project funding and project management, and leasing. Infrastructure Canada replaced Transport Canada as the lead Canadian agency. In alignment with the arrangement detailed within the agreement, the Windsor-Detroit Bridge Authority provided funding for the design and construction of the Gordie Howe International Bridge and the U.S. Plaza.

Construction began in October of 2018. The final steps necessary prior to

opening the Gordie Howe International Bridge border crossing, including the assignment of CBP officers, have subsequently been completed.

III. Statutory and Regulatory Reviews

A. Inapplicability of Notice and Public Procedure Requirements

Under section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553), rulemaking generally requires prior notice and comment, subject to specified exceptions. Pursuant to 5 U.S.C. 553(b)(A), rules of agency organization, procedure, and practice are exempted from the notice and comment requirements of the APA. The “procedural exception” applies where a rule is “primarily directed towards improving the efficient and effective operations of an agency.”⁴ The purpose of the exception is to “ensure that agencies retain latitude in organizing their internal operations.”⁵ A critical feature of a rule that satisfies the procedural exception is that it does not alter the substantive rights or impose substantive burdens to parties subject to the rule.⁶

This rule is about the efficient allocation of CBP personnel to address the opening of a new entry into the United States.⁷ As needed, CBP establishes, expands, and consolidates ports of entry throughout the United States and assigns CBP officers and other personnel to accommodate the volume of CBP-related activity to effectively manage CBP’s mission of protecting the American people, safeguarding our borders, and enhancing the nation’s economic prosperity. This final rule relates to agency organization (5 U.S.C. 553(b)(A)) because it pertains to CBP’s organization of ports of entry to accommodate the opening of the Gordie Howe International Bridge, which provides an additional pathway for border crossings relating to international trade and immigration-related functions. The rule also implicates CBP’s organization, as it merely involves the distribution of CBP personnel and resources to the new crossing within the existing port limits of Detroit.

Further, this rule does not alter the substantive rights or interests of parties, including commercial and private vehicles seeking to enter the United States, as it has no impact on the determinations CBP personnel will be making regarding immigration or customs related matters at the crossing.⁸ Rather, as explained above, this rule merely modifies the organization of CBP’s personnel and resources at the newly opened crossing to more effectively address the activities that are already occurring along the border with Canada. Therefore, advance notice and comment are unnecessary because this rule satisfies the procedural exception. 5 U.S.C. 553(b)(A).

B. Executive Orders 12866, 13563, and 14192

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review) 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 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Executive Order 14192 (Unleashing Prosperity Through Deregulation) directs agencies to significantly reduce the private expenditures required to comply with Federal regulations and provides that “any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.”

The Office of Management and Budget (OMB) has not designated this rulemaking as a significant regulatory action under section 3(f) of Executive Order 12866. Accordingly, OMB has not reviewed it. Pursuant to section 5(a) of Executive Order 14192, the requirements of that Executive Order do not apply to regulations issued with respect to immigration-related functions of the United States. As discussed above, this rule is issued with respect to an immigration-related function of the United States Government (such as those functions to be performed at the Gordie Howe International Bridge border crossing with respect to aliens).

Additionally, pursuant to section 5(b) of Executive Order 14192, the requirements of that Executive Order do not apply to regulations related to agency organization. As discussed above, this rule is related to agency organization because the Gordie Howe International Bridge provides an additional pathway for border crossings relating to international trade and it involves the distribution of CBP personnel and resources to the new crossing within the existing port limits of Detroit. Accordingly, this rule is exempt from the requirements of Executive Order 14192.

However, this final rule is considered an Executive Order 14192 deregulatory action because it expands consumption and production options and is therefore an enabling regulatory action. See OMB’s Memorandum “Guidance Implementing Section 3 of Executive Order 14192, titled ‘Unleashing Prosperity Through Deregulation’” (March 26, 2025). Opening the Gordie Howe International Bridge border crossing increases production and consumption by easing the flow of traffic across the international border and increasing international trade. Additionally, the opening will create an average annual cost savings of \$5.1 million for personal vehicles and an average annual cost savings of \$7.6 million for commercial vehicles.

Purpose of the Rule

This rule will designate Gordie Howe International Bridge (GHIB) port of entry (POE) status as a Class A Port and as an immigration and customs port of entry. GHIB will be an international bridge connecting Detroit, Michigan, and Windsor, Ontario. The new construction includes a U.S. and Canadian Customs Plaza with associated roadway development. The bridge and crossing will be located 2 miles west of Ambassador Bridge and 4 miles from the Detroit-Windsor Tunnel. GHIB will be an innovative crossing as it will have a highway-to-highway connection. This seamless connection benefits the international trade industry and the public. Additionally, GHIB may bring new traffic into the area. The crossing is set to open in fiscal year (FY) 2026. The new crossing is planned to operate under the Windsor-Detroit Bridge Authority.

In the regulatory impact analysis herein, CBP discusses the existing crossings in the Detroit, Michigan area and how the new bridge will affect traffic patterns. The GHIB and associated construction are being built by state authorities and the Windsor-Detroit Bridge Authority. CBP is not

⁴ *Mendoza v. Perez*, 754 F.3d 1002, 1023 (D.C. Cir. 2014); *Batterton v. Marshall*, 648 F.2d 694, 702 n.34 (D.D.C. 1980) (“An internal agency ‘practice or procedure’ is primarily directed towards improving the efficient and effective operations of an agency, not toward a determination of the rights or interests of affected parties.”).

⁵ *Mendoza*, 754 F.3d at 1023 (quoting *Batterton*, 648 F.2d at 707).

⁶ *James V. Hurson Assocs., Inc. v. Glickman*, 229 F.3d 277, 280 (D.C. Cir. 2000) (internal quotation marks omitted).

⁷ *Mendoza v. Perez*, 754 F.3d at 1023.

⁸ *James V. Hurson Assocs., Inc. v. Glickman*, 229 F.3d 277, 280 (D.C. Cir. 2000) (“The critical feature of a rule that satisfies the so-called procedural exception is that it covers agency actions that do not themselves alter the rights or interests of parties, although it may alter the manner in which the parties present themselves or their viewpoints to the agency.”)

responsible for the construction of this facility. However, this rule will allow CBP to staff and operate the facility as a POE. As CBP begins to process traffic at GHIB, it will create benefits, cost savings, and costs for the public and CBP. In this analysis, CBP discusses relevant background information, costs, benefits, and net impact of this rule for all parties. Costs and benefits will be described in qualitative, and when possible, quantitative, and monetized terms.

Background

In fiscal year 2023, Detroit was the second largest U.S. freight port by value and was the largest on the U.S.-Canada border. It handled \$126 billion of value traded by commercial trucks.⁹ It also ranked second in total overall truck volume into the United States and first on the U.S.-Canada border, with 1,548,406 trucks entering the United

States in FY 2023.¹⁰ Currently, there are two land crossings that are operational in Detroit, Michigan—the Ambassador Bridge (AMB) and the Detroit-Windsor Tunnel (DWT). Additionally, Port Huron's Blue Water Bridge (BWB) is a viable alternative due to location and highway placement, so it is included in this analysis to account for traffic flows. Timely travel between the United States and Canada is imperative to facilitate international trade. Industries rely on deliveries between the two countries to maintain production levels. The next paragraphs will discuss each crossing and their historical traffic volumes.

Ambassador Bridge is a tolled suspension bridge that connects Detroit to Windsor. The AMB opened in 1930 with a predicted lifespan of 100 years. The 94-year-old bridge is currently under construction to extend its lifespan by 75 more years. Currently, the U.S.

border crossing facility has a maximum of 13 lanes to process commercial vehicles (COVs) and 17 lanes for passenger vehicles (POVs). However, all these lanes may not be open at the same time. Lanes are open/closed based on staffing, demand, and other factors.

In addition to AMB, there is the underwater Detroit-Windsor Tunnel that opened in 1930. It currently has 11 lanes, with 1 devoted to commercial vehicles with the remaining lanes used for POVs.

Lastly, Blue Water Bridge is an international crossing in Port Huron that crosses the St. Clair River, approximately 60 miles north of Detroit. It opened in 1938. At maximum operation, Blue Water Bridge has 9 commercial lanes and 7 passenger lanes.

Table 1 presents data on the levels of crossings by vehicle type for AMB, DWT, and BWB.¹¹

TABLE 1—DETROIT AREA & BLUE WATER BRIDGE HISTORICAL SOUTH BOUND CROSSINGS

Fiscal year	AMB		DWT		BWB	
	POV	COV	POV	COV	POV	COV
2010	2,317,955	1,434,904	1,656,471	0	1,603,130	689,502
2011	2,291,402	1,418,076	1,774,060	54,947	1,821,179	666,760
2012	2,248,255	1,486,471	1,908,647	40,215	1,961,278	685,417
2013	2,199,988	1,482,278	1,934,006	43,407	2,009,544	719,686
2014	2,097,123	1,502,999	1,954,513	39,217	1,966,384	761,311
2015	2,035,978	1,496,240	2,048,521	35,188	1,734,643	798,112
2016	1,910,264	1,566,291	2,148,006	34,350	1,572,286	833,810
2017	1,839,278	1,555,861	2,210,505	26,367	1,583,801	831,676
2018	2,097,747	1,556,653	1,890,476	22,340	1,553,230	819,856
2019	2,027,532	1,518,680	2,053,488	19,855	1,475,484	823,255
2020	1,095,065	1,352,415	1,124,632	13,400	616,818	723,797
2021	588,492	1,384,678	434,789	10,287	121,617	835,303
2022	964,229	1,388,712	1,143,098	19,131	578,075	884,593
2023	1,528,735	1,528,542	1,755,245	20,051	952,209	796,004
2024	1,736,254	1,472,790	1,913,455	18,482	1,028,978	880,887

Construction Costs

CBP will not be responsible for design, construction, maintenance, or rent of the new facility.¹² Additionally, the cost of both the bridge and Michigan Interchange (connecting ramps from I-75 to the U.S. POE and associated road improvements) will be covered by a 36-year design-build-finance-operate-maintain availability payment conception that will be managed by

Windsor-Detroit Bridge Authority, a not-for-profit owned by the Canadian Government.¹³ The total cost for the Canadian and U.S. POE, GHIB, the Michigan Interchange, and maintenance for 30 years is \$6.4B Canadian (\$4.7B USD) and will be recovered through toll revenues.^{14 15} The annual cost over the lifetime of the agreement (30 years) is approximately \$158,000,000 USD. As this final rule is not responsible for the cost of building the bridge or facility,

these costs will not be included in the analysis, nor is the toll that recovers those costs. This final rule will allow CBP to operate the facility as a POE and all associated costs or cost savings that stem from port operations will be reported in this analysis, including reduced travel time for the public, as this rule enables the public to access a faster travel route.

⁹ Data retrieved from the Department of Transportation's Border Crossing/Entry Data. Available at: https://explore.dot.gov/views/Dashboard_PortbyCommodity/PortsbyCommodities. Last accessed: June 12th, 2024.

¹⁰ Data retrieved from the Department of Transportation's Border Crossing/Entry Data. Available at: <https://data.bts.gov/Research-and-Statistics/Border-Crossings-by-Mode-Border-and-State/erjk-mneb>. Last accessed: June 13th, 2024.

¹¹ Note: CBP does not keep records of traffic exiting the United States (north bound traffic).

¹² Source for CBP costs: Data provided by CBP, Office of Field Operations, Fleet & Facilities Division, on March 25th, 2024. Note: Rent will be covered by tolls for the next 100 years (2025–2125); after this, CBP may or may not be responsible for rent costs.

¹³ Source for project funding: U.S. Department of Transportation Federal Highway Administration Project Profile. Available at: https://www.fhwa.dot.gov/ipd/project_profiles/mi_gordie_howe_int_bridge.aspx. Last accessed June 13th, 2024.

¹⁴ Source for tolls: Data provided by CBP, Office of Field Operations, Fleet & Facilities Division, on April 11th, 2024.

¹⁵ Canadian dollars are converted to U.S. dollars using the "Yearly Average Exchange Rates for Converting Foreign Currencies into U.S. Dollars". The yearly average exchange rate for Canada was 1.350 in 2023. Available at: <https://www.irs.gov/individuals/international-taxpayers/yearly-average-currency-exchange-rates>. Last accessed July 3rd, 2024.

Future Traffic Patterns—Baseline

In order to forecast future traffic shifts, we must establish a baseline of traffic over the period of analysis. The forecasted period will be FY2025 to FY2030, and we use data from FY2016 to FY2024 to inform our analysis of this period. This baseline will assume that Gordie Howe International Bridge was not built, and current traffic patterns remain constant. Additionally, we assume that no major unpredictable events (natural disaster, pandemic, etc.) occur in the future. To forecast years 2025–2030, we used growth rates from the “*Supplemental Travel Demand Modeling Technical Report*,” prepared for the Michigan Department of Transportation in April 2018.¹⁶ These growth rates can be found in Table 2.

While these growth rates were developed before the COVID–19 pandemic, CBP operational subject matter experts believe they are still a reasonable estimate of expected growth now that traffic has largely rebounded to pre-pandemic levels. The multiplier was found using the following formula:

$$\text{Multiplier} = 1 + \text{Growth Rate}.$$

To calculate the number of crossings for our target year, we multiply the previous year’s number of crossings by vehicle type by the corresponding multiplier. For example, to find the crossings in 2025 for the Ambassador Bridge, we used the following formula:

$$\text{AMB Crossings}_{\text{POV}, 2025} = \text{AMB}$$

$$\text{Crossings}_{\text{POV}, 2024} * \text{AMB multiplier}.$$

We repeated this calculation for each year in the scope of the analysis (2025–

2030). In order to account for all traffic (north and south bound), we assume that all traffic that enters the United States will also leave. This assumption is necessary as north bound (*i.e.*, outbound) traffic will experience benefits from this rule and quality data on outbound traffic is not available. In order to ensure that these benefits are recorded, south bound traffic data will be doubled. The results for each crossing by vehicle type are reported in Table 3. Table 4 calculates the traffic distributions by vehicle type for each crossing. This distribution is calculated by taking the number of crossings of each port and vehicle type then dividing total number of all crossings by vehicle type.

TABLE 2—PROJECTED GROWTH RATES

Crossing	Rate
AMB	0.0071
AMB multiplier	1.0071
DWT	0.0041
DWT multiplier	1.0041
BWB	0.0101
BWB multiplier	1.0101
GHIB	0.0082
GHIB multiplier	1.0082

Source: Supplemental Travel Demand Modeling Technical Report.

TABLE 3—BASELINE FORECAST IN THOUSANDS—NO GHIB

[North and south bound traffic]

Fiscal year	AMB		DWT		BWB		Total	
	POV	COV	POV	COV	POV	COV	POV	COV
2025	3,497	2,966	3,843	37	2,079	1,780	9,419	4,783
2026	3,522	2,988	3,858	37	2,100	1,798	9,480	4,822
2027	3,547	3,009	3,874	37	2,121	1,816	9,542	4,862
2028	3,572	3,030	3,890	38	2,142	1,834	9,605	4,902
2029	3,598	3,052	3,906	38	2,164	1,853	9,668	4,942
2030	3,623	3,073	3,922	38	2,186	1,871	9,731	4,982

TABLE 4—TRAFFIC SHARE DISTRIBUTION 2026—NO GHIB

POE	POV (%)	COV (%)
AMB	36.13	65.07
DWT	41.23	0.85
BWB	22.64	34.09

Future Traffic Patterns—Gordie Howe International Bridge

We next estimate the future traffic patterns taking into account that Gordie Howe International Bridge will open in FY 2026 and change traffic patterns as

vehicles select to use the new bridge. Again, the forecast will assume no major unpredictable events (natural disaster, pandemic, etc.) occur in the future. Traffic forecasts are based on the most recent years and do not factor in new traffic being brought into the area by

this crossing. If substantial growth occurs, then traffic may be higher at all crossings. However, there is not sufficient data to predict how new traffic will react to the GHIB crossing. Our analysis will assume that recent year trends continue and that growth

¹⁶ Mich. Dep’t of Transp., Supplemental Travel Demand Modeling Technical Report: Gordie Howe International Bridge 18 (2018).

rates from Table 2 are sufficient. The first step is to calculate the number of crossings by port and vehicle type in FY 2024. To do this, the number of crossings in 2024 is multiplied by the corresponding growth rate (see Table 2). When Ghib is complete in FY 2026 and is open to the public, traffic will disperse between all four potential crossings. To account for the shifting traffic flows, we use traffic distributions from the “*Preliminary Results of the Comprehensive Traffic and Toll Revenue Study for the DRIC Project Forecast Refresh and Update*” report prepared for the Michigan Department of Transportation.¹⁷ The aforementioned study estimates the distribution of traffic shares using the

weekday traffic volumes and vehicle type. Additionally, the estimates account for any weekend traffic or seasonal variations. The estimated traffic share distributions are in Table 5.¹⁸ Next, to determine the number of crossings at each port of entry in 2026, we multiply the forecasted number of crossings in 2025 for each vehicle type by their respective distribution and the respective growth rate in Table 2 (see example below). Total numbers of crossings are found by summing the number of crossings by port and vehicle type. To account for all traffic (north and south bound), we assume that all traffic that enters the United States will also leave. This assumption is necessary as north bound traffic will experience

benefits from this rule and quality data on outbound traffic is not available. To ensure that these benefits are recorded, south bound traffic data will be doubled. See Table 6.

$$AMB\ Crossings_{POV,2025} = Total\ Crossings_{POV,2024} * AMB\ POV\ Distribution * AMB\ Multiplier$$

To account for growth in traffic over time, we use the same methodology from the baseline section to calculate the growth for each crossing. This is done by multiplying the corresponding multiplier in Table 2 by the previous year's crossings. This process was repeated for years 2026–2030 and results for each crossing by vehicle type are reported in Table 6.

TABLE 5—TRAFFIC SHARE DISTRIBUTIONS WITH Ghib

POE	POV (%)	COV (%)
AMB	23.70	33.10
DWT	23.20	1.00
BWB	25.00	21.40
Ghib	28.10	44.50

Source: Preliminary Results of the Comprehensive Traffic and Toll Revenue Study for the DRIC Project Forecast Refresh and Update.

TABLE 6—FORECASTED TRAFFIC VOLUMES IN THOUSANDS—Ghib

Fiscal year	AMB		DWT		BWB		Ghib		Total	
	POV	COV	POV	COV	POV	COV	POV	COV	POV	COV
2025	3,497	2,966	3,843	37	2,079	1,780	*	*	9,419	4,783
2026	2,248	1,594	2,194	48	2,378	1,034	2,668	2,146	9,489	4,822
2027	2,264	1,606	2,203	48	2,402	1,044	2,690	2,164	9,560	4,862
2028	2,280	1,617	2,212	48	2,427	1,055	2,712	2,181	9,631	4,902
2029	2,296	1,629	2,221	49	2,451	1,066	2,734	2,199	9,703	4,942
2030	2,313	1,640	2,230	49	2,476	1,076	2,757	2,217	9,776	4,983

Costs

The construction of the new U.S. border crossing at Gordie Howe International Bridge will create new costs for CBP. Passenger and commercial vehicles will not experience new costs as a result of this regulation. In this section, CBP will discuss costs in qualitative and, when possible, quantitative and monetized terms.

CBP

CBP will be responsible for the costs of providing government furnished equipment (GFE) to the new border crossing facility. The cost of furnishing

the facility is estimated at \$55 million in FY 2026 and \$7.5 million each additional year. See Table 7 for total annual costs.

Additionally, CBP will be responsible for staffing the POE. Staffing levels for CBP are determined by Congress with nation-wide mission requirements and operational tempo driving the placement of personnel. CBP utilizes a Workload Staffing Model (WSM) to project frontline CBP officer staffing requirements at each of our POEs. The WSM is the initial, data-driven, step in the process of quantifying workload, uses transactional workload performed

at all POEs, and incorporates operational analysis, stakeholder reports, and scenario planning to ensure coverage of planned operations. As CBP continues to mitigate attrition and plan for projected increased retirements in FY 2028, CBP has implemented an efficient hiring strategy to ensure that it meets staffing goals while capitalizing on a healthy pipeline of dedicated applicants. CBP allocates new personnel to duty stations based on need, and CBP would hire positions regardless of the Ghib POE opening. Therefore, these costs will not be included in the analysis.

¹⁷ Source: Traffic Distributions are pulled from “Preliminary Results of the Comprehensive Traffic and Toll Revenue Study for the DRIC Project Forecast Refresh and Update—Traffic-Only Summary—May 2010” prepared for the Michigan DOT. Available at: <https://www.partnershipborderstudy.com/pdf/2-2010/DRIC>

%20Comprehensive%20TR%20Study%20Draft%20Final%20Report%20February%202010%20two-sided.pdf. Last accessed: July 3rd, 2024.

¹⁸ The “Preliminary Results of the Comprehensive Traffic and Toll Revenue Study for the DRIC Project Forecast Refresh and Update” was completed in May 2010 and assumes the new crossing will open

in 2015. However, due to delays the crossing will be completed in FY2026. In this economic analysis, the distributions for 2015 will be used. This will match the first year of the original study to the first year of Gordie Howe International Bridge's operation and account for the initial “ramp-up” period as traffic patterns shift over time.

TABLE 7—CBP ANNUAL COSTS TO OPERATE GHIB
[In 2024 undiscounted dollars]

Fiscal year	GFE
2020	\$0
2021	0
2022	0
2023	0
2024	0
2025	0
2026	55,000,000
2027	7,500,000
2028	7,500,000
2029	7,500,000
2030	7,500,000

Public: Passenger Vehicles & Commercial Vehicles

Users will pay a toll to use GHIB, but both passenger and commercial vehicles already pay a toll to use DWT, AMB, or BWB. The amount of the toll has not yet been set, but CBP believes that the tolls charged to use GHIB will be comparable

to the alternative routes. Additionally, the public will choose their best route based on personal preferences (toll costs, time, and distance), and to remain competitive, all routes will charge tolls that are close in costs. For this reason, tolls are not a new cost charged by this rule.

Total Costs

CBP is expected to experience an undiscounted average annual cost of \$17,000,000 as a result of this rule (2026–2030). Private and commercial vehicles will not experience any costs. See Table 8 for average annual costs and Table 9 for annual total costs.

TABLE 8—AVERAGE ANNUAL TOTAL COSTS
[In undiscounted 2024 dollars]

	Baseline period (2016–2025)	Regulatory period (2026–2030)
POV	\$0	\$0
COV	0	0
CBP	0	17,000,000

TABLE 9—ANNUAL TOTAL COSTS
[In undiscounted 2024 dollars]

Fiscal year	POV	COV	CBP
2026	\$0	\$0	\$55,000,000
2027	0	0	7,500,000
2028	0	0	7,500,000
2029	0	0	7,500,000
2030	0	0	7,500,000

Table 10 shows the discounted costs for POV, COV, and CBP as a result of the rule. CBP is projected to experience a

cost of \$85,000,000 and annualized costs between \$17,569,750 (3% discount rate) and \$18,326,923 (7% discount

rate). Private and commercial vehicles do not see any costs as a result of this rule.

TABLE 10—MONETIZED PRESENT VALUE AND ANNUALIZED COSTS, FY 2016–2024
[2024 U.S. dollars]

	Undiscounted costs	Net present value	Annualized costs
3% Discount Rate			
POV	\$0	\$0	\$0
COV	0	0	0
CBP	85,000,000	80,464,309	17,569,750
Total	85,000,000	80,464,309	17,569,750
7% Discount Rate			
POV	0	0	0
COV	0	0	0

TABLE 10—MONETIZED PRESENT VALUE AND ANNUALIZED COSTS, FY 2016–2024—Continued
[2024 U.S. dollars]

	Undiscounted costs	Net present value	Annualized costs
CBP	85,000,000	75,144,004	18,326,923
Total	85,000,000	75,144,004	18,326,923

Benefits & Cost Savings

Gordie Howe International Bridge will create benefits and cost savings for the public. In this section, CBP will discuss benefits for all parties in qualitative and, when possible, quantitative and monetized terms.

Public: Passenger Vehicles & Commercial Vehicles

The public will benefit greatly from the new crossing facility at GHIB. First, it provides a highway-to-highway connection that will reduce total travel time. Additionally, it will afford extra overall capacity to process vehicles that has the potential to reduce wait times at all border crossings in the area. The cost savings are quantifiable and will be described in monetary terms in this section.

However, there are several benefits that cannot be quantified and must be discussed qualitatively. Consequently, the total benefits may be larger than what the analysis captures in its quantitative calculations. Benefits may

increase if traffic grows at a faster rate than forecasted and substantial new traffic is brought into the area as a result of this new crossing. However, there is not sufficient data to predict the level of new traffic in the region. Additionally, if total traffic increases, the new crossing also has the potential to increase international trade between the United States and Canada. CBP does not have sufficient data to estimate the effect of GHIB on increasing international trade. Lastly, the highway-to-highway connection that the GHIB provides will reduce heavy traffic on small roads and may improve safety.

The first quantifiable cost savings is that the use of GHIB will reduce travel time when compared to AMB and DWT. In this analysis, we will use the two most likely routes as determined in a report for Michigan DOT.¹⁹ The first route is U.S. I–75 South to Canadian Highway 401 (Route 1) and the second is U.S. I–96 North to Canadian Highway 401 (Route 2). CBP does not have travel data on the usage of each route. We assume that half of the traffic will use

Route 1 and half will use Route 2. A map of each route is in the supporting documents titled “*Supplemental Material—Potential Routes in Detroit, Michigan*”. Table 11 reports the total distance and travel time compared with each crossing option (GHIB, AMB, DWT). Next, to determine the value of time savings that drivers will receive using GHIB, we must calculate the number of drivers diverting to GHIB from each existing crossing. We find this amount by multiplying the yearly traffic at GHIB by the traffic distributions in Table 2. See Table 12 for a breakdown by crossing and vehicle type. Annual time savings for POV and COV are then found by multiplying diverted traffic by the time savings in hours of the corresponding crossing and route. To monetize time savings, the hours that will be saved (Table 13) are multiplied by the corresponding hourly wage rate. For commercial truck drivers, the wage rate is \$33.50 and, for all purpose city travelers, it is \$26.60.²⁰ The values are reported in Table 14.

TABLE 11—TRAVEL TIME SAVINGS

Crossing	Direction	Distance (mile)	Travel time (min)	Time saving in hours	Change in dist.
Time Travel Savings between Highway 401 and I–75 South					
GHIB	To U.S	23.60	29.80		
AMB	To U.S	24.76	33.30	0.06	1.16
DWT	To U.S	26.01	37.60	0.13	2.41
GHIB	To Canada	23.50	27.00		
AMB	To Canada	24.60	29.70	0.05	1.10
DWT	To Canada	26.20	34.00	0.12	2.70
Time Travel Savings between Highway 401 and I–96 North					
GHIB	To U.S	25.60	29.40		
AMB	To U.S	24.20	30.10	0.01	– 1.40
DWT	To U.S	23.80	31.80	0.04	– 1.80
GHIB	To Canada	25.80	29.00		
AMB	To Canada	23.70	28.60	– 0.01	– 2.10
DWT	To Canada	24.10	31.60	0.04	– 1.70

¹⁹ Source for time savings, travel routes, and distance: “Preliminary Results of the Comprehensive Traffic and Toll Revenue Study for the DRIC Project Forecast Refresh and Update—Traffic-Only Summary—May 2010” prepared for the Michigan DOT. Available at: <https://www.partnershipborderstudy.com/pdf/2-2010/DRIC%20Comprehensive%20TR%20Study%20Draft%20Final%20Report%20February>

%202010%20two-sided.pdf. Last accessed June 13th, 2024.

²⁰ Source: U.S. Department of Transportation, Office of Transportation Policy. The Value of Travel Time Savings: Departmental Guidance for Conducting Economic Evaluations Revision 2 (2016 Update), “Table 4 (Revision 2—2016 Update): Recommended Hourly Values of Travel Time Savings.” September 27, 2016. The original hourly

value is provided in 2015 U.S. dollars, CBP adjusted this hourly rate to 2022 values using the methodology provided by DOT. Original DOT policy is available at <https://www.transportation.gov/sites/dot.gov/files/docs/2016%20Revised%20Value%20of%20Travel%20Time%20Guidance.pdf>. Last accessed: July 3rd, 2024.

TABLE 12—NUMBER OF VEHICLES DIVERTING TO GHIB ANNUALLY

Fiscal year	AMB		DWT	
	POV	COV	POV	COV
2026	632,388	710,315	619,046	21,460
2027	637,573	716,140	624,122	21,636
2028	642,801	722,012	629,240	21,813
2029	648,072	727,933	634,400	21,992
2030	653,386	733,902	639,602	22,172

TABLE 13—ANNUAL TIME SAVINGS BY VEHICLE TYPE AND CROSSING
[In hours]

Fiscal year	AMB		DWT	
	POV	COV	POV	COV
2026	17,127	19,238	51,071	1,770
2027	17,268	19,395	51,490	1,785
2028	17,409	19,554	51,912	1,800
2029	17,552	19,715	52,338	1,814
2030	17,696	19,877	52,767	1,829

TABLE 14—ANNUAL MONETIZED TIME SAVINGS FOR TRAFFIC DIVERTED TO GHIB
[In undiscounted 2024 dollars]

Fiscal year	AMB		DWT	
	POV	COV	POV	COV
2026	\$492,406	\$590,598	\$1,468,300	\$54,352
2027	496,444	595,440	1,480,340	54,798
2028	500,514	600,323	1,492,479	55,247
2029	504,619	605,246	1,504,717	55,700
2030	508,757	610,209	1,517,056	56,157

A new crossing has the potential to reduce wait times at all crossings (AMB, DWT, BWB) as traffic will disperse among the four potential routes. For the purpose of this analysis, we assume that wait times will change based on the percent change in traffic when compared to the baseline traffic in Table 3 and that Canadian wait times will be the same as the United States. To calculate the percentage change of traffic, the new level of traffic (Table 6) is divided by the baseline forecast (Table 3).²¹ The percentage is multiplied by the average wait time in FY2023

(Table 15) for each crossing and mode to calculate the new wait time. For example, in 2026 traffic for POVs at AMB will be 65.6% of the baseline forecast. We find this percentage by taking the projected POV traffic at AMB with GHIB built reported in Table 6 (2,248,034) and divide it by the baseline projected AMB traffic without GHIB built in Table 3 (3,521,993). We multiply this percentage by the historical wait time for POVs at AMB (0.07 hours) to find the new wait time of 0.04 hours. Projected wait times for all modes and crossings are reported in

Table 15. Next, time saved by crossing and mode of travel is found by subtracting the historical wait time from the projected wait time (Table 16). To calculate the total time saved per crossing, we multiply the corresponding time savings by the total traffic volumes, see Table 17. To monetize time savings, the hours that will be saved are multiplied by the corresponding hourly wage rate used above. See Table 18 for the value of time saved by reducing wait times.

TABLE 15—PROJECTED AND ACTUAL WAIT TIMES PER CROSSING
[In hours]

Fiscal year	AMB		DWT		BWB	
	POV	COV	POV	COV	POV	COV
2023 *	0.067	0.138	0.055	0.048	0.153	0.274
2024 **	0.067	0.138	0.055	0.048	0.153	0.274
2025 **	0.067	0.138	0.055	0.048	0.153	0.274
2026	0.043	0.074	0.031	0.000	0.000	0.158
2027	0.043	0.074	0.031	0.000	0.000	0.158

²¹ We find a slight increase in traffic for COVs at DWT and POVs at BWB under our model; this is likely due to using older studies to form our

estimates. However, no recent study exists and CBP does not have traffic data available to recalculate the traffic distribution estimates or traffic growth

rates. CBP will assume that the wait times in these categories will remain the same (time saving is equal to 0.00).

TABLE 15—PROJECTED AND ACTUAL WAIT TIMES PER CROSSING—Continued
[In hours]

Fiscal year	AMB		DWT		BWB	
	POV	COV	POV	COV	POV	COV
2028	0.043	0.074	0.031	0.000	0.000	0.158
2029	0.043	0.074	0.031	0.000	0.000	0.158
2030	0.043	0.074	0.031	0.000	0.000	0.158

* Denotes actual wait times.

** FY 2024 and FY 2025 wait times are assumed to stay the same as FY 2023.

TABLE 16—TIME SAVED BY REDUCING WAIT TIMES FOR INDIVIDUAL TRIP
[In hours]

Fiscal year	AMB		DWT		BWB	
	POV	COV	POV	COV	POV	COV
2026	0.02	0.07	0.02	0.00	0.00	0.10
2027	0.02	0.07	0.02	0.00	0.00	0.10
2028	0.02	0.07	0.02	0.00	0.00	0.10
2029	0.02	0.07	0.02	0.00	0.00	0.10
2030	0.02	0.07	0.02	0.00	0.00	0.10

TABLE 17—TOTAL TIME SAVED BY REDUCING WAIT TIMES
[In hours]

Fiscal year	AMB		DWT		BWB	
	POV	COV	POV	COV	POV	COV
2026	54,688	102,791	52,394	0	0	120,469
2027	55,076	103,521	52,608	0	0	121,686
2028	55,467	104,256	52,824	0	0	122,915
2029	55,861	104,996	53,041	0	0	124,156
2030	56,257	105,741	53,258	0	0	125,410

TABLE 18—ANNUAL MONETIZED TIME SAVINGS FOR REDUCED WAIT TIMES
[In undiscounted 2024 dollars]

Fiscal year	AMB		DWT		BWB	
	POV	COV	POV	COV	POV	COV
2026	\$1,572,267	\$3,155,678	\$1,506,317	\$0	\$0	\$3,698,404
2027	1,583,430	3,178,084	1,512,493	0	0	3,735,758
2028	1,594,672	3,200,648	1,518,694	0	0	3,773,489
2029	1,605,994	3,223,373	1,524,921	0	0	3,811,601
2030	1,617,397	3,246,259	1,531,173	0	0	3,850,098

Total Cost Savings

POVs are expected to experience an undiscounted average annual cost savings of \$5,106,598 as a result of this

rule (2026–2030). Additionally, COVs are expected to experience an undiscounted average annual cost savings of \$7,630,292 as a result of this

rule. CBP will not experience any benefit or cost savings. See Table 19 for average annual cost savings and Table 20 for annual total cost savings.

TABLE 19—AVERAGE ANNUAL TOTAL COST SAVINGS
[In undiscounted 2024 dollars]

	Baseline period (2016–2025)	Regulatory period (2026–2030)
POV	\$0	\$5,106,598
COV	0	7,630,292
CBP	0	0

TABLE 20—ANNUAL TOTAL COST SAVINGS
[In undiscounted 2024 dollars]

Fiscal year	POV	COV	CBP	Total
2016	\$0	\$0	\$0	\$0
2017	0	0	0	0
2018	0	0	0	0
2019	0	0	0	0
2020	0	0	0	0
2021	0	0	0	0
2022	0	0	0	0
2023	0	0	0	0
2024	0	0	0	0
2025	0	0	0	0
2026	5,039,289	7,499,032	0	12,538,321
2027	5,072,706	7,564,080	0	12,636,786
2028	5,106,359	7,629,707	0	12,736,067
2029	5,140,251	7,695,920	0	12,836,170
2030	5,174,382	7,762,723	0	12,937,105

No party will receive a benefit or cost savings before the opening of GHIB. In Table 21, the discounted cost savings are shown for POV and COV, as a result of this rule in 2026–2030. CBP will see no benefit or cost savings. POVs see annualized cost savings between \$5,102,037 (7% discount rate) and \$5,104,602 (3% discount rate). COVs will see annualized cost savings between \$7,621,391 (7% discount rate) and \$7,626,397 (3% discount rate).

TABLE 21—MONETIZED PRESENT VALUE AND ANNUALIZED COST SAVINGS, FY 2026–2030
[2024 U.S. dollars]

	Undiscounted cost savings	Present value	Annualized cost savings
3% Discount Rate			
POV	\$25,532,988	\$23,377,582	\$5,104,602
COV	38,151,461	34,926,665	7,626,397
CBP	0	0	0
Total	63,684,449	58,304,247	12,730,999
7% Discount Rate			
POV	25,532,988	20,919,360	5,102,037
COV	38,151,461	31,249,209	7,621,391
CBP	0	0	0
Total	63,684,449	52,168,569	12,723,429

Gordie Howe International Bridge will provide cost savings through reduced driving time and reduced wait times. In addition to these savings, there are several benefits that cannot be quantified. The estimated benefits may increase if traffic grows at a faster rate than forecasted or if substantial new traffic is brought to the area. Additionally, there may be increased international trade between the United States and Canada. Lastly, there may be an increase in public safety as traffic is diverted from smaller roads to large highways.

Net Impact

The net impact of the rule is calculated by subtracting the expected costs from the expected benefits. Table 23 provides estimates of the discounted net benefits of this rule from 2026–2030. POVs and COVs are expected to experience a total net benefit from 2026 to 2030 as a result of this rule. POVs will experience annualized net benefits of \$5,102,037 (7% discount rate) and \$5,104,602 (3% discount rate). COVs will experience annualized net benefits between \$7,621,391 (7% discount rate) and \$7,626,397 (3% discount rate). Lastly, CBP will have a total net cost as a result of this rule. The annualized net cost for CBP will be between \$17,569,750 (3% discount rate) and \$18,326,923 (7% discount rate). While the net effects of the rule are negative, the builders of the bridge and the governments of the United States and Canada believe that the new crossing will increase traffic over time to become a public benefit. Additionally, they believe that the new crossing will increase international trade between the two nations. While we lack the information needed to calculate these benefits, it is plausible that they would exceed the net costs estimated in this rule. Lastly, the highway-to-highway connection will reduce heavy traffic on small roads and may improve safety.

TABLE 22—NET BENEFIT—REGULATORY PERIOD
[In undiscounted 2024 dollars]

Fiscal year	POV	COV	CBP	Total
2026	\$5,039,289	\$7,499,032	– \$55,000,000	– \$42,461,679
2027	5,072,706	7,564,080	– 7,500,000	5,136,786
2028	5,106,359	7,629,707	– 7,500,000	5,236,067
2029	5,140,251	7,695,920	– 7,500,000	5,336,170
2030	5,174,382	7,762,723	– 7,500,000	5,437,105
Total	25,532,988	38,151,461	– 85,000,000	– 21,315,551
Average	5,106,598	7,630,292	– 17,000,000	– 4,263,110

TABLE 23—MONETIZED NET BENEFITS, FY 2026–2030
[2024 U.S. dollars]

	Undiscounted benefits	Three percent		Seven percent	
		Present value	Annualized cost	Present value	Annualized cost
POV	\$25,532,988	\$23,377,582	\$5,104,602	\$20,919,360	\$5,102,037
COV	38,151,461	34,926,665	7,626,397	31,249,209	7,621,391
CBP	– 85,000,000	– 80,464,309	– 17,569,750	– 75,144,004	– 18,326,923
Total	– 21,315,551	– 22,160,062	– 4,838,751	– 22,975,435	– 5,603,495

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), requires agencies to assess the impact of regulations on small entities. A small entity may be a small business (defined as any independently owned and operated business not dominant in its field that qualifies as a small business per the Small Business Act); a small not-for-profit organization; or a small governmental jurisdiction (locality with fewer than 50,000 people). This analysis is not mandated when an agency is exempted from notice and comment requirements. Since this document is not subject to the notice and comment requirements of 5 U.S.C. 553, it is not subject to the provisions of the Regulatory Flexibility Act. 5 U.S.C. 601 *et seq.*

D. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), an agency may not conduct, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number assigned by OMB. This regulatory action does not require additional information from the public and is not subject to the Paperwork Reduction Act of 1995.

E. Unfunded Mandates Reform Act of 1995

This rule will not result in new expenditures by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

F. Executive Order 13132

This rule will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

Signing Authority

The signing authority for this document falls under 19 CFR 0.2(a), which provides that the authority of the Secretary of the Treasury with respect to CBP regulations that are not related to customs revenue functions was transferred to the Secretary of DHS pursuant to section 403(1) of the Homeland Security Act of 2002 (Pub. L. 107–296, 116 Stat. 2178, 6 U.S.C. 203(1)). Accordingly, this final rule may

be signed by the Secretary of Homeland Security (or her delegate).

List of Subjects in 8 CFR Part 100

Organization and functions (Government agencies).

Amendments to the Regulations

For the reasons set forth above, DHS amends 8 CFR part 100 as follows:

PART 100—STATEMENT OF ORGANIZATION

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 8 U.S.C. 1103; 8 U.S.C. 1185 note (section 7209 of Pub. L. 108–458); 8 CFR part 2.

■ 2. In § 100.4(a), in the table under the headings “District No. 8—Detroit, Michigan” and “Class A” add, in alphabetical order, the entry for “Detroit, MI, Gordie Howe International Bridge” to read as follows:

§ 100.4 Field offices.

(a) * * *
* * * * *
District No. 8—Detroit, Michigan
Class A
* * * * *

Detroit, MI, Gordie Howe International Bridge

* * * * *

Kristi Noem,

Secretary of Homeland Security.

[FR Doc. 2026–01868 Filed 1–29–26; 8:45 am]

BILLING CODE 9111–14–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

[NRC–2025–0025]

RIN 3150–AL30

List of Approved Spent Fuel Storage Casks: NAC International, Inc., NAC–UMS® Universal Storage System, Certificate of Compliance No. 1015, Amendment No. 10, and Revision 1 to Amendment Nos. 5 Through 9

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is confirming the effective date of February 23, 2026, for the direct final rule that was published in the **Federal Register** on December 8, 2025. This direct final rule amended the certificate of compliance (CoC) to correct licensing basis deficiencies and updated the address in the CoC to reflect the new address of the applicant's headquarters offices.

DATES:

Effective date: The effective date of February 23, 2026, for the direct final rule published December 8, 2025 (90 FR 56657), is confirmed.

ADDRESSES: Please refer to Docket ID: NRC–2025–0025 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–2025–0025. Address questions about NRC dockets to Helen Chang; telephone: 301–415–3228; email: Helen.Chang@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at

<https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to PDR.Resource@nrc.gov. The revision of Certificate of Compliance No. 1015, the associated change(s) to the technical specification(s), and the final safety evaluation report(s) are available in ADAMS under Accession No. ML26007A266.

NRC's PDR: The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Amy McKenna, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; email: amy.mckenna@nrc.gov.

SUPPLEMENTARY INFORMATION: On December 8, 2025 (90 FR 56657), the NRC published a direct final rule amending its regulations in part 72 of title 10 of the *Code of Federal Regulations* to correct licensing basis deficiencies and updates the address in the CoC to reflect the new address of the applicant's headquarters offices.

In the direct final rule, the NRC stated that if no significant adverse comments were received, the direct final rule would become effective on February 23, 2026. The NRC received and docketed one comment on the companion proposed rule (90 FR 56697; December 8, 2025). An electronic copy of the comment can be obtained from the Federal Rulemaking website at <https://www.regulations.gov> under Docket ID NRC–2025–0025 and is also available in ADAMS under Accession No. ML26012A381. The NRC evaluated the comment against the criteria described in the direct final rule and determined that the comment was not significant and adverse. Specifically, the comment was outside the scope of this rulemaking. The comment did not raise a relevant issue that was not previously addressed or considered by the NRC. It did not cause the NRC to either reevaluate its position or conduct additional analysis. It did not propose a change or an addition to the rule or cause the NRC to make a change to the rule, the certificate of compliance, or the accompanying technical specifications.

Therefore, this direct final rule will become effective as scheduled.

Dated: January 27, 2026.

For the Nuclear Regulatory Commission.

Krupskaya Castellon,

Acting Chief, Regulatory Analysis and Rulemaking Support Branch, Division of Rulemaking, Environmental, and Financial Support Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2026–01842 Filed 1–29–26; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2026–0731; Project Identifier MCAI–2025–01864–R; Amendment 39–23248; AD 2026–02–12]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters Deutschland GmbH (AHD) Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Airbus Helicopters Deutschland GmbH (AHD) Model MBB–BK117 D–3 helicopters. This AD was prompted by a report of excessive wear on the bearing bolts, installed on the swashplate, connecting the cardan ring and the control ring assembly. This AD requires initial and repetitive inspections of the swashplate for vertical and radial play and, depending on the results of the inspections, corrective actions. This AD also prohibits installing any affected bolt unless the bolts are new or certain requirements are met. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective February 17, 2026.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of February 17, 2026.

The FAA must receive comments on this AD by March 16, 2026.

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

- *Federal eRulemaking Portal:* Go to [regulations.gov](https://www.regulations.gov). Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.

- **Mail:** U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

- **Hand Delivery:** Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

AD Docket: You may examine the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA-2026-0731; 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 mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For European Union Aviation Safety Agency (EASA) material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: ADs@easa.europa.eu; website: easa.europa.eu. You may find the EASA material on the EASA website at ad.easa.europa.eu.

- You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Parkway, Room 6N-321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222-5110. It is also available at [regulations.gov](https://www.regulations.gov) under Docket No. FAA-2026-0731.

FOR FURTHER INFORMATION CONTACT: Steven Warwick, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (817) 222-5225; email: steven.r.warwick@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments using a method listed under **ADDRESSES**. Include “Docket No. FAA-2026-0731; Project Identifier MCAI-2025-01864-R” at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments

received, without change, to [regulations.gov](https://www.regulations.gov), including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this final rule.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as “PROPIN.” The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Steven Warwick, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA Emergency AD 2025-0298-E, dated December 23, 2025 (EASA Emergency AD 2025-0298-E) (also referred to as the MCAI), to correct an unsafe condition on AHD Model MBB-BK117 D-3 and D-3m helicopters. The MCAI states that there was a report of excessive wear on the bearing bolts connecting the cardan ring and the control ring assembly discovered during maintenance. The MCAI further states that investigations are still ongoing and therefore repetitive inspections of the swashplate are necessary. Accordingly, EASA considers this MCAI an interim action and further action may follow.

The FAA is issuing this AD to prevent failure of the bearing bolts, which could result in loss of control of the helicopter.

You may examine the MCAI in the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA-2026-0731.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed EASA Emergency AD 2025-0298-E, which specifies procedures for inspecting the swashplates for vertical and radial play and depending on the inspection

results, replacing any affected bolts. EASA Emergency AD 2025-0298-E, also prohibits installing any affected bolt on any helicopter unless it is new or certain requirements have been met.

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.

FAA's Determination

These products have been approved by the civil aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, that authority has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA is issuing this AD after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

AD Requirements

This AD requires accomplishing the actions specified in EASA Emergency AD 2025-0298-E, described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this AD. See “Differences Between this AD and the MCAI” for a discussion of the general differences included in this AD.

Differences Between This AD and the MCAI

The MCAI applies to AHD Model MBB-BK117 D-3m helicopters, whereas this AD does not because that model does not have an FAA type certificate.

Interim Action

The FAA considers that this AD is an interim action. If final action is later identified, the FAA may consider further rulemaking action.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some CAA ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, EASA Emergency AD 2025-0298-E is incorporated by reference in this AD. This AD requires compliance with EASA Emergency AD 2025-0298-E in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this AD. Using common terms that are the

same as the heading of a particular section in EASA Emergency AD 2025–0298–E does not mean that operators need comply only with that section. For example, where the AD requirement refers to “all required actions and compliance times,” compliance with this AD requirement is not limited to the section titled “Required Action(s) and Compliance Time(s)” in EASA Emergency AD 2025–0298–E. Material required by EASA Emergency AD 2025–0298–E for compliance will be available at *regulations.gov* under Docket No. FAA–2026–0731 after this AD is published.

Justification for Immediate Adoption and Determination of the Effective Date

Section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) authorizes agencies to dispense with notice and comment procedures for rules when the agency, for “good cause,” finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under this section, an agency, upon finding good cause, may issue a final rule without providing notice and seeking comment prior to issuance. Further, section 553(d) of the APA authorizes agencies to

make rules effective in less than thirty days, upon a finding of good cause. An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies forgoing notice and comment prior to adoption of this rule because the swashplate is part of an assembly that is critical to the flight control of a helicopter, such that if failure occurs in the affected part, loss of control of a helicopter could occur. The FAA has no information pertaining to the extent of fatigue of the affected component that may currently exist in helicopters or how quickly the condition may propagate to failure. The initial compliance requirement for the swashplate inspection mandates completion within 830 hours time-in-service (TIS) since new accumulated by the bearing bolt, or within 10 hours TIS after the effective date of this AD, whichever occurs later. If the TIS since new of the bolt is unknown, the TIS since new of the swashplate must be used instead. An estimated 16 helicopters have already exceeded the 830 hours TIS threshold. Consequently, these helicopters are subject to the 10-

hour compliance timeframe, which is shorter than the time necessary for the public to comment and for publication of the final rule. Accordingly, notice and opportunity for prior public comment are impracticable and contrary to the public interest pursuant to 5 U.S.C. 553(b). In addition, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days, for the same reasons the FAA found good cause to forgo notice and comment. **Regulatory Flexibility Act** The requirements of the Regulatory Flexibility Act (RFA) do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because the FAA has determined that it has good cause to adopt this rule without prior notice and comment, RFA analysis is not required. **Costs of Compliance** The FAA estimates that this AD affects 55 helicopters of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspect swashplate	3 work-hours × \$85 per hour = \$255	\$0	\$255	\$14,025

The FAA estimates the following costs to do any replacements that would be required based on the results of the inspection. The agency has no way of determining the number of helicopters that might need these replacements:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replace bearing bolt	30 work-hours × \$85 per hour = \$2,550	\$700	\$3,250

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA’s authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs describes in more detail the scope of the Agency’s authority. The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds

necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action. **Regulatory Findings** 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, and (2) Will not affect intrastate aviation in Alaska. **List of Subjects in 14 CFR Part 39** Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety. **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 adding the following new airworthiness directive:

2026–02–12 Airbus Helicopters

Deutschland GmbH (AHD): Amendment 39–23248; Docket No. FAA–2026–0731; Project Identifier MCAI–2025–01864–R.

(a) Effective Date

This airworthiness directive (AD) is effective February 17, 2026.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Airbus Helicopters Deutschland GmbH (AHD) Model MBB–BK117 D–3 helicopters.

(d) Subject

Joint Aircraft System Component (JASC) Code 6230, Main Rotor Mast/Swashplate.

(e) Unsafe Condition

This AD was prompted by a report of excessive wear on the bearing bolts, installed on the swashplate, connecting the cardan ring and the control ring assembly. The FAA is issuing this AD to prevent failure of the bearing bolts. The unsafe condition, if not addressed, could lead to loss of control of the helicopter.

(f) Compliance

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

(g) Required Actions

Except as specified in paragraphs (h) and (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency Emergency AD 2025–0298–E, dated December 23, 2025 (EASA Emergency AD 2025–0298–E).

(h) Exceptions to EASA Emergency AD 2025–0298–E

(1) Where EASA Emergency AD 2025–0298–E refers to its effective date, this AD requires using the effective date of this AD.

(2) Where EASA Emergency AD 2025–0298–E requires compliance in terms of flight hours, this AD requires using hours time-in-service.

(3) Where EASA Emergency AD 2025–0298–E uses the term “new”, this AD requires replacing that term with “new (zero hours time-in-service)”.

(4) This AD does not adopt the “Remarks” section of EASA Emergency AD 2025–0298–E.

(i) No Reporting Requirement

Although the material referenced in EASA Emergency AD 2025–0298–E specifies to

submit certain information to the manufacturer, this AD does not require any of these actions.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation 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 manager of the International Validation Branch, send it to the attention of the person identified in paragraph (k) of this AD and email to: AMOC@faa.gov.

(2) 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.

(k) Additional Information

For more information about this AD, contact Steven Warwick, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (817) 222–5225; email: steven.r.warwick@faa.gov.

(l) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) Emergency AD 2025–0298–E, dated December 23, 2025.

(ii) [Reserved]

(3) For EASA material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: ADs@easa.europa.eu; website: easa.europa.eu. You may find the EASA material on the EASA website at ad.easa.europa.eu.

(4) You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Parkway, Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov.

Issued on January 22, 2026.

Steven W. Thompson,

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

[FR Doc. 2026–01878 Filed 1–29–26; 8:45 am]

BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0516; FRL 13148–01–OCSPP]

Chlorate; Exemption From the Requirement of a Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of chlorate (CAS Reg. No. 7775–09–9) in or on several food commodities. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), TriNova LLC submitted a petition to EPA requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of this pesticide when used in accordance with the terms of the exemption.

DATES: This rule is effective on January 30, 2026. Objections and requests for hearings must be received on or before March 31, 2026, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of this document).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2021–0516, is available online at <https://www.regulations.gov>. Additional information about dockets generally, along with instructions for visiting the docket center in person, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Kristen Willis, Antimicrobials Division (7510M), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: 202–566–0793; email address: ADFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document might apply to them:

- Crop production (NAICS code 111).

- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. What is EPA's authority for taking this action?

EPA is issuing this rulemaking under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. FFDCA section 408(c)(2)(A)(i) allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." FFDCA section 408(c)(2)(A)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue" Additionally, FFDCA section 408(b)(2)(D) requires that the Agency consider, among other things, "available information concerning the cumulative effects of a particular pesticide's residues" and "other substances that have a common mechanism of toxicity."

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. If you fail to file an objection to the final rule within the time period specified in the final rule, you will have waived the right to raise any issues resolved in the final rule. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify the docket ID number EPA-HQ-OPP-2021-0516 in the subject line on the first page of your

submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before March 31, 2026.

EPA's Office of Administrative Law Judges (OALJ), in which the Hearing Clerk is housed, urges parties to file and serve documents by electronic means only, notwithstanding any other particular requirements set forth in other procedural rules governing those proceedings. See "Revised Order Urging Electronic Filing and Service," dated June 22, 2023, which can be found at <https://www.epa.gov/system/files/documents/2023-06/2023-06-22%20%20revised%20order%20urging%20electronic%20filing%20and%20service.pdf>. Although EPA's regulations require submission via U.S. Mail or hand delivery, EPA intends to treat submissions filed via electronic means as properly filed submissions; therefore, EPA believes the preference for submission via electronic means will not be prejudicial. When submitting documents to the OALJ electronically, a person should utilize the OALJ e-filing system at https://yosemite.epa.gov/oa/eab/eab-alj_upload.nsf.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute. If you wish to include CBI in your request, please follow the applicable instructions at <https://www.epa.gov/dockets/commenting-epa-dockets#rules> and clearly mark the information that you claim to be CBI. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice.

II. Summary of Petitioned-For Exemptions

In the **Federal Register** of January 13, 2025 (90 FR 2661) (FRL 11682-11-OCSP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1F8916) by ICA TriNova LLC, 1 Beavers Street Suite B, Newman, GA 30263. The January 13, 2025 document superseded the Notice of Filing published on November 23, 2021 (86 FR 66152) (FRL 879-05-OCSP) regarding PP 1F8916. The petition requested that 40 CFR 180.1364 be amended by expanding the

exemption from the requirement of a tolerance for residues of chlorate to include the following crop groups: Crop Group 1 (root and tuber vegetables), Crop Group 3 (bulb vegetables, bulbs), Crop Group 8 (fruiting vegetables), Crop Group 9 (cucurbit vegetables), Crop Group 10 (citrus), Crop Group 11 (pome fruits), Crop Group 12 (stone fruits), Crop Group 13 (berries), Crop Group 14 (tree nuts), Crop Group 16 (forage, fodder, and straw of cereal grains), Crop Group 17 (grass forage, fodder, and hay), Crop Group 18 (non-grass animal feeds), Crop Group 21 (edible fungi), Crop Group 23 (tropical and subtropical fruits, edible peel), and Crop Group 24 (tropical and subtropical fruits, inedible peel). A summary in support of the petition is available in the docket (EPA-HQ-OPP-2021-0516), <https://www.regulations.gov>. Two public comments were received on the first Notice of Filing submitted on November 23, 2021, and one public comment was received on the Notice of Filing submitted on January 13, 2025, that superseded the November 23, 2021 Notice of Filing. The comment period for the November 23, 2021 Notice of Filing ended on December 23, 2021. The comment period for the January 13, 2025 Notice of Filing ended on February 12, 2025.

III. Final Tolerance Action

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for chlorate, including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with chlorate follows.

In an effort to streamline its publications in the **Federal Register**, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemaking of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemaking and republishing the same sections is unnecessary. EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA previously published a tolerance rulemaking for chlorate on December 26, 2018, in which the Agency

concluded that there is a reasonable certainty that no harm would result from aggregate exposure to chlorate and established exemptions for residues on tomatoes and cantaloupes. The publication of the rulemaking can be found at 83 FR 66138 (FRL-9986-85). EPA's assessment of safety in support of the 2018 rulemaking, *Risk Assessment of Tomato and Cantaloupe Fumigation with Sodium Chlorite 3.2% (chlorine dioxide gas)* (hereafter 2018 EPA Risk Assessment), is included in the docket for this current rulemaking, as it also supports this current rulemaking.

Since the time of the initial tolerance exemption, EPA has evaluated the potential for dietary exposures to chlorates in three different assessments: (1) an Agency memo that was signed on November 10, 2020, titled "Sodium Chlorate: Summary of Hazard and Science Policy Council (HASPOC) Meeting of October 15, 2020: Recommendations on Conducting a Qualitative Assessment of Chlorate and Waiving All Crop Chlorate Residue Data (hereafter "2020 EPA HASPOC memo"); (2) the Inorganic Chlorates Revised Draft Human Health Risk Assessment (DRA) in Support of Registration Review (hereafter "2021 EPA Revised DRA"), and (3) the 2022 crop expansion assessment titled Review of Petition, Residue Data Waiver, and Risk Assessment of 3.2% Sodium Chlorite (Chlorine Dioxide Gas) Fumigation for Crop Expansion (hereafter "2022 EPA Risk Assessment"), all of which are part of the docket for this current rulemaking. The Agency has concluded that there are no risks of concern from aggregate exposure to chlorate from currently registered uses. This conclusion is based on the following relevant conclusions from the three assessments mentioned above: (1) Chlorate residues in food are generally low and can be removed by washing; (2) aggregate exposure from food and drinking water were not of concern when quantitatively assessed in the 2018 EPA Risk Assessment; and (3) the main driver of the dietary assessment is from drinking water exposures from sanitation treatment.

A. Toxicological Profile and Points of Departure/Levels of Concern

Inorganic chlorates (also known as chlorate salts) encompass all chlorates, including sodium chlorate. As an antimicrobial pesticide, sodium chlorate (Pesticide Code (PC code) 073301) is used to generate a chlorine dioxide (PC Code 020503) solution in post-harvest applications to various crops. Sodium chlorate is also generated as a by-product of sodium chlorite (PC Code

020502) when it is used to generate chlorine dioxide for fumigation of crops post-harvest and during storage and shipment. Inorganic chlorates encompass all chlorates including the most abundant salt, sodium chlorate.

The toxicological profile for chlorate remains unchanged from the December 26, 2018 rulemaking and is available in the 2018 EPA Risk Assessment and the 2021 EPA Revised DRA. As discussed in the 2020 EPA HASPOC Memo, EPA conducted a qualitative assessment as part of the current tolerance action.

B. Exposure Assessment

1. *Dietary exposure from food and drinking water.* In support of the 2018 rulemaking, EPA performed a quantitative risk assessment on sodium chlorite at a 3.2% application rate as well as other uses with potential chlorate residue exposure (paper mill, drinking water, and conventional food uses). Based on the 2018 EPA Risk Assessment, the total dietary risks (including the use on tomatoes and cantaloupe, conventional herbicidal uses, paper mill dietary uses, and drinking water) are not of concern. The most highly exposed population was children 1–2 years of age which occupied 8.4% of the chronic population adjustment dose (cPAD) and was thus not of concern.

Following the 2018 EPA Risk Assessment and 2018 rulemaking, EPA determined that it would be more appropriate to assess the safety of chlorate tolerances with a qualitative dietary (food and drinking water) assessment for the reasons noted above (see "2021 EPA Revised DRA" and "2020 EPA HASPOC Memo"). The use of sodium chlorite on the additional crops at issue in this rule are not expected to meaningfully impact the previously assessed risk estimates, since residues can be washed off and the main driver of the dietary assessment is from drinking water exposures from sanitation treatment, which is not expected to change upon approval of these additional uses.

2. *From non-dietary exposure.* There are no residential (non-occupational) exposures associated with the new proposed uses and there are no registered uses of chlorate that result in non-occupational, residential exposure.

3. *Cumulative effects from substances with a common mechanism of toxicity.* EPA has not found inorganic chlorates to share a common mechanism of toxicity with any other substances, and sodium chlorate does not appear to produce a toxic metabolite produced by other substances. For a discussion, see

Unit III (C)(4) of the December 26, 2018 rulemaking.

C. Safety Factor for Infants and Children

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA concludes that a different margin of safety will be safe for infants and children. Because EPA is conducting a qualitative assessment without uncertainty factors, the additional 10X safety factor cannot be applied.

D. Aggregate Risks and Determination of Safety

In a quantitative risk assessment, EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate Margin of Exposure (MOE) exists.

The 2022 EPA Risk Assessment in support of this action is based on the 2018 EPA Risk Assessment (e.g., drinking water, pulp mill, FruitGard dietary use, drinking water), the 2021 EPA Revised DRA, the 2020 EPA HASPOC memo, and the supportive materials submitted with this petition. That assessment evaluates the aggregate exposure from existing uses and the new proposed fumigation uses on the additional crop groups. EPA has determined that the fumigation of additional crops is not expected to meaningfully increase dietary (food or drinking water) exposures or risks of chlorate from the active ingredient sodium chlorite (chlorine dioxide). This is primarily because (1) residues on food are expected to be low, based on other residue studies indicating that use on food results in low residues and the fact that residues can be removed by washing; (2) the drinking water from water treatment systems is the primary source of exposure to chlorate, which would not change based on these additional crops; and (3) EPA's Risk Assessment 2018, which already accounted for the drinking water exposure and limited expectation of residues on food, found that the residues would be safe.

Given that the previous quantitative assessment indicated a very low risk estimate, EPA concludes that aggregate exposure would continue to be safe with these new exemptions. Therefore, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to chlorate residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation for residues of chlorate in or on the listed food commodities.

B. Response to Comments

Two public comments were received on the first Notice of Filing that was published on November 23, 2021 and one public comment was received on the Notice of Filing that was published on January 13, 2025 that superseded the November 23, 2021 Notice of Filing. The comment period for the November 23, 2021 Notice of Filing ended on December 23, 2021. The comment period for the January 13, 2025 revised Notice of Filing ended on February 12, 2025.

Two public comments were received in response to the Notice of Filing published on November 23, 2021 (located under the Docket ID EPA-HQ-OPP-2021-0516 at <https://www.regulations.gov>). The first comment was submitted by the United Fresh Produce Association supporting the expansion of crop groups for products containing the active ingredient sodium chlorite as a post-harvest application of gaseous chlorine dioxide. The Agency acknowledges the comment from United Fresh Produce Association and support for the expansion of crop groups for the active ingredient sodium chlorite. The second comment was submitted by a member of the general public, and raised issues related to the safety of the tolerance exemption in this action, including the potential for thyroid gland tumors and neurotoxic effects in the available toxicity database for sodium chlorate. Furthermore, the commenter noted that chlorate has been banned in the European Union due to concerns that chlorate can decrease iodine uptake, causing thyroid problems.

With regard to potential thyroid effects, EPA explained in the 2018 rulemaking (and supporting risk assessments) that while there was some

evidence of thyroid gland tumors found in the drinking water study, EPA concluded that exposure to chlorate would not likely pose cancer risk because the Agency was regulating exposure at doses lower than the high doses required to induce tumors. *See* Chlorate; Pesticide Exemptions From Tolerance, 83 FR 66138, 66139 (FRL-9986-85, December 26, 2018). EPA conducted a quantitative assessment in which it concluded that risks would not exceed safe levels, (*i.e.*, the levels at which no chronic nor carcinogenic effects would be expected) and thus there is no expectation that exposure to chlorate would result in cancer. In this rule, EPA has concluded that the additional uses will not meaningfully increase residues of chlorate on food, and thus there is similarly no expectation that exposure to chlorate would result in thyroid gland tumors.

The commenter (Docket ID EPA-HQ-OPP-2021-0516) also states that sodium chlorate has not been evaluated for neurotoxic effects. As discussed in the 2018 EPA Risk Assessment, neurotoxic effects were not observed in any of the available acute, subchronic, and reproduction toxicity studies. Therefore, the potential for neurotoxic effects is not a concern for chlorate.

Regarding the supporting materials provided by the commenter, it is unclear to the Agency what specific points the materials are meant to support. The Dobson (2002) citation is a publication from the International Programme on Chemical Safety (IPCS)—a cooperative program of the World Health Organization (WHO), the International Labour Organization (ILO), and the United Nations Environment Programme (UNEP). It is not a study; therefore, the results reported in the publication cannot be used to reassess EPA's toxicological endpoints. Furthermore, none of the Agency's risk assessments found risk levels of concern for humans for the currently registered pesticidal uses of sodium chlorate. The Trinetta et al. (2011) study cited concludes, "(c)hlorine dioxide technology leaves minimal to no detectable chemical residues in several food products, thus result in no significant risks to consumers." Therefore, the Trinetta study seems to support the conclusions from the Agency's recent risk assessments (2021 EPA Revised DRA, 2022 EPA Risk Assessment).

Furthermore, the Agency acknowledges the commenter's concerns about environmental impacts, including potential toxicity to algae, but notes that this topic is not required for consideration for an EPA determination

of safety under the FFDCA, which stipulates only that EPA consider human health risks.

There was one public comment that was received in response to the revised Notice of Filing submitted on January 13, 2025 (located under the Docket ID EPA-HQ-OPP-2021-0516 at <https://www.regulations.gov>), from a member of the general public, supported the expansion of crop groups for products containing the active ingredient sodium chlorite as a post-harvest application of gaseous chlorine dioxide. The Agency acknowledges the public commenter's submission in support of expanding the tolerance exemption to cover certain crop groups for the active ingredient sodium chlorite.

In conclusion, the public comments do not include any information that alters the Agency's conclusion regarding the safety of the chlorate tolerance exemption.

C. Revisions to Petitioned-For Tolerances

The petitioner requested tolerances on several crop groups that have been updated. Specifically, crop groups 3, 8, 10, 11, 12, 13, 14, and 16 have been updated. As stated in EPA's regulations (40 CFR 180.40(j)(4)), once the revised crop group is established, EPA will no longer establish tolerances under pre-existing crop groups. As such, EPA is establishing the requested tolerance exemptions with the updated crop groupings which are supported by the Agency's qualitative assessments.

V. Conclusion

Therefore, an exemption from the requirement of a tolerance is established for residues of chlorate in or on commodities in the following crop groups: Vegetable, root and tuber, group 1; Vegetable, bulb, group 3-07; Vegetable, fruiting, group 8-10; vegetable, cucurbit, group 9; Fruit, citrus, group 10-10; Fruit, pome, group 11-10; Fruit, stone, group 12-12; Berry and small fruit, group 13-07; Nut, tree, group 14-12; Grain, cereal, forage, hay, stover, and straw, group 16-22; Grass, forage, fodder and hay, group 17; Animal feed, nongrass, group 18; Fungi, edible, group 21; Fruit, tropical and subtropical, edible peel, group 23; and Fruit tropical and subtropical, inedible peel, group 24.

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <https://www.epa.gov/laws-regulations/and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review

This action is exempt from review under Executive Order 12866 (58 FR 51735, October 4, 1993), because it establishes or modifies a pesticide tolerance or a tolerance exemption under FFDCA section 408 in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866.

B. Executive Order 14192: Unleashing Prosperity Through Deregulation

Executive Order 14192 (90 FR 9065, February 6, 2025) does not apply because actions that establish a tolerance under FFDCA section 408 are exempted from review under Executive Order 12866.

C. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA 44 U.S.C. 3501 *et seq.*, because it does not contain any information collection activities.

D. Regulatory Flexibility Act (RFA)

This action is not subject to the RFA, 5 U.S.C. 601 *et seq.* The RFA applies only to rules subject to notice and comment rulemaking requirements under the Administrative Procedure Act (APA), 5 U.S.C. 553, or any other statute. This rule is not subject to the APA but is subject to FFDCA section 408(d), which does not require notice and comment rulemaking to take this action in response to a petition.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of \$100 million or more (in 1995 dollars and adjusted annually for inflation) as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any State, local, or Tribal governments or the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have Tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is not a significant regulatory action under section 3(f)(1) of Executive Order 12866, and because EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children.

However, EPA's 2021 *Policy on Children's Health* applies to this action. This rule finalizes tolerance actions under the FFDCA, which requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . ." (FFDCA 408(b)(2)(C)). The Agency's consideration is documented in the pesticide-specific review documents, located in the applicable docket at <https://www.regulations.gov>.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211 (66 FR 28355) (May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer Advancement Act (NTTAA)

This action does not involve technical standards that would require Agency consideration under NTTAA section 12(d), 15 U.S.C. 272.

K. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801 *et seq.*, and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not

a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 26, 2026.

Edward Messina,

Director, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I is amended as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Revise § 180.1364 to read as follows:

§ 180.1364 Chlorate; exemption from the requirement of a tolerance.

Residues of chlorate in or on commodities in the following crop groups are exempt from the requirement of a tolerance when resulting from the application of gaseous chlorine dioxide as a fungicide, bactericide, or antimicrobial pesticide: Vegetable, root and tuber, group 1; Vegetable, bulb, group 3–07; Vegetable, fruiting, group 8–10; vegetable, cucurbit, group 9; Fruit, citrus, group 10–10; Fruit, pome, group 11–10; Fruit, stone, group 12–12; Berry and small fruit, group 13–07; Nut, tree, group 14–12; Grain, cereal, forage, hay, stover, and straw, group 16–22; Grass, forage, fodder and hay, group 17; Animal feed, nongrass, group 18; Fungi, edible, group 21; Fruit, tropical and subtropical, edible peel, group 23; and Fruit tropical and subtropical, inedible peel, group 24.

[FR Doc. 2026–01902 Filed 1–29–26; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2024–0157; FRL–13197–01–OCSPP]

PDHP 68949; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a

tolerance for residues of PDHP 68949 in or on all food commodities if used according to the label and good agricultural practices. Plant Health Care, Inc. submitted a petition to the EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of PDHP 68949 under FFDCA when used in accordance with this exemption.

DATES: This regulation is effective January 30, 2026. Objections and requests for hearings must be received on or before March 31, 2026 and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of this document).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2024–0157, is available at <https://www.regulations.gov>. Additional information about dockets generally, along with instructions for visiting the docket in-person, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Shannon Borges, Biopesticides and Pollution Prevention Division (7511M), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1400; email address: BPPDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is EPA's authority for taking this action?

EPA is issuing this rulemaking under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. FFDCA section 408(c)(2)(A)(i) allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is “safe.” FFDCA section 408(c)(2)(A)(ii) defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .” Additionally, FFDCA section 408(b)(2)(D) requires that the Agency consider, among other things, “available information concerning the cumulative effects of a particular pesticide’s residues” and “other substances that have a common mechanism of toxicity.”

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. If you fail to file an objection to the final rule within the time period specified in the final rule, you will have waived the right to raise any issues resolved in the final rule. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by the EPA, you must identify docket ID number EPA–HQ–OPP–2024–0157 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before March 31, 2026.

EPA’s Office of Administrative Law Judges (OALJ), in which the Hearing

Clerk is housed, urges parties to file and serve documents by electronic means only, notwithstanding any other particular requirements set forth in other procedural rules governing those proceedings. See “Revised Order Urging Electronic Filing and Service,” dated June 22, 2023, which can be found at <https://www.epa.gov/system/files/documents/2023-06/2023-06-22%20-%20revised%20order%20urging%20electronic%20filing%20and%20service.pdf>. Although EPA’s regulations require submission via U.S. Mail or hand delivery, EPA intends to treat submissions filed via electronic means as properly filed submissions; therefore, EPA believes the preference for submission via electronic means will not be prejudicial. When submitting documents to the OALJ electronically, a person should utilize the OALJ e-filing system at https://yosemite.epa.gov/OA/EAB/EAB-ALJ_upload.nsf.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute. If you wish to include CBI in your request, please follow the applicable instructions at <https://www.epa.gov/dockets/commenting-epa-dockets#rules> and clearly mark the information that you claim to be CBI. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice.

II. Petitioned-For Exemption

In the **Federal Register** of May 3, 2024 (89 FR 36737) (FRL–11682–03–OCSPP), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance exemption petition (PP 3F9091) by Plant Health Care, Inc., 242 South Main Street, Suite 216, Holly Springs, NC 27540. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of the biochemical pesticide PDHP 68949 in or on all food commodities. That notice referenced a summary of the petition prepared by the petitioner Plant Health Care, Inc., which is available in the docket. EPA did not receive any comments in response to the notice of filing.

III. Final Tolerance Actions

A. EPA's Safety Determination

EPA evaluated the available toxicological and exposure data on PDHP 68949 and considered their validity, completeness, and reliability, as well as the relationship of this information to human risk. A full explanation of the data upon which the EPA relied and its risk assessment based on those data can be found within the document entitled "Human Health Risk Assessment in Support of the Registration of PHC 68949 End Use Product Containing the New Active Ingredient PDHP 68949 (1%) and Associated Petition to Establish a Permanent Tolerance Exemption" (Human Health Risk Assessment). This document, as well as other relevant information, is available in the docket for this action as described under

ADDRESSES.

PDHP 68949 is a modified peptide derived from a bacterial harpin protein that acts as a plant growth regulator and activates resistance to nematodes in treated plants (PDHP refers to peptide derived from harpin protein). Harpins are naturally occurring proteins expressed by certain phytopathogenic bacteria that stimulate the innate immune response in plants, commonly referred to as systemic acquired resistance (SAR), which increases the general ability of plants to respond to infections and some soil-borne pests.

EPA used a weight-of-evidence approach, considering available hazard and exposure data, to assess the risk to human health from the use of products containing the active ingredient PDHP 68949. The active ingredient is intended for direct applications to a wide range of plants, including ornamentals, turf, conifers and trees in commercial nurseries, plantation forests, landscapes and parks, as well as agricultural crops as foliar, seed, and root treatments. Accordingly, dietary exposure may result from consumption of treated foods. However, any risks associated with dietary exposures are expected to be negligible because PDHP 68949 is of low oral toxicity, does not exhibit protein homology to putative or known allergens, and is readily digested in both simulated gastric fluids and simulated intestinal fluids containing only chymotrypsin. In addition, there is an expectation of lability of PDHP 68949 in the environment. PDHP 68949 is a protein, which is a biological substance that is subject to biodegradation and decay through mechanisms such as photodegradation, hydrolysis, and active degradation through microbial activity in the environment. Further,

food crops undergo a post-harvest washing process to remove soil and surface residues, therefore reducing the amounts of PDHP 68949 on the treated crops. Seed and root treatments are expected to result in negligible exposures of above-ground plant parts to PDHP 68949. Exposure through drinking water is expected to be negligible because the PDHP 68949 peptide is expected to be susceptible to biodegradation, degradation due to environmental conditions, and water treatment processes.

To assess hazard, an acute oral toxicity study was conducted on the end-use product, PHC 68949, 1% active ingredient PDHP 68949, because the product is manufactured using an integrated process, meaning that the active ingredient is never isolated in the process. The acute oral toxicity study found no toxicity or adverse effects from PHC 68949 and was classified as EPA Toxicity Category IV, indicating minimal toxicity.

One method of assessing allergenicity is to search for homologous sequences (*i.e.*, amino acid similarity) of a protein of interest to known allergenic proteins in databases that contain peer-reviewed protein sequences from allergenic proteins. Matches of greater than 35% identity over 80 amino acids are considered to be indicative of a potential for cross-reactivity. Sometimes a contiguous eight amino acid sequence is also used as an indicator. An analysis of PDHP 68949 found no alignments with greater than 35% identity over 80 contiguous amino acids or eight amino acid exact matches. These data indicate that there is negligible likelihood for cross reactivity of PDHP 68949 with any known allergen sequences deposited in these databases.

To further address the potential allergenicity of PDHP 68949, a gastrointestinal stability study of PHC 68949 was conducted. Proteins are broken into their amino acid components upon ingestion and subsequently used as a nutritional source. Some proteins are more stable in the gastrointestinal tract than others, and it is thought that this relative stability may increase the likelihood of sensitization potential to the protein (*i.e.*, its allergenic potential). Therefore, peptide lability was simulated by incubating PHC 68949 peptide in simulated gastric fluids (pepsin) and simulated intestinal fluids (chymotrypsin) to simulate digestion and assess degradation. Pepsin began to digest PHC 68949 quickly within one minute with a fraction present until 20 minutes. Chymotrypsin fully digested PHC 68949 within five minutes, again

with digestion starting at one minute. Both enzymatic digestions were not conducted at the recommended body temperature (37 °C) to mimic real-world conditions, but rather at suboptimal temperatures (between 0 °C and 25 °C) for both pepsin and chymotrypsin activity, thus skewing the results towards slower digestion in the assay compared to what would be expected to occur upon ingestion of the peptide. Together, the data show that PDHP 68949 is expected to be labile in the gastric system, albeit at a faster rate than indicated by the two assays.

Exposure of bystanders may occur with landscaping, turf, and in field uses, especially when applied aerially. In those cases, exposure may result from spray drift and are likely to be minimal as, per the label instructions, application may only occur in low wind conditions and medium and coarse droplet sizes are to be used. Additionally, both the aerial application rate (0.5–3 ounces/acre) and frequency (every 2–4 weeks) are low. Should significant non-occupational exposures occur, the results of the mammalian inhalation and oral (and by extension dermal) toxicology testing performed with the end-use product demonstrated PDHP 68949 is of low toxicity. Therefore, a quantitative non-occupational exposure assessment was not performed for PDHP 68949. The proposed end-use product does not include residential (non-occupational) uses of PDHP 68949; therefore, no exposure is expected, and residential and post-application risk assessments have not been conducted.

Although FFDCA section 408(b)(2)(C) provides for an additional tenfold margin of safety for infants and children in the case of threshold effects, EPA has determined that there are no such effects due to the negligible hazard of PDHP 68949. As a result, an additional margin of safety for the protection of infants and children is unnecessary.

B. Analytical Enforcement Methodology

An analytical method is not required for PDHP 68949 because the EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation.

C. Conclusion

Based upon its evaluation in the Human Health Risk Assessment, the EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of PDHP 68949. Therefore, an exemption from the requirement of a tolerance is established for residues of

PDHP 68949 in or on all food commodities.

IV. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <https://www.epa.gov/regulations-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review

This action is exempt from review under Executive Order 12866 (58 FR 51735, October 4, 1993), because it establishes or modifies a pesticide tolerance or a tolerance exemption under FFDCA section 408 in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866.

B. Executive Order 14192: Unleashing Prosperity Through Deregulation

Executive Order 14192 (90 FR 9065, February 6, 2025) does not apply because actions that establish a tolerance under FFDCA section 408 are exempted from review under Executive Order 12866.

C. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA, 44 U.S.C. 3501 *et seq.*, because it does not contain any information collection activities.

D. Regulatory Flexibility Act (RFA)

This action is not subject to the RFA, 5 U.S.C. 601 *et seq.* The RFA applies only to rules subject to notice and comment rulemaking requirements under the Administrative Procedure Act (APA), 5 U.S.C. 553, or any other statute. This rule is not subject to the APA but is subject to FFDCA section 408(d), which does not require notice and comment rulemaking to take this action in response to a petition.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of \$100 million or more (in 1995 dollars and adjusted annually for inflation) as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10,

1999), because it will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is not a significant regulatory action under section 3(f)(1) of Executive Order 12866 (See Unit IV.A.), and because EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. However, EPA's 2021 Policy on Children's Health applies to this action. This rule finalizes an exemption from the requirement of a tolerance under the FFDCA, which requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . ." (FFDCA 408(b)(2)(C)). The Agency's consideration is documented in Unit III.A.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211 (66 FR 28355) (May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer Advancement Act (NTTAA)

This action does not involve technical standards that would require Agency consideration under NTTAA section 12(d), 15 U.S.C. 272.

K. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801 *et seq.*, and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 26, 2026.

Edward Messina,

Director, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, the EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Add § 180.1422 to subpart D to read as follows:

§ 180.1422 PDHP 68949; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of PDHP 68949 in or on all food commodities when used in accordance with label directions and good agricultural practices.

[FR Doc. 2026–01901 Filed 1–29–26; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 423

[EPA–HQ–OW–2009–0819; FRL–8794.3–05–OW]

RIN 2040–AG54

Effluent Limitations Guidelines and Standards for the Steam Electric Power Generating Point Source Category—Deadline Extensions; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correction.

SUMMARY: The U.S. Environmental Protection Agency (the EPA or Agency) is issuing a notice to correct some of the deadlines listed in the final rule, "Effluent Limitations Guidelines and

Standards for the Steam Electric Generating Point Source Category—Deadline Extensions,” which published in the **Federal Register** on December 31, 2025. After publication, the EPA became aware of post-signature typographical errors in the published regulatory text concerning compliance deadlines for pretreatment standards and related reporting recordkeeping requirements in the rule. This correction will ensure that the rule’s compliance deadlines and reporting and recordkeeping deadlines match those in the version of the rule signed by the EPA Administrator.

DATES: Effective on March 2, 2026.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OW–2009–0819. All documents in the docket are listed on the <https://www.regulations.gov> website. Although listed in the index, some information is not publicly available, *e.g.*, confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through <https://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Richard Benware, Engineering and Science Division, Office of Water (Mail Code 4303T), Environmental Protection Agency, 1200 Pennsylvania Avenue NW; Washington, DC 20460; telephone number: 202–566–1369; email address: benware.richard@epa.gov. Information about the Steam Electric Effluent Limitations Guidelines and Standards (ELGs) is available online at: <https://www.epa.gov/eg/steam-electric-power-generating-effluent-guidelines>.

SUPPLEMENTARY INFORMATION: The final rule, “Effluent Limitations Guidelines and Standards for the Steam Electric Generating Point Source Category—Deadline Extensions,” which published in the **Federal Register** on December 31, 2025 (90 FR 61328), contained several typographical errors that were introduced during the publication process. These typographical errors, which appear in 40 CFR 423.16 and 423.19, pertain to compliance dates for achievement of certain pretreatment standards. These errors do not reflect the correct dates set forth in the rule, as signed by the EPA Administrator on December 23, 2025. This action ensures that the correct dates appear in the CFR. The Agency finds that it has good cause under section 553(b)(B) of the Administrative Procedure Act, 5 U.S.C. 553, to dispense with notice and

comment on this correction because it is unnecessary, as the correction merely redresses a typographical error in the regulatory text made by OFR in the post-signature publication process. Moreover, as the correction is being made before the effective date of the Deadline Extensions Rule, there should be no confusion as to the applicable compliance dates.

Corrections

■ 1. Effective March 2, 2026, in rule document 2025–24102 at 90 FR 61328 in the issue of December 31, 2025, on page 61353, in the second column, in amendatory instruction 3, paragraphs (e)(3), (g)(3), and (j)(1) are corrected to read as follows:

§ 423.16 [Corrected]

(e) * * *

(3) *2024 PSES.* Except as provided for in paragraph (e)(4) of this section, for any electric generating unit with a total nameplate generating capacity of more than 50 megawatts and that is not an oil-fired unit:

(i) Dischargers must meet the standards in paragraph (e)(1) of this section by January 1, 2029. The standards in paragraph (e)(1) of this section apply to the discharge of FGD wastewater generated on and after January 1, 2029.

(ii) By the dates in paragraph (e)(3)(ii)(A) or (B) of this section there shall be no discharge of pollutants in FGD wastewater:

(A) January 2, 2029; or

(B) Where a certification statement has been submitted pursuant to § 423.19(p), December 31, 2034.

* * * * *

(g) * * *

(3) *2024 PSES.* Except as provided for in paragraph (g)(4) of this section, for any electric generating unit with a total nameplate generating capacity of more than 50 megawatts and that is not an oil-fired unit:

(i) Dischargers must meet the standards in paragraph (g)(1) of this section by January 1, 2029. The standards in paragraph (g)(1) of this section apply to the discharge of bottom ash transport water generated on and after January 1, 2029.

(ii) By the dates in paragraph (g)(3)(ii)(A) or (B) of this section, there shall be no discharge of pollutants in bottom ash transport water:

(A) January 2, 2029; or

(B) Where a certification statement has been submitted pursuant to § 423.19(p), December 31, 2034.

* * * * *

(j) * * *

(1) *2024 PSES.* Until and including the dates specified in paragraphs (j)(1)(i) and (ii), or paragraph (j)(2) of this section, the EPA is declining to establish PSES for combustion residual leachate and is reserving such standards to be established by the control authority on a case-by-case.

(i) Except for those discharges to which paragraph (j)(1)(ii) of this section applies, by the dates in paragraph (j)(1)(i)(A) or (B) of this section, there shall be no discharge of pollutants in combustion residual leachate:

(A) January 2, 2029; or

(B) Where a certification statement has been submitted pursuant to section 423.19(p), December 31, 2034.

(ii) After the retirement of all units at a facility, the quantity of pollutants in CRL shall not exceed the quantity determined by multiplying the flow of CRL permeate times the concentrations listed in the table 7 to § 423.13(g)(3)(i) or the flow of CRL distillate times the concentrations listed in the table in § 423.15(b)(13).

■ 2. Effective March 2, 2026, in rule document 2025–24102 at 90 FR 61328 in the issue of December 31, 2025, on page 61354, in the first column, in amendatory instruction 5, paragraph (p) is corrected to read as follows:

§ 423.19 [Corrected]

(p) *Requirements for facilities subject to zero discharge pretreatment standards for existing sources by 2034.* For sources seeking to be subject to the second tier of the tiered standards in § 423.16(e)(3)(ii)(B), (g)(3)(ii)(B), or (j)(2)(i)(B), a certification statement shall be submitted to the control authority by January 1, 2029, stating that the facility has submitted a permit application, permit renewal application, or permit modification request to its permitting authority seeking an as soon as possible date for achieving the corresponding generally applicable zero discharge limitations in § 423.13(g)(4)(i), (k)(4)(i), or (l)(1)(i), subject to the considerations in § 423.11(t). Furthermore, the certification statement will include an affirmative statement that the facility will also cease its indirect discharge by the as soon as possible date determined in this permitting action.

* * * * *

Jessica L. Kramer,

Assistant Administrator.

[FR Doc. 2026–01913 Filed 1–29–26; 8:45 am]

BILLING CODE 6560–50–P

**FEDERAL COMMUNICATIONS
COMMISSION****47 CFR Parts 80 and 88**

[GN Docket No. 25–133; FCC 25–77; FR ID 328173]

Delete, Delete, Delete; Withdrawal

AGENCY: Federal Communications Commission.

ACTION: Direct final rule; partial withdrawal.

SUMMARY: The Federal Communications Commission published a direct final rule in the **Federal Register** on December 12, 2025, concerning the elimination of certain outdated, obsolete, and unnecessary rules. The Commission identified rules for repeal that plainly no longer serve the public interest because they are duplicative, outdated, or unnecessary. However, this document identifies certain rule deletions from the direct final rule that either drew “significant adverse” public comments or that the Commission itself

has determined require additional notice and comment procedures. This document provides notice that the repeal instructions for these specific rules and rule parts are withdrawn, and the rules are retained.

DATES: Effective February 10, 2026.

ADDRESSES: Federal Communications Commission, 45 L Street NE, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Thomas Reed, Wireless Telecommunications Bureau, Mobility Division, (202) 418–0531 or *Thomas.Reed@fcc.gov*.

SUPPLEMENTARY INFORMATION: The Commission is partially withdrawing provisions of the direct final that published in the **Federal Register** of December 12, 2025, and is effective February 10, 2026. In the direct final rule that published at 90 FR 57698, remove the following amendatory instructions:

1. On page 57707, in the second column, remove amendatory

instructions 130 (§ 80.71) and 134 (§ 80.86).

2. On page 57707, in the third column, remove amendatory instructions 135 (§ 80.96), 143 (§ 80.159), and 144 (§ 80.175).

3. On page 57709, in the first column, remove amendatory instructions 150 (§ 80.314), 152 (§ 80.333), and 159 (§ 80.409).

4. On page 57709, in the second column, remove amendatory instruction 171 (§ 80.953).

5. On page 57709, in the third column, remove amendatory instruction 173 (§ 80.1114).

6. On page 57710, in the first column, remove amendatory instruction 187 (§ 88.111).

Dated: January 28, 2026.
Federal Communications Commission.

Marlene Dortch,
Secretary.

[FR Doc. 2026–01884 Filed 1–29–26; 8:45 am]

BILLING CODE 6712–01–P

Proposed Rules

Federal Register

Vol. 91, No. 20

Friday, January 30, 2026

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 TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2026-0735; Project Identifier MCAI-2025-00162-T]

RIN 2120-AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2024-24-10, which applies to certain Airbus SAS Model A318 and Model A320 series airplanes; Model A319-111, -112, -113, -114, -115, -131, -132, -133, -151N, -153N, and 171N airplanes; and Model A321-111, -112, -131, -211, -212, -213, -231, -232, -251N, -251NX, -252N, -252NX, -253N, -253NX, -271N, -271NX, -272N, and -272NX airplanes. AD 2024-24-10 requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. Since the FAA issued AD 2024-24-10, the FAA has determined that new or more restrictive airworthiness limitations are necessary. This proposed AD would continue to require certain actions in AD 2024-24-10 and would require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. This proposed AD would also add Model A319-173N and Model A321-253NY airplanes to the applicability. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by March 16, 2026.

ADDRESSES: You may send comments, using the procedures found in 14 CFR

11.43 and 11.45, by any of the following methods:

- **Federal eRulemaking Portal:** Go to [regulations.gov](https://www.regulations.gov). Follow the instructions for submitting comments.

- **Fax:** 202-493-2251.

- **Mail:** U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

- **Hand Delivery:** Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

AD Docket: You may examine the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA-2026-0735; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For European Union Aviation Safety Agency (EASA) material identified in this proposed AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email ADS@easa.europa.eu. You may find this material on the EASA website at ad.easa.europa.eu. It is also available at [regulations.gov](https://www.regulations.gov) under Docket No. FAA-2026-0735.

- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206-231-3195.

FOR FURTHER INFORMATION CONTACT:

Frank Carreras, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206-231-3539; email: frank.carreras@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments using a method listed under the **ADDRESSES** section. Include “Docket No. FAA-2026-0735; Project Identifier MCAI-2025-00162-T” at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the

reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as “PROPIN.” The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Frank Carreras, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206-231-3539; email: frank.carreras@faa.gov. Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued AD 2024-24-10, Amendment 39-22900 (89 FR 97505, December 9, 2024) (AD 2024-24-10), for certain Airbus SAS Model A318 and A320 series airplanes; Model A319-111, -112, -113, -114, -115, -131, -132, -133, -151N, -153N, and 171N airplanes; and Model A321-111, -112, -131, -211, -212, -213, -231, -232, -251N, -251NX, -252N, -252NX, -253N, -253NX, -271N, -271NX, -272N, and -272NX airplanes. AD 2024-24-10 was prompted by an MCAI originated by EASA, which is the

Technical Agent for the Member States of the European Union. EASA issued AD 2024–0046, dated February 19, 2024 (EASA AD 2024–0046) (which corresponds to FAA AD 2024–24–10), to correct an unsafe condition.

AD 2024–24–10 requires revising the existing maintenance or inspection program, as applicable, to incorporate additional new or more restrictive airworthiness limitations. The FAA issued AD 2024–24–10 to address the risks associated with the effects of aging on airplane systems. Such effects could change system characteristics. The unsafe condition, if not addressed, could result in an increased potential for failure of certain life-limited parts, and reduced structural integrity of the airplane.

AD 2024–24–10 specifies that accomplishing the revision of the existing maintenance or inspection program required by that AD terminates the requirements of paragraphs (g) through (k) of AD 2018–23–02, Amendment 39–19488 (83 FR 59278, November 23, 2018). This proposed AD would therefore continue to allow that terminating action.

Actions Since AD 2024–24–10 Was Issued

Since the FAA issued AD 2024–24–10, EASA superseded AD 2024–0046 and issued EASA AD 2025–0032, dated February 10, 2025 (EASA AD 2025–0032) (also referred to as the MCAI), for all Airbus SAS Model A318 and A319 series airplanes; Model A320–211, –212, –214, –215, –216, –231, –232, –233, –251N, –252N, –253N, 271N, –272N, and –273N airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, –232, –251N, –251NX, –252N, –252NX, –253N, –253NX, –253NY, –271N, –271NX, –272N, and –272NX airplanes. Model A320–215 airplanes are not certificated by the FAA and are not included on the U.S. type certificate data sheet; this proposed AD therefore does not include those airplanes in the applicability. The MCAI states that new or more restrictive airworthiness limitations have been developed.

Airplanes with an original airworthiness certificate or original export certificate of airworthiness issued after November 28, 2024, must comply with the airworthiness limitations specified as part of the approved type design and referenced on the type certificate data sheet; this proposed AD therefore does not include those airplanes in the applicability.

The FAA is proposing this AD to address the risks associated with the effects of aging on airplane systems. Such effects could change system

characteristics. The unsafe condition, if not addressed, could result in an increased potential for failure of certain life-limited parts, and reduced structural integrity of the airplane. You may examine the MCAI in the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA–2026–0735.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed EASA AD 2025–0032. This material specifies new or more restrictive airworthiness limitations for airplane structures and safe life limits.

This proposed AD would also require EASA AD 2024–0046, dated February 19, 2024, which the Director of the Federal Register approved for incorporation by reference as of January 13, 2025 (89 FR 97505, December 9, 2024).

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.

FAA’s Determination

These products have been approved by the civil aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA’s bilateral agreement with this State of Design Authority, that authority has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would retain certain requirements of AD 2024–24–10. This proposed AD would also require revising the existing maintenance or inspection program, as applicable, to incorporate additional new or more restrictive airworthiness limitations, which are specified in EASA AD 2025–0032 already described, as proposed for incorporation by reference. Any differences with EASA AD 2025–0032 are identified as exceptions in the regulatory text of this proposed AD.

This proposed AD would require revisions to certain operator maintenance documents to include new actions (e.g., inspections). Compliance with these actions is required by 14 CFR 91.403(c). For airplanes that have been previously modified, altered, or repaired in the areas addressed by this proposed AD, the operator may not be able to accomplish the actions described in the

revisions. In this situation, to comply with 14 CFR 91.403(c), the operator must request approval for an alternative method of compliance (AMOC) according to paragraph (n)(1) of this proposed AD.

Explanation of Required Compliance Information

In the FAA’s ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to retain the Incorporation by Reference (IBR) of EASA AD 2024–0046 and to incorporate EASA AD 2025–0032 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2024–0046 and EASA AD 2025–0032 through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2024–0046 and EASA AD 2025–0032 does not mean that operators need comply only with that section. For example, where the AD requirement refers to “all required actions and compliance times,” compliance with this proposed AD requirement is not limited to the section titled “Required Action(s) and Compliance Time(s)” in EASA AD 2024–0046 and EASA AD 2025–0032. Material required by EASA AD 2024–0046 and EASA AD 2025–0032 for compliance will be available at [regulations.gov](https://www.regulations.gov) by searching for and locating Docket No. FAA–2026–0735 after the FAA final rule is published.

Airworthiness Limitation ADs Using the New Process

The FAA’s process of incorporating by reference MCAI ADs as the primary source of information for compliance with corresponding FAA ADs has been limited to certain MCAI ADs (primarily those with service bulletins as the primary source of information for accomplishing the actions required by the FAA AD). However, the FAA is now expanding the process to include MCAI ADs that require a change to airworthiness limitation documents, such as airworthiness limitation sections.

For these ADs that incorporate by reference an MCAI AD that changes airworthiness limitations, the FAA requirements are unchanged. Operators must revise the existing maintenance or

inspection program, as applicable, to incorporate the information specified in the new airworthiness limitation document. The airworthiness limitations must be followed according to 14 CFR 91.403(c) and 91.409(e).

The previous format of the airworthiness limitation ADs included a paragraph that specified that no alternative actions (e.g., inspections) or intervals may be used unless the actions and intervals are approved as an AMOC in accordance with the procedures specified in the AMOCs paragraph under “Additional AD Provisions.” This new format includes a “New Provisions for Alternative Actions and Intervals” paragraph that does not specifically refer to AMOCs, but operators may still request an AMOC to use an alternative action or interval.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 1,920 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

The FAA estimates the total cost per operator for the retained actions from AD 2024–24–10 to be \$7,650 (90 work-hours × \$85 per work-hour).

The FAA has determined that revising the existing maintenance or inspection program takes an average of 90 work-hours per operator, although the agency recognizes that this number may vary from operator to operator. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), the FAA has determined that a per-operator estimate is more accurate than a per-airplane estimate.

The FAA estimates the total cost per operator for the new proposed actions to be \$7,650 (90 work-hours × \$85 per work-hour).

Authority for This Rulemaking

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

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of

that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

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

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

- (1) Is not a “significant regulatory action” under Executive Order 12866,
- (2) Would not affect intrastate aviation in Alaska, and
- (3) Would not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

- 2. The FAA amends § 39.13 by:
 - a. Removing Airworthiness Directive (AD) 2024–24–10, Amendment 39–22900 (89 FR 97505, December 9, 2024); and
 - b. Adding the following new AD:

Airbus SAS; Docket No. FAA–2026–0735; Project Identifier MCAI–2025–00162–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by March 16, 2026.

(b) Affected ADs

- (1) This AD replaces AD 2024–24–10, Amendment 39–22900 (89 FR 97505, December 9, 2024) (AD 2024–24–10).
- (2) This AD affects AD 2018–23–02, Amendment 39–19488 (83 FR 59278, November 23, 2018) (AD 2018–23–02).

(c) Applicability

This AD applies to the Airbus SAS airplanes specified in paragraphs (c)(1)

through (4) of this AD, certificated in any category, with an original airworthiness certificate or original export certificate of airworthiness issued on or before November 28, 2024.

(1) Model A318–111, –112, –121, and –122 airplanes.

(2) Model A319–111, –112, –113, –114, –115, –131, –132, –133, –151N, –153N, –171N, and –173N airplanes.

(3) Model A320–211, –212, –214, –216, –231, –232, –233, –251N, –252N, –253N, –271N, –272N, and –273N airplanes.

(4) Model A321–111, –112, –131, –211, –212, –213, –231, –232, –251N, –251NX, –252N, –252NX, –253N, –253NX, –253NY, –271N, –271NX, –272N, and –272NX airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 05, Time Limits/Maintenance Checks.

(e) Unsafe Condition

This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is issuing this AD to address the risks associated with the effects of aging on airplane systems. Such effects could change system characteristics. The unsafe condition, if not addressed, could result in an increased potential for failure of certain life-limited parts, and reduced structural integrity of the airplane.

(f) Compliance

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

(g) Retained Revision of the Existing Maintenance or Inspection Program, With a New Terminating Action

This paragraph restates the requirements of paragraph (j) of AD 2024–24–10, with a new terminating action. For airplanes with an original airworthiness certificate or original export certificate of airworthiness issued on or before November 6, 2023, except for Model A319–173N and Model A321–253NY airplanes: Except as specified in paragraph (h) of this AD, comply with all required actions and compliance times specified in, and in accordance with European Union Aviation Safety Agency (EASA) AD 2024–0046, dated February 19, 2024 (EASA AD 2024–0046). Accomplishing the revision of the existing maintenance or inspection program required by paragraph (j) of this AD terminates the requirements of this paragraph.

(h) Retained Exceptions to EASA AD 2024–0046, With No Changes

This paragraph restates the exceptions specified in paragraph (k) of AD 2024–24–10, with no changes.

(1) This AD does not adopt the requirements specified in paragraphs (1) and (2) of EASA AD 2024–0046.

(2) Paragraph (3) of EASA AD 2024–0046 specifies revising “the AMP,” within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90

days after January 13, 2025 (the effective date of AD 2024–24–10).

(3) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2024–0046 is at the applicable “limitations” and “associated thresholds” as incorporated by the requirements of paragraph (3) of EASA AD 2024–0046, or within 90 days after January 13, 2025 (the effective date of AD 2024–24–10), whichever occurs later.

(4) This AD does not adopt the provisions specified in paragraphs (4) and (5) of EASA AD 2024–0046.

(5) This AD does not adopt the “Remarks” section of EASA AD 2024–0046.

(i) Retained Restrictions on Alternative Actions and Intervals, With a New Exception

This paragraph restates the requirements of paragraph (l) of AD 2024–24–10, with a new exception. Except as required by paragraph (j) of this AD, after the existing maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (*e.g.*, inspections) and intervals are allowed unless they are approved as specified in the provisions of the “Ref. Publications” section of EASA AD 2024–0046.

(j) New Revision of the Existing Maintenance or Inspection Program

Except as specified in paragraph (k) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2025–0032, dated February 10, 2025 (EASA AD 2025–0032). Accomplishing the revision of the existing maintenance or inspection program required by this paragraph terminates the requirements of paragraph (g) of this AD.

(k) Exceptions to EASA AD 2025–0032

(1) This AD does not adopt the requirements specified in paragraphs (1) and (2) of EASA AD 2025–0032.

(2) Paragraph (3) of EASA AD 2025–0032 specifies revising “the approved AMP,” within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after the effective date of this AD.

(3) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2025–0032 is at the applicable “limitations” and “associated thresholds” as incorporated by the requirements of paragraph (3) of EASA AD 2025–0032, or within 90 days after the effective date of this AD, whichever occurs later.

(4) This AD does not adopt the provisions specified in paragraphs (4) and (5) of EASA AD 2025–0032.

(5) This AD does not adopt the “Remarks” section of EASA AD 2025–0032.

(l) New Provisions for Alternative Actions and Intervals

After the existing maintenance or inspection program has been revised as required by paragraph (j) of this AD, no alternative actions (*e.g.*, inspections) and intervals are allowed unless they are approved as specified in the provisions of the

“Ref. Publications” section of EASA AD 2025–0032.

(m) Terminating Action for Certain Requirements of AD 2018–23–02

Accomplishing the revision of the existing maintenance or inspection program required by paragraph (g) or (j) of this AD terminates the requirements of paragraphs (g) through (k) of AD 2018–23–02.

(n) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, AIR–520, Continued Operational Safety Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the Continued Operational Safety Branch, send it to the attention of the person identified in paragraph (o) of this AD and email to: AMOC@faa.gov.

(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, AIR–520, Continued Operational Safety 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.

(o) Additional Information

For more information about this AD, contact Frank Carreras, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3539; email: frank.carreras@faa.gov.

(p) Material Incorporated by Reference

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

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

(3) The following material was approved for IBR on [DATE 35 DAYS AFTER PUBLICATION OF THE FINAL RULE].

(i) European Union Aviation Safety Agency (EASA) AD 2025–0032, dated February 10, 2025.

(ii) [Reserved]

(4) The following material was approved for IBR on January 13, 2025 (89 FR 97505, December 9, 2024).

(i) EASA AD 2024–0046, dated February 19, 2024.

(ii) [Reserved]

(5) For EASA material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email ADs@easa.europa.eu. You may find this material on the EASA website at ad.easa.europa.eu.

(6) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the

availability of this material at the FAA, call 206–231–3195.

(7) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov.

Issued on January 28, 2026.

Peter A. White,

Deputy Director, Integrated Certificate Management Division, Aircraft Certification Service.

[FR Doc. 2026–01928 Filed 1–29–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2026–0018]

RIN 1625–AA00

Safety Zone; Inner Harbor, Baltimore, MD

AGENCY: Coast Guard, Department of Homeland Security.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to establish a temporary safety zone for certain navigable waters of the Inner Harbor in Baltimore, MD. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created during an Air Show. This proposed rulemaking would prohibit persons and vessels from being in the safety zone unless specifically authorized by the Captain of the Port, Sector Maryland-National Capital Region, or a designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before March 2, 2026.

ADDRESSES: To submit comments and view available documents, go to <https://www.regulations.gov> and search for USCG–2026–0018.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rule, contact Mr. Charles Bullock, Sector Maryland-National Capital Region Waterways Management Division, U.S. Coast Guard; telephone 410–576–2674, email Charles.d.bullock@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port, Sector Maryland-National Capital Region

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

II. Background and Authority

SAIL250® Maryland & Airshow Baltimore (SAIL250) is planning a week-long celebration of maritime and aviation events in Baltimore's Inner Harbor between June 24–30, 2026. Among these events are flyovers and aviation demonstrations. They may include a U.S. Coast Guard Search and Rescue Drill and WWII-era “Warbird” flyovers.

To protect personnel, vessels, and the marine environment from potential hazards arising from these activities in these navigable waters before, during, and after the air demonstrations, the Captain of the Port, Sector Maryland-National Capital Region (COTP) is proposing to establish a safety zone from 10 a.m. on June 24, 2026, through 6 p.m. on July 1, 2026. We are proposing this rule under the authority in 46 U.S.C. 70034.

III. Discussion of the Rule

Although the safety zone would be in effect for a week, it would only be subject to enforcement beginning thirty minutes prior to a demonstration and ending at the conclusion of that demonstration. It would cover all navigable waters of the Inner Harbor, encompassed by a line connecting the following points: beginning at Inner Harbor Pier 6 at position latitude 39°16'59" N, longitude 076°36'12" W, thence south to the Harborview Towers pier at latitude 39°16'41" N, longitude 076°36'12" W, thence northerly and easterly along the shoreline to and terminating at the point of origin located in Baltimore, MD. The dimensions of the safety zone are approximately 2,000 yards in length and 500 yards in width. The regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders.

A. 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. Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities for the following reasons.

This regulation will only impact a small area for a few hours at a time. In addition, the Coast Guard will issue a Broadcast Notice to Mariners via VHF FM marine channel 16, which will allow small entities to adjust their transit plans, and the rule allows vessels to request permission to enter the regulated area from the COTP.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this proposed rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this proposed rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), if this proposed rule will affect your small business, organization, or governmental jurisdiction and you have questions, contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Small businesses may send comments to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards by calling 1–888–REG–FAIR (1–888–734–3247).

B. Collection of Information

This proposed rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

C. Federalism and Indian Tribal Governments

We have analyzed this proposed rule under Executive Order 13132, Federalism, and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in that Order.

Also, this proposed 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.

D. Unfunded Mandates Reform Act

As required by The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538), the Coast Guard certifies that this proposed rule will not result in an annual expenditure of \$100,000,000 or more (adjusted for inflation) by a State, local, or tribal government, in the aggregate, or by the private sector.

E. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have 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 proposed rule is a safety zone. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

Submitting comments. We encourage you to submit comments at <https://www.regulations.gov>. To do so, go to <https://www.regulations.gov>, type USCG–2026–0018 in the search box and click “Search.” Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If you cannot submit your material by using <https://www.regulations.gov>, call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule for alternate instructions.

Viewing material in the docket. To view available documents, find the docket as described in the previous paragraph, and then select “Supporting & Related Material” in the Document Type column. We will post public comments in our online docket. Additional information is on the <https://www.regulations.gov> Frequently Asked Questions web page.

Personal information. We accept anonymous comments. Comments we post to <https://www.regulations.gov> will include any personal information you have provided. For more about privacy and submissions to the docket in response to this document, see DHS’s eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

List of Subjects in 33 CFR Part 165

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

For the reasons discussed in the preamble, the Coast Guard is proposing to amend 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, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.4.

- 2. Add § 165.T05–0018 to read as follows:

§ 165.T05–0018 Safety Zone; Inner Harbor, Baltimore, MD.

(a) *Location.* The following area is a safety zone: All waters of the Inner Harbor, encompassed by a line connecting the following points: beginning at Inner Harbor Pier 6 at position latitude 39°16′59″ N, longitude 076°36′12″ W, thence south to the Harborview Towers pier at latitude 39°16′41″ N, longitude 076°36′12″ W, thence northerly and easterly along the shoreline to and terminating at the point of origin, located in Baltimore, MD. These coordinates are based on the World Geodetic System (WGS 84)/North American Datum 83 (NAD 83).

(b) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Sector Maryland-National Capital Region (COTP) in the enforcement of the safety zone.

(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, contact the COTP or the COTP’s representative on VHF–FM channel 16 or by telephone at (410) 576–2693. 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.

(d) *Enforcement period.* This section will be enforced as needed from June 24, 2026, to July 1, 2026.

Dated: January 22, 2026.

Patrick C. Burkett,

Captain, U.S. Coast Guard, Captain of the Port, Sector Maryland—National Capital Region.

[FR Doc. 2026–01882 Filed 1–29–26; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 4

RIN 2900–AS40

Providing a Minimum Evaluation for Bradycardia

AGENCY: Department of Veterans Affairs.
ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) proposes to revise diagnostic code (DC) 7009, Bradycardia (Bradycardia), to provide a minimum 10% evaluation after pacemaker implantation. This revision will allow VA to align DC 7009 with DC 7018, Implantable cardiac pacemakers. VA also proposes to remove Note (1) found under DC 7009.

DATES: Comments must be received by March 31, 2026.

ADDRESSES: You may submit comments through www.regulations.gov under RIN 2900–AS40. That website includes a plain-language summary of this rulemaking. Instructions for accessing agency documents, submitting comments, and viewing the rulemaking docket are available on www.regulations.gov under “FAQ.”

FOR FURTHER INFORMATION CONTACT: Argentina Hauser and Cintia Darlington, Veterans Benefit Administration, (202) 461–9700.

SUPPLEMENTARY INFORMATION:

I. Background

VA published a final rule in the *Federal Register* at 86 FR 54089 on

September 30, 2021, that amended the portion of the rating schedule that addresses the cardiovascular system and added DC 7009 to evaluate symptomatic bradycardia that requires pacemaker implantation. Bradycardia is characterized by a resting heart rate slower than 60 beats per minute, and bradycardia is a slow heart rate resulting from an irregular heartbeat or arrhythmia. See “Bradycardia,” Cleveland Clinic, <https://my.clevelandclinic.org/health/diseases/23349-bradycardia> (last visited January 12, 2026). Like other types of arrhythmias or heart conditions, providers may recommend pacemaker implantation to help regulate and maintain a healthy heart rate. Id.; see also “Pacemakers, Who Needs Them,” National Heart, Lung, and Blood Institute, <https://www.nhlbi.nih.gov/health/pacemakers/who-needs> (last visited January 12, 2026).

Prior to establishing this new DC, VA evaluated bradycardia requiring pacemaker implantation under DC 7018, Implantable cardiac pacemakers. Therefore, VA intended to mirror the criteria within DC 7018, which allowed VA to properly evaluate bradycardia while distinguishing it from other arrhythmias. However, VA did not provide a minimum evaluation under DC 7009.

II. Minimum Evaluation

VA is proposing to add a minimum 10% evaluation under DC 7009 after pacemaker implantation. Currently, VA uses DC 7009 to assign a temporary 100% evaluation for one month following hospital discharge for implantation or re-implantation of a pacemaker. Thereafter, VA evaluates the condition using the General Rating Formula for Diseases of the Heart with no minimum evaluation. However, under DC 7018, VA assigns a temporary 100% evaluation for one month following hospital discharge for implantation or re-implantation of a pacemaker, but thereafter VA evaluates the condition as supraventricular tachycardia (DC 7010), ventricular arrhythmias (DC 7011), or atrioventricular block (DC 7015) with a minimum 10% evaluation. Since both DCs involve pacemaker implantation, the criteria for DC 7009 should also include a minimum 10% evaluation after pacemaker implantation or re-implantation to align it with DC 7018. Additionally, this action is comparable to the assignment of 10% evaluation for other diseases of the heart when continuous medication is required. While it is possible that Veterans with bradycardia treated by a pacemaker

may qualify for a 10% evaluation or higher under the General Rating Formula for Diseases of the Heart due to their metabolic equivalent workload, requirement for continuous medication, or evidence of cardiac hypertrophy or dilatation, VA is proposing to revise DC 7009 to ensure there is no disparity between DCs 7009 and 7018 regarding minimum evaluations.

III. Note (1)

VA is also proposing to remove Note (1) under DC 7009. Within Note (1), VA defines Bradycardia (bradyarrhythmia) as conduction abnormalities leading to a heart rate below 60 beats per minute and provides the five general classes of bradyarrhythmia, which are (1) sinus bradycardia, (2) atrioventricular (AV) junctional (nodal) escape rhythm, (3) AV heart block (second or third degree) or AV dissociation, (4) atrial fibrillation, or flutter with a slow ventricular response, and (5) idioventricular escape rhythm. VA originally added Note (1) to define bradycardia and aid rating personnel in comprehending and assessing bradycardia. While Note (1) is informative, it could potentially lead to confusion if the American Heart Association or some other authoritative organization proposes to change the definition or the bradyarrhythmia classes. Since it is not necessary to include a definition or the classifications of bradycardia within 38 CFR 4.104, the removal of Note (1) is appropriate. Due to the proposed removal of Note (1), VA must redesignate Note (2) as the only note under DC 7009.

Executive Orders 12866, 13563, and 14192

VA examined the impact of this rulemaking as required by Executive Orders 12866 (Sept. 30, 1993) and 13563 (Jan. 18, 2011), which 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. The Office of Information and Regulatory Affairs has determined that this rulemaking *is not* a significant regulatory action under Executive Order 12866, as supplemented by Executive Order 13563. This proposed rule *is not expected* to be an Executive Order 14192 regulatory action because this rule is not significant under Executive Order 12866. The Regulatory Impact Analysis associated with this rulemaking can be found as a supporting document at www.regulations.gov.

Regulatory Flexibility Act

The Secretary hereby certifies that the adoption of this proposed rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (5 U.S.C. 601–612). This certification is based on the fact that small entities or businesses are not impacted by revisions to the VA Schedule for Rating Disabilities. Therefore, pursuant to 5 U.S.C. 605(b), this rule is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Unfunded Mandates

This proposed rule would not result in the expenditure by State, local, and Tribal governments, in the aggregate, or

by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year.

Paperwork Reduction Act

This proposed rule contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521).

List of Subjects in 38 CFR Part 4

Disability benefits, Pension, Veterans.

Signing Authority

Douglas A. Collins, Secretary of Veterans Affairs, approved this document on January 27, 2026 and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Nicole R. Cherry,

*Alternate Federal Register Liaison Officer,
Department of Veterans Affairs.*

For the reasons stated in the preamble, VA proposes to amend 38 CFR part 4 as set forth below:

PART 4—SCHEDULE FOR RATING DISABILITIES

Subpart B—Disability Ratings

- 1. The authority citation for part 4, subpart B continues to read as follows:

Authority: 38 U.S.C. 1155, unless otherwise noted.

- 2. Amend § 4.104 by revising the entry for DC 7009 to read as follows:

§ 4.104 Schedule of ratings—cardiovascular system.—cardiovascular system.

DISEASES OF THE HEART

	Rating
7009 Bradycardia (Bradyarrhythmia) symptomatic, requiring permanent pacemaker implantation: For one month following hospital discharge for implantation or re-implantation	100
Thereafter: Evaluate under the General Rating Formula. Minimum	10
<i>Note:</i> Asymptomatic bradycardia (bradyarrhythmia) is a medical finding only. It is not a disability subject to compensation.	

* * * * *

- 3. Amend appendix A to part 4 by revising the entry for diagnostic code 7009 to read as follows:

Appendix A to Part 4—Table of Amendments and Effective Dates Since 1946

Sec.	Diagnostic code No.
*	*
7009	Added November 14, 2021; criterion and note [INSERT EFFECTIVE DATE OF FINAL RULE].
*	*

[FR Doc. 2026–01875 Filed 1–29–26; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–HQ–OAR–2025–0192; FRL–12716–01–OAR]

RIN 2060–AW63

Interstate Transport Plan Review for the 2015 Ozone NAAQS

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; reconsideration of final rule.

SUMMARY: Pursuant to the Clean Air Act (CAA), the U.S. Environmental Protection Agency (EPA) is proposing to approve State Implementation Plan (SIP) submissions from eight States—Alabama, Arizona, Kentucky, Minnesota, Mississippi, Nevada, New Mexico, and Tennessee—regarding interstate transport for the 2015 8-hour ozone National Ambient Air Quality Standards (NAAQS). This action also explains why the EPA anticipates withdrawing previously proposed EPA error-correction actions related to interstate transport obligations for Iowa and Kansas and withdrawing previously proposed SIP disapproval actions for Tennessee, New Mexico, and Arizona. The “good neighbor” or “interstate transport” provision requires that each State’s SIP contain adequate provisions to prohibit emissions from within the State from significantly contributing to nonattainment or interfering with maintenance of the NAAQS in other States. If finalized as proposed, this action would resolve these 10 States’ obligations to eliminate significant contribution to nonattainment or interference with maintenance of the 2015 8-hour ozone NAAQS in other States.

DATES: Comments must be received on or before March 2, 2026.

ADDRESSES: *Comments:* You may send comments, identified by Docket ID No. EPA–HQ–OAR–2025–0192, by any of the following methods:

- *Federal eRulemaking Portal:* www.regulations.gov (our preferred method). Follow the online instructions for submitting comments.

- *Email:* a-and-r-docket@epa.gov. Include Docket ID No. EPA–HQ–OAR–2025–0192 in the subject line of the message.

- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, Docket ID No. EPA–HQ–OAR–2025–0192, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.

- *Hand Delivery or Courier:* EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center’s hours of operation are 8:30 a.m.–4:30 p.m., Monday–Friday (except Federal holidays).

Instructions: All submissions received must include the Docket ID No. for this proposed rulemaking. Comments received may be posted without change to www.regulations.gov, including personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the “Public Participation” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: For information about this proposed rule, contact Gwyndolyn Sofka, Air Quality Planning Division, Office of State Air Partnerships (C539–04), Environmental Protection Agency, 109 TW Alexander Drive, Research Triangle Park, NC 27711; telephone number (919) 541–5121; email address: sofka.gwyndolyn@epa.gov OR Thomas Uher, Air Quality Planning Division, Office of State Air Partnerships (C539–04), Environmental Protection Agency, 109 TW Alexander Drive, Research Triangle Park, NC 27711; telephone number: (919) 541–5534; email address: uher.thomas@epa.gov.

SUPPLEMENTARY INFORMATION:

Docket. The EPA established a docket for this action under Docket ID No. EPA–HQ–OAR–2025–0192. All documents in the docket are listed in www.regulations.gov/. Although listed, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only as PDF versions that can only be accessed on the EPA computers in the docket office reading room. Certain databases and physical items cannot be downloaded from the docket but may be requested by contacting the docket office at 202–566–1744. The docket office has up to 10 business days to respond to these requests. With the exception of such material, publicly available docket materials and a plain language summary of the proposed rule are available electronically at www.regulations.gov.

Instructions. Direct your comments to Docket ID No. EPA–HQ–OAR–2025–0192. The EPA’s policy is that all comments received will be included in the public docket without change and may be made available online at www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be CBI or other information whose disclosure is restricted by statute. Do not submit electronically to www.regulations.gov any information that you consider to be CBI or other information whose disclosure is restricted by statute. This type of information should be submitted as discussed below.

The EPA may publish any comment received to its public docket. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (i.e., on the Web,

cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit www.epa.gov/dockets/commenting-epa-dockets.

The www.regulations.gov/website allows you to submit your comment anonymously, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through www.regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any digital storage media you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should not include special characters or any form of encryption and should be free of any defects or viruses. For additional information about the EPA's public docket, visit the EPA Docket Center homepage at www.epa.gov/dockets.

Submitting CBI. Do not submit information containing CBI to the EPA through www.regulations.gov. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on any digital storage media that you mail to the EPA, note the docket ID, mark the outside of the digital storage media as CBI, and identify electronically within the digital storage media the specific information that is claimed as CBI. In addition to one complete version of the comments that includes information claimed as CBI, you must submit a copy of the comments that does not contain the information claimed as CBI directly to the public docket through the procedures outlined in *Instructions* above. If you submit any digital storage media that does not contain CBI, mark the outside of the digital storage media clearly that it does not contain CBI and note the docket ID. Information not marked as CBI will be included in the public docket and the EPA's electronic public docket without prior notice. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 Code of Federal Regulations (CFR) part 2.

Our preferred method to receive CBI is for it to be transmitted electronically using email attachments, File Transfer Protocol (FTP), or other online file sharing services (e.g., Dropbox, OneDrive, Google Drive). Electronic submissions must be transmitted directly to the Office of State Air Partnerships (OSAP) CBI Office at the email address oaqps_cbi@epa.gov and, as described above, should include clear CBI markings and note the docket ID. If assistance is needed with submitting large electronic files that exceed the file size limit for email attachments, and if you do not have your own file sharing service, please email oaqps_cbi@epa.gov to request a file transfer link. If sending CBI information through the postal service, please send it to the following address: U.S. EPA, Attn: OAQPS Document Control Officer, Mail Drop: C404-02, 109 T.W. Alexander Drive, P.O. Box 12055, Research Triangle Park, North Carolina 27711, Attention Docket ID No. EPA-HQ-OAR-2025-0192. The mailed CBI material should be double wrapped and clearly marked. Any CBI markings should not show through the outer envelope.

Preamble acronyms and abbreviations. Throughout this preamble the use of "we," "us," or "our" is intended to refer to the EPA. We use multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

2016v1 2016 Version 1 Emissions Modeling Platform
 2016v2 2016 Version 2 Emissions Modeling Platform
 2016v3 2016 Version 3 Emissions Modeling Platform
 CAA Clean Air Act
 CAIR Clean Air Interstate Rule
 CBI Confidential Business Information
 CFR Code of Federal Regulations
 CSAPR Cross-State Air Pollution Rule
 EGU Electric Generating Unit
 EHD Environmental Health Department
 EPA United States Environmental Protection Agency
 FIP Federal Implementation Plan
 LADCO Lake Michigan Air Directors Consortium
 NAAQS National Ambient Air Quality Standards
 NDEP Nevada Division of Environmental Protection
 NMED New Mexico Environment Department
 NO_x Nitrogen Oxides
 OMB United States Office of Management and Budget
 ppb parts per billion
 ppm parts per million
 PRA Paperwork Reduction Act
 RFA Regulatory Flexibility Act

SIP State Implementation Plan
 TSD Technical Support Document
 UMRA Unfunded Mandates Reform Act
 VOCs Volatile Organic Compounds
 WOE Weight of Evidence

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I. Executive Summary

On October 1, 2015, the EPA revised the primary and secondary 8-hour standards for ozone to 70 parts per billion (ppb) in the final rule entitled “National Ambient Air Quality Standards for Ozone” (“2015 8-hour ozone NAAQS”).¹ States were required to provide ozone infrastructure SIP submissions to fulfill interstate transport obligations for the 2015 8-hour ozone NAAQS by October 1, 2018.² Pursuant to the “good neighbor” or “interstate transport” provision of CAA section 110, the SIP submissions were required to include provisions sufficient to prevent emissions within the State that “contribute significantly to nonattainment in, or interfere with maintenance by, any other State with respect to [the NAAQS].”³

In a series of memoranda released in 2018, the EPA provided guidance to States on the content of SIP submissions that address the interstate transport provision for the 2015 ozone NAAQS. In March 2018, we released modeling results that use a 2011 base year and a 2023 analytical year (“March 2018

memorandum”).⁴ In August 2018, we issued further guidance advising that it “may be reasonable and appropriate for states to use a 1 ppb contribution threshold, as an alternative to a 1 percent threshold.” (“August 2018 memorandum”).⁵ Many States, including States covered by this rulemaking, submitted SIP submissions that relied on the modeling and analysis in the March 2018 and August 2018 memoranda.

When acting on certain submissions in 2023, however, the EPA interpreted the March 2018 and August 2018 memoranda as allowing EPA to give greater weight to the EPA's latest modeling results (referred to as “2016v3”) when it showed linkages not identified in the March 2018 memorandum modeling and to apply a 1 percent of the NAAQS contribution threshold. Based on the SIP submissions, the EPA's interpretation of its memoranda, and the 2016v3 modeling, the EPA disapproved the SIP submissions from Alabama, Kentucky, Minnesota, Mississippi, Nevada, and 16 other States in “Air Plan Disapprovals; Interstate Transport of Air Pollution for the 2015 8-Hour Ozone National Ambient Air Quality Standards” (“SIP Disapproval Action”).⁶ Using the same approach, the EPA also proposed to disapprove the SIP submissions from Arizona, New Mexico, and Tennessee, and proposed to error correct the previous approval of the SIPs from Iowa and Kansas to disapprovals in “Supplemental Air Plan Actions: Interstate Transport of Air Pollution for the 2015 8-Hour Ozone National Ambient Air Quality Standards and Supplemental Federal ‘Good Neighbor Plan’ Requirements for the 2015 8-Hour Ozone National Ambient Air Quality Standards” (“Proposed Supplemental Air Plan Action”).⁷

Many of the EPA's disapprovals were challenged in regional circuit courts and

stayed.⁸ The Fifth Circuit vacated and remanded the EPA's disapproval of Mississippi's SIP submission concluding that the EPA failed to recognize or reasonably explain its decision to consider the updated modeling in an “outcome determinative” way.⁹ The Sixth Circuit vacated and remanded the EPA's disapproval of Kentucky's SIP in part for failing to address reliance interests Kentucky had in guidance provided by EPA to Kentucky, including specific feedback on a draft version of Kentucky's submission.¹⁰ The challenges against the disapprovals of the SIP submissions from Alabama, Minnesota, and Nevada remain pending, but in abeyance, pending the EPA's reconsideration.¹¹

In light of the Fifth and Sixth Circuit judicial decisions and upon further review, the EPA now proposes to evaluate the relevant SIP submissions under policies related to the contribution threshold and choice of modeling consistent with the Fifth and Sixth Circuits' interpretation of the March 2018 and August 2018 memoranda. This proposed rule, if finalized, would approve the portion of SIP submissions addressing interstate transport for the 2015 8-hour ozone NAAQS of eight States. Additionally, at the final stage of this rulemaking, the EPA anticipates withdrawing the proposed error correction of the EPA's past approvals for two additional States and withdrawing the proposed partial disapproval of SIP submissions for three States included in the EPA's Proposed Supplemental Air Plan Action under CAA section 110(a)(2)(D)(i)(I), referred to as the “good neighbor” or the “interstate transport” provision of the CAA, for the 2015 8-hour ozone NAAQS.

The EPA proposes to find that interstate transport of ozone precursor emissions from eight upwind States (Alabama, Arizona, Kentucky, Mississippi, Minnesota, Nevada, New

⁴ See Information on the Interstate Transport State Implementation Plan Submissions for the 2015 Ozone National Ambient Air Quality Standards under Clean Air Act section 110(a)(2)(D)(i)(I), March 27, 2018. The version of 2023 contribution modeling referenced in the March 2018 memorandum may also be referred to as 2011-base year modeling. The memo is available in the docket (Docket ID No. EPA-HQ-OAR-2025-0192) and at www.epa.gov/Cross-State-Air-Pollution/memo-and-supplemental-information-regarding-interstate-transport-sips.

⁵ See Analysis of Contribution Thresholds for Use in Clean Air Act Section 110(a)(2)(D)(i)(I) Interstate Transport State Implementation Plan Submissions for the 2015 Ozone National Ambient Air Quality Standards, August 31, 2018 at 3, available in the docket and at www.epa.gov/Cross-State-Air-Pollution/memo-and-supplemental-information-regarding-interstate-transport-sips.

⁶ See 88 FR 9336 (Feb. 13, 2023).

⁷ See 89 FR 12666 (Feb. 16, 2024).

⁸ See, e.g., *Alabama et al. v. EPA*, No. 23–11173, ECF No. 33 (11th Cir. August 17, 2023) (Alabama); *Allete, Inc. et al. v. EPA*, No. 23–1776, ECF No. 5292580 (8th Cir. July 5, 2023) (Minnesota).

⁹ *Texas v. EPA*, 132 F.4th 808, 860–862 (5th Cir. 2025). The Fifth Circuit has withheld the mandate pending the resolution of pending petitions for rehearing en banc, which are focused on the portion of the opinion upholding the EPA's disapproval of Texas's SIP submission. See *Texas et al. v. EPA*, No. 23–60069 ECF No. 588 (5th Cir. May 22, 2025).

¹⁰ *Kentucky v. EPA*, 123 F.4th 447, 468–471 (6th Cir. 2024). See Sections III.C.3 and III.C.4 for further discussion of the Sixth Circuit's decision.

¹¹ See *Alabama et al. v. EPA*, No. 23–11173 (11th Cir.); *Alabama Power Company v. EPA*, No. 23–11196 (11th Cir.); *Allete, Inc. et al. v. EPA*, No. 23–1776 (8th Cir.); *Nevada Cement Co. LLC, v. EPA*, No. 23–682 (9th Cir.).

¹ 80 FR 65292 (Oct. 26, 2015).

² See 42 U.S.C. 7410(a)(1).

³ *Id.* 7410(a)(2)(D)(i)(I).

Mexico, and Tennessee) do not significantly contribute to nonattainment or interfere with maintenance of the 2015 8-hour ozone NAAQS in other States. On that basis, we propose to approve the relevant portions of these States' SIPs, which do not need to impose additional restrictions to satisfy obligations under the interstate transport provision. We, therefore, propose to reconsider the previous full or partial disapprovals of the 2015 ozone NAAQS SIP submissions from Alabama, Minnesota, and Nevada included in the SIP Disapproval Action. In response to the circuit courts' remands of the EPA's disapprovals of the 2015 ozone NAAQS interstate transport SIP submissions from Kentucky and Mississippi, we are proposing to approve these SIPs.¹²

The EPA previously proposed to partially disapprove the 2015 8-hour ozone NAAQS interstate transport SIP submissions from Arizona, New Mexico, and Tennessee.¹³ The EPA also proposed error corrections related to the prior approval of Iowa and Kansas's 2015 8-hour ozone NAAQS interstate transport SIPs.¹⁴ For consistent treatment between States, the EPA anticipates withdrawing these prior proposals at the final stage of this rulemaking. For clarification, the EPA notes that the prior SIP approvals for Iowa and Kansas remain in place.

The EPA previously promulgated 2015 8-hour ozone NAAQS interstate transport Federal Implementation Plans (FIPs) for Alabama, Kentucky, Minnesota, Mississippi, and Nevada,¹⁵ which have been stayed under the EPA's actions in response to various judicial stays of the SIP Disapproval Action and to the Supreme Court's stay of the Good Neighbor Plan.¹⁶ If this action is finalized as proposed, the EPA would no longer have the authority or the intention to lift the current stay of those FIPs, or otherwise attempt to implement those FIPs, for these or any other States with approved SIPs with respect to the interstate transport obligations for the 2015 ozone NAAQS.¹⁷

Taken together, these steps, if finalized, will fully resolve the included States' interstate transport obligations for the 2015 8-hour ozone NAAQS. The EPA intends to take a subsequent action consistent with this proposal, subject to further public input, to address interstate transport obligations for the 2015 8-hour ozone NAAQS for other States.

II. General Information

A. Does this action apply to me?

This proposed rule is relevant to 10 States. It affects five upwind States (Alabama, Kentucky, Mississippi, Minnesota, and Nevada) with prior full or partial disapprovals and three upwind States (Arizona, New Mexico, and Tennessee) with proposed partial disapprovals of the portion of their SIP submittals addressing interstate transport for the 2015 8-hour ozone NAAQS by approving their SIPs. The EPA finds that these States do not significantly contribute to nonattainment or interfere with maintenance of the 2015 8-hour ozone NAAQS in any other State. In addition, this proposed rule explains why the EPA anticipates withdrawing the EPA's prior proposed error correction regarding Iowa and Kansas' 2015 8-hour ozone NAAQS interstate transport SIPs.¹⁸ For clarification, the EPA notes that the prior approvals for Kansas and Iowa's SIPs remain in place.

B. What action is the EPA taking?

In this rule, as stated in Section I of this preamble, the EPA is proposing approval of the portion of SIP submissions addressing interstate transport for the 2015 8-hour ozone NAAQS of eight States, including areas of Indian country located within the geographic bounds of the covered States. As part of these broader actions, the EPA is proposing to reconsider three prior final SIP actions and respond to the remand of two SIP actions to the EPA. At the final stage of this rulemaking, the EPA anticipates withdrawing the EPA's prior proposed error correction of past approvals for

two additional States and withdrawing the proposed partial disapproval of SIP submissions for three States included in the Proposed Supplemental Air Plan Action.¹⁹

This action does not propose any action on the "Federal 'Good Neighbor Plan' for the 2015 Ozone National Ambient Air Quality Standards" ("Good Neighbor Plan").²⁰ However, the EPA would no longer have the authority or the intention to lift the current stay of those FIPs, or otherwise attempt to implement the Good Neighbor Plan requirements, for these or any other State with approved SIPs with respect to the interstate transport obligations for the 2015 ozone NAAQS.

The EPA intends to address the Good Neighbor Plan, and the remaining States covered by that action which are not addressed in this action, in a future action. We anticipate that action will also address, as relevant, the applicability of any Good Neighbor Plan FIPs in areas in Indian country.

C. What is the EPA's authority for taking this action?

The statutory authority for this proposed action is provided by the CAA as amended (42 U.S.C. 7401 *et seq.*). Specifically, CAA section 110 provides the primary statutory underpinning for this action. The most relevant portions of CAA section 110 are subsections 110(a)(1), 110(a)(2) (including 110(a)(2)(D)(i)(I)), 110(k)(2), and 110(k)(3). The EPA has historically referred to SIP submissions made for the purpose of satisfying the applicable requirements of CAA sections 110(a)(1) and 110(a)(2) as "infrastructure SIP" or "iSIP" submissions. CAA section 110(a)(1) addresses the timing and general requirements for iSIP submissions and CAA section 110(a)(2) provides more details concerning the required content of these submissions.²¹ CAA section 110(a)(2) includes a list of specific elements that "[e]ach such plan" must address, including the requirements of CAA section 110(a)(2)(D)(i)(I).²²

CAA section 110(a)(2)(D)(i)(I), also known as the "good neighbor" or "interstate transport" provision,

¹² See *Kentucky v. EPA*, 123 F.4th 447 (6th Cir. 2024); *Texas v. EPA*, 132 F.4th 808 (5th Cir. 2025).

¹³ 89 FR 12666 (Feb. 16, 2024).

¹⁴ *Id.*

¹⁵ 88 FR 36654 (June 5, 2023) (Good Neighbor Plan).

¹⁶ 88 FR 49295 (July 31, 2023) (staying the Good Neighbor Plan FIPs for, *inter alia*, Kentucky and Mississippi); 88 FR 67102 (Sept. 29, 2023) (staying the Good Neighbor Plan FIPs for, *inter alia*, Alabama, Minnesota, and Nevada); 89 FR 87960 (Nov. 6, 2024) (staying the Good Neighbor Plan as to all subject emissions sources).

¹⁷ The EPA is not at this time withdrawing the Good Neighbor Plan FIPs for states with proposed

SIP approvals but anticipates taking that step in a future action for all states that obtain final SIP approvals for the relevant obligations. Because the Good Neighbor Plan FIPs are stayed for Alabama, Kentucky, Minnesota, Mississippi, and Nevada, and the EPA has no current authority to bring them into effect, leaving the stayed regulatory provisions in place has no practical or legal effect for any party. We acknowledge that the removal of regulatory language promulgating such FIPs is a matter that is important to be resolved quickly to provide certainty to the relevant states. However, we believe such an action would be subject to CAA section 307(d) and is beyond the scope of this action.

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ 88 FR 36654 (June 5, 2023).

²¹ 42 U.S.C. 7410(a)(2).

²² The EPA's general approach to infrastructure SIP submissions is explained in greater detail in individual documents acting or proposing to act on state infrastructure SIP submissions and in guidance. See, e.g., Memorandum from Stephen D. Page on Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act Sections 110(a)(1) and 110(a)(2) (Sept. 13, 2013) included in the docket for this proposed action, Docket ID No. EPA-HQ-OAR-2025-0192.

provides the primary basis for this proposed action. It requires that each State's SIP include provisions sufficient to "prohibit[,], consistent with the provisions of this subchapter, any source or other type of emissions activity within the state from emitting any air pollutant in amounts which will—(I) contribute significantly to nonattainment in, or interfere with maintenance by, any other State with respect to any [NAAQS]." ²³ The EPA often refers to the emissions reduction requirements under this provision as "good neighbor obligations" or "interstate transport obligations" and submissions addressing these requirements as "good neighbor SIPs" or "interstate transport SIPs."

CAA section 301(a)(1) gives the Administrator the general authority to prescribe such regulations as necessary to carry out functions under the CAA.²⁴ Pursuant to this section, the EPA has authority to clarify the applicability of CAA requirements and undertake other rulemaking action as necessary to implement CAA requirements.

CAA section 110(k)(2) gives the Administrator authority to act on a complete SIP submission in accordance with CAA section 110(k)(3), which gives the Administrator authority to approve in whole, disapprove, or approve in part and disapprove in part SIP submissions based on the EPA's determination whether the submission meets the relevant requirements of the CAA.²⁵ The authority to review and approve or disapprove submissions, based on the EPA's interpretation of the CAA, also implicitly includes the authority to reconsider the EPA's previous action on a SIP submission. Two judicial decisions described in Sections III.C.3 and 4 of this preamble have caused the EPA to reconsider key policies related to interstate transport requirements under CAA section 110(a)(2)(A)(i)(I) for the 2015 8-hour ozone NAAQS.²⁶ The EPA's new understanding is applicable not just to the States who were the subject of those judicial decisions but to other States as well.

In addition to the forgoing provisions, the EPA proposes this action consistent with agencies' authority to reconsider prior decisions.²⁷

III. Background & Approach for Evaluation

A. Description of Statutory, Regulatory, and Judicial Background

On October 1, 2015, the EPA promulgated a revision to the ozone NAAQS, lowering both the primary and secondary standards to 70 ppb for the 8-hour standard.²⁸ CAA section 110(a)(1) requires States to submit, within three years after promulgation of a new or revised standard, SIP submissions meeting the applicable requirements of CAA section 110(a)(2).²⁹ One of these applicable requirements is found in CAA section 110(a)(2)(D)(i)(I), which generally requires that SIPs contain adequate provisions to prohibit in-state emissions activities from having certain adverse air quality effects on other States due to interstate transport of pollution. There are two so-called "prongs" within CAA section 110(a)(2)(D)(i)(I). A SIP for a new or revised NAAQS must contain adequate provisions prohibiting any source or other type of emissions activity within the State from emitting air pollutants in amounts that will significantly contribute to nonattainment of the NAAQS in another State (Prong 1) or interfere with maintenance of the NAAQS in another State (Prong 2). The EPA and States must give independent significance to Prong 1 and Prong 2 when evaluating downwind air quality problems under CAA section 110(a)(2)(D)(i)(I).³⁰

On January 31, 2023, the EPA signed final disapprovals for 19 SIP submissions and partially approved and partially disapproved two SIP submissions addressing the good neighbor provision for the 2015 ozone NAAQS, including from Alabama, Kentucky, Minnesota, Mississippi, and Nevada.³¹ On March 15, 2023, the EPA promulgated FIPs for Alabama, Kentucky, Minnesota, Mississippi, and Nevada in the Good Neighbor Plan, which were later stayed. On February 16, 2024, the EPA proposed partial disapproval of SIP submissions from Arizona, New Mexico, and Tennessee; proposed error corrections to change past approvals to partial disapprovals

for Iowa and Kansas; and proposed FIPs for all five States.³²

In *Ohio v. EPA*, the Supreme Court stayed enforcement of FIPs promulgated in the Good Neighbor Plan as to certain parties pending judicial review.³³ The EPA complied with that order by staying the FIPs as to all sources in all the remaining 23 States not already under stays.³⁴ The EPA's disapprovals of the SIP submissions from Kentucky and Mississippi were later vacated and remanded back to the EPA by circuit courts, which means that the EPA has an outstanding duty to act on those SIP submissions consistent with the court opinions.^{35 36}

B. Description of the EPA's 4-Step Interstate Transport Regulatory Process

When evaluating interstate transport obligations, the EPA consistently utilizes the 4-step interstate transport framework (the "Framework"), which was developed to explicate the critical statutory terms in CAA section 110(a)(2)(D)(i)(I) and to provide a reasonable organization to the analysis of the complex air quality challenge of interstate ozone transport. The EPA addressed the interstate transport requirements of CAA section 110(a)(2)(D)(i)(I) with respect to implementation of prior NAAQS using the Framework in several regulatory actions, including the original Cross-State Air Pollution Rule (CSAPR),³⁷ which addressed interstate transport with respect to the 1997 ozone NAAQS as well as the 1997 and 2006 fine particulate matter standards, and the CSAPR Update³⁸ and the Revised CSAPR Update,³⁹ which addressed the 2008 ozone NAAQS.⁴⁰ For the 2015 8-

³² 89 FR 12666 (Feb. 16, 2024).

³³ *Ohio v. EPA*, 603 U.S. 279 (2024).

³⁴ 89 FR 87960 (Nov. 6, 2024) (staying the Good Neighbor Plan as to all subject emissions sources); see also 88 FR 49295 (July 31, 2023); 88 FR 67102 (Sept. 29, 2023).

³⁵ *Kentucky v. EPA*, 123 F.4th 447 (6th Cir. 2024); *Texas v. EPA*, 132 F.4th 808 (5th Cir. 2025).

³⁶ Texas petitioners' petitions for rehearing en banc of *Texas* remain pending. See *Texas et al. v. EPA*, No. 23–60069, ECF Nos. 582, 583 (5th Cir. May 9, 2025).

³⁷ See Federal Implementation Plans: Interstate Transport of Fine Particulate Matter and Ozone and Correction of SIP Approvals; 76 FR 48208 (Aug. 8, 2011) (CSAPR).

³⁸ Cross-State Air Pollution Rule Update for the 2008 Ozone NAAQS; 81 FR 74504 (Oct. 26, 2016).

³⁹ Revised Cross-State Air Pollution Rule Update for the 2008 Ozone NAAQS; 86 FR 23054 (Apr. 30, 2021).

⁴⁰ In 2019, the D.C. Circuit Court of Appeals remanded the CSAPR Update to the extent it failed to require upwind states to eliminate their significant contribution by the next applicable attainment date by which downwind states must come into compliance with the NAAQS, as established under CAA section 181(a). *Wisconsin v.*

²³ 42 U.S.C. 7410(a)(2)(D)(i)(I).

²⁴ *Id.* 7601(a)(1).

²⁵ *Id.* 7410(k)(2)–(3).

²⁶ See *Kentucky v. EPA*, 123 F.4th 447 (6th Cir. 2024); *Texas v. EPA*, 132 F.4th 808 (5th Cir. 2025).

²⁷ See *FDA v. Wages & White Lion Invs., LLC*, 145 S. Ct. 898 (2025); *FCC v. Fox TV Stations, Inc.*, 556 U.S. 502 (2009); *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983); *Clean Air Council v. Pruitt*, 862 F.3d 1, 8 (D.C. Cir. 2017).

²⁸ Although the level of the standard is specified in the units of ppb, ozone concentrations are also described in parts per million (ppm). For example, 70 ppb is equivalent to 0.070 ppm.

²⁹ SIP submissions that are intended to meet the applicable requirements of CAA section 110(a)(1) and (2) of the CAA are often referred to as infrastructure SIPs and the applicable elements under CAA section 110(a)(2) are referred to as infrastructure requirements.

³⁰ See *North Carolina v. EPA*, 531 F.3d 896, 909–11 (D.C. Cir. 2008).

³¹ 88 FR 9336 (Feb. 13, 2023).

hour ozone NAAQS, the EPA used this framework in evaluating SIP submissions (while considering any alternative approaches States may have put forth in the submission) and applied this framework in the Good Neighbor Plan.⁴¹

Shaped by input from State air agencies⁴² and other stakeholders on the EPA's prior interstate transport rulemakings and SIP submission actions,⁴³ as well as several court decisions,⁴⁴ the EPA developed and used the Framework to evaluate States' obligations to eliminate interstate transport emissions under the interstate transport provision for the ozone NAAQS:

(1) identify monitoring sites that are projected to have problems attaining and/or maintaining the NAAQS (*i.e.*, nonattainment and/or maintenance receptors);

(2) identify States that impact those air quality problems in other (*i.e.*, downwind) States sufficiently such that the States are considered to "contribute" (*i.e.*, are considered "linked") to those receptors and whose emissions, therefore, warrant further review and analysis;

(3) identify the emissions reductions necessary (if any), applying a multifactor analysis, to eliminate each linked upwind State's significant contribution to nonattainment or interference with maintenance of the NAAQS at the locations identified in Step 1; and

(4) adopt permanent and enforceable measures needed to achieve those emissions reductions.

The EPA does not require States to use the Framework in interstate transport SIP submissions, but it is a useful organizational tool that has been upheld by the Supreme Court as "permissible, workable, and equitable."⁴⁵

C. The EPA's Approach To Evaluating Interstate Transport for the 2015 Ozone NAAQS

1. Selection of Analytic Year

In this section, the EPA describes the process for identifying an appropriate analytic year for this proposed rule. Every State covered by this proposed rule utilized an analytic year of 2023. The EPA is retaining the 2023 analytical year used to inform past action on States' interstate transport SIP submissions, to ensure consistency and equitable treatment of all States, and to give consideration to the information and data available to States at the time they developed these SIP submissions. In the EPA's March 2018 memorandum, the EPA provided air quality information that States could use to identify receptors in Step 1 and evaluate interstate contributions in Step 2 using a 2023 analytic year.⁴⁶ The EPA selected the year 2023 because it was the last full ozone season before the August 3, 2024, Moderate area attainment date for the 2015 ozone NAAQS.⁴⁷ Ozone seasons for purposes of interstate transport obligations run each year from May 1–September 30.⁴⁸ To demonstrate attainment by these deadlines, downwind States would be required to rely on design values calculated using ozone data from 2021 through 2023.⁴⁹ Areas that do not attain by the deadline may be "bumped up" to a higher nonattainment classification level per CAA sections 181 and 182, thereby incurring additional ongoing obligations. Thus, consistent with prior interstate transport rulemakings, the EPA's analysis focuses on the last full ozone season before the attainment dates (*i.e.*, 2023). The later versions of the EPA's modeling (2016v2, 2016v3) also used a 2023 analytic year.

The EPA recognizes that in applying the EPA's 2023 analytics to inform this action, *see* Section III.C.4 of this preamble, the EPA may be perceived as acting inconsistently with the EPA's previous policy of considering a future analytic year from the standpoint of the

timing of the EPA's rulemaking action. The EPA's general policy has been to use forward-looking projections associated with a future analytic year, consistent with its interpretation that the interstate transport provision is a forward-looking statute.⁵⁰ Courts have generally upheld that interpretation.⁵¹ However, no court has ruled (nor has the EPA interpreted) that the statute compels the EPA to always use a future analytic year from the standpoint of every particular interstate transport rulemaking. Here, the EPA proposes that several important, overriding considerations warrant retaining the 2023 analytic year in this rulemaking. Were the EPA to consider air quality information tied to year(s) after 2023,⁵² the EPA would separately evaluate these States using different data than that which informed our prior evaluation of the State submissions, solely as a result of the timing of the EPA's action on these States.

Where the need for parity among States or other jurisdictions in like circumstances warrants it, courts have recognized that it may be appropriate for the EPA to rely on a unified dataset to ensure consistency in treatment.⁵³ Here, for two States, the EPA is acting on remand following adverse court rulings, and the EPA is otherwise conducting reconsideration as to the other States included in this action, taking those adverse decisions into account. Comparable to the situation in *Weld County*, it makes sense to conduct this re-evaluation using the existing information in the record, rather than become trapped in a cycle of constantly shifting analysis and output. Indeed, the court in *Kentucky* faulted the EPA for failing to consider States' reliance interests when switching to updated analytics in our disapproval of Kentucky's SIP submission, rather than evaluating the submission according to the EPA's March 2018 memorandum modeling, which was provided to States for use in drafting their plans if they chose.⁵⁴

EPA, 938 F.3d 303, 313 (D.C. Cir. 2019). The Revised CSAPR Update responded to the remand of the CSAPR Update in *Wisconsin* and the vacatur of a separate rule, the "CSAPR Close-Out," 83 FR 65878 (Dec. 21, 2018), in *New York v. EPA*, 781 F. App'x. 4 (D.C. Cir. 2019).

⁴¹ 88 FR 9338; 88 FR 36671.

⁴² 63 FR 57356, 57361 (Oct. 27, 1998).

⁴³ In addition to CSAPR rulemakings, other regional rulemakings addressing ozone transport include the "NO_x SIP Call," 63 FR 57356 (Oct. 27, 1998), and the "Clean Air Interstate Rule" (CAIR); 70 FR 25162 (May 12, 2005).

⁴⁴ *See, e.g., EPA v. EME Homer City Generation, L.P.*, 572 U.S. 489 (2014) (*EME Homer City*).

⁴⁵ *EME Homer City*, 572 U.S. at 524.

⁴⁶ *See* March 2018 memorandum. The version of 2023 contribution modeling referenced in the March 2018 memorandum may also be referred to as 2011-base year modeling. The memo is available in the docket (Docket ID No. EPA-HQ-OAR-2025-0192) and at www.epa.gov/Cross-State-Air-Pollution/memo-and-supplemental-information-regarding-interstate-transport-sips.

⁴⁷ *See* CAA section 181(a); 40 Code of Federal Regulations (CFR) 51.1303; 83 FR 25776 (June 4, 2018), effective Aug. 3, 2018).

⁴⁸ *See* 40 CFR 52.38(b)(1), 52.40(c)(1).

⁴⁹ The ozone design value for a monitoring site for the 2015 ozone NAAQS is the 3-year average of the annual fourth-highest daily maximum 8-hour average ozone concentrations at the site. 40 CFR part 50, appendix U, section 4(a).

⁵⁰ *See, e.g.*, 86 FR 23054, 23074 (April 30, 2021).

⁵¹ *See North Carolina v. EPA*, 531 F.3d 896, 913–14 (D.C. Cir. 2008).

⁵² The EPA used an analytic year of 2023 in previously promulgated FIPs for the 2015 ozone NAAQS. The EPA also used a 2026 analytic year, but the additional analysis for 2026 was conducted for purposes of the Agency's Step 3 analysis in that rulemaking. *See* 88 FR at 36694.

⁵³ *See Bd. Cnty. Comm'rs of Weld Cnty. v. EPA*, 72 F.4th 284, 290 (D.C. Cir. 2023) ("*Weld County*") (upholding as reasonable the EPA's determination that "greater parity among counties and faster turnaround make the original data a better choice than partial updating").

⁵⁴ *See Kentucky*, 123 F.4th 447, 469–70.

In addition, the EPA recognizes that the Agency provided information to States for use in the development of these SIP submissions including air quality projections for the analytic year 2023 as released in the March 2018 memorandum. In this respect, we find it appropriate to use the same analytic year as the one the EPA's guidance communicated to States (*i.e.*, 2023) during SIP development. Therefore, when evaluating the SIP submissions for the 2015 8-hour ozone NAAQS included in this action, the EPA proposes to rely solely on projected air quality data for the 2023 analytic year. In doing so, the EPA is mindful of the unique and case-specific reliance interests the March 2018 memorandum may have engendered in State air agencies, since that memorandum said States "may consider using this [2023 modeling data] to develop SIPs that address requirements of [CAA section 110(a)(2)(D)(i)(I)] for the 2015 ozone NAAQS" and did not address the use of air quality information for an analytic year after 2023.⁵⁵ This determination is not being made, and should not be understood, to extend to any other CAA requirements or situations. In addition, as described in Section III.C.4. of this preamble, the EPA's proposed approach for evaluating air quality information in this action is to first rely on information provided in the March 2018 memorandum, as included by States in their SIP submissions, and then consider more recent EPA modeling information only if necessary to determine whether any linkages are still projected to persist.

2. Step 1 of the 4-Step Interstate Transport Framework

In Step 1, a State (or the EPA in the context of a FIP) identifies monitoring sites that are projected to have problems attaining and/or maintaining the NAAQS in the analytic year. Where the EPA's analysis shows that a site does not fall under the definition of a nonattainment or maintenance receptor, that site is excluded from further analysis under the EPA's Framework. For sites that are identified as a nonattainment or maintenance receptor in 2023, the EPA proceeds to the next step of the Framework by identifying which upwind States contribute above the threshold to those receptors.

The EPA's approach to identifying ozone nonattainment and maintenance receptors in this action gives independent consideration to both the "contribute significantly to nonattainment" and the "interfere with

maintenance" prongs of CAA section 110(a)(2)(D)(i)(I), consistent with the D.C. Circuit's direction in *North Carolina*.⁵⁶

The EPA identifies nonattainment receptors as those monitoring sites that are projected to have average design values that exceed the NAAQS, based on air quality modeling, and that are also measuring nonattainment based on the most recent monitored design values. This approach is consistent with prior transport rulemakings, such as the CSAPR Update, where the EPA defined nonattainment receptors as those sites that both currently measure nonattainment and that the EPA projects will be in nonattainment in the analytic year (*i.e.*, 2023).⁵⁷

In addition, the EPA identifies a receptor as a "maintenance" receptor for purposes of defining interference with maintenance, consistent with the method used in CSAPR and upheld by the D.C. Circuit in *EME Homer City Generation, L.P. v. EPA*, 795 F.3d 118, 136 (D.C. Cir. 2015).⁵⁸ Specifically, the EPA identifies maintenance receptors as those receptors that would have difficulty maintaining the relevant NAAQS in a scenario that takes into account historical variability in air quality at that receptor. The variability in air quality is determined by evaluating the projected "maximum" design value at each monitoring site. These future year maximum design values are derived from model projections of the maximum measured design value during the relevant base year time period. The EPA interprets the projected maximum future design value to be a potential future air quality outcome consistent with the meteorology that yielded maximum measured concentrations in the ambient data set analyzed for that receptor (*i.e.*, ozone conducive meteorology). The EPA also recognizes that previously experienced meteorological conditions (*e.g.*, dominant wind direction, temperatures, air mass patterns) promoting ozone formation that led to maximum concentrations in the measured data may reoccur in the

future. The maximum design value gives a reasonable projection of future air quality at the receptor under a scenario in which such conditions do, in fact, reoccur. The projected maximum design value is used to identify upwind emissions that, under those circumstances, could interfere with the downwind area's ability to maintain the NAAQS.

Recognizing that nonattainment receptors are also, by definition, maintenance receptors, the EPA often uses the term "maintenance-only" to refer to those receptors that are not nonattainment receptors. Consistent with the concepts for maintenance receptors, as described earlier, the EPA identifies "maintenance-only" receptors as those monitoring sites that have projected average design values above the level of the applicable NAAQS but that are not currently measuring nonattainment based on the most recent official design values. In addition, those monitoring sites with projected average design values below the NAAQS, but with projected maximum design values above the NAAQS, are also identified as "maintenance-only" receptors, even if they are currently measuring nonattainment based on the most recent official design values.

3. Step 2 of the 4-Step Interstate Transport Framework

In Step 2, a State (or the EPA in the context of a FIP) uses air quality modeling to quantify the impacts of emissions from each upwind State to each receptor in the 2023 analytic year. The EPA then evaluates these impacts with respect to an air quality screening threshold. Emissions impacts above that threshold are considered to constitute a "contribution" to that receptor, whether a nonattainment or maintenance receptor. Emissions impacts below that threshold are considered *de minimis* and so categorically are excluded from being considered "contribution" (or, for purposes of Prong 2, are categorically not considered "interference with maintenance"). The CAA does not define "contribution" or "interference" as used in the interstate transport provision, and this approach gives technical meaning to these statutory terms through screening out *de minimis* impacts. States with emissions impacts above the contribution threshold proceed to Step 3 analysis, where both air quality and cost factors are considered as part of a multi-factor analysis, to determine what, if any, emissions might be deemed "significant" and, thus, must be

⁵⁶ See *North Carolina*, 531 F.3d at 910–11 (holding that the EPA must give "independent significance" to each prong of CAA section 110(a)(2)(D)(i)(I)).

⁵⁷ 81 FR 74504 (Oct. 26, 2016). This same concept, relying on both current monitoring data and modeling to define nonattainment receptor, was also applied in CAIR. See 70 FR 25241, 25249 (Jan. 14, 2005); see also *North Carolina*, 531 F.3d at 913–14 (affirming as reasonable the EPA's approach to defining nonattainment in CAIR).

⁵⁸ 76 FR 48208 (Aug. 8, 2011). The CSAPR Update and Revised CSAPR Update also used this approach. See 81 FR 74504 (Oct. 26, 2016) and 86 FR 23054 (Apr. 30, 2021).

⁵⁵ March 2018 memorandum at 4.

eliminated pursuant to the requirements of CAA section 110(a)(2)(D)(i)(I).⁵⁹

A relatively low contribution threshold has historically been used for ozone NAAQS considering the collective contribution problem posed by interstate ozone pollution.⁶⁰ The contribution metric used in Step 2 is defined as the average impact from each State to each receptor on the days in 2023 with the highest ozone concentrations at the receptor, based on the future year modeling.⁶¹ To quantify the contribution of emissions from individual upwind States to projected 2023 ozone design values for the identified downwind nonattainment and maintenance receptors in Step 2, the EPA performed nationwide, State-level ozone source apportionment modeling. The source apportionment modeling provides contributions to ozone at receptors from precursor emissions of anthropogenic nitrogen oxides (NO_x) and volatile organic compounds (VOCs) in individual upwind States. The EPA released contribution modeling results for 2023 with the March 2018 memorandum, which uses a base year of 2011.⁶² The EPA later released contribution modeling results for 2023 using a 2016 base year.⁶³

Determining an appropriate screening threshold is a critical component of designing and applying Step 2. The assessment completed in the August 2018 memorandum⁶⁴ used data and air quality analyses that were specifically applicable to the NAAQS being considered and the relevant air quality conditions (e.g., pollutant concentrations and the magnitude of interstate transport). As a result, conclusions made with respect to one NAAQS are not by default applicable to another NAAQS. In previous actions, the EPA's analysis of collective contribution concluded that a screening threshold equivalent to 1 percent of the

1997 and 2008 ozone NAAQS was appropriate in Step 2.⁶⁵

In the August 2018 memorandum, the EPA evaluated data pertinent to several alternative thresholds that could be applicable to the development of SIP revisions to address transport for the 2015 8-hour ozone NAAQS. This evaluation compared the 1 percent of the 8-hour ozone NAAQS threshold (1-percent threshold), which is 0.70 ppb, and two potential alternative thresholds, 1 ppb and 2 ppb. The purpose of that analysis was to examine the amount of collective upwind contribution (i.e., the sum of contributions from upwind States that are linked to each receptor) that would be captured at each of these alternative thresholds nationwide. The EPA's conclusion in that memorandum was that a threshold of 1 ppb may be appropriate for States to use and develop SIP revisions addressing the interstate transport provision for the 2015 8-hour ozone NAAQS because, nationwide, the difference in the amount of total upwind contribution captured using a 1-ppb threshold is relatively small compared to the amount captured using a 1-percent threshold (roughly a 7 percentage point difference). The August 2018 memorandum also indicated a 2-ppb threshold may be insufficient to address collective upwind State contribution to downwind air quality problems.⁶⁶

Subsequent case law reviewing the EPA's disapproval of Kentucky's SIP submission interpreted the August 2018 memorandum as establishing a presumptively approvable Step 2 threshold of 1 ppb. The Sixth Circuit determined that the "August 2018 memorandum treated the 1 ppb threshold as presumptively acceptable unless a state's unique facts made the threshold improper[.]"⁶⁷ Further, the Sixth Circuit found that the August 2018 memorandum, together with feedback provided by the EPA during Kentucky's SIP development process, established an EPA policy that Kentucky could apply a 1-ppb contribution threshold in Step 2 in its SIP submission for the 2015 ozone NAAQS without further justification.⁶⁸

The Fifth Circuit reached a similar result in vacating and remanding the EPA's disapproval of Mississippi's SIP

submission.⁶⁹ The Fifth Circuit found that the EPA had improperly dismissed Mississippi's use of a 1-ppb threshold as "inconsequential" to the EPA's disposition of the SIP, which was incorrect when considered in conjunction with the choice of modeling used.⁷⁰ The Court found that the EPA had failed to provide an adequate explanation for the EPA's disapproval of Mississippi's SIP.⁷¹ In reviewing this decision on remand, the EPA notes that in reaching this conclusion, the Fifth Circuit necessarily found unpersuasive the EPA's explanations concerning why a 1-ppb threshold was inappropriate for States to use without adequate justification.⁷² The EPA cited and discussed this analysis in its merits brief.⁷³ The EPA believes it prudent to implement a policy more consistent with the Sixth Circuit's interpretation of the August 2018 memorandum in *Kentucky*, which is that 1 ppb is a "presumptively acceptable" threshold for all States.⁷⁴

Thus, in response to these opinions and in light of the 2018 August Memorandum and any reliance interests it may have engendered in State air agencies, the EPA is proposing to determine that a 1-ppb threshold is the appropriate Step 2 threshold to rely on in the first instance for the 2015 ozone NAAQS for all States in this action and any future actions related to the 2015 ozone NAAQS.⁷⁵ As noted in the August 2018 memorandum, nationally the 1-ppb threshold captures a generally comparable amount of total upwind contributions overall (70 percent using 1 ppb versus 77 percent using 1 percent (0.70 ppb))—when considering all receptors. Further, in the EPA's latest modeling, 2016 Version 3 Emissions Platform Modeling ("2016v3"), the difference in the amount of total upwind contributions captured is even less, identifying a difference of only 5

⁶⁹ *Texas*, 132 F.4th at 860–62.

⁷⁰ *Id.* at 861.

⁷¹ *Id.* at 862.

⁷² See 88 FR at 9371–73; see also *id.* at 9357–58.

⁷³ See EPA Resp. Br. at 138–46, No. 23–60069 (5th Cir. filed Aug. 15, 2023); see also *id.* at 34, 42–43, 124–29.

⁷⁴ *Kentucky*, 123 F.4th. at 469.

⁷⁵ The EPA is identifying the 1 ppb threshold as acceptable based on the specific facts and circumstances associated with this reconsideration of interstate transport obligations for the 2015 ozone NAAQS. Previously identified thresholds used in interstate transport analysis associated with other NAAQS, which were based on their own unique records, are not affected or intended to be affected. In addition, the use of a 1 ppb threshold does not undermine the basis for prior approvals of interstate transport SIPs for the 2015 ozone NAAQS that had used the 1 percent threshold. Any SIP that was approved under that threshold, which translates to .7 ppb, would be approvable under the 1 ppb threshold.

⁵⁹ Note that upwind states that are linked to a downwind receptor at Step 2 may nevertheless be found to not significantly contribute to nonattainment or interfere with maintenance at the receptor depending on the outcome of the Step 3 analysis. See 81 FR 74553.

⁶⁰ See 88 FR at 9342.

⁶¹ See Air Quality Modeling Final Rule Technical Support Document—2015 Ozone NAAQS Good Neighbor Plan in Docket ID No. EPA–HQ–OAR–2025–0192 ("2016v3 Technical Support Document (TSD)").

⁶² For an explanation of how the base year is used, see the 2016v3 TSD in the docket for this proposed action.

⁶³ 88 FR 9352–9354 (Feb. 13, 2023).

⁶⁴ August 2018 memorandum, available in the docket and at www.epa.gov/Cross-State-Air-Pollution/memo-and-supplemental-information-regarding-interstate-transport-sips.

⁶⁵ In CSAPR, the EPA used 0.80 ppb as the threshold, which is 1 percent of the 1997 ozone NAAQS. 76 FR 48208, 48238 (Aug. 8, 2011). In the CSAPR Update, the EPA used 0.75 ppb as the threshold, which is 1 percent of the 2008 ozone NAAQS. 81 FR 74504, 74518 (Oct. 26, 2016).

⁶⁶ August 2018 Memorandum at 4.

⁶⁷ *Kentucky*, 123 F.4th. at 469.

⁶⁸ *Id.* at 468–469.

percentage points.⁷⁶ By relying on a 1-ppb threshold rather than a 1-percent threshold, the EPA continues to provide the potential, in Step 3, for meaningful emissions reductions in remaining linked upwind States to aid downwind States with attainment and maintenance of the 2015 ozone NAAQS, while also focusing the EPA's efforts on areas that are more likely to have impactful outcomes should any emissions reductions be deemed appropriate. In this proposal, the EPA also solicits comment on the use of thresholds other than the 1-percent or 1-ppb thresholds discussed in this action, such as a 5-percent threshold or a 2-ppb threshold, including a basis for relying on any suggested alternative threshold.

The EPA recognizes that not all States elected to rely on the 1-ppb threshold when developing their SIP submissions, either because the State did not consider an alternative threshold due to the facts and circumstances available at the time of submission (e.g., the State was linked above or below both the 1-percent and 1-ppb threshold), or they found it appropriate to rely on the 1-percent threshold. However, the EPA finds it appropriate to presumptively apply a 1-ppb contribution threshold for the consistent treatment of all States. The availability of different thresholds in Step 2 has the potential to result in inconsistent application of interstate transport obligations based solely on the decisions of a State in Step 2 of the Framework. While alternative thresholds for purposes of Step 2 may be "similar" in terms of capturing the relative amount of upwind contribution (as described in the August 2018 memorandum), nonetheless, use of an alternative threshold would omit some States from further evaluation of potential emissions controls while other States with a similar level of contribution would proceed to a Step 3 analysis. This can create significant consistency problems among States. Finally, the August 2018 memorandum cautioned that contribution thresholds higher than 1 ppb, such as 2 ppb, would capture "notably less [upwind contribution] at most receptors than the amount captured with either a 1 ppb or 1 percent threshold, and therefore emission reductions from states linked at that higher threshold may be insufficient to address collective upwind state contribution to downwind air quality problems."⁷⁷ The EPA is not currently aware of information that

would support a threshold other than 1 ppb for any state.

4. Choice of Modeling To Inform Steps 1 and 2

The EPA released the October 2017 memorandum⁷⁸ containing updated modeling data for 2023, which incorporated changes made in response to comments on the January 6, 2017, Notice of Data Availability,⁷⁹ and was intended to provide information to assist States' efforts to develop SIP submissions to address interstate transport obligations for the 2008 ozone NAAQS. The March 2018 memorandum noted that the same 2011 base-year modeling data released in the October 2017 memorandum could also be useful for identifying potential downwind air quality problems with respect to the 2015 ozone NAAQS in Step 1 of the Framework. The March 2018 memorandum also included newly available contribution modeling data for 2023 to assist States in evaluating their impact on potential downwind air quality problems for the 2015 8-hour ozone NAAQS under Step 2 of the Framework.⁸⁰

Following the release of the March 2018 memorandum modeling, through a collaborative multi-year joint effort by the EPA, multi-jurisdictional organizations, and States, the EPA developed an updated air quality modeling platform with base year emissions for 2016 and projected emissions for 2023 (i.e., 2016 Version 1 Emissions Platform Modeling ("2016v1")).⁸¹ The EPA made further updates to the 2016-based emissions platform to include updated onroad mobile emissions from Version 3 of the EPA's Motor Vehicle Emission Simulator (MOVES) model

("MOVES3")⁸² and updated emissions projections for electric generating units (EGUs) that reflected the emissions reductions from the Revised CSAPR Update, recent information on plant closures, and other inventory improvements (i.e., 2016 Version 2 Emissions Platform Modeling ("2016v2")).⁸³ The EPA's latest version of air quality modeling incorporated additional feedback, and was released in early 2023 ("2016v3 modeling").⁸⁴

In the final SIP Disapproval Action, the EPA explained that in evaluating all SIP submissions, the EPA considered the entire record before the EPA, including updated modeling and other air quality analytics, even if such information was not available to States at the time they developed their submissions.⁸⁵ The EPA explained that, in our view, we had the authority and responsibility in evaluating interstate transport obligations to consider the best available information.⁸⁶ However, the Fifth Circuit found that the EPA had inappropriately applied the 2016v3 modeling in an outcome-determinative way in the EPA's evaluation of Mississippi's SIP submission.⁸⁷ In addition, the Sixth Circuit found that in disapproving Kentucky's SIP submission, the EPA inappropriately failed to acknowledge the reliance interests Kentucky had in the March 2018 memorandum modeling as the EPA stated in the March 2018 memorandum that States could use such modeling in developing their interstate transport SIPs.⁸⁸ ⁸⁹ Therefore, the EPA is reconsidering the EPA's approach regarding States' choice of modeling for evaluating interstate transport SIP

⁸² Additional details and documentation related to the MOVES3 model can be found at www.epa.gov/moves/latest-version-motor-vehicle-emission-simulator-moves.

⁸³ The construct of the 2016v2 emissions platform is described in the "Technical Support Document (TSD): Preparation of Emissions Inventories for the 2016v2 North American Emissions Modeling Platform," and is included in the docket for this proposed action. See also, "Air Quality Modeling Technical Support Document for the Federal Implementation Plan Addressing Regional Ozone Transport for the 2015 Ozone National Ambient Air Quality Standards Proposed Rulemaking," ("2016v2 TSD") also included in the docket.

⁸⁴ Details on the 2016v3 air quality modeling and the methods for projecting design values and determining contributions in 2023 and 2026 based on this platform are described in 2016v3 TSD included in the docket for this proposed action.

⁸⁵ 88 FR at 9343.

⁸⁶ *Id.* at 9365–67.

⁸⁷ *Texas*, 132 F.4th at 861–62.

⁸⁸ *Kentucky*, 123 F.4th at 468–69.

⁸⁹ EPA Resp. Br. at 185–211, No. 23–60069, ECF No. 397 (5th Cir. filed Aug. 15, 2023); EPA Resp. Br. at 76–95, No. 23–3216, ECF No. 73 (6th Cir. filed Jan. 29, 2024).

⁷⁶ 88 FR 9336, 9374 (Feb. 13, 2023).

⁷⁷ August 2018 memorandum at 4.

⁷⁸ See Information on the Interstate Transport State Implementation Plan Submissions for the 2008 Ozone National Ambient Air Quality Standards under Clean Air Act section 110(a)(2)(D)(i)(I), October 27, 2017, ("October 2017 Memorandum"), available in the docket for this proposed action.

⁷⁹ See Notice of Availability of the Environmental Protection Agency's Preliminary Interstate Ozone Transport Modeling Data for the 2015 8-hour Ozone National Ambient Air Quality Standard (NAAQS), ("Notice of Data Availability"); 82 FR 1733 (Jan. 6, 2017).

⁸⁰ The March 2018 memorandum stated "While the information in this memorandum and the associated air quality analysis data could be used to inform the development of these SIPs, the information is not a final determination regarding states' obligations under the good neighbor provision. Any such determination would be made through notice-and-comment rulemaking." March 2018 memorandum at 2.

⁸¹ See the Air Quality Modeling Technical Support Document for the Final Revised Cross-State Air Pollution Rule Update, included in the docket for this proposed action, Docket ID No. EPA–HQ–OAR–2025–0192.

submissions for the 2015 ozone NAAQS in Steps 1 and 2.

When acting on several SIP submissions in 2023, including those from five States covered by this proposal, the EPA looked at the modeling relied upon by States but also relied in a “primary” way on the results of the 2016v3 modeling, which identifies receptors and contributions in 2023, using a 2016 base year; one reviewing court observed that the effect of this approach was “outcome determinative” for some States such as Mississippi.⁹⁰ As noted above, compared to the March 2018 memorandum modeling, the 2016v3 modeling uses more recent emissions data and incorporates other technical updates to the modeling platform.⁹¹ The differences between the March 2018 memorandum modeling and 2016v3 modeling, depending on the contribution threshold, result in differences in receptor classification (e.g., nonattainment versus maintenance-only) and/or the magnitude of downwind contributions. In the final SIP Disapproval Action and the Proposed Supplemental Air Plan Action, the EPA considered whether a State identified itself as linked based on whichever modeling it chose but ultimately relied on the 2016v3 modeling for determining whether a State was linked in Step 2 because the 2016v3 was the most-up-to-date information at the time.⁹²

The Fifth and Sixth Circuits did not determine that the EPA may not consider updated information in taking action on these SIP submissions or any other types of SIP submissions.⁹³ Instead, as described above, these courts viewed the EPA as having failed to explain the EPA’s reasoning, considering the unique circumstances associated with the history of the 2015 ozone NAAQS interstate transport obligations and how the EPA had interpreted the March 2018 memorandum and the August 2018 memorandum in its disapprovals of Kentucky and Mississippi’s SIP submissions.⁹⁴ The EPA’s approach here is limited to this reconsideration of

certain 2015 ozone NAAQS good neighbor SIP actions and does not reflect a broader legal or policy judgment concerning the EPA’s authority to consider information more generally under the interstate transport provision or other provisions of the CAA. In general, the EPA views the choice of which information to consider or rely on to involve consideration of case-specific circumstances. Further, in the context of this proposed action, the EPA believes it is appropriate to apply a common approach to evaluate interstate transport obligations among States for parity. Therefore, to respond to the Fifth and Sixth Circuits’ remands concerning how the EPA previously applied the 2016v3 modeling to Kentucky and Mississippi (and to apply those precedents in a consistent manner in its reconsideration of its 2015 ozone NAAQS transport actions⁹⁵), to acknowledge and accommodate reliance interests States may have had in the March 2018 memorandum modeling, and to treat States’ interstate transport obligations consistently for the 2015 8-hour ozone NAAQS, the EPA is proposing to approach the choice of modeling in Steps 1 and 2 in the following way: the EPA will rely first on the modeling the State used in its SIP submission to identify receptors and the magnitude of contributions to those receptors.⁹⁶ If that modeling indicates a State is not linked in the 2023 analytic year to any receptors above 1 ppb, the EPA will approve that submission. If, however, the modeling a State used indicates that a State is linked above 1 ppb to at least one receptor, the EPA will consider the best available modeling (i.e., the 2016v3 modeling) to determine whether any linkages above 1 ppb are still anticipated to persist in 2023.⁹⁷ If no linkages persist, the EPA

will consider that State to have resolved its linkages and will approve such submissions under these circumstances. This approach ensures that full consideration is given to the modeling available to the States at the time they develop their interstate transport SIP submissions, whether that be developed by the EPA or otherwise, which is consistent with the cooperative-federalism framework of NAAQS implementation.

For the purposes of this action, as further explained in Section IV of this preamble, this approach to choice of modeling, in conjunction with the use of a 1-ppb threshold, supports proposing approval of eight States’ SIP submissions (Alabama, Arizona, Kentucky, Mississippi, Minnesota, Nevada, New Mexico, and Tennessee) and withdrawing prior proposed error corrections for two other States (Iowa and Kansas).

5. Step 3 of the 4-Step Interstate Transport Framework

In Step 3 of the Framework, a State (or the EPA in the context of a FIP) further evaluates a State’s emissions, considering multiple factors, including air quality and cost, to determine what, if any, emissions significantly contribute to nonattainment or interfere with maintenance and, thus, must be eliminated under CAA section 110(a)(2)(D)(i)(I). Because all States included in this proposal can be approved in Steps 1 and 2, there is no need to further discuss Step 3.

6. Step 4 of the 4-Step Interstate Transport Framework

In Step 4, a State (or the EPA in the context of a FIP) develop control strategies to achieve the emissions reductions determined to be necessary in Step 3 to eliminate significant contribution to nonattainment or interference with maintenance of the NAAQS, which become permanent and enforceable when adopted. Because all States included in this proposal can be approved in Steps 1 and 2, there is no need to further discuss Step 4.

monitor maintenance-only” approach to maintenance receptor identification that was developed for the final SIP Disapproval Action. This approach gave greater consideration to more recent monitoring data when identifying receptors at Step 1 of the Framework. The monitoring information used in this approach (measured 2021–2022 air quality monitoring data) post-dates the information available to States when they developed their 2015 8-hour ozone NAAQS interstate transport SIPs. Further, the EPA has not applied that methodology in an “outcome-determinative” way to date for any State.

⁹⁰ 88 FR 9380–9381; *Texas*, 132 F.4th at 860–62. The *Texas* court also recognized that for other States this was not the case, and the EPA’s more recent modeling was merely confirmatory. *Id.* at 861.

⁹¹ See 2016v3 TSD and “Air Quality Modeling Technical Support Document for the 2015 Ozone NAAQS Preliminary Interstate Transport Assessment” in the docket for this proposed action.

⁹² 87 FR 9343, 9380.

⁹³ *Texas*, 132 F.4th at 860, 862; *Kentucky*, 123 F.4th at 472.

⁹⁴ *Texas*, 132 F.4th at 860–861; *Kentucky*, 123 F.4th at 468–471.

⁹⁵ The EPA’s regulations provide that the EPA need not necessarily revise provisions of a rule meant to maintain national uniformity in response to one or more regional circuit decisions arising from actions that are locally or regionally applicable. See, e.g., 40 CFR 56.4(c). However, we believe it is “essential” to have national consistency in the implementation of interstate ozone obligations, see, e.g., 87 FR at 9373–74, and so we propose to apply the logic of these judicial decisions more broadly to the EPA’s national policies for interstate transport obligations for the 2015 8-hour ozone NAAQS to avoid any unfairness that could result from the uneven application of judicial rulings from different regional circuits.

⁹⁶ The EPA has the statutory authority to evaluate the sufficiency of States’ modeling and technical analyses in their SIP submissions. See *Texas v. EPA*, 156 F.4th 523, 542–43 (5th Cir. 2025). In this instance, the EPA finds that the photochemical grid modeling the States covered by this proposal used was technically sufficient for the purpose of evaluating interstate contribution for the 2015 ozone NAAQS.

⁹⁷ Under this proposed approach, we note that the EPA is also not considering the novel “violating

IV. SIP Submissions Addressing Interstate Transport of Air Pollution for the 2015 8-Hour Ozone NAAQS

A. SIP Summaries and the EPA's Evaluation

As described in Section III.C. of this preamble, in light of the EPA's implementation of policies consistent with the Sixth and Fifth Circuits' decisions in *Kentucky* and *Texas*, the EPA is reconsidering its previous final and proposed actions on the SIP submissions from Alabama, Arizona, Kentucky, Minnesota, Mississippi, Nevada, New Mexico, and Tennessee and anticipates withdrawing the prior proposed error corrections related to Iowa and Kansas's SIPs.⁹⁸ This section summarizes and evaluates the submissions from these 10 States. As explained throughout Section IV of this preamble, the EPA is proposing to find that these 10 States are screened out from further review after determining their contributions fall below the contribution threshold, and so the EPA need not examine the additional information contained in the submissions despite having done so in previous **Federal Register** notices. This proposed action, if finalized, would replace the EPA's previous final actions disapproving the SIP submissions from Alabama, Minnesota, and Nevada.

The EPA acknowledges that there are other States in the SIP Disapproval Action that are not included in this proposal, which is limited to those states for which proposed approval is warranted on the basis of the policies explained in Section III.C. The EPA intends to reconsider the SIP Disapproval Action, and/or the basis for disapproval, as to other states, including but not necessarily limited to Arkansas, Missouri, Oklahoma, Utah, and West Virginia, in a separate, upcoming rulemaking.

1. Alabama

a. Prior Notices Related to Alabama's SIP Submission

On June 21, 2022, the Alabama Department of Environmental Management submitted a SIP addressing CAA section 110(a)(2)(D)(i)(I) interstate transport requirements for the 2015 ozone NAAQS for the State of Alabama.⁹⁹ The EPA's proposed disapproval of Alabama's submission

was published on October 25, 2022,¹⁰⁰ and later finalized on January 31, 2023.¹⁰¹ However, the EPA is reconsidering the policy decisions made in our prior actions addressing interstate transport obligations for the 2015 8-hour ozone NAAQS following the remand and vacatur of the EPA's disapproval of Kentucky's and Mississippi's SIP submissions by the Sixth and Fifth Circuits, respectively, as described in Section III.C. of this preamble. As a result, the EPA now proposes to reconsider the disapproval and proposes to approve Alabama's SIP submission.

b. Summary of Alabama's Submission

Alabama's SIP submission provides the State's evaluation of its impact on downwind States and concludes that emissions from the State will not significantly contribute to nonattainment or interfere with maintenance of the 2015 8-hour ozone NAAQS in other States in 2023. Alabama relies on the results of the EPA's 2016v2 modeling to identify downwind nonattainment and maintenance receptors that may be impacted by emissions from sources in the State in Steps 1 and 2 of the Framework.¹⁰²

Alabama's SIP submission also identifies existing SIP-approved regulations and Federal programs that regulate ozone precursor emissions from sources in the State, including the CSAPR trading programs.¹⁰³ Alabama's SIP submission acknowledges that CSAPR does not address interstate transport for the 2015 8-hour ozone standard but does provide residual NO_x emissions reductions. Alabama notes that the implementation of the existing SIP-approved regulations and Federal programs provides for a decline in ozone precursor emissions in the State. Alabama also notes there are no nonattainment or maintenance areas in Alabama and that ozone precursor emissions will continue to decline in the State.

Alabama's SIP submission also includes a "weight of evidence" (WOE) analysis evaluating the EPA's 2016v2 emissions modeling platform, which showed that Alabama is projected to contribute above 0.70 ppb to one nonattainment monitor and one maintenance monitor.¹⁰⁴ In support of its WOE analysis, Alabama cites the EPA's October 2018 memorandum,¹⁰⁵

which discusses alternative methods to identifying maintenance receptors, as well as the March and August 2018 memoranda as supporting Alabama's use of a 1-ppb threshold.

Alabama's WOE analysis includes a Hybrid Single Particle Lagrangian Integrated Trajectory model back trajectory analysis to receptors in Denton County and Harris County, Texas. Alabama concludes that, based on the back trajectories, monitored exceedances at the Texas receptors are locally driven. Alabama also notes that the design values for the two Texas monitors have been stagnant, while design values in Alabama continue to trend downward.

Finally, Alabama provides a review of the State's NO_x emissions for point and mobile sources. Alabama indicates that the highest contributor of NO_x emissions in the State are from mobile sources but that NO_x emissions from this source category have decreased and will continue to decrease.

Based on this information, Alabama's SIP submission states that emissions from Alabama do not contribute above 1 ppb of the 2015 8-hour ozone NAAQS to any projected nonattainment or maintenance receptors in Step 2 of the Framework.

c. Evaluation of Alabama's Submission

As described in Section III.C. of this preamble, in light of the EPA's implementation of policies consistent with the Sixth and Fifth Circuits' decisions in *Kentucky* and *Texas*, the EPA is reconsidering its previous disapproval of the SIP submission from Alabama. As stated previously, Alabama's SIP submission uses the EPA's 2016v2 modeling. This modeling showed that Alabama's projected maximum contribution is 0.88 ppb to a nonattainment receptor (receptor ID 482010055 in Harris County, Texas) and 0.71 ppb to a maintenance receptor (receptor ID 481210034 in Denton County, Texas).¹⁰⁶ Both contributions from the State's chosen modeling are below the 1-ppb threshold. Thus, in accordance with the policies articulated in Section III.C. of this preamble, the EPA proposes to find that Alabama does not impact downwind air quality problems such that the State should be considered "linked" in Step 2 of the Framework and, therefore, further

⁹⁸ 88 FR 9336 (Feb. 13, 2023) (Alabama, Kentucky, Minnesota, Mississippi, and Nevada); 89 FR 12666 (Arizona, Iowa, Kansas, New Mexico, and Tennessee) (Feb. 16, 2024).

⁹⁹ See "AL-127 6.21.2022 Submittal For Ozone 2015 ISIP" ("Alabama's SIP submission") in the docket for this proposed action, Docket ID No. EPA-HQ-OAR-2025-0192.

¹⁰⁰ 87 FR 64412 (Oct. 25, 2022).

¹⁰¹ 88 FR 9336 (Feb. 13, 2023).

¹⁰² Alabama's SIP submission at Part E.

¹⁰³ *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ See Considerations for Identifying Maintenance Receptors for Use in Clean Air Act

Section 110(a)(2)(D)(i)(I) Interstate Transport State Implementation Plan Submissions for the 2015 Ozone National Ambient Air Quality Standards, October 19, 2018 ("October 2018 Memorandum"), available in the docket and at www.epa.gov/Cross-State-Air-Pollution/memo-and-supplemental-information-regarding-interstate-transport-sips.

¹⁰⁶ 2016v2 TSD, Appendix C.

review and analysis in Steps 3 and 4 is not warranted. Therefore, the EPA is proposing to approve Alabama's SIP submission because the State will not contribute significantly to nonattainment or interfere with maintenance of the 2015 8-hour ozone NAAQS in any other State.¹⁰⁷ This proposed action, if finalized, would replace the EPA's previous final action disapproving the SIP submission from Alabama.¹⁰⁸

2. Arizona

a. Prior Notices Related to Arizona's SIP Submission

On September 24, 2018, the Arizona Department of Environmental Quality submitted a SIP addressing the "infrastructure" requirements of CAA section 110(a)(2), including the interstate transport requirements under CAA section 110(a)(2)(D)(i)(I), for the 2015 8-hour ozone NAAQS.¹⁰⁹ On June 24, 2022, the EPA's proposed approval of Arizona's SIP submission was published.¹¹⁰ The EPA then withdrew the 2022 proposed approval of Arizona's SIP submission with respect to CAA section 110(a)(2)(d)(i)(I) and proposed to partially disapprove Arizona's SIP submission as to Prong 2 in the Proposed Supplemental Air Plan Action.¹¹¹ However, the EPA is reconsidering the policy decisions made in our prior actions addressing interstate transport obligations under the 2015 8-hour ozone NAAQS following the remand and vacatur of the EPA's disapproval of Kentucky's and Mississippi's SIP submissions by the Sixth and Fifth Circuits, respectively, as described in Section III.C. of this preamble. As a result, the EPA is proposing to fully approve Arizona's SIP submission.

b. Summary of Arizona's Submission

Arizona's SIP submission relies on the March 2018 memorandum modeling to identify downwind nonattainment and maintenance receptors that may be impacted by emissions from sources in the State in Steps 1 and 2 of the Framework.¹¹² Arizona further relies on the 1-percent threshold in Step 2.¹¹³ Arizona notes that the March 2018

memorandum modeling shows that Arizona does not contribute greater than 1 percent of the NAAQS to any of the modeled nonattainment or maintenance receptors in other States.¹¹⁴ Therefore, Arizona finds that the State does not contribute significantly to nonattainment or maintenance receptors in other States and that it is not necessary to identify emissions reductions or adopt any permanent or enforceable controls under the interstate transport provision for the 2015 8-hour ozone NAAQS.¹¹⁵ Arizona also states that Arizona's SIP submission contains adequate provisions to ensure that emissions from the State will not significantly contribute to nonattainment or interfere with maintenance of the 2015 8-hour ozone NAAQS in any other State in the future.¹¹⁶

c. Evaluation of Arizona's Submission

As described in Section III.C. of this preamble, in light of the EPA's implementation of policies consistent with the Sixth and Fifth Circuits' decisions in *Kentucky* and *Texas*, the EPA is reconsidering its previous proposed disapproval of the SIP submission from Arizona. Arizona's SIP submission uses the EPA's March 2018 memorandum modeling. This modeling showed that Arizona's projected maximum contribution is 0.49 ppb to a nonattainment receptor (receptor ID 80590006 in Jefferson County, Colorado) and 0.49 ppb to a maintenance receptor (receptor ID 81230009 in Weld County, Colorado).¹¹⁷ Arizona is not linked above the 1-ppb threshold to any downwind receptor in the State's chosen modeling. Thus, in accordance with the policies articulated in Section III.C. of this preamble, the EPA proposes to find that Arizona does not impact downwind air quality problems such that the State should be considered "linked" in Step 2 of the Framework and, therefore, further review and analysis in Steps 3 and 4 is not warranted. Therefore, the EPA is proposing to approve Arizona's SIP submission because the State will not contribute significantly to nonattainment or interfere with maintenance of the 2015 8-hour ozone NAAQS in any other State.¹¹⁸ If finalized, the EPA will withdraw the prior proposed partial disapproval.

¹¹⁴ *Id.*

¹¹⁵ *Id.*

¹¹⁶ *Id.* at 14.

¹¹⁷ See Attachment C to the EPA's March 2018 Memorandum.

¹¹⁸ See 42 U.S.C. 7410(a)(2)(D)(i)(I).

3. Iowa

a. Prior Notices Related to Iowa's SIP Submission

On November 30, 2018, Iowa submitted a SIP revision addressing CAA section 110(a)(2)(D)(i)(I) interstate transport requirements for the 2015 8-hour ozone NAAQS.¹¹⁹ On March 2, 2020, the EPA's proposed approval of the portion of Iowa's SIP submission addressing CAA section 110(a)(2)(D)(i)(I) was published.¹²⁰ This proposed approval was later withdrawn,¹²¹ and the EPA issued a new approval for Iowa's SIP submission, which was published on April 15, 2022.¹²² The EPA then proposed an error correction of our previous approval to partially disapprove Iowa's SIP submission in the Proposed Supplemental Air Plan Action.¹²³ However, the EPA is now reconsidering the policy decisions made in prior actions addressing interstate transport obligations under the 2015 8-hour ozone NAAQS following the remand and vacatur of the EPA's disapproval of Kentucky's and Mississippi's SIP submissions by the Sixth and Fifth Circuits, respectively, as described in Section III.C. of this preamble. As a result, the EPA anticipates withdrawing the proposed error correction of the April 15, 2022, final approval of Iowa's SIP submission.

b. Summary of Iowa's Submission

Iowa relies on the EPA's March 2018 memorandum modeling to identify downwind nonattainment and maintenance receptors that may be impacted by emissions from sources in Iowa and concludes that the State does not contribute significantly to nonattainment or interfere with maintenance of the 2015 8-hour ozone NAAQS in any other State.¹²⁴ Iowa references the August 2018 memorandum as a basis to use a 1-ppb threshold when evaluating the State's contribution to downwind receptors in Step 2. Iowa identifies projected contributions greater than 1 percent of the NAAQS to two downwind receptors: a nonattainment receptor in Milwaukee County, Wisconsin (Milwaukee receptor), and a maintenance-only

¹¹⁹ See "Iowa State Implementation Plan Revision for the 2015 Ozone National Ambient Air Quality Standards" ("Iowa's SIP submission") in the docket for this proposed action, Docket ID No. EPA-HQ-OAR-2025-0192.

¹²⁰ 85 FR 12232 (Mar. 2, 2020).

¹²¹ 87 FR 9477 (Feb. 22, 2022).

¹²² 87 FR 22463 (Apr. 15, 2022).

¹²³ 89 FR 12666 (Feb. 16, 2024).

¹²⁴ Iowa's SIP submission at 7.

¹⁰⁷ See 42 U.S.C. 7410(a)(2)(D)(i)(I).

¹⁰⁸ 88 FR 9336.

¹⁰⁹ See "Arizona State Implementation Plan Revision under Clean Air Act Sections 110(a)(1) and 110(a)(2) for the 2015 Ozone National Ambient Air Quality Standards" ("Arizona's SIP submission") in the docket for this proposed action, Docket ID No. EPA-HQ-OAR-2025-0192.

¹¹⁰ 87 FR 37776 (June 24, 2022).

¹¹¹ 89 FR 12666 (Feb. 16, 2024).

¹¹² Arizona's SIP submission at 12–13.

¹¹³ *Id.* at 13.

receptor in Allegan County, Michigan (Allegan receptor).¹²⁵

Iowa notes that, of the contribution greater than 1 percent of the NAAQS, application of the 1-ppb threshold captures 83 percent of the upwind contribution at the Milwaukee receptor and 94 percent of the upwind contribution at the Allegan receptor.¹²⁶ Based on these data, Iowa concludes that the 1-ppb threshold is therefore an appropriate contribution threshold with respect to the 2015 8-hour ozone NAAQS because it captures a “substantial portion” of the upwind contribution when compared to the 1-percent threshold at both receptors.¹²⁷ Because Iowa’s impact on both receptors is projected to be below the 1-ppb threshold, Iowa concludes that the State’s emissions will not contribute significantly to nonattainment or interfere with maintenance of the 2015 8-hour ozone NAAQS at either receptor.

c. Evaluation of Iowa’s Submission

As described in Section III.C. of this preamble, in light of the EPA’s implementation of policies consistent with the Sixth and Fifth Circuits’ decisions in *Kentucky* and *Texas*, the EPA is reconsidering its previous proposed error correction of the previous approval of Iowa’s SIP. Iowa’s SIP submission uses the EPA’s March 2018 memorandum modeling. This modeling showed that Iowa’s projected maximum contribution is 0.79 ppb to a nonattainment receptor (receptor ID 550790085 in Milwaukee County, Wisconsin) and 0.77 ppb to a maintenance receptor (receptor ID 260050003 in Allegan County, Michigan).¹²⁸ Both contributions from the State’s chosen modeling are below the 1-ppb threshold. Thus, in accordance with the policies articulated in Section III.C. of this preamble, the EPA proposes to find that Iowa does not impact downwind air quality problems such that the State should be considered “linked” in Step 2 of the Framework and, therefore, further review and analysis in Steps 3 and 4 is not warranted. Therefore, the EPA anticipates withdrawing the proposed error correction of the April 15, 2022, final approval of Iowa’s SIP submission.¹²⁹ For clarification, the EPA notes that the previous approval of Iowa’s SIP remains in place.

4. Kansas

a. Prior Notices Related to Kansas’ SIP Submission

On September 27, 2018, Kansas submitted a SIP revision addressing CAA section 110(a)(2)(D)(i)(I) interstate transport requirements for the 2015 8-hour ozone NAAQS.¹³⁰ The EPA’s proposed approval of Kansas’ SIP submission was published on February 8, 2022,¹³¹ and the EPA’s final approval was published on April 4, 2022.¹³² The EPA then proposed an error correction of the past approval to partially disapprove Kansas’ SIP in the Proposed Supplemental Air Plan Action.¹³³ However, the EPA is now reconsidering policy decisions made in our prior actions addressing interstate transport obligations for the 2015 8-hour ozone NAAQS following the remand and vacatur of the EPA’s disapproval of Kentucky’s and Mississippi’s SIP submissions by the Sixth and Fifth Circuits, respectively, as described in Section III.C. of this preamble. As a result, the EPA anticipates withdrawing the proposed error correction of the April 4, 2022, final approval of Kansas’ SIP submission.

b. Summary of Kansas’ Submission

Kansas relies on the EPA’s March 2018 memorandum modeling to identify downwind nonattainment and maintenance receptors that may be impacted by emissions from sources in Kansas in the year 2023.¹³⁴ Kansas notes that the State’s greatest contribution to a projected nonattainment or maintenance receptor is 0.77 ppb, which is between 0.7 ppb and 1 ppb.¹³⁵ Because Kansas’s maximum contribution to receptors in downwind States is between 1 percent of the NAAQS and 1 ppb, the State cites the EPA’s August 2018 memorandum to rely on a 1-ppb threshold.¹³⁶ Therefore, Kansas concludes that emissions from sources within the State will not significantly contribute to nonattainment or interfere with maintenance of the 2015 8-hour ozone NAAQS in any other State.

¹³⁰ See “Kansas Air Quality State Implementation Plan Revision for the Implementation, Maintenance, and Enforcement of the 2015 Ozone (O₃) National Ambient Air Quality Standards” (“Kansas’ SIP submission”) in the docket for this proposed action, Docket ID No. EPA–HQ–OAR–2025–0192.

¹³¹ 87 FR 7071 (Feb. 8, 2022).

¹³² 87 FR 19390 (Apr. 4, 2022).

¹³³ 89 FR 12666 (Feb. 16, 2024).

¹³⁴ Attachment A to Kansas’ SIP submission at 24–26.

¹³⁵ *Id.*

¹³⁶ *Id.*

c. Evaluation of Kansas’ Submission

As described in Section III.C. of this preamble, in light of the EPA’s implementation of policies consistent with the Sixth and Fifth Circuits’ decisions in *Kentucky* and *Texas*, the EPA is reconsidering its previous proposed error correction of the approval of Kansas’ SIP. Kansas’ SIP submission uses the EPA’s March 2018 memorandum modeling. This modeling showed that Kansas’ projected maximum contribution is 0.69 ppb to a nonattainment receptor (receptor ID 484392003 in Tarrant County, Texas) and 0.77 ppb (receptor ID 260050003 in Allegan County, Michigan).¹³⁷ This contribution from the State’s chosen modeling is below the 1-ppb threshold. Thus, in accordance with the policies articulated in Section III.C. of this preamble, the EPA proposes to find that Kansas does not impact downwind air quality problems such that the State should be considered “linked” in Step 2 of the Framework and, therefore, further review and analysis in Steps 3 and 4 is not warranted. Therefore, the EPA anticipates withdrawing the proposed error correction of the April 4, 2022, final approval of Kansas’s SIP submission.¹³⁸ For clarification, the EPA notes that the previous approval of Kansas’ SIP remains in place.

5. Kentucky

a. Prior Notices Related to Kentucky’s SIP Submission

On January 9, 2019, the Commonwealth of Kentucky submitted a SIP revision, a portion of which addressed CAA section 110(a)(2)(D)(i)(I) interstate transport requirements for the 2015 8-hour ozone NAAQS.¹³⁹ The EPA’s proposed disapproval of Kentucky’s SIP submission was published on February 22, 2022,¹⁴⁰ and the EPA’s final disapproval was published on February 13, 2023.¹⁴¹ The Sixth Circuit vacated and remanded that disapproval to the EPA.¹⁴² Additionally, the EPA is now reconsidering policy decisions made in our prior actions addressing interstate transport obligations for the 2015 8-hour ozone NAAQS following *Kentucky* and the remand and vacatur of the EPA’s disapproval of Mississippi’s SIP

¹³⁷ See Attachment C to the EPA’s March 2018 memorandum.

¹³⁸ See 42 U.S.C. 7410(a)(2)(D)(i)(I).

¹³⁹ See “Final Kentucky Infrastructure State Implementation Plan,” Element D (“Kentucky’s SIP submission”) included in the docket for this proposed action, Docket ID No. EPA–HQ–OAR–2025–0192.

¹⁴⁰ 87 FR 9498 (Feb. 22, 2022).

¹⁴¹ 88 FR 9336 (Feb. 13, 2023).

¹⁴² *Kentucky*, 123 F.4th at 473.

¹²⁵ *Id.*

¹²⁶ *Id.* at 8.

¹²⁷ *Id.*

¹²⁸ See Attachment C to the EPA’s March 2018 memorandum.

¹²⁹ See 42 U.S.C. 7410(a)(2)(D)(i)(I).

submission by the Fifth Circuit, as described in Section III.C. of this preamble. As a result, the EPA now proposes to approve Kentucky's SIP submission.

b. Summary of Kentucky's Submission

Kentucky's SIP submission provides the Commonwealth's analysis of its impact to downwind States and concludes that the Commonwealth meets the requirements of CAA section 110(a)(2)(D)(i)(I) because Kentucky's SIP submission contains adequate provisions to prevent sources and other types of emissions activities within the Commonwealth from significantly contributing to nonattainment, or interfering with the maintenance, of downwind States with respect to the 2015 8-hour ozone NAAQS.

Kentucky's SIP submission relies on the results of the EPA's March 2018 memorandum modeling to identify downwind nonattainment and maintenance receptors that may be "linked" to emissions from sources in Kentucky.¹⁴³ Kentucky notes that these modeling results showed Kentucky is projected to be linked to four nonattainment receptors and one maintenance receptor above 1 percent of the NAAQS.

Kentucky relies on the EPA's August 2018 memorandum to apply a 1-ppb threshold and finds that the Commonwealth is no longer projected to be linked to the four nonattainment receptors.¹⁴⁴ Kentucky, therefore, concludes that no further controls are required to address the Commonwealth's contribution to those four receptors and that Kentucky's SIP submission contains adequate provisions to prevent sources and other types of emissions activities within the Commonwealth from contributing significantly to nonattainment in any other State (*i.e.*, "Prong 1" of CAA section 110(a)(2)(D)(i)(I) for the 2015 8-hour ozone NAAQS).¹⁴⁵

After application of the 1-ppb contribution threshold, Kentucky notes it contributes over 1 ppb to one maintenance receptor in Harford County, Maryland ("Harford receptor").¹⁴⁶ Kentucky's SIP submission states that emissions reductions required for an upwind State should not be the same for a monitor that is projected to be attaining the NAAQS under average conditions as for a nonattainment monitor. Kentucky further maintains that local controls

should be implemented before requiring upwind States to control their sources.

Kentucky also reviews NO_x emissions trends in the Commonwealth, comparing annual NO_x emissions from 2008 to 2016 and finding that NO_x emissions in Kentucky have significantly decreased since 2008.¹⁴⁷ Kentucky indicates that scheduled shutdowns, fuel switches, and retirements of facilities in the Commonwealth mean Kentucky's emissions will continue to decrease. In addition, Kentucky lists existing State, SIP-approved regulations and Federal programs for sources in the Commonwealth that it concluded address the requirements of CAA 110(a)(2)(D)(i)(I) for the 2015 8-hour ozone NAAQS.¹⁴⁸ Thus, Kentucky concludes that no further reductions other than existing and anticipated measures are required to address the Commonwealth's interstate transport obligation to eliminate its contribution to the Harford receptor (Prong 2).

c. Evaluation of Kentucky's Submission

The Sixth Circuit vacated and remanded the EPA's prior disapproval of Kentucky's SIP submission on the grounds that the disapproval was arbitrary and capricious for improperly departing from past policy.¹⁴⁹ In particular, the Sixth Circuit found that the EPA had ignored Kentucky's reliance interests in the modeling results released with the March 2018 memorandum and that the August 2018 memorandum, together with feedback provided by the EPA during Kentucky's SIP submission development process, established that Kentucky could apply a 1-ppb contribution threshold in Step 2 in its SIP submission for the 2015 ozone NAAQS without further justification.¹⁵⁰

On remand, the EPA is reevaluating Kentucky's submission in accordance with the court's identification of the EPA's previous missteps. As described in Section III.C.3. of this preamble, the EPA is applying a 1-ppb contribution threshold. Furthermore, as described in Section III.C.4. of this preamble, to accommodate Kentucky's reliance interests, the EPA is referring in the first instance to the State's chosen modeling. When the modeling a State relies on in its SIP submission shows a contribution over 1 ppb to at least one receptor in 2023, the EPA will confirm whether any linkages are projected to exist in the EPA's updated modeling. Though not

explicitly endorsed by the court, the Sixth Circuit suggested this approach could be a possible route for the EPA on remand.¹⁵¹ Kentucky's SIP submission uses the EPA's March 2018 memorandum modeling. This modeling showed that Kentucky's projected maximum contribution is 0.89 ppb to a nonattainment receptor (receptor ID 90013007 in Fairfield County, Connecticut) and 1.52 ppb to a maintenance receptor (receptor ID 240251001 in Harford County, Maryland).¹⁵² The EPA's 2016v3 modeling shows a maximum contribution of 0.84 ppb to a nonattainment receptor (receptor ID 90013007 in Fairfield County, Connecticut) and 0.79 ppb to a maintenance receptor (receptor ID 90099002 in New Haven County, Connecticut).¹⁵³ Thus, in accordance with the policies articulated in Section III.C. of this preamble, the EPA proposes to find that Kentucky does not impact downwind air quality problems such that the Commonwealth should be considered "linked" in Step 2 of the Framework, and therefore further review and analysis at Steps 3 and 4 is not warranted. Therefore, the EPA is proposing to approve Kentucky's SIP submission because the Commonwealth will not contribute significantly to nonattainment or interfere with maintenance of the 2015 8-hour ozone NAAQS in any other State.¹⁵⁴ This proposed action, if finalized, will respond to the Sixth Circuit's vacatur and remand of the previous disapproval of Kentucky's SIP submission.

6. Minnesota

a. Prior Notices Related to Minnesota's SIP Submission

On October 1, 2018, the Minnesota Pollution Control Agency submitted a SIP revision to address CAA section 110(a)(2)(D)(i)(I) interstate transport requirements for the 2015 8-hour ozone NAAQS.¹⁵⁵ The EPA's proposed partial disapproval of Minnesota's SIP submission was published on February 22, 2022,¹⁵⁶ and the EPA's final partial disapproval (as to Prong 2) was published on February 13, 2023.¹⁵⁷

¹⁵¹ *Id.* at 472.

¹⁵² See Attachment C to the EPA's March 2018 memorandum.

¹⁵³ 2016v3 TSD, Table 4–1.

¹⁵⁴ See 42 U.S.C. 7410(a)(2)(D)(i)(I).

¹⁵⁵ See "Infrastructure/110(a) requirements for the 2015 Ozone National Ambient Air Quality Standard" ("Minnesota's SIP submission") available in the docket for this proposed action, Docket ID No. EPA-HQ-OAR-2025-0192.

¹⁵⁶ 87 FR 9838 (Feb. 22, 2022).

¹⁵⁷ 88 FR 9336 (Feb. 13, 2023).

¹⁴³ Kentucky's SIP submission at 18–19.

¹⁴⁴ *Id.* at 19.

¹⁴⁵ *Id.* at 45.

¹⁴⁶ *Id.* at 19.

¹⁴⁷ *Id.* at 30–31.

¹⁴⁸ See Kentucky's SIP submission, at 20–30 for the list of state, SIP-approved regulations and Federal programs identified by Kentucky.

¹⁴⁹ *Kentucky*, 123 F.4th at 468.

¹⁵⁰ *Id.* at 468–469.

However, the EPA is now reconsidering the policy decisions made in our prior actions addressing interstate transport obligations under the 2015 8-hour ozone NAAQS following the remand and vacatur of the EPA's disapproval of Kentucky's and Mississippi's SIP submissions by the Sixth and Fifth Circuits, respectively, as described in Section III.C. of this preamble. As a result, the EPA now proposes to reconsider the February 13, 2023, partial disapproval of Minnesota's SIP submission and is proposing to fully approve Minnesota's SIP submission.

b. Summary of Minnesota's Submission

Minnesota's SIP submission cites both the EPA's March 2018 memorandum modeling and modeling conducted by the Lake Michigan Air Directors Consortium (LADCO).¹⁵⁸ In Step 1 of the Framework, Minnesota identifies monitoring sites that are projected to have problems attaining and/or maintaining the 2015 8-hour ozone NAAQS in 2023 according to LADCO modeling, which used the Eastern Regional Technical Advisory Committee (ERTAC) EGU Tool version 2.7¹⁵⁹ and the EPA's March 2018 modeling.¹⁶⁰ LADCO performed a modeling demonstration like that of the EPA's 2018 transport modeling, except with use of the ERTAC EGU Tool to supplement State-specific EGU information.

In Step 2, Minnesota's SIP submission presents the State's projected 2023 ozone contributions to maintenance and nonattainment receptors identified by both LADCO modeling and the EPA's March 2018 modeling.¹⁶¹ Minnesota's SIP submission notes there were differences in identified receptors between the two modeling results, and the LADCO results overall yielded slightly lower projected contributions to downwind receptors from Minnesota sources than the EPA's modeling.¹⁶²

Minnesota relies on the 1-percent threshold to define linkages. Both the LADCO modeling and the EPA's March 2018 modeling showed that Minnesota contributes less than 1 percent of the NAAQS to all downwind receptors. Minnesota shows in Table 2 of the State's SIP submission that the highest projected contribution to a receptor in 2023 is 0.40 ppb, based on the EPA's March 2018 modeling, or 0.45 ppb,

based on LADCO modeling, to a receptor in Milwaukee County, Wisconsin.¹⁶³ Minnesota concludes that the State is not linked above 1 percent of the NAAQS to any downwind receptor and therefore does not contribute to nonattainment or interference with maintenance in other States with respect to the 2015 8-hour ozone NAAQS.

Although Minnesota concludes it is not linked in Step 2, Minnesota proceeds with a Step 3 analysis. Minnesota provides air quality data to demonstrate that no additional emissions reductions are necessary to satisfy the State's transport obligations, including evidence of decreasing ambient ozone concentrations in the State from the mid-1990s through 2017 as well as decreasing NO_x and VOC emissions from the State from 2002 through 2015.¹⁶⁴ Minnesota concludes that decreasing emissions in the State make it unlikely for the State to contribute significantly to nonattainment or interference with maintenance of the 2015 8-hour ozone NAAQS in downwind States.

Minnesota therefore concludes that no additional permanent or enforceable measures are needed to address ozone transport contribution from Minnesota sources beyond existing control measures. Therefore, Minnesota did not consider any new permanent and enforceable measures to reduce emissions as part of the Step 4 analysis.

c. Evaluation of Minnesota's Submission

As described in Section III.C. of this preamble, in light of the EPA's implementation of policies consistent with the Sixth and Fifth Circuits' decisions in *Kentucky* and *Texas*, the EPA is reconsidering its previous disapproval of the SIP submission from Minnesota. In Steps 1 and 2 of the Framework, Minnesota relies on both LADCO modeling and the EPA's March 2018 memorandum modeling in its SIP submission. The March 2018 memorandum modeling showed that Minnesota's projected maximum contribution is 0.40 ppb to a nonattainment receptor (receptor ID 550790085 in Milwaukee County, Wisconsin) and 0.31 ppb to a maintenance receptor (receptor ID 261630019 in Wayne County, Michigan).¹⁶⁵ LADCO modeling similarly showed that Minnesota's projected maximum contribution to any downwind receptor is 0.45 ppb

(receptor ID 550790085 in Milwaukee County, Wisconsin).¹⁶⁶ Minnesota does not contribute above the 1-ppb threshold to any receptor in its modeling of choice. Thus, in accordance with the policies articulated in Section III.C. of this preamble, the EPA proposes to find that Minnesota does not impact downwind air quality problems such that the State should be considered "linked" in Step 2 of the Framework and, therefore, further review and analysis at Steps 3 and 4 is not warranted. Therefore, the EPA is proposing to fully approve Minnesota's SIP submission because the State will not contribute significantly to nonattainment or interfere with maintenance of the 2015 8-hour ozone NAAQS in any other State.¹⁶⁷ This proposed action, if finalized, would replace the EPA's previous final action disapproving the SIP submission from Minnesota.¹⁶⁸

7. Mississippi

a. Prior Notices Related to Mississippi's SIP Submission

On September 3, 2019, the Mississippi Department of Environmental Quality submitted a SIP revision addressing CAA section 110(a)(2)(D)(i)(I) interstate transport requirements for the 2015 8-hour ozone NAAQS.¹⁶⁹ The EPA's proposed disapproval of Mississippi's SIP submission was published on February 22, 2022,¹⁷⁰ and the EPA's final disapproval was published on February 13, 2023.¹⁷¹ The Fifth Circuit vacated and remanded that disapproval to the EPA.¹⁷² Additionally, the EPA is now reconsidering policy decisions made in our prior actions addressing interstate transport obligations under the 2015 8-hour ozone NAAQS following *Texas* and the remand and vacatur of the EPA's disapproval of Kentucky's SIP submission by the Sixth Circuit, as described in Section III.C. of this preamble. As a result, the EPA proposes to approve Mississippi's SIP submission.

b. Summary of Mississippi's Submission

Mississippi's SIP submission provides the State's analysis of its impact to downwind States and concludes that emissions from the State will not

¹⁵⁸ See Minnesota's SIP submission at 1.

¹⁵⁹ Information about the ERTAC EGU tool can be found at <https://marama.org/technical-center/ertac-egu/>.

¹⁶⁰ Minnesota's SIP submission at Tables 2 and 3, pages 8–9.

¹⁶¹ *Id.*

¹⁶² *Id.* at 7.

¹⁶³ *Id.* at 8–9.

¹⁶⁴ *Id.* Figures 1–3, pages 10–11.

¹⁶⁵ See Attachment C to the EPA's March 2018 memorandum.

¹⁶⁶ Minnesota's SIP submission, Table 2 at 8.

¹⁶⁷ See 42 U.S.C. 7410(a)(2)(D)(i)(I).

¹⁶⁸ 88 FR 9336.

¹⁶⁹ See "Mississippi 2015 Ozone Infrastructure SIP Prongs 1 & 2" ("Mississippi's SIP submission") included in the docket for this proposed action, Docket ID No. EPA–HQ–OAR–2025–0192.

¹⁷⁰ 87 FR 9545 (Feb. 22, 2022).

¹⁷¹ 88 FR 9336 (Feb. 13, 2023).

¹⁷² *Texas*, 132 F.4th at 863.

significantly contribute to nonattainment or interfere with maintenance of the 2015 8-hour ozone NAAQS in other States.

Mississippi's SIP submission relies on the EPA's March 2018 memorandum modeling to identify projected downwind nonattainment and maintenance receptors and contribution linkages in 2023 that may be impacted by emissions from sources in Mississippi in Steps 1 and 2 of the Framework, respectively.¹⁷³ Mississippi notes that the modeled contributions for Mississippi are below 1 percent of the NAAQS for all nonattainment and maintenance receptors, except the Deer Park nonattainment receptor in Harris County, Texas ("Deer Park receptor").¹⁷⁴ Mississippi's SIP submission identifies that the State is projected to contribute 0.79 ppb to the Deer Park receptor.¹⁷⁵

Mississippi discusses the EPA's August 2018 memorandum, noting that 0.79 ppb is between 1 percent of the NAAQS and 1 ppb.¹⁷⁶ Mississippi's SIP submission also states that the Deer Park receptor design value was projected to be greater than the 2015 8-hour ozone standards in 2023, but the actual 2015–2017 design value was below the NAAQS at 68 ppb.¹⁷⁷ Based on the EPA's March 2018 modeling, along with application of a 1-ppb threshold and information regarding 2015–2017 monitored values at the Deer Park receptor, Mississippi concludes that sources in the State are not linked to downwind nonattainment or maintenance receptors in Step 2 and, therefore, the State does not significantly contribute to nonattainment in another State for the 2015 8-hour ozone standards. Further, Mississippi states that the State's SIP submission contains adequate provisions to prohibit sources and other types of emissions activities within the State from contributing to nonattainment (Prong 1) in another State with respect to the 2015 8-hour ozone NAAQS.

In Mississippi's SIP submission, the State treats the Deer Park receptor as a maintenance receptor because the 2017 design value of 68 ppb was below the level of the NAAQS at this monitor.¹⁷⁸ Mississippi cites the EPA's October 2018 memorandum to apply this alternative definition of a maintenance receptor. Based on the alternative definition of a maintenance receptor

and the application of a 1-ppb threshold, Mississippi concludes that the State does not significantly interfere with maintenance (Prong 2) in another State for the 2015 8-hour ozone standards. c. Evaluation of Mississippi's Submission

c. Evaluation of Mississippi's Submission

The Fifth Circuit vacated and remanded the EPA's prior disapproval of Mississippi's SIP submission on the grounds that the disapproval was arbitrary and capricious for inadequate explanation.¹⁷⁹ Applying a 1-percent threshold to 2016v3 modeling results, the EPA found Mississippi to be linked to at least one out-of-state receptor. The court noted that the EPA had said that Mississippi's use of a 1-ppb contribution threshold was "inconsequential" to the outcome; however, Mississippi did not contribute above 1 ppb in the older modeling provided in its SIP submission and so would not have been linked had the EPA limited its consideration only to the modeling used in Mississippi's SIP submission.¹⁸⁰ Due to this, the court found that the EPA failed to recognize or reasonably explain its decision to consider the updated modeling in an "outcome determinative" way.¹⁸¹

On remand, the EPA is reevaluating Mississippi's submission in accordance with the court's identification of the EPA's previous missteps. As described in Section III.C.4. of this preamble, the EPA relies in the first instance on the modeling the State chose to use in its submission and will only consider its updated modeling information to confirm that at least one linkage above 1 ppb continues to persist. In Steps 1 and 2 of the Framework, Mississippi relies on the EPA's March 2018 memorandum modeling to identify nonattainment and maintenance receptors and identify upwind State linkages to nonattainment and maintenance receptors.¹⁸² This modeling showed that Mississippi's projected maximum contribution is 0.79 ppb to a nonattainment receptor (receptor ID 482011039 in Harris County, Texas) and 0.50 ppb to a maintenance receptor (receptor ID

482010024 in Harris County, Texas).¹⁸³ Mississippi does not contribute above the 1-ppb threshold to any receptor in its modeling of choice. Thus, in accordance with the policies articulated in Section III.C. of this preamble, the EPA proposes to find that Mississippi does not impact downwind air quality problems such that the State should be considered "linked" in Step 2 of the Framework and, therefore, further review and analysis at Steps 3 and 4 is not warranted. Therefore, the EPA is proposing to approve Mississippi's SIP submission because the State will not contribute significantly to nonattainment or interfere with maintenance of the 2015 8-hour ozone NAAQS in any other State.¹⁸⁴ Here, the EPA is not using its updated information in an outcome determinative way as it is not relying on its updated modeling information to approve Mississippi's submission. This proposal, if finalized, will respond to the Fifth Circuit's vacatur and remand of the previous disapproval of Mississippi's SIP submission.

8. Nevada

a. Prior Notices Related to Nevada's SIP Submission

On September 28, 2018, the Nevada Division of Environmental Protection (NDEP) submitted Nevada's infrastructure SIP revision for the 2015 8-hour ozone NAAQS.¹⁸⁵ The EPA's proposed disapproval of Nevada's SIP submission was published on May 24, 2022,¹⁸⁶ and the final disapproval was published on February 13, 2023.¹⁸⁷ However, the EPA is now reconsidering policy decisions made in our prior actions addressing interstate transport obligations under the 2015 8-hour ozone NAAQS following the remand and vacatur of the EPA's disapproval of Kentucky's and Mississippi's SIP submissions by the Sixth and Fifth Circuits, respectively, as described in Section III.C of this preamble. As a result, the EPA is proposing to reconsider the February 13, 2023, disapproval of Nevada's SIP submission and is proposing to approve Nevada's SIP submission.

¹⁸³ See Attachment C to the EPA's March 2018 memorandum.

¹⁸⁴ See 42 U.S.C. 7410(a)(2)(D)(i)(I).

¹⁸⁵ See "The Nevada Division of Environmental Protection Portion of the Nevada State Implementation Plan for the 2015 Ozone NAAQS: Demonstration of Adequacy" ("Nevada's SIP submission") included in the docket for this proposed action, Docket ID No. EPA-HQ-OAR-2025-0192.

¹⁸⁶ 87 FR 31485 (May 24, 2022).

¹⁸⁷ 88 FR 9336 (Feb. 13, 2023).

¹⁷³ Mississippi's SIP submission at 4.

¹⁷⁴ *Id.*

¹⁷⁵ *Id.* Table 1.

¹⁷⁶ *Id.* at 6.

¹⁷⁷ *Id.* Table 4.

¹⁷⁸ *Id.* at 9.

¹⁷⁹ *Texas*, 132 F.4th at 860–862.

¹⁸⁰ See *id.* at 861–862.

¹⁸¹ *Id.* at 862.

¹⁸² In Step 1, Mississippi also applied an alternative definition of a maintenance receptor using the EPA's October 2018 Memorandum and 2014 to 2017 Design Values. However, based on the EPA's conclusions identified in this section, the EPA does not find it necessary to review in depth the State's application of an alternative maintenance receptor definition.

b. Summary of Nevada's Submission

NDEP addresses CAA section 110(a)(2)(D)(i)(I) interstate transport requirements for the 2015 8-hour ozone NAAQS in Appendix E of Nevada's SIP submission.¹⁸⁸ Nevada's SIP submission follows the Framework to analyze Nevada's impact on other States. In Steps 1 and 2, Nevada relies on the EPA's March 2018 memorandum modeling.¹⁸⁹ Further, in Step 2, Nevada applies a 1-percent threshold.¹⁹⁰ Based on the EPA's March 2018 memorandum modeling results, Nevada's SIP submission concludes that the largest projected contribution from Nevada to a nonattainment or maintenance receptor in another State is 0.9 percent of the 2015 8-hour ozone NAAQS.¹⁹¹

Based on the conclusion that emissions sources in Nevada do not contribute above 1 percent of the NAAQS to any nonattainment or maintenance receptors, Nevada's SIP submission concludes that identification of necessary emissions reductions in Step 3 of the EPA's Framework is not needed.¹⁹² Accordingly, Nevada does not consider any new permanent and enforceable measures to reduce emissions in Step 4 of the Framework.¹⁹³

c. Evaluation of Nevada's Submission

As described in Section III.C. of this preamble, in light of the EPA's implementation of policies consistent with the Sixth and Fifth Circuits' decisions in *Kentucky* and *Texas*, the EPA is reconsidering its previous disapproval of the SIP submission from Nevada. In Steps 1 and 2 of the Framework, Nevada relies on the EPA's March 2018 memorandum modeling to identify nonattainment and maintenance receptors and upwind State linkages to nonattainment and maintenance receptors in 2023. This modeling showed that, outside of

California, Nevada's projected maximum contribution is 0.38 ppb to a maintenance receptor (receptor ID 8059001 in Jefferson County, Colorado) and 0.37 ppb to a nonattainment receptor (receptor ID 80690011 in Larimer County, Colorado).¹⁹⁴ ¹⁹⁵ Nevada is not linked to any downwind receptor above the 1-ppb threshold in its modeling of choice. Thus, in accordance with the policies articulated in Section III.C. of this preamble, the EPA proposes to find that Nevada does not impact downwind air quality problems such that the State should be considered "linked" in Step 2 of the Framework and, therefore, further review and analysis in Steps 3 and 4 is not warranted. Therefore, the EPA is proposing to approve Nevada's SIP submission because the State will not contribute significantly to nonattainment or interfere with maintenance of the 2015 8-hour ozone NAAQS in any other State.¹⁹⁶ This proposed action, if finalized, would replace the EPA's previous final action disapproving the SIP submission from Nevada.¹⁹⁷

9. New Mexico

a. Prior Notices Related to New Mexico's SIP Submission

In 2019, the EPA found that New Mexico had failed to submit a complete interstate transport SIP submission for the 2015 8-hour ozone NAAQS.¹⁹⁸ This triggered the EPA's obligation to promulgate a FIP for New Mexico within two years.¹⁹⁹ When the EPA did not do so, multiple parties brought deadline-suit litigation against the EPA. This resulted in a consent decree deadline of June 1, 2024, for the EPA to either promulgate a FIP for New Mexico or approve a SIP submission fully resolving New Mexico's interstate transport obligations.²⁰⁰ By stipulation of the parties, that deadline has now been extended to February 26, 2026.²⁰¹

On July 20, 2021, on behalf of the City of Albuquerque Environmental Health Department (EHD), the New Mexico Environment Department (NMED) submitted a certification that Albuquerque-Bernalillo County "does not cause or contribute to nonattainment or interfere with maintenance of the 2015 8-hour ozone NAAQS in any other state."²⁰² On July 27, 2021, NMED then submitted an interstate transport SIP submission certifying that New Mexico's SIP submission satisfies interstate transport requirements for the 2015 8-hour ozone NAAQS.²⁰³ On July 5, 2023, NMED submitted a supplemental letter that contains additional data for the EPA's consideration in the Agency's review of the New Mexico SIP submission.²⁰⁴ The EPA proposed to partially disapprove New Mexico's SIP submission as to Prong 2 in the Proposed Supplemental Air Plan Action.²⁰⁵ However, the EPA is now reconsidering policy decisions made in our prior actions addressing interstate transport obligations under the 2015 8-hour ozone NAAQS following the remand and vacatur of the EPA's disapproval of Kentucky's and Mississippi's SIP submissions by the Sixth and Fifth Circuits, respectively, as described in Section III.C of this preamble. As a result, the EPA is proposing full approval of New Mexico's SIP submission.

b. Summary of New Mexico's Submission

New Mexico's SIP submission contains what NMED characterizes as a WOE analysis of New Mexico's contribution to ozone transport receptors. In Step 1 of the Framework, New Mexico's SIP submission relies on the EPA's March 2018 memorandum modeling.²⁰⁶ In Step 2, New Mexico identifies that the State contributes above 1 percent of the NAAQS to one maintenance receptor and one

¹⁸⁸ Nevada's SIP submission also includes information from two other agencies that regulate air quality in Nevada: the Clark County Department of Air Quality and the Washoe County Health District Air Quality Management Division. Though these two county level agencies provided their own submissions, they do not include their own separate transport evaluation and instead incorporate Appendix E of Nevada's SIP verbatim. The individual submissions from Clark County and Washoe County are included in the docket, and for simplicity in this section "Nevada's SIP submission" refers to the collection of submissions from NDEP, Clark County, and Washoe County.

¹⁸⁹ Nevada's SIP submission, at E-2 and E-3.

¹⁹⁰ Nevada's SIP submission at E-2, E-3, and E-10.

¹⁹¹ *Id.* at E-6 and Attachment A. Specific contributions to nonattainment and maintenance monitors are contained in Table E-A3.

¹⁹² *Id.* at E-11.

¹⁹³ *Id.*

¹⁹⁴ See Attachment C to the EPA's March 2018 memorandum.

¹⁹⁵ Nevada identified its maximum contribution to be 0.9 percent of the NAAQS (or 0.65 ppb) to a monitoring site in California. Because this is below the 1 ppb threshold (as well as a 1% of NAAQS threshold), we do not need to resolve whether this monitoring site should be considered a transport receptor. See 88 FR at 36718.

¹⁹⁶ See 42 U.S.C. 7410(a)(2)(D)(i)(I).

¹⁹⁷ 88 FR 9336.

¹⁹⁸ 84 FR 66612 (Dec. 4, 2019).

¹⁹⁹ 42 U.S.C. 7410(c)(1)(A).

²⁰⁰ *WildEarth Guardians v. Zeldin*, No. 22-cv-0174-RB-GBW (D.N.M. Aug. 16, 2022); *Sierra Club v. Zeldin*, No. 3:22-cv-01992-JD (N.D. Cal. Jan. 24, 2023).

²⁰¹ Joint Stipulation Extending Consent Decree Deadlines, *WildEarth Guardians v. Zeldin*, No. 1:22-cv-0174, ECF No. 20 (D.N.M. Nov. 25, 2024); Joint Notice of Stipulated Extension of Consent

Decree Deadline, *Sierra Club v. Zeldin*, No. 3:22-cv-01992-JD, ECF No. 44 (N.D. Cal. Nov. 25, 2024).

²⁰² See "New Mexico Good Neighbor State Implementation Plan Certification for the 2015 Ozone NAAQS, Submitted on Behalf of Albuquerque-Bernalillo County" ("EHD SIP submission") in the docket for this action, Docket ID No. EPA-HQ-OAR-2025-0192.

²⁰³ See "New Mexico's Good Neighbor State Implementation Plan Certification for the 2015 Ozone National Ambient Air Quality Standard" ("NMED's SIP submission") in the docket for this action. For simplicity in this section, "New Mexico's SIP submission" refers to the collective information in NMED's submission and EHD's submission.

²⁰⁴ This additional data was included under the heading "Exhibit A Estimates of Emission Reductions ("Exhibit A").

²⁰⁵ 89 FR 12666 (Feb. 16, 2024).

²⁰⁶ NMED's Exhibit A acknowledged the EPA's 2016v3 modeling results and linkages.

nonattainment receptor, both in Colorado.²⁰⁷

New Mexico used a WOE analysis rather than relying on a single, national standard for identifying linkages and determining whether contributions from an upwind State are significant.²⁰⁸ NMED and EHD find that New Mexico should not be considered linked to Colorado receptors in Step 2 because the majority of the contribution to these receptors comes directly from Colorado. New Mexico's submission also states that the relative share of in-state versus out-of-state contribution in Colorado, topographical influences on the transport of ozone in Colorado, and other air quality information support its WOE analysis.²⁰⁹

New Mexico concludes it would be unreasonable for the State to take further actions to address its interstate transport requirements for the 2015 8-hour ozone NAAQS and therefore do not conduct an analysis of emissions control opportunities within the State in Step 3. Thus, in Step 4, NMED and EHD determine that no additional permanent and enforceable measures are necessary to reduce the State's emissions.

The supplemental information NMED submitted for the EPA's consideration in 2023 provides more information in response to the EPA's indication that the EPA may disapprove New Mexico's SIP submission. To the EPA's knowledge, this letter was not subject to public notice or rulemaking process at the State level and does not in itself purport to be a SIP submission or a revision to New Mexico's SIP submission. As such, the EPA takes the information in the letter under advisement but does not consider the letter to be a new SIP submission in its own right or part of New Mexico's SIP submission.

c. Evaluation of New Mexico's Submission

As described in Section III.C. of this preamble, in light of the EPA's implementation of policies consistent with the Sixth and Fifth Circuits' decisions in *Kentucky* and *Texas*, the EPA is reconsidering its previous proposed disapproval of the SIP submission from New Mexico. New Mexico relies on the EPA's March 2018 memorandum modeling in the State's SIP submission. This modeling showed that New Mexico's maximum contribution is 0.77 ppb to a maintenance receptor (receptor ID 81230009 in Weld County, Colorado)

and 0.70 ppb to a nonattainment (receptor ID 80590006 in Jefferson County, Colorado).²¹⁰ Both contributions in the State's modeling of choice are below the 1-ppb threshold. Thus, in accordance with the policies articulated in Section III.C. of this preamble, the EPA proposes to find that New Mexico does not impact downwind air quality problems such that it should be considered "linked" in Step 2 of the Framework and, therefore, further review and analysis in Steps 3 and 4 is not warranted. Therefore, the EPA is proposing to approve New Mexico's SIP submission because the State will not contribute significantly to nonattainment or interfere with maintenance of the 2015 8-hour ozone NAAQS in any other State.²¹¹ If finalized, the EPA will withdraw the prior proposed partial disapproval.

10. Tennessee

a. Prior Notices Related to Tennessee's SIP Submission

On September 13, 2018, the Tennessee Department of Environment and Conservation submitted a SIP addressing CAA section 110(a)(2)(D)(i)(I) interstate transport requirements for the 2015 8-hour ozone NAAQS.²¹² The EPA previously proposed approval of Tennessee's SIP submission on December 30, 2019.²¹³ The EPA then withdrew this proposed approval and proposed to disapprove Tennessee's SIP submission in a notice published on February 22, 2022.²¹⁴ In the Proposed Supplemental Air Plan Action, the EPA then withdrew the proposed disapproval and proposed to partially disapprove Tennessee's SIP submission as to Prong 2.²¹⁵ However, the EPA is now reconsidering policy decisions made in our prior actions addressing interstate transport obligations under the 2015 8-hour ozone NAAQS following the remand and vacatur of the EPA's disapproval of Kentucky's and Mississippi's SIP submissions by the Sixth and Fifth Circuits, respectively, as described in Section III.C. of this preamble. As a

result, the EPA is proposing full approval of Tennessee's SIP submission.

b. Summary of Tennessee's Submission

Tennessee's SIP submission provides the State's analysis of its impact to downwind States and concludes that emissions from the State will not significantly contribute to nonattainment or interfere with maintenance of the 2015 8-hour ozone NAAQS in other States. Tennessee's SIP submission relies on the EPA's March 2018 memorandum modeling to identify downwind nonattainment and maintenance receptors that may be impacted by emissions from sources in the State in Steps 1 and 2 of the Framework.²¹⁶ Tennessee summarizes the State's upwind contribution and notes Tennessee's largest impact on a projected downwind receptor is 0.31 ppb and 0.65 ppb to a nonattainment and maintenance receptor, respectively. Tennessee finds that, based on these modeling results, emissions from Tennessee do not contribute above 1 percent of the NAAQS or above 1 ppb at any monitors that are projected to be in nonattainment or maintenance.²¹⁷

Tennessee's SIP submission emphasizes a significant reduction in NO_x emissions from coal-fired EGUs and other large NO_x sources leading to improvements in air quality, including reductions attributable to previous transport rulemakings.²¹⁸ Additionally, Tennessee identifies existing SIP-approved provisions, Federal regulations and programs, court settlements, and statewide source shutdowns that Tennessee believes limit ozone precursor emissions in the State.²¹⁹

Based on this information, Tennessee concludes that the State does not significantly contribute to nonattainment or interfere with maintenance in another State of the 2015 8-hour ozone NAAQS, and the existing approved SIP, found at 40 CFR part 52, subpart RR, provides for adequate measures to control ozone precursor emissions.

c. Evaluation of Tennessee's Submission

As described in Section III.C. of this preamble, in light of the EPA's implementation of policies consistent with the Sixth and Fifth Circuits' decisions in *Kentucky* and *Texas*, the EPA is reconsidering its previous

²¹⁰ See Attachment C to the EPA's March 2018 memorandum.

²¹¹ See 42 U.S.C. 7410(a)(2)(D)(i)(I).

²¹² The September 13, 2018, SIP submission provided by TDEC was received by the EPA on September 17, 2018. On September 18, 2018, Tennessee submitted multiple SIP submissions under one cover letter. The EPA is only acting on Tennessee's 2015 8-hour ozone NAAQS interstate transport SIP requirements in this notice ("Tennessee's SIP submission").

²¹³ 84 FR 71854 (Dec. 30, 2019).

²¹⁴ 87 FR 9545 (Feb. 22, 2022).

²¹⁵ 89 FR 12666 (Feb. 16, 2024).

²¹⁶ Tennessee's SIP submission at 9.

²¹⁷ *Id.*

²¹⁸ Tennessee's SIP submission cites Federal and state rules at pages 9–12.

²¹⁹ See pages 9 through 12 of Tennessee's SIP submission for a list of SIP-approved state rules and Federal rules.

²⁰⁷ *Id.* at Table 1, page 4; page 5.

²⁰⁸ New Mexico SIP submission at 5.

²⁰⁹ *Id.* at 5–16.

proposed disapproval of the SIP submission from Tennessee. Tennessee relied on the EPA's March 2018 memorandum modeling to identify nonattainment and maintenance receptors and upwind State linkages to nonattainment and maintenance receptors in 2023. Tennessee relies on a 1-ppb threshold in its SIP submission. This modeling showed that Tennessee's projected maximum contribution is 0.31 ppb to a nonattainment receptor (receptor ID 551170006 in Sheboygan County, Wisconsin) and 0.65 ppb to a maintenance receptor (receptor ID 260050003 in Allegan County, Michigan).²²⁰ Therefore, Tennessee is not linked to any downwind receptors above the 1-ppb threshold in its modeling of choice. Thus, in accordance with the policies articulated in Section III.C. of this preamble, based on the EPA's evaluation of the information provided in Tennessee's SIP submission, the EPA proposes to find that Tennessee does not impact downwind air quality problems such that the State should be considered "linked" in Step 2 of the Framework and, therefore, further review and analysis at Steps 3 and 4 is not warranted. Therefore, the EPA is proposing to approve Tennessee's SIP submission because the State will not contribute significantly to nonattainment or interfere with maintenance of the 2015 8-hour ozone NAAQS in any other State.²²¹ If finalized, the EPA will withdraw the prior proposed partial disapproval.

B. CAA Section 110(l)

Under CAA section 110(l), "the Administrator shall not approve a revision of a plan if the revision would interfere with any applicable requirement concerning attainment . . . or any other applicable requirement of this chapter." Section 110(l) applies to all CAA requirements, including section 110(a)(2)(D) requirements relating to interstate transport.²²²

For the 2015 8-hour ozone NAAQS, the EPA previously disapproved interstate transport SIP submissions from, and promulgated interstate transport FIPs for sources in, Alabama, Kentucky, Minnesota, Mississippi, and Nevada.²²³ The EPA's predicate authority for the FIPs as to each of these States was judicially stayed or judicially

vacated.²²⁴ However, the Ninth Circuit later lifted the stay of Nevada's SIP submission.²²⁵ The EPA never promulgated interstate transport FIPs for Arizona, Iowa, Kansas, New Mexico, or Tennessee. Therefore, this proposed action, if finalized, will not revise any existing requirement in any lawfully promulgated implementation plan for any State included in this proposed action. In the case of Nevada, even if the Good Neighbor Plan were considered in the baseline (which is assumed only for the sake of argument, given that the stay of its SIP disapproval was lifted), the EPA is not aware of any interference with other requirements of the CAA that would result from this proposed action.

V. Summary of Changes to Existing Regulatory Text

This section describes proposed amendments to the regulatory text in the CFR to approve and promulgate SIPs for eight States (Alabama, Arizona, Kentucky, Minnesota, Mississippi, Nevada, New Mexico, and Tennessee).

The primary CFR amendments that would apply the approval and promulgation of the SIPs will be made in the respective State's subpart of 40 CFR part 52. The subparts are as follows: Alabama—subpart B, Arizona—subpart D, Kentucky—subpart S, Minnesota—subpart Y, Mississippi—subpart Z, Nevada—subpart DD, New Mexico—subpart GG, Tennessee—subpart RR. Where appropriate, the approval status for the 2015 8-hour ozone NAAQS will be changed from disapproved to approved, and, where appropriate, the approval status will be changed to indicate the SIP has now been approved.

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at www.epa.gov/laws-regulations/laws-and-executive-orders.

A. Executive Order 12866: Regulatory Planning and Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB). Any

changes made in response to Executive Order 12866 review have been documented in the docket for this action.

B. Executive Order 14192: Unleashing Prosperity Through Deregulation

This action is expected to be an Executive Order 14192 deregulatory action. This proposed rule is expected to provide burden reduction. If finalized, this action would resolve the interstate transport obligations of eight States for the 2015 8-hour ozone NAAQS. Therefore, this action would result in reduced regulatory burden for those States.

C. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA because it does not contain any information collection activities.

D. Regulatory Flexibility Act (RFA)

I certify this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action proposes to approve SIP submissions as satisfying interstate transport requirements under CAA section 110(a)(2)(D)(i)(I) for the 2015 ozone NAAQS, and these SIP submissions do not impose any requirements on small entities.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA 2 U.S.C. 1531–1538 and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any State, local, or Tribal governments or the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have Tribal implications as specified in Executive Order 13175. This proposed rule does not 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. Thus,

²²⁰ See Attachment C to the EPA's March 2018 memorandum.

²²¹ See 42 U.S.C. 7410(a)(2)(D)(i)(I).

²²² *Id.* 7410(l).

²²³ 88 FR 9336 (Feb. 13, 2023); 88 FR 36654 (June 5, 2023).

²²⁴ *Alabama et al. v. EPA*, No. 23–11173, ECF No. 33 (11th Cir. Aug. 17, 2023) (SIP Disapproval Action as to Alabama stayed); *Kentucky v. EPA*, 123 F.4th 447 (6th Cir. 2024) (SIP Disapproval Action as to Kentucky vacated); *Allete, Inc. d/b/a Minnesota Power et al. v. EPA*, No. 23–1776, ECF No. 5292580 (8th Cir. July 5, 2023) (SIP Disapproval Action as to Minnesota stayed); *Texas v. EPA*, 132 F.4th 808 (5th Cir. 2025) (SIP Disapproval Action as to Mississippi vacated); *Nevada Cement Co. v. EPA*, No. 23–682, ECF No. 27 (9th Cir. July 3, 2023) (SIP Disapproval Action as to Nevada stayed).

²²⁵ *Nevada Cement Co. v. EPA*, No. 23–682, ECF No. 65 (9th Cir. Dec. 17, 2024).

Executive Order 13175 does not apply to this action.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2–202 of the Executive Order. Therefore, this action is not subject to Executive Order 13045 because it merely approves SIP submissions as containing the necessary provisions to satisfy interstate transport requirements under CAA section 110(a)(2)(D)(i)(I).

Furthermore, since this action does not concern human health risks, EPA’s Policy on Children’s Health also does not apply.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a “significant energy action” because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The purpose of this proposed rule is to resolve the interstate transport requirements for the 2015 8-hour ozone NAAQS for 10 States. The EPA does not expect these activities to adversely affect energy suppliers, distributors, or users.

J. National Technology Transfer and Advancement Act

This rulemaking does not involve technical standards.

List of Subjects in 40 CFR Part 52

Environmental protection, Administrative practice and procedure, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen oxides, Ozone, Particulate matter, Sulfur dioxide.

Lee Zeldin,
Administrator.

[FR Doc. 2026–01844 Filed 1–29–26; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Part 3170

[A2407–014–004–065516, #O2509–014–004–125222]

RIN 1004–AF38

Requirements for Site Security and Production Handling; Applying for Commingling and Allocation Approval

AGENCY: Bureau of Land Management, Interior.

ACTION: Proposed rule.

SUMMARY: The Bureau of Land Management (BLM) proposes to revise its regulations governing site security and production handling and commingling applications to reflect Congress’s direction in section 50101(d)(3) of the “One Big Beautiful Bill Act” (OBBA) and policy direction in Executive Orders (E.O.s) entitled, *Unleashing American Energy* and *Ensuring Lawful Governance and Implementing the President’s “Department of Government Efficiency” Deregulatory Initiative* and policy guidance in Secretary’s Order (S.O.) 3418, entitled, *Unleashing American Energy*. The BLM is proposing to revise the regulations to allow for commingling of production more broadly to promote oil and gas production on Federal, Indian, private and State lands. Commingling of production can reduce an operator’s cost which could extend the economic life of a well, thereby allowing the operator to continue producing from a well that might otherwise be abandoned.

DATES: Send your comments on this proposed rule to the BLM on or before March 31, 2026. The BLM is not obligated to consider any comments received after this date in making its decision on the final rule.

Information Collection Requirements: This proposed rule includes revised information-collection requirements that must be approved by the Office of Management and Budget (OMB). If you wish to comment on the information collection requirements, please note that those comments should be sent directly to OMB. OMB is required to make a decision concerning the collection of information contained in this proposed rule between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment to the OMB on the proposed information-collection revisions is best

assured of being given full consideration if the OMB receives it by March 2, 2026.

ADDRESSES: Mail, personal, or messenger delivery: U.S. Department of the Interior, Director (630), Bureau of Land Management, 1849 C St. NW, Room 5646, Washington, DC 20240, Attention: 1004–AF38. *Federal eRulemaking Portal:* <https://www.regulations.gov>. In the Search-box, enter “BLM–2025–0070” and click the “Search” button. Follow the instructions at this website.

For Comments on Information-Collection Activities: Written comments and suggestions on the information-collection requirements should be submitted by the date specified in the **DATES** section to www.reginfo.gov/public/do/PRAMain. Find this specific information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. If you submit comments on the information collection burdens, you should provide the BLM with a copy at the addresses shown earlier in this section, so that we can summarize all written comments and address them in the final rule. Please indicate “Attention: OMB Control Number 1004–0137 (RIN 1004–AF38)” regardless of the method used to submit comments on the information collection burdens. Comments not pertaining to the proposed rule’s information collection burdens should not be submitted to OMB. The BLM is not obligated to consider or include in the administrative record for the final rule any comments that are improperly directed to OMB.

FOR FURTHER INFORMATION CONTACT: Amanda Fox at telephone: 907–538–2300; email: afox@blm.gov. Individuals in the United States who are deaf, blind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services for contacting Mr. Warren. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

For a summary of the rule, please click on the Docket Details tab in docket number BLM–2025–0070 on www.regulations.gov.

SUPPLEMENTARY INFORMATION:

Executive Summary

The Bureau of Land Management (BLM) proposes to revise its regulations governing site security and production handling and commingling applications to reflect Congress’s direction in section

50101(d)(3) of the OBBB and policy direction in E.O. 14154, entitled, *Unleashing American Energy and Ensuring Lawful Governance* and; E.O. 14219, entitled, *Implementing the President's "Department of Government Efficiency" Deregulatory Initiative*; and policy guidance in S.O. 3418 entitled, *Unleashing American Energy*. The BLM is proposing to revise 43 Code of Federal Regulations (CFR) 3173.1, 3173.14, 3173.15, and 3173.16 to allow for commingling of production more broadly in order to promote oil and gas production on Federal, Indian, private, and State lands.

The BLM is proposing the revisions to these regulations to address barriers that limit the BLM's ability to approve commingling and allocation agreements (CAAs) that involve multiple sources. Commingling is the approved method for combining production from multiple leases, unit participating areas (PAs), and communitization areas (CAs) at one measurement point with an approved method to allocate production back to each lease, unit PA, or CA. The Mineral Leasing Act of 1920 requires all production leaving a lease to be measured before it leaves the lease. Commingling allows production to leave a lease and be measured at an approved point off the lease. These agreements can be used to promote production in situations where either State spacing regulations or mixed ownership patterns may otherwise inhibit an operator's ability to develop our Nation's vital oil and natural gas resources. The existing regulations have resulted in significant operational costs, administrative burdens, and a backlog in the approval of these agreements. The proposed revisions are also intended to promote operational and business efficiency, foster responsible resource development, reduce environmental impacts, prevent the orphaning of wells from premature abandonment, and ensure that the public receives a fair return from the use of public resources. Broader commingling approvals allows more leases, unit PAs, and CAs to be combined at one facility reducing the overall facility cost and the number of points where production is transferred to buyers. Centralizing these facilities reduces the environmental impacts by reducing the number of sites where production processing occurs. Commingling can be used to move equipment out of sensitive environments to reduce the potential environmental impacts of the oil and gas development.

The Department undertakes this rulemaking pursuant to section 50101(d)(3) of the OBBB, which requires

the BLM to approve applications for commingling of production if the applicant agrees to one of three standard practices to ensure accurate royalty allocation. In addition, section 226(q) of the Mineral Leasing Act (MLA), 30 U.S.C. 226 *et seq.*, which authorizes the Secretary of the Interior to enter into agreements apportioning production or royalties among tracts of land when they cannot be independently developed and the Federal Oil and Gas Royalty Management Act (FOGRMA), 43 U.S.C. 1701 *et seq.*, authorizes the Secretary to enforce regulations governing inspection of production activities on Federal and Indian lands.

In fiscal year (FY) 2024, onshore Federal oil and gas leases produced about 675 million barrels of oil and 4.6 trillion cubic feet of natural gas, with a market value of more than \$70 billion and generating royalties of almost \$9.3 billion. Nearly half of these revenues were distributed to the States in which the leases are located.

Given the magnitude of this production and the BLM's statutory and management obligations, it is critically important that the BLM ensure that operators accurately measure, properly report, and account for that production and, where appropriate, allow for the commingling of production from Federal and Indian oil and gas leases with production from other sources.

The BLM is proposing updates to existing commingling regulations because: (1) the OBBB statutory direction to the Secretary states that he "shall approve applications allowing for commingling of production from 2 or more sources" if the applicant agrees to use one of three methods for production measurement and allocation, and (2) the regulatory updates are necessary to reflect changes in oil and gas measurement practices and technology since the existing regulations were first promulgated in 2016. Technology is more precise today than it was in 2016. This leads to better measurement equipment, such as Coriolis meters and ultrasonic meters. The OBBB modifies how BLM should address commingling approvals and allocation methodologies to address today's demands. Specifically, this proposed rule is designed to ensure the proper and secure handling of production from Federal and Indian oil and gas leases when commingled with production from other sources.

In the proposed rule, the BLM is proposing to update 43 CFR 3173.14, and codify the requirements for commingling, as explained below, consistent with section 50101(d)(3) of the OBBB and the authority granted

under 30 U.S.C. 226(q). Specifically, the proposed changes to the regulations would allow the Secretary of the Interior, through the BLM, to consider proposed commingling applications based on a variety of possible methodologies referred to in 30 U.S.C. 226(q). These proposed changes are intended to account for advancements in technology and industry practices that have occurred since the existing regulations were first issued in 2016 are expected to:

1. Increase clarity and predictability for industry operators by codifying uniform approval criteria;
2. Reduce administrative delays for commingling requests;
3. Maintain robust royalty accuracy and transparency through high-precision metering or well testing; and
4. Support integrated reservoir development and reduce unnecessary surface disturbance by encouraging centralized production infrastructure.

The proposed changes to 43 CFR 3173.14, "Conditions for commingling and allocation approval (surface and downhole)," are intended to remove conditions in the existing regulations that can limit the circumstances under which the BLM can approve a commingling application. For example, under the existing regulations, in instances when the production proposed for inclusion in the application includes production from leases, unit participating areas (PAs), or CAs, where the Federal interests are disproportionate to one another, the BLM would not allow commingling. For example, under one CA the government may own 100 percent of the minerals while only owning 50 percent on another CA. Under the current regulations, the minerals produced from these leases may not be commingled. However, under the proposed rule, such production could be commingled if certain conditions outlined in the statute are met. The BLM expects that more leases, unit PAs, and CAs could be included in commingling agreements under the proposed rule, thereby promoting additional production, particularly through the combination of producing wells and marginal wells or stripper wells. This supports the statutory directive that the BLM does not waste Federal minerals and ensures that resources are developed efficiently.

Further, the changes made to 43 CFR 3173.15, "Applying for a Commingling and Allocation Approval," are intended to account for certain uncertainties associated with measurement and ensuring that the uncertainty percentage meets the requirements proposed in 43 CFR 3173.14. The changes made to 43

CFR 3173.16, “Existing Commingling and Allocation Approvals,” would allow for all existing CAAs to remain in effect unless the operator adds or removes wells or modifies the facility layout, in which case the operator would need to submit a Sundry Notice Form 3160–5 to the BLM. This is important, for example, because individual wells may report to different leases, unit PAs, or CAs and can cause the uncertainty in measurement to change, resulting in a change to the allocation methodology for production reporting.

Costs and Benefits

This rule could benefit industry by improving economic efficiency at the wellsite by allowing operators to share production facilities across leases such that each lease can reduce operating costs needed to produce Federal or Indian oil and gas.

The BLM estimates that it would spend \$352,170 per year in processing the additional commingling applications. The BLM has further assumed that applicants would need an additional 10 hours per application to provide a complete application to the BLM. This is represented in the Administrative Burden column on the table below.

In the benefit cost analysis of this rule, royalty payments are not considered a cost or a benefit but rather as recurring income to the United States and Indian mineral owners and costs to the operator or lessee. As such, they are transfer payments that do not affect the total resources available to society. An important but sometimes difficult problem in cost estimation is distinguishing between real costs and transfer payments. While transfers should not be included in the economic analysis estimates of the benefits and costs of a regulation, they may be important for describing the distributional effects of a regulation. This proposed rule would allow a variance or error in measuring commingled production of up to ± 5 percent. At the extremes, if commingling happened at all Federal and Indian oil and gas leases, this rule could increase or decrease royalties from Federal onshore leases by \$365 million relative to the royalties based upon the true level of production and increase or decrease (depending on whether the uncertainty is positive or negative) royalties from Indian leases by \$54 million per year relative to the royalties based upon the true level of Indian production. These two examples are extreme because it is highly unlikely that every Federal and Indian lease

would be commingled, and that the measurement uncertainty would also vary by the maximum of ± 5 percent. The change in royalties could, however, be within those two extreme bounds.

I. Public Comment Procedures

If you wish to comment on this proposed rule, you may submit your comments to the BLM by mail, personal or messenger delivery, or through <https://www.regulations.gov> (see the **ADDRESSES** section). Please note that comments on this proposed rule’s information collection burdens should be submitted to the Office of Management and Budget as described in the **ADDRESSES** section.

Please make your comments on the proposed rule as specific as possible, confine them to issues pertinent to the proposed rule, and explain the reason for any changes you recommend. Where possible, your comments should reference the specific section or paragraph of the proposal that you are addressing. The BLM is not obligated to consider or include in the administrative record for the final rule comments that we receive after the close of the comment period (see **DATES**) or comments delivered to an address other than those listed above (see **ADDRESSES**).

Comments, including names and street addresses of respondents, will be available for public review at the address listed under **ADDRESSES**: Personal or messenger delivery” during regular hours (7:45 a.m. to 4:15 p.m.), Monday through Friday, except holidays. Before including your address, telephone number, email address, or other personal identifying information in your comment, be advised 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 from public review your personal identifying information, we cannot guarantee that we will be able to do so.

II. Background

Because of the increasing reliance on directional drilling through lands owned by varying entities, it has become more important for operators to commingle production from leases, unit PAs, and CAs. The BLM is proposing the revisions to these regulations to conform with the statutory direction in section 50101(d)(3) of the “One Big Beautiful Bill Act” (Pub. L. 119–21) (OBBA) and to address barriers in the current regulations that limit the BLM’s ability to approve these types of CAAs. Because of the BLM’s limitations, these agreements have been underutilized by

the regulated community as the application process is burdensome under the current regulations. As revised, the process would be streamlined and allow for more diverse mineral interests to be commingled, especially in situations where either State spacing regulations or mixed ownership patterns may otherwise inhibit an operator’s ability to develop our Nation’s vital oil and natural gas resources.

The Secretary of the Interior has the authority to undertake these regulations pursuant to Congress’s direction in section 50101(d)(3) of the OBBA and his authority under section 226(q) of the MLA, which authorizes the Secretary to enter into agreements apportioning production or royalties among tracts of land when they cannot be independently developed. In addition, the FOGMA, 30 U.S.C. 29, authorizes the Secretary to enforce regulations governing inspection of production activities on Federal and Indian lands. The Secretary has delegated this authority to the BLM. 235 DM 1.1.

III. Discussion of Proposed Rule

A. Summary

The BLM is undertaking this rulemaking for two primary reasons: (1) To reflect Congress’s direction provided in section 50101(d)(3) of the OBBA and policy direction provided in recently issued E.O.s and S.O.; and (2) To remove existing barriers to the commingling of oil and gas production to promote the development of oil and gas to meet the energy needs of the American public. As documented in S.O. 3418 released in February 2025,¹ the BLM aims to reduce barriers to the use of Federal lands for energy development, consistent with the principle of multiple use.

The Secretary of the Interior manages Federal oil and gas resources pursuant to the MLA; FOGMA; Federal Land Policy and Management Act (FLPMA), 43 U.S.C. 1701 *et seq.*; and other statutes. The BLM is the agency within DOI responsible for regulating onshore oil and gas leasing activities for federally managed lands and the subsurface mineral estate. The BLM also regulates oil and gas development on Indian (except Osage Tribe) lands for the Secretary. The Department regulations governing site security and production allocation for onshore oil and gas are set out in 43 CFR subpart 3173. The BLM is proposing to revise some of the definitions in § 3173.1 to

¹ DOI, S.O. 3418—Unleashing American Energy, www.doi.gov/document-library/secretary-order/so-3418-unleashing-american-energy.

align with the proposed changes to the regulations governing commingling applications and is proposing to revise § 3173.14, Conditions for Commingling and Allocation Approval (Surface and Downhole); § 3173.15, Applying for a Commingling Approval and Allocation to simplify the procedures to promote the development of needed oil and gas resources; and § 3173.16, Existing Commingling and Allocation Approvals.

By revising these regulations, the BLM is removing barriers to oil and gas development thereby providing greater flexibility to oil and gas operators to coordinate their operations and reduce overall costs of producing oil and gas. The existing regulations have resulted in significant operational costs, administrative burdens, and a backlog in the approval of these agreements. The proposed revisions are also intended to promote operational and business efficiency, foster responsible resource development, reduce environmental impacts, prevent the stranding of oil and gas resources from premature abandonment, and ensure that the public receives a fair return from the use of public resources.

The proposed modifications to §§ 3173.1, 3173.14, 3173.15 and 3173.16 are described in more detail in the section-by-section analysis below.

B. Section-by-Section Discussion

The following discussion addresses proposed changes to the regulations. If a provision is not presented in this section-by-section analysis, then the provision remains unchanged from the current regulatory language.

1. Section-by-section for changes to 43 CFR subpart 3173.

Section 3173.1 Definitions

The BLM has added a new definition for “acceptable methodology” to clarify the level of measurement uncertainty that would be allowed when determining a method to allocate production from each source to be included in the commingling approval. The proposed rule would require a 2 percent measurement uncertainty or up to 5 percent measurement uncertainty if there are appropriate technical or economic justifications provided by the applicant and approved by the BLM.

The BLM has revised the definition of “access” by including a new paragraph that addresses the need for the BLM to have access to facilities that may be located on State or private lands so it can ensure the proper accounting of produced Federal and Indian oil and gas resources. Any such access would be limited to ensuring that the requirements of these regulations are

met and would not provide the BLM with any more general inspection authority as that is beyond the scope of these regulations.

The BLM proposes to remove the definition of “economically marginal property” as this concept is no longer a factor in the BLM’s analysis of a commingling application.

The BLM proposes to add a new definition for “overriding considerations” to allow the BLM to consider approval of a commingling application in situations that do not specifically meet the regulatory requirements in 43 CFR 3173.14(a).

The BLM proposes to remove the definition of a “payout period” as this definition is no longer needed based on the BLM’s proposed changes to 43 CFR 3173.14.

The BLM proposes to remove the definition of “royalty net present value” as this concept is no longer needed based on the BLM’s proposed changes to 43 CFR 3173.14.

The BLM is soliciting feedback on whether any additional definitions would be useful to implement Congress’ direction to BLM to allow for increased use of commingling.

Section 3173.14 Conditions for Commingling and Allocation Approval (Surface and Downhole)

The BLM proposes to revise this section in its entirety to remove conditions in the existing regulations that can limit the circumstances under which the BLM can approve a commingling application. For example, under the existing regulation at § 3173.14(a)(3), the applicant for a CAA must demonstrate that each lease, unit PA or communitization agreement (CA) to be included in the commingling application is capable of production in paying quantities. By removing this provision, the BLM expects that more leases and CAs could be included thereby promoting additional production. By allowing for the approval of more commingling applications, the BLM expects that some leases and CAs that are not currently capable of producing in paying quantities would become capable of producing in paying quantities. This is due to the fact an approved CAA would allow an operator to reduce the number of measurement facilities thereby reducing the day-to-day operating expenses of the lease or CA such that the lease or CA would become capable of producing in paying quantities. BLM is seeking comments from operators on this point, particularly the effect on the day-to-day operating costs due to facility consolidation. The BLM has

retained the existing requirement that all facility measurement points (FMPs) for the proposed CAA measure production originating only from the leases, unit PAs, or CAs that are proposed for inclusion in the CAA. The BLM has proposed a new provision to specifically address an application that proposes to include Indian leases. In this instance, the BIA must first approve the inclusion of that production in the CAA. Overall, the BLM’s proposed revisions to § 3173.14 (a) would allow for commingling, consistent with 30 U.S.C. 226(q), regardless of the nature of the Federal, Indian, State or private mineral interests, royalty rates or revenue distribution thereby promoting greater production while also providing the opportunity for operators to reduce their overall costs of production.

If the production proposed for inclusion in the application includes production from leases, unit PAs or CAs where the Federal interests are disproportionate to one another (for example, if there are varying royalty rates), this production can still be commingled if certain enumerated conditions are met. The production must be measured by an FMP that meets the requirements of subparts 3174 (Measurement of Oil) and 3175 (Measurement of Gas) and the allocation methodology must demonstrate the inclusion of measurement devices that can meet measurement uncertainties as set out in the regulations.

The BLM has also proposed revising this section to include requiring the applicant to provide notice to all interest owners that their production is proposed for inclusion in a commingling agreement and to clarify what information is needed for the application to be complete.

The BLM is proposing a new paragraph (b) that would allow the BLM to approve a commingling application if it does not meet the requirements of paragraph (a). The BLM is proposing four conditions, under which, if an applicant meets at least one of the enumerated conditions, the BLM would still approve the application. The first condition would allow the BLM to approve the application if the production to be included is 1,000 cubic feet (Mcf) per month or less over the preceding 12-month period for gas or 100 barrels (bbls) per month or less for oil. The second condition would allow the BLM to approve the application if it includes Indian leases, unit PAs, or CAs, and has been authorized under tribal law or otherwise approved by a Tribe or the allottees of the allotted lease. The third condition would allow the BLM to approve the application if it

covers the downhole commingling of production from multiple formations that are covered by separate leases, unit PAs, or CAs, and the BLM has determined that the proposed commingling from those formations is an acceptable practice for the purpose of increasing ultimate economic recovery and resource conservation. The fourth condition would allow the BLM to approve the application if there are overriding considerations that indicate the BLM should approve a commingling application: (i) If it is in the public interest, notwithstanding potential negative royalty impacts from the allocation method, unless Indian leases or mineral interests are to be included, in which case the CAA cannot be approved; (ii) If the operator reasonably demonstrates that approval is necessary to prevent waste or increase ultimate recovery, but only to the extent that such considerations outweigh the possibility of incremental error in measurement of the quantity or quality of production, unless Indian leases or mineral interests are to be included, in which case the CAA cannot be approved; and (iii) Under either (i) or (ii), the BLM may approve a CAA if the Indian mineral owner consents to the CAA and has been made aware of the potential negative royalty impact. The BLM is soliciting feedback on whether these conditions are appropriate and whether there are any other conditions that should be considered.

The BLM is also proposing to revise paragraph (c), addressing the timing for the BLM's approval of an application. Under the proposed regulation, the BLM would approve a complete application within 60 days of receipt, unless additional time is needed to complete any required environmental analysis. The BLM is soliciting feedback on whether approving the application in 60 days from receipt is the appropriate timeframe.

The BLM is soliciting feedback on whether there are additional conditions for commingling and allocation approvals that should be included in light of the broad mandate in the OBBBA to allow for commingling.

Section 3173.15 Applying for a Commingling and Allocation Approval

The BLM is proposing changes to the process of applying for a commingling allocation and approval. In § 3173.15(c), the BLM is proposing to add “with a calculated uncertainty percentage” to demonstrate that the uncertainty percentage meets the proposed requirements in § 3173.14. The definition of acceptable methodology places a bound of no more than 5

percent uncertainty in the reported production. The operator would be required to demonstrate in their application that the proposal is within 5 percent uncertainty or there would be overriding considerations the BLM should account for in the decision. In § 3173.15(d), the BLM is proposing to add State or private lease numbers to the list of leases, unit PAs and CAs as the BLM is now proposing to allow inclusion of these types of leases in an application under this section. The BLM proposes to revise § 3173.15(f) which requires the submittal of a Sundry Notice in certain situations by deleting “BLM managed lands” and adding instead “Federal or Indian” to address the proposed changes to the types of leases that may now be included in an application.

The BLM is proposing to substantially revise § 3173.15(k) while still maintaining the BLM's ability to ensure that production streams proposed for commingling are compatible. Instead of the current requirement to provide all gas analyses or oil gravities, depending on the type of production proposed for commingling, the BLM is revising this provision to require only the most recent gas analysis or oil gravity. The BLM is also proposing new language in this section to provide more flexibility and to address those situations for which the BTU or gravity is unknown. In this case, the applicant may provide the BLM with BTU or gravity obtained from nearby wells, unit PAs or CAs.

The BLM is also proposing to add three new paragraphs to address the expansion of the types of mineral interests that can be included in an application. In § 3173.15(l), the BLM would require the submittal of documentation that the mineral interest owners have consented to the CAA and to the BLM's inspection of any equipment required for compliance with this subpart. In § 3173.15(m), the BLM proposes to require documentation that the operator has secured access from the surface owners to allow BLM personnel to access the measurement facilities to verify production and royalty. In many cases, the surface owners and the mineral owners are different requiring consent from multiple parties to carry out the requirements of this part. Paragraph (n) addresses those situations in which the measurement equipment is not located on a Federal or Indian lease. In this instance, the operator would be required to provide documentation that the measurement equipment will be maintained in accordance with subparts 3174 and 3175.

The BLM is soliciting feedback on whether any additional changes to this

section should be made in light of the broad mandate in the OBBBA to allow for commingling.

Section 3173.16 Existing Commingling and Allocation Approvals

The BLM is proposing to significantly revise this section as most of it is no longer applicable. Under the BLM's proposal, all existing CAAs would remain in effect unless the operator adds or removes wells or modifies the facility layout. In this case, the operator would need to submit a Sundry Notice Form 3160–5 to the BLM. Any changes to the existing leases, unit PAs, or CAs included in an existing CAA would require the operator to submit a new application meeting the requirements of the new regulations.

The BLM is soliciting feedback on whether the requirements above are those necessary to effectuate the purposes of the OBBBA.

IV. Procedural Matters

Unleashing Prosperity Through Deregulation (E.O. 14192)

DOI has examined this proposed rulemaking and has determined that it is consistent with the policies and directives outlined in E.O. 14154 “Unleashing American Energy,” and E.O. 14192, “Unleashing Prosperity Through Deregulation.” This proposed rule, if finalized as proposed, is expected to be an E.O. 14192 deregulatory action.

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

Executive Order 12866 provides that the Office of Information and Regulatory Affairs in the Office of Management and Budget will review all significant rules. The Office of Information and Regulatory Affairs has determined that this rule is significant.

Executive Order 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.

This proposed rule revises the BLM's regulations governing applications for and approval of commingling application agreements which are contained in 43 CFR subparts 3173, 3173.14, 3173.15 and 3173.16. The BLM developed this proposed rule in a manner consistent with the requirements in E.O. 12866 and E.O. 13563.

Regulatory Flexibility Act

This rule would have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Many of the operators affected by this rule are considered small businesses and the rule would have a significant overall effect. The effect would be positive as it would reduce the regulatory burden and overall expenses for small businesses. Please refer to the Regulatory Impact Analysis attached to this rulemaking for detailed information regarding the impacts and benefits to small businesses.

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, because it does not impose any costs on these entities. Therefore, a statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

Takings (E.O. 12630)

This rule does not effect a taking of private property or otherwise have taking implications under E.O. 12630. The proposed rule would revise portions of the BLM's current rules governing measurement and site security which are contained in 43 CFR subpart 3173 and more specifically 3173.1, 3173.14, 3173.15 and 3173.16. These terms in the regulations are not considered a taking of private property as such operations are subject to the existing lease terms which expressly require that subsequent lease activities be conducted in compliance with subsequently adopted Federal laws and regulations. The proposed rule is not a government action capable of interfering with constitutionally protected property rights. Therefore, the BLM has determined that the rule would not cause a taking of private property or require further discussion of takings implications under E.O. 12630. A

takings implication assessment is therefore not required.

Federalism (E.O. 13132)

Under the criteria in section 1 of E.O. 13132, this proposed rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement; therefore, a federalism impact statement is not required.

The proposed rule would not have a substantial direct effect on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the levels of government. It would not apply to States or local governments or State or local governmental entities. The rule would affect the relationship between operators, lessees, and the BLM, but it would not directly impact the States. Therefore, in accordance with E.O. 13132, the BLM has determined that this proposed rule would not have sufficient federalism implications to warrant preparation of a Federalism Assessment.

Civil Justice Reform (E.O. 12988)

This rule complies with the requirements of E.O. 12988. Specifically, this rule meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

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

The Department strives to strengthen its government-to-government relationship 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 under the criteria in E.O. 13175 and have identified the potential for substantial direct effects on federally recognized Indian tribes from this proposed rule.

This proposed rule could have an effect on Indian tribes as it would allow for production from Indian leases to be commingled with production from Federal, State and private leases potentially negatively impacting royalty payments to Indian Tribes or allottees. Conversely, though, it could extend the productive life of tribal wells and hence the royalties to Tribes by reducing some operating costs. However, the proposed

rule does require the consent of Indian tribes prior to any production from Indian leases being included in a commingling agreement and requires the approval of the BIA if production from Indian leases is proposed for inclusion in a commingling agreement. Accordingly, we will consult with the affected tribe(s) on a government-to-government basis.

*Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*)*

The Paperwork Reduction Act (PRA) (44 U.S.C. 3501–3521) generally provides that an agency may not conduct or sponsor and, not withstanding any other provision of law, a person is not required to respond to a collection of information, unless it displays a currently valid OMB control number. Collections of information include any request or requirement to obtain, maintain, retain, or report information to an agency, or disclose information to a third party or to the public (44 U.S.C. 3502(3) and 5 CFR 1320.3(c)).

This proposed rule contains revised information collection requirements that are subject to review by OMB under the PRA. OMB has approved the existing information collection requirements contained in 43 CFR parts 3170 and pertaining to CAAs, specifically 43 CFR 3173.15 and 3173.16, under OMB control number 1004–0137. Additionally, certain information collection requirements contained in 43 CFR part 3170 make use of the standard form, SF–299, *Application for Transportation, Utility System, Telecommunications and Facilities on Federal Lands and Property*. OMB has approved Form SF–299 under OMB Control Number 0596–0249. The U.S. Forest Service administers OMB Control Number 0596–0249. This proposed rule would not result in changes to Form SF–299.

Currently, there are 102,439 total annual responses and 278,904 total annual burden hours approved under OMB Control Number 1004–0137. While the proposed revisions would introduce certain efficiencies and potential cost savings for both operators and the BLM, we do not anticipate that the burden would change because of the revisions contained in this proposed rule. The proposed revisions to the information collection requirements, along with the projected burden changes, are discussed below.

Revised Information Collections

1. Request for Approval of a CAA—43 FR 3173.15.

In addition to the current information collection requirements contained in § 3173.15 for CAAs, the proposed rule would add the following additional requirements:

- The most recent gas analysis performed, including BTU content (if the CAA request includes gas), and the most recent oil gravity data (if the CAA request includes oil) from each of the leases, units, unit PAs, or CAs proposed for inclusion in the CAA. In lieu of the requirements in paragraph, the operator or operators may instead submit a CAA for BLM consideration using analogous BTU content and/or oil gravity data from nearby wells for instances where BTU content and/or oil gravity are not explicitly known for the given leases, unit PAs or CAs.

- Documentation demonstrating that all other interest owners, such as private, State, or Indian, consent to both the CAA and the BLM's inspection of the equipment to ensure compliance with 43 CFR 3173, 3174 and 3175.

- Documentation demonstrating that the operator has secured all necessary access rights from the surface owner(s), whether private, State, or Indian, to ensure that BLM staff may access the measurement facilities within the CAA for conducting and verifying production, measurement and royalty.

- Documentation demonstrating that the operator maintains and operates the measurement equipment in accordance with 43 CFR 3174 and 3175 for production equipment that is not on a federal lease.

The BLM believes that this revision would introduce efficiencies for operators by revising the gas and oil analysis submission by requiring only the most recent analysis instead of all analyses for the last 6 years. The BLM is broadening the scope of operations that can be included in a CAA to include lands that do not fall under the authority of the existing regulations. This results in additional requirements from the proponent of the CAA to ensure the BLM has the ability to inspect and verify production from non-federal and non-Indian lands.

2. Additions, Removals, or Modifications of Facility Layout (Form 3160-5)—43 CFR 3173.16.

The proposed rule would replace the current information collection requirements pertaining to the operator's requirements to address any inconsistencies or deficiencies with the following information collection requirements:

- If the operator adds or removes wells or modifies the facility layout, a Sundry Notice Form 3160-5 notice would be required.

- Modifications to existing leases, unit PAs, or CAs within the approved CAA would require the operator to reapply for commingling approval in accordance with the existing regulations prior to implementing the proposed changes.

The revised regulations would reduce additional efficiencies and potential cost savings on both operators and the BLM by allowing existing approvals to remain in effect unless modified. The current regulations require a review and renewal of existing CAAs upon implementation of the rule.

The resulting new estimated total burdens for OMB Control Number 1004-0137 are provided below.

Title of Collection: Onshore Oil and Gas Operations and Production (43 CFR part 3170).

OMB Control Number: 1004-0137.

Form Numbers: BLM Form 3160-005 and SF-299 (OMB Control Number 0596-0249).

Type of Review: Extension with revision of a currently approved collection.

Respondents/Affected Public: Oil and gas operators on public lands and some Indian lands.

Total Estimated Number of Annual Respondents: 864.

Total Estimated Number of Annual Responses: 102,439.

Estimated Completion Time per Response: Varies depending on activity.

Total Estimated Number of Annual Burden Hours: 278,904.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion; One-time; and Monthly.

Total Estimated Annual Non-hour Burden Cost: None.

The complete information-collection request that has been submitted to OMB for this proposed rule is available at www.reginfo.gov/public/do/PRAMain. Find this information collection by selecting "Currently under Review—Open for Public Comments" or by using the search function. If you want to comment on the information-collection requirements of this proposed rule, please send your comments and suggestions on this information-collection by the date indicated in the **DATES** and **ADDRESSES** sections as previously described.

National Environmental Policy Act (NEPA)

A detailed environmental analysis under NEPA is not required because the proposed rule would be covered by a categorical exclusion (see 43 CFR 46.205). This proposed rule meets the criteria set forth at 43 CFR 46.210(i) for

a Departmental categorical exclusion in that this proposed rule is "of an administrative, financial, legal, technical, or procedural nature." We have also determined that the proposed rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA. Environmental analysis under NEPA is not required because the proposed rule would be covered by a categorical exclusion (see 43 CFR 46.205).

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

Under E.O. 13211, agencies are required to prepare and submit to OMB a Statement of Energy Effects for significant energy actions. This statement is to include a detailed statement of "any adverse effects on energy supply, distribution, or use (including a shortfall in supply, price increases, and increase use of foreign supplies)" for the action and reasonable alternatives and their effects.

Section 4(b) of E.O. 13211 defines a "significant energy action" as "any action by an agency (normally published in the **Federal Register**) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking; (1)(i) that is a significant regulatory action under E.O. 12866 or any successor order, and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (2) that is designated by OIRA as a significant energy action."

We conclude that this proposed rule would not warrant preparation of a Statement of Energy Effects.

Clarity of This Regulation

We are required by E.O. 12866 (section 1 (b)(12)), E.O. 12988 (section 3(b)(1)(B)), and E.O. 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 believe 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 feel lists or tables would be useful, etc.

Author

The principal author(s) of this rule are Matthew Warren, Senior Petroleum Engineer and Natalie Eades, Attorney-advisor, Office of the Solicitor; Technical support provided by Scott Rickard, Economist.

List of Subjects in 43 CFR Part 3170

Administrative practice and procedure, Immediate assessments, Indians—lands, Mineral royalties, Oil and gas reserves, Public lands—mineral resources.

Lanny E. Erdos,

Director, Office of Surface Mining, Reclamation, and Enforcement, Exercising Authority of the Assistant Secretary—Land and Minerals Management.

For the reasons set out in the preamble, the Bureau of Land Management proposes to amend 43 CFR part 3170 as follows:

PART 3170—ONSHORE OIL AND GAS PRODUCTION: GENERAL

- 1. The authority citation for part 3170 continues to read as follows:

Authority: 25 U.S.C. 396d and 2107; 30 U.S.C. 189, 306, 359, and 1751; and 43 U.S.C. 1732(b), 1733, and 1740.

- 2. Revise 3173.1 to read as follows:

§ 3173.1 Definitions and acronyms.

(a) As used in this subpart, the term: *Acceptable methodology* means, consistent with 30 U.S.C. 226(q), (1) use of a measurement device for each commingled source, (2) a description of how the applicant will use an allocation method that achieves volume measurement uncertainty levels within 2 percent or up to five percent if there are appropriate technical and economic justifications, or (3) use of an approved periodic well testing methodology.

Access means:

- (i) The ability to add liquids to or remove liquids from any tank or piping system, through a valve or combination of valves or by moving liquids from one tank to another tank; or
- (ii) The ability to enter any component in a measuring system affecting the accuracy of the measurement of the quality or quantity of the liquid being measured; or
- (iii) A written agreement that BLM officials can enter onto private or State lands for inspection and enforcement actions conducted by the BLM.

Appropriate valves means those valves that must be sealed during the production or sales phase (e.g., fill lines, equalizer, overflow lines, sales lines, circulating lines, or drain lines).

Authorized representative (AR) has the same meaning as defined in 43 CFR 3160.0–5.

Business day means any day Monday through Friday, excluding Federal holidays.

Commingling and allocation approval (CAA) means a formal allocation agreement to combine production from two or more sources (leases, unit PAs, CAs, or non-Federal or non-Indian properties) before that product reaches an FMP.

Effectively sealed means the placement of a seal in such a manner that the sealed component cannot be accessed, moved, or altered without breaking the seal.

Free water means the measured volume of water that is present in a container and that is not in suspension in the contained liquid at observed temperature.

Land description means a location surveyed in accordance with the U.S. Department of the Interior's Manual of Surveying Instructions (2009), that includes the quarter-quarter section, section, township, range, and principal meridian, or other authorized survey designation acceptable to the AO, such as metes-and-bounds, or latitude and longitude.

Maximum ultimate economic recovery has the same meaning as defined in 43 CFR 3160.0–5.

Mishandling means failing to measure or account for removal of production from a facility.

Overriding considerations means any condition that makes non-commingled measurement physically impractical or that results in unnecessary or undue impacts.

Permanent measurement facility means all equipment constructed or installed and used on-site for 6 months or longer, for the purpose of determining the quantity, quality, or storage of production, and which meets the definition of FMP under § 3170.3.

Piping means a tubular system (e.g., metallic, plastic, fiberglass, or rubber) used to move fluids (liquids and gases).

Production phase means that event during which oil is delivered directly to or through production equipment to the storage facilities and includes all operations at the facility other than those defined by the sales phase.

Sales phase means that event during which oil is removed from storage facilities for sale at an FMP.

Seal means a uniquely numbered device that completely secures either a valve or those components of a measuring system that affect the quality or quantity of the oil being measured.

(b) As used in this subpart, the following additional acronyms apply:

BIA means the Bureau of Indian Affairs.
BMP means Best Management Practice.
CA means Communitization Agreement.
PA means Participating Area.
AO means Authorized Officer.

- 3. Revise § 3173.14 to read as follows:

§ 3173.14 Conditions for commingling and allocation approval (surface and downhole).

(a) Subject to the exceptions provided in paragraph (b) of this section, the BLM will grant a CAA for all leases, unit PAs, or CAs if the following criteria are met:

(1) The operator or operators provides an acceptable methodology to the BLM for accurate allocation of production among the properties from which production is to be commingled (including a method for allocating produced water), as provided in 30 U.S.C. 226(q), with an agreement signed by all operators if there is more than one operator;

(2) The FMP(s) for the proposed CAA measure production originating only from the leases, unit PAs, or CAs in the CAA, and

(3) If production from an Indian lease is to be included in the CAA, the Bureau of Indian Affairs approves of the inclusion of that production in the proposed CAA.

(4) Subject to paragraph (c), the BLM will approve a CAA in instances where the proposed commingling of production involves production from leases, unit PAs, or CAs, even if the Federal interests at issue are disproportionate to one another, including Federal interests that are subject to varying royalty rates, dissimilar fixed royalty rates, or revenue distributions, but only if the following conditions are met:

(i) Production from each lease, unit PA, or CA is measured by an FMP that satisfies the requirements under subpart 3174 for oil measurement or subpart 3175 for gas measurement; or

(ii) The proposed commingling allocation methodology demonstrates the installation of measurement devices for oil and gas sources that: (1) can reasonably achieve volume measurement uncertainty levels with plus or minus (+2 percent), between the allocation point and FMP (including off-lease measurement FMPs, where applicable), during the production phase of the well or (2) uses the allocation methods and reporting requirements provided in subpart 3174

and subpart 3175 as reported on a monthly basis using a twelve-month average.

(5) The BLM will approve a CAA under this section only after:

(i) The applicant provides notice to all interest owners of the production to be commingled or, in lieu of notice, the applicant provides to the BLM a signed operator agreement that includes a methodology that is acceptable to the BLM for accurate allocation of production among the properties from which production is to be commingled (including a method for allocating produced water); and

(ii) The BLM receives a complete CAA from the applicant pursuant to 43 CFR 3173.15 that includes a statement by the applicant attesting that, on or before the date the applicant submitted the CAA, the applicant notified each interest owner by sending a copy of the application and the attachments to the CAA, by certified mail, return receipt requested to each interest owner.

(b) The BLM may also approve a CAA in instances where the proposed commingling of production involves production from leases, unit PAs, or CAs that do not meet the criteria of paragraph (a) of this section. In order to be approved under this paragraph, a CAA must meet at least one of the following conditions:

(1) The average monthly production over the preceding 12 months for each lease, unit PA, or CA proposed for the CAA on an individual basis is less than 1,000 Mcf of gas per month, or 100 bbl of oil per month;

(2) The CAA, which includes Indian leases, unit PAs, or CAs, has been authorized under tribal law or otherwise approved by a tribe or the allottees of the allotted lease;

(3) The CAA covers the downhole commingling of production from multiple formations that are covered by separate leases, unit PAs, or CAs, where the BLM has determined that the proposed commingling from those formations is an acceptable practice for the purpose of increasing ultimate economic recovery and resource conservation; or

(4) There are overriding considerations that indicate the BLM should approve a commingling application: (i) in the public interest notwithstanding potential negative royalty impacts from the allocation method, unless Indian leases or mineral interests are to be included, in which case the CAA cannot be approved; (ii) if the operator reasonably demonstrates that approval is necessary to prevent waste or increase ultimate recovery, but only to the extent that such

considerations outweigh the possibility of incremental error in measurement of the quantity or quality of production, unless Indian leases or mineral interests are to be included, in which case the CAA cannot be approved; (iii) under either (i) or (ii), the BLM may approve a CAA if the Indian mineral owner consents to the CAA and has been made aware of the potential negative royalty impact.

(c) If the applicant meets the requirements for a CAA in this subpart, the BLM will issue the CAA within 60 days of submission of a complete CAA, unless an additional 30 days is necessary to complete any required environmental analysis. A complete CAA includes all applicable requirements from (a) and (b) of this section and § 3173.15.

■ 4. Revise § 3173.15 to read as follows:

§ 3173.15 Applying for a commingling and allocation approval.

To apply for a CAA, the operator(s) must submit the following, if applicable, to the BLM office having jurisdiction over the leases, unit PAs, or CAs from which production is proposed to be commingled:

(a) A completed Sundry Notice for approval of commingling and allocation (if off-lease measurement is a feature of the commingling and allocation proposal, then a separate Sundry Notice under 3173.23 is not necessary as long as the information required under 3173.23(b) through (e) and, where applicable, 3173.23(f) through (i) is included as part of the request for approval of commingling and allocation);

(b) A completed Sundry Notice for approval of off-lease measurement under 3173.23, if any of the proposed FMPs are outside the boundaries of any of the leases, units, or CAs from which production would be commingled (which may be included in the same Sundry Notice as the request for approval of commingling and allocation), except as provided in paragraph (a) of this section;

(c) A proposed allocation agreement with a calculated uncertainty percentage, including an allocation methodology (including allocation of produced water), with an example of how the methodology is applied, signed by each operator of each of the leases, unit PAs, or CAs from which production would be included in the CAA;

(d) A list of all Federal, Indian, State, or private leases, unit PA, or CA numbers in the proposed CAA, specifying the type of production (*i.e.*, oil, gas, or both) for which commingling is requested;

(e) A topographic map or maps of appropriate scale showing the following:

(1) The boundaries of all the leases, units, unit PAs, or communitized areas whose production is proposed to be commingled; and

(2) The location of existing or planned facilities and the relative location of all wellheads (including the API number) and piping included in the CAA, and existing FMPs or FMPs proposed to be installed to the extent known or anticipated;

(f) A surface use plan of operations (which may be included in the same Sundry Notice as the request for approval of commingling and allocation) if new surface disturbance is proposed for the FMP and its associated facilities are located within the boundaries of the Federal or Indian lease, units, or CA from which production would be commingled;

(g) A right-of-way grant application (Standard Form 299), filed under 43 CFR part 2880, if the proposed FMP is on a pipeline, or under 43 CFR part 2800, if the proposed FMP is a meter or storage tank. This requirement applies only when new surface disturbance is proposed for the FMP, and its associated facilities are located on BLM-managed land outside any of the leases, units, or communitized areas whose production would be commingled;

(h) Written approval from the appropriate surface-management agency, if new surface disturbance is proposed for the FMP and its associated facilities are located on Federal land managed by an agency other than the BLM;

(i) A right-of-way grant application for the proposed FMP, filed under 25 CFR part 169, with the appropriate BIA office, if any of the proposed surface facilities are on Indian land outside the lease, unit, or communitized area from which the production would be commingled;

(j) Documentation demonstrating that each of the leases, unit PAs, or CAs proposed for inclusion in the CAA is producing in paying quantities (or, in the case of Federal leases, is capable of production in paying quantities) pending approval of the CAA; and

(k) Documentation demonstrating that the production from each of the leases, unit PAs, or CAs is compatible with each other by providing the following:

(1) The most recent gas analysis performed, including BTU content (if the CAA request includes gas), and the most recent oil gravity data (if the CAA request includes oil) from each of the leases, units, unit PAs, or CAs proposed for inclusion in the CAA. (2) In lieu of

the requirements in paragraph (1), the operator or operators may instead submit a CAA for BLM consideration using analogous BTU content and/or oil gravity data from nearby wells for instances where BTU content and/or oil gravity are not explicitly known for the given leases, unit PAs or CAs.

(l) Documentation demonstrating that all other interest owners, such as private, State, or Indian, consent to both the CAA and the BLM's inspection of the equipment to ensure compliance with §§ 3173, 3174, and 3175.

(m) Documentation demonstrating that the operator has secured all necessary access rights from the surface owner(s), whether private, State, or Indian, to ensure that BLM staff may access the measurement facilities within the CAA for conducting and verifying production, measurement and royalty.

(n) Documentation demonstrating that the operator maintains and operates the measurement equipment in accordance with §§ 3174 and 3175 for production equipment that is not allocated within a Federal or Indian lease, unit PA, or CA.

■ 5. Revise § 3173.16 to read as follows:

§ 3173.16 Existing commingling and allocation approvals.

All existing CAAs in effect on [EFFECTIVE DATE OF FINAL RULE] will remain in effect, unless the operator adds or removes wells or modifies the facility layout, in which case a Sundry Notice Form 3160–5 notice will be required. Otherwise, modifications to existing leases, unit PAs, or CAs within the approved CAA will require the operator to reapply for commingling approval in accordance with the existing regulations prior to implementing the proposed changes.

[FR Doc. 2026–01926 Filed 1–29–26; 8:45 am]

BILLING CODE 4331–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 170

RIN 0955–AA11

Request for Information: Diagnostic Imaging Interoperability Standards and Certification

AGENCY: Assistant Secretary for Technology Policy (ASTP)/Office of the National Coordinator for Health Information Technology (ONC) (collectively, ASTP/ONC), Department of Health and Human Services (HHS).

ACTION: Request for information.

SUMMARY: This request for information (RFI) seeks input from the public regarding the potential adoption of diagnostic imaging technical standards and certification criteria for health information technology (IT) under the ONC Health IT Certification Program (Certification Program) to better enable the access, exchange, and use of diagnostic images by health care providers and patients. Responses to this RFI will be used to inform potential future rulemaking.

DATES: To be assured consideration, written or electronic comments must be received at one of the addresses provided below, by March 16, 2026.

ADDRESSES: You may submit comments, identified by RIN 0955–AA11, by any of the following methods (please do not submit duplicate comments). Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

- *Federal eRulemaking Portal:* Follow the instructions for submitting comments. Attachments should be in Microsoft Word, Microsoft Excel, or Adobe PDF; however, we prefer Microsoft Word. <http://www.regulations.gov>.

- *Regular, Express, or Overnight Mail:* Department of Health and Human Services, Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology, Attention: Request for Information: Diagnostic Imaging Interoperability Standards and Certification, Mary E. Switzer Building, Mail Stop: 7033A, 330 C Street SW, Washington, DC 20201. Please submit one original and two copies.

- *Hand Delivery or Courier:* Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology, Attention: Request for Information: Diagnostic Imaging Interoperability Standards and Certification, Mary E. Switzer Building, Mail Stop: 7033A, 330 C Street SW, Washington, DC 20201. Please submit one original and two copies. (Because access to the interior of the Mary E. Switzer Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the mail drop slots located in the main lobby of the building.)

Inspection of Public Comments: All comments received before the close of the comment period will be available for public inspection, including any personally identifiable or confidential business information that is included in a comment. Please do not include

anything in your comment submission that you do not wish to share with the general public. Such information includes, but is not limited to: a person's social security number; date of birth; driver's license number; state identification number or foreign country equivalent; passport number; financial account number; credit or debit card number; any personal health information; or any business information that could be considered proprietary. We will post comments that are received before the close of the comment period at <http://www.regulations.gov>.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> or the Department of Health and Human Services, Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology, Mary E. Switzer Building, Mail Stop: 7033A, 330 C Street SW, Washington, DC 20201 (call ahead to the contact listed below to arrange for inspection).

FOR FURTHER INFORMATION CONTACT: Michael Lipinski, Office of Policy, Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology, 202–690–7151.

SUPPLEMENTARY INFORMATION:

I. Purpose

Diagnostic images, including, but not limited to, radiographic, photographic, and video images produced by light, radiation, sound waves, or magnetic resonance, are critical to supporting care in a variety of health care settings and are routinely used by health care providers to help determine a patient's course of treatment.¹ Diagnostic images are often stored in systems external to an electronic health record (EHR),² such as picture archiving and communication systems (PACS), vendor neutral archives (VNAs), and other imaging platforms. While health care providers (e.g., radiologists, ophthalmologists, dermatologists, and pathologists) who work within the same organization generally have direct access to the

¹ For purposes of this RFI, "treatment" generally means the provision, coordination, or management of health care and related services among health care providers or by a health care provider with a third party, consultation between health care providers regarding a patient, or the referral of a patient from one health care provider to another. See 45 CFR 164.501.

² For purposes of this RFI, an electronic health record (EHR) generally means health IT certified under the Certification Program that would meet the criteria of the Qualified EHR definition (42 U.S.C. 300jj).

diagnostic images obtained by the organization, access to such images by health care providers from outside the organization can be nonexistent, inconsistent, and highly dependent on several technical, operational, and organizational factors. In some cases, organizations' vendors use proprietary formats that impede exchange and external access by "outside" providers. In other cases, outside providers are denied access to full-resolution Digital Imaging and Communications in Medicine® (DICOM®) files, and are instead given access to low resolution, incomplete, or inferior (*e.g.*, encapsulated PDF) images through web-based viewers. They may also be denied access to prior imaging studies. In addition, originating organizations frequently refuse to securely electronically transmit diagnostic images despite the source organization's technical capability to do so. Ultimately, the burden to "exchange" these images is placed on the patient or their caregiver. In such instances, patients too are often unable to access their own imaging directly or with a patient-facing application (app). Consequently, patients and their caregivers are left to carry around physical media (*e.g.*, CDs and DVDs), or printed images and reports, from provider to provider. These outcomes are far from ideal, particularly due to the quality of the images and even sometimes due to the lack of provider hardware to view the images stored on CDs and DVDs.

Enhanced access to diagnostic images can improve care and health outcomes, decrease the need for duplicative imaging tests, and reduce costs within the United States (U.S.) health care system. Therefore, we seek comments on whether the adoption of technical standards and/or certification criteria for health IT would improve the access, exchange, and use of diagnostic images for both providers and patients.

II. Regulatory Background

On March 7, 2012, the Secretary of HHS issued a proposed rule with request for comments titled "Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology" (77 FR 13832) (2014 Edition Proposed Rule), which proposed new and revised standards, implementation specifications, and certification criteria. In the 2014 Edition Proposed Rule, we proposed certification to the 2014 Edition "imaging" certification criterion

(§ 170.314(a)(12)) without use of the DICOM standard but requested comments on using the standard (77 FR 13838). We also proposed to require EHR technology that would be certified to the 2014 Edition "view, download, and transmit to 3rd party" (VDT) certification criterion (§ 170.314(e)(1)) to be capable of enabling images formatted according to the DICOM standard to be downloaded and transmitted to a third party (77 FR 13839 and 13840).

On September 4, 2012, the Secretary published a final rule titled "Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology" (77 FR 54163) (2014 Edition Final Rule). In the 2014 Edition Final Rule, we adopted an "image results" certification criterion (without the DICOM standard) to support the Medicare and Medicaid EHR Incentive Programs (now referred to as the Medicare Promoting Interoperability Program and the Merit-based Incentive Payment System Promoting Interoperability performance category) requirement, also known as the Meaningful Use or "MU Stage 2 Objective" requirement. The MU Stage 2 Objective required eligible clinicians, hospitals, and critical access hospitals to have access to imaging results and information through Certified EHR Technology (77 FR 54172 and 54173). The associated MU Stage 2 Objective certification criterion required a Health IT Module to be capable of indicating the availability of a patient's images and narrative interpretations and enable access to those images and narrative interpretations. We stated that the requirements of the certification criterion could be met via the capability to directly link to images stored in the EHR system or by providing a context-sensitive link to an external application which provided access to images and their related narrative. We also stated in the 2014 Edition Final Rule that the use of the DICOM standard (or any other imaging standards) was unnecessary to meet the functional requirement expressed in the image results certification criterion (77 FR 54172 and 54173). Instead, we reiterated our understanding, stated in the 2014 Edition Proposed Rule, that the adoption of standards was unnecessary to enable users to electronically access images and their narrative interpretations, as required by this certification criterion (77 FR 13838). Further, in the 2014 Edition Final Rule,

after considering the comments received and the complexity and potential burden identified by commenters, we removed the requirement that images be made available for download and transmission to a third party as part of the VDT certification criterion (77 FR 54183).

On February 26, 2014, the Secretary published a proposed rule titled "Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements" (79 FR 10880) (Voluntary Edition Proposed Rule). The proposed rule proposed a voluntary edition of certification criteria that was designed to enhance interoperability, promote innovation, and incorporate "bug fixes" to improve upon the 2014 Edition (79 FR 10880). In the proposed rule, we contemplated improvements that could be made to the VDT certification criterion in § 170.314(e)(1) for the "2017 Edition" (79 FR 10907). We requested public comments on whether we should again propose (in the future) to require that images be part of this certification criterion. More specifically, we requested comment on: (1) whether images for patients need to be of diagnostic quality; (2) whether they should be viewable and downloadable, but not required to be transmitted; and (3) whether cloud-based technology could allow for a link to the image to be made accessible (79 FR 10907). On September 11, 2014, a final rule was published titled "2014 Edition Release 2 Electronic Health Record (EHR) Certification Criteria and the ONC HIT Certification Program; Regulatory Flexibilities, Improvements, and Enhanced Health Information Exchange" (79 FR 54430) (2014 Edition Release 2 Final Rule), which did not include any updates to the VDT certification criterion related to diagnostic imaging (79 FR 54439 and 54465).

On March 30, 2015, the Secretary of HHS published a proposed rule titled "2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications" (80 FR 16804) (2015 Edition Proposed Rule). In the 2015 Edition Proposed Rule, we proposed to maintain the image results certification criterion (80 FR 16822). While some commenters supported this proposal, we ultimately removed the image results certification criterion in the 2015 Edition Final Rule (80 FR 62602), published October 16, 2015, because the associated CMS EHR Incentive Programs

objective (now referred to as Promoting Interoperability objectives) was removed and no longer required technological support (80 FR 62683).

On August 5, 2024, we published a proposed rule titled “Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability” (89 FR 63498) (HTI–2 Proposed Rule) to revise the certification criteria adopted in § 170.315(b)(1), (e)(1), (g)(9), and (g)(10) to include new certification requirements to support access, exchange, and use of diagnostic images via imaging links. On December 29, 2025, the Secretary published a withdrawal notice titled “Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability; Withdrawal” (90 FR 60602) (HTI–2 Proposed Rule Withdrawal Notice) to withdraw the remaining proposals that were not finalized from the HTI–2 Proposed Rule, including our proposed revisions to the certification criteria adopted in § 170.315(b)(1), (e)(1), (g)(9), and (g)(10).

ASTP/ONC’s joint Request for Information (RFI) with the Centers for Medicare & Medicaid Services (CMS) (90 FR 21034), published May 16, 2025, sought input from the public regarding the market of digital health products for Medicare beneficiaries as well as the state of data interoperability and broader health technology infrastructure. Responses to the RFI covered a broad range of topics, including ways to increase patient access to effective digital capabilities needed to inform health decisions and increase data availability for health care providers and patients. Among these comments were the identification of challenges specific to the access, exchange, and use of diagnostic images, including: (1) a fragmented ecosystem where diagnostic image exchange is manual, burdensome, and unreliable; (2) continued reliance on physical media (such as CDs and DVDs), which is generally inefficient, not secure, and presents barriers to timely care; and (3) lack of patient access to their own diagnostic images through modern, application programming interface (API)-driven tools.

III. Solicitation of Public Comments

The access, exchange, and use of diagnostic images is crucial for timely and accurate diagnosis, leading to better patient outcomes and lower treatment costs. As we evaluate the best and least burdensome ways to support the access, exchange, and use of electronic health

information (EHI), including diagnostic images, through the adoption of standards and the certification of health IT under the Certification Program, we invite public comment to help us further explore how we can achieve these goals for the purpose of accessing, exchanging, and using diagnostic images.

We encourage interested parties to share their responses for as many of the questions below as possible. The questions are not intended for a specific audience but are meant to solicit feedback from multiple individuals and groups. To aid in our understanding of submitted responses, please prioritize clarity and conciseness and annotate your responses with question label(s) (for example, PM–1).

A. Transition From Physical Media to Electronic Access, Exchange, and Use

We acknowledge there are certain outlying use cases and circumstances where access via physical media may be more appropriate than internet-based access to diagnostic images (e.g., locations with inadequate internet capabilities). However, we believe the health care ecosystem’s continued default to physical media and the slow shift from this practice is due to a combination of limited investment in image exchange standards, business practices that silo images within systems, and a lack of policy drivers to reinforce a shift to electronic access and exchange of diagnostic images.

Ultimately, the status quo creates a perfect storm of administrative burden, unnecessary costs, and uncoordinated care for providers and patients alike. For example, health care providers often rely on imaging to evaluate how well treatments are working. When a health care provider assumes the care of a new patient, access to prior imaging from outside facilities is a key component for accurate treatment planning. However, patients may not always have physical media (e.g., CDs and DVDs) or access to online diagnostic images to share with their providers. In time-sensitive situations, this lack of access may result in delayed or inappropriate treatment or unnecessary health care costs through duplicative testing.

PM–1. What barriers do patients experience with electronic access to diagnostic images? Are there examples today where patients can successfully access, exchange, and use diagnostic images outside of a particular hospital or network system without use of physical media?

PM–2. What existing policies do you believe limit or interfere with diagnostic image access, exchange, and use? What

policies would you introduce to accelerate the transition to electronic, standards-based diagnostic image access and exchange and to reduce the practice of imaging silos that impede electronic access, exchange, or use of diagnostic images?

- PM–2A. What other policy or financial barriers do providers face in accessing diagnostic images from outside facilities? For example, are there concerns about compliance with health care facility policies or procedures (e.g., security or overall policies on data sharing outside the facility), state laws, or malpractice liability?

- PM–2B. What technical/ interoperability concerns exist, such as compatibility between systems, authorization issues from external sources, or issues with the provenance of diagnostic images?

PM–3. What technical, operational, and policy approaches can best support health care providers in transitioning from physical media (e.g., CDs and DVDs) to secure, electronic exchange-based methods for sharing diagnostic images outside of their operating environment/health care organization system? If possible, please be detailed in your response.

PM–4. Do health care providers and/or patients (including patient-facing apps) need access to the full resolution diagnostic images stored in PACS or is a reference image (e.g., a DICOM image rendered as a JPEG) sufficient for clinical decision-making and use by health care providers and patients? Does this vary by clinician specialty or by type(s) of care provided to the patient? Please feel free to elaborate with rationale.

PM–5. Do health care providers and/or patients need access to quantitative parameters³ derived from images for clinical decision-making and use by providers and patients? Please feel free to elaborate with rationale.

B. Standards and Certified Health IT Functionality

The Certification Program⁴ is a voluntary program under which health IT developers can obtain ONC certification for their health IT products that meet certain requirements. Requirements for certification are established by standards,

³ Quantitative parameters are numerical measurements that describe specific (e.g., physical, anatomical, or functional) properties. We have received information that quantitative image parameters are being manually entered into EHRs due to the lack of standards adoption.

⁴ For more information, see <https://www.healthit.gov/topic/certification-ehrs/certification-health-it>.

implementation specifications, and certification criteria adopted through rulemaking by the Secretary of HHS. The Certification Program supports the availability of certified health IT for use by health care providers under other federal, state, and private programs.

Health IT developers often rely on custom interfaces and connections for individual customer (e.g., health care provider) systems resulting in incompatibilities between different health IT developers' technology platforms. For example, survey findings suggest that although many U.S. children's hospitals have electronic image-sharing platforms, substantial challenges in radiologic image sharing persist, primarily due to ongoing reliance on CDs and the lack of interoperability between existing image-sharing platforms.⁵

SC-1. What technical approaches are currently in use to enable access and/or exchange of diagnostic images between health care systems and health information networks? To what extent are these methods based on standards (e.g., DICOM, DICOMweb™, FHIR®, IHE® XDS-I, IHE® XCA-I) versus proprietary or custom integrations?

SC-2. What metadata and other information is currently associated with diagnostic images for purposes of access and exchange, including images exchanged using different standards and custom integrations? Please feel free to elaborate on the use of artificial intelligence tools in adding metadata to images and additional information to accompany an image.

SC-3. What technical barriers, such as proprietary interfaces or ambiguous standards, limit the access, exchange,

and use of diagnostic images across health IT systems (including by patient-facing apps), and should existing technical standards be further modified (please identify the standard)?

SC-4. How do certified health IT and/or EHRs enable or facilitate access, exchange, and use of diagnostic images today? Specifically, do EHRs play an active role in diagnostic image exchange, or is the functionality primarily driven by imaging systems such as PACS and VNAs?

SC-5. Should ASTP/ONC update the Certification Program to support the access, exchange, and use of diagnostic images? For example, an image access requirement could be added to the existing VDT certification criterion or additional imaging data elements could be included in the United States Core Data for Interoperability (USCDI).⁶

SC-6. Should there be a focus on particular, individual diagnosis and treatment use cases (e.g., ocular imaging)? Are there specific requirements that need to be considered for use cases in other fields?

SC-7. Could image management systems, such as PACS and VNAs, be certified to specific certification criteria that would improve interoperability between these systems and EHRs and make access to diagnostic images available to "outside" providers and patients (including patient-facing apps)? What standards and capabilities should these certification criteria include?

SC-8. Beyond or absent the certification of health IT to specific technical standards, what diagnostic image-related standards should ASTP/ONC adopt on behalf of HHS to improve

interoperability and health IT alignment?⁷

SC-9. Are there unique privacy and security concerns related to the access, exchange, and use of diagnostic images that may not exist with other types of health information?

SC-10. Would further development and adoption of the SMART® Imaging Access draft specification⁸ help address the access, exchange, and use of diagnostic images, as well as any specific privacy and security concerns related to such access, exchange, and use?

IV. Collection of Information Requirements

In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), and OMB guidance, we believe this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

[FR Doc. 2026-01866 Filed 1-29-26; 8:45 am]

BILLING CODE 4150-45-P

⁵ <https://link.springer.com/article/10.1007/s00247-022-05474-9>.

⁶ <https://www.healthit.gov/isp/united-states-core-data-interoperability-uscdi>.

⁷ <https://www.healthit.gov/topic/hhs-health-it-alignment-program>.

⁸ <https://github.com/sync-for-science/imaging>.

Notices

Federal Register

Vol. 91, No. 20

Friday, January 30, 2026

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding: whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by March 2, 2026 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it

displays a currently valid OMB control number.

National Institute of Food and Agriculture

Title: Veterinary Medicine Loan Repayment Program (VMLRP).

OMB Control Number: 0524–0050.

Summary of Collection: In January 2003, the National Veterinary Medical Service Act (NVMSA) passed into law adding section 1415A to the National Agricultural Research, Extension, and Teaching Policy Act of 1997. This law established a new Veterinary Medicine Loan Repayment Program (VMLRP) (7 U.S.C. 3151a) authorizing the Secretary of Agriculture to carry out a program of entering into agreements with veterinarians under which they agree to provide veterinary services in veterinarian shortage situations. The purpose of the program is to assure an adequate supply of trained food animal veterinarians in shortage situations and provide USDA with a pool of veterinary specialists to assist in the control and eradication of animal disease outbreaks. The National Institute of Food and Agriculture (NIFA) will designate geographic and practice areas that have a shortage of food supply veterinarians to carry out the VMLRP goals of strengthening the nation's animal health infrastructure and supplementing the Federal response during animal health emergencies. NIFA will carry out NVMSA by entering into educational loan repayment agreements with veterinarians who agree to provide veterinary services in veterinarian shortage for a specific duration. NIFA will collect information using the Shortage Situation Nomination Form, Application Form, Records and Reports, and Surveys.

Need and Use of the Information: The information collected allows the National Institute of Food and Agriculture to request VMLRP applicants' information related to eligibility, qualification, career interests, and recommendations necessary to evaluate their applications for repayment of educational indebtedness in return for agreeing to provide veterinary services in veterinarian shortage situations. The information will also be used to determine an applicant's eligibility for participation in the program. The information also allows the VMLRP to assess program processes and impact, make program

improvements based on process feedback, and provide feedback to State Animal Health Officials on veterinarian shortage situations, which can aid them during the nomination process.

Description of Respondents:

Individuals or households; Business or other for-profit.

Number of Respondents: 880.

Frequency of Responses: Reporting: Quarterly, Annually, Biennially.

Total Burden Hours: 2,540.

Levi S. Harrell,

Departmental Information Collection Clearance Officer.

[FR Doc. 2026–01841 Filed 1–29–26; 8:45 am]

BILLING CODE 3410–09–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–10–2026]

Foreign-Trade Zone (FTZ) 102 Notification of Proposed Production Activity; BASF Agricultural Solutions US LLC; (Agricultural Fungicide and Herbicide Products); Fenton/Palmyra, Missouri

BASF Agricultural Solutions US LLC submitted a notification of proposed production activity to the FTZ Board (the Board) for its facilities in Fenton and Palmyra, Missouri within FTZ 102. The notification conforming to the requirements of the Board's regulations (15 CFR 400.22) was received on January 26, 2026.

Pursuant to 15 CFR 400.14(b), FTZ production activity would be limited to the specific foreign-status material(s)/ component(s) and specific finished product(s) described in the submitted notification (summarized below) and subsequently authorized by the Board. The benefits that may stem from conducting production activity under FTZ procedures are explained in the background section of the Board's website—accessible via www.trade.gov/ftz.

The proposed finished products include REVYSOL Fungicide (Mefentrifluconazole) and KIXOR Herbicide (Saflufenacil) (duty rate is 6.5%).

The proposed foreign-status materials/components include: 1,2,4-Triazole; CPTAP (1-[4-(4-chlorophenoxy)-2-(trifluoromethyl)]

phenyl]ethenone); Dimethyl Sulfate; Dimethyl Sulfide; N,N-Dimethyl formamide; Ethylaminocrotonate; and PCM (4-chloro-2-fluoro-5-[[[methyl(1-methylethyl)amino]sulfonyl]amino]carbonyl]phenyl]-ethyl ester) (duty rate ranges from 3.7% to 6.5%).

The request indicates that certain materials/components are subject to duties under section 1702(a)(1)(B) of the International Emergency Economic Powers Act (section 1702) or section 301 of the Trade Act of 1974 (section 301), depending on the country of origin. The applicable section 1702 and 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 March 11, 2026.

A copy of the notification will be available for public inspection in the "Online FTZ Information System" section of the Board's website.

For further information, contact John Frye at john.frye@trade.gov.

Dated: January 28, 2026.

Elizabeth Whiteman,
Executive Secretary.

[FR Doc. 2026-01892 Filed 1-29-26; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B-11-2026]

Foreign-Trade Zone 124; Application for Subzone; ECI Gulf Coast Parts and Service, Inc.; New Iberia, Louisiana

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the Port of South Louisiana, grantee of FTZ 124, requesting subzone status for the facility of ECI Gulf Coast Parts and Service, Inc., located in New Iberia, Louisiana. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a-81u), and the regulations of the FTZ Board (15 CFR part 400). It was formally docketed on January 28, 2026.

The proposed subzone (11.87 acres) is located at 1309 Unifab Road, New Iberia, Louisiana. No authorization for production activity has been requested at this time.

In accordance with the FTZ Board's regulations, Camille Evans of the FTZ Staff is designated examiner to review the application and make 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 March 11, 2026. Rebuttal comments in response to material submitted during the foregoing period may be submitted through March 26, 2026.

A copy of the application will be available for public inspection in the "Online FTZ Information Section" section of the FTZ Board's website, which is accessible via www.trade.gov/ftz.

For further information, contact Camille Evans at Camille.Evans@trade.gov.

Dated: January 28, 2026.

Elizabeth Whiteman,
Executive Secretary.

[FR Doc. 2026-01897 Filed 1-29-26; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-201-857]

Certain Freight Rail Couplers and Parts Thereof From Mexico: Preliminary Results and Partial Rescission of Antidumping Duty Administrative Review; 2023-2024

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) is conducting an administrative review of the antidumping duty order on certain freight rail couplers and parts thereof (freight rail couplers) from Mexico. The period of review (POR) is May 3, 2023, through October 31, 2024. Commerce preliminarily determines that Amsted Rail Company, Inc.; ASF-K de Mexico, S. de R.L. de C.V. (Amsted) made sales of subject merchandise at less than normal value during the POR. We invite interested parties to comment on these preliminary results.

DATES: Applicable January 30, 2026.

FOR FURTHER INFORMATION CONTACT: Patrick Barton, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-0012.

SUPPLEMENTARY INFORMATION:

Background

On November 15, 2023, Commerce published in the **Federal Register** the antidumping duty order on freight rail

couplers from Mexico.¹ On December 18, 2024, based on timely requests for review, Commerce initiated an administrative review covering 23 companies.²

On December 9, 2024, Commerce tolled the deadline to issue the preliminary results in administrative reviews for which the opportunity to request the review was published in November or December 2024, by 90 days.³ Additionally, due to the lapse in appropriations and Federal Government shutdown, on November 14, 2025, Commerce tolled all deadlines in administrative proceedings by 47 days,⁴ and, due to a backlog of documents that were electronically filed via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS) during the Federal Government shutdown, on November 24, 2025, Commerce tolled all deadlines in administrative proceedings by an additional 21 days.⁵ On December 30, 2025, Commerce extended the deadline for these preliminary results to February 6, 2026.⁶

For a complete description of the events that followed the initiation of this review, see the Preliminary Decision Memorandum.⁷ A list of topics discussed in the Preliminary Decision Memorandum is attached as Appendix I to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via ACCESS. ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete

¹ See *Certain Freight Rail Couplers and Parts Thereof from Mexico: Antidumping Duty Order*, 88 FR 78308 (November 15, 2023) (*Order*).

² See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 89 FR 102856, 102860 (December 18, 2024) (*Initiation Notice*).

³ See Memorandum, "Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings," dated December 9, 2024. The opportunity notice to request this administrative review was published on November 1, 2024. See *Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review and Join Annual Inquiry Service List*, 89 FR 87338 (November 1, 2024).

⁴ See Memorandum, "Deadlines Affected by the Shutdown of the Federal Government," dated November 14, 2025.

⁵ See Memorandum, "Tolling of all Case Deadlines," dated November 24, 2025.

⁶ See Memorandum, "Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review," dated December 30, 2025.

⁷ See Memorandum, "Decision Memorandum for the Preliminary Results of Antidumping Duty Administrative Review: Certain Freight Rail Couplers and Parts Thereof from Mexico; 2023-2024," dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

version of the Preliminary Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Scope of the Order

The product covered by this *Order* is freight rail couplers from Mexico. For a full description of the scope, *see* the Preliminary Decision Memorandum.⁸

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(B) of the Tariff Act of 1930, as amended (the Act). Constructed 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. A list of the topics discussed in the Preliminary Decision Memorandum is included as an appendix to this notice.

Rescission of Administrative Review, in Part

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the parties that requested a review withdraw the request within 90 days of the date of publication of the notice of initiation. On January 9, 2025,

the Coalition of Freight Coupler Producers (the petitioner) timely withdrew its request for a review of 22 companies upon which we initiated the review.⁹ No other parties requested an administrative review of these companies. Therefore, in accordance with 19 CFR 351.213(d)(1), Commerce is rescinding this administrative review with respect to the 22 companies listed in Appendix II to this notice.

Preliminary Results of Review

We preliminarily determine that the following estimated weighted-average dumping margin exists for the period May 3, 2023, through October 31, 2024:

Exporter/producer	Weighted-average dumping margin (percent)
Amsted Rail Company, Inc.; ASF–K de Mexico, S. de R.L. de C.V	6.50

Disclosure

Commerce intends to disclose its calculations and analysis performed to interested parties in these preliminary results within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance. Pursuant to 19 CFR 351.309(c)(1)(ii), we have modified the deadline for interested parties to submit case briefs to Commerce to no later than 21 days after the date of the publication of this notice.¹⁰ 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.¹¹ Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) a statement of the issue; and (2) a brief summary of the argument; and (3) a table of authorities.¹² All briefs must be filed electronically using ACCESS. An electronically filed document must be received successfully in its entirety in

ACCESS by 5:00 p.m. Eastern Time on the established deadline. As provided under 19 CFR 351.309(c)(2)(iii) and (d)(2)(iii), we request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.¹³ Further, we request that interested parties limit their executive summary of each issue to no more than 450 words, not including citations. We intend to use the executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).¹⁴ 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 via ACCESS by 5:00 p.m. Eastern Time within 30 days after the date of publication of this notice.¹⁵ Requests

should contain: (1) the party’s name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs. Commerce intends to issue the final results of this administrative review, including the results of its analysis of the issues raised in any written briefs, not later than 120 days after the date of publication of these preliminary results in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act, unless extended.

Assessment Rate

Pursuant to section 751(a)(2)(A) of the Act, upon issuance of the final results, Commerce will determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review.¹⁶ If a respondent’s weighted-average dumping margin is above *de minimis* in the final results of this review, we will calculate an importer-specific assessment rate based on the ratio of the total amount of dumping calculated for each importer’s examined sales and the total entered value of the sales in accordance with 19 CFR

⁸ *Id.* at 2–3.

⁹ *See* Petitioner’s Letter, “Withdrawal of Administrative Review Request,” dated January 9, 2025.

¹⁰ Commerce is exercising its discretion under 19 CFR 351.309(c)(1)(ii) to alter the time limit for the filing of case briefs. *See* 19 CFR 351.309(c)(1)(ii).

¹¹ *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings*, 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Final Rule*).

¹² *See* 19 CFR 351.309(c)(2) and (d)(2).

¹³ We use the term “issue” here to describe an argument that Commerce would normally address

in a comment of the Issues and Decision Memorandum.

¹⁴ *See Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings; Final Rule*, 88 FR 67069 (September 29, 2023).

¹⁵ *See* 19 CFR 351.310(c).

¹⁶ *See* 19 CFR 351.212(b).

351.212(b)(1).¹⁷ Where the respondent did not report entered value, we calculated a per-unit assessment rate for each importer by dividing the total amount of dumping calculated for the examined sales made to that importer by the total quantity associated with those sales. To determine whether an importer-specific, per-unit assessment rate is *de minimis*, in accordance with 19 CFR 351.106(c)(2), we also calculated an importer-specific *ad valorem* ratio based on estimated entered values. If a respondent's weighted-average dumping margin or an importer-specific assessment rate is zero or *de minimis* in the final results of review, we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties in accordance with the *Final Modification for Reviews*.¹⁸

In accordance with Commerce's "automatic assessment" practice, for entries of subject merchandise during the POR produced by Amsted for which it did not know that the merchandise was destined for the United States, we will instruct CBP to liquidate such entries at the all-others rate in the original less-than-fair-value (LTFV) investigation (*i.e.*, 48.10 percent) if there is no rate for the intermediate company(ies) involved in the transaction.¹⁹

The final results of this administrative review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.²⁰ We intend to issue assessment instructions to CBP no earlier than 41 days after the date of publication of the final results of this review in the **Federal Register**, in accordance with 19 CFR 356.8(a).

For the companies for which this review is being rescinded, antidumping duties shall be assessed on entries at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to

issue assessment instructions to CBP for the companies listed in Appendix II to this notice no earlier than 41 days after the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 356.8(a).

Cash Deposit Requirements

The following cash deposit requirements for estimated antidumping duties will be effective upon publication of the notice of final results of this review for all shipments of freight rail couplers from Mexico entered, or withdrawn from warehouse, for consumption on or after the date of publication as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for companies subject to this review will be equal to the dumping margin established in the final results of the review; (2) for merchandise exported by companies not covered in this review but covered in a prior segment of this proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the LTFV investigation but the producer is, the cash deposit rate will be the rate established for the most recently completed segment for the producer of the merchandise; (4) the cash deposit rate for all other producers or exporters will continue to be the 48.10 percent, the all-others rate established in the LTFV investigation.²¹ These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping countervailing duties prior to liquidation of the relevant entries during this period of review. 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

Commerce is issuing and publishing these preliminary results in accordance with sections 751(a)(1) and 777(i) of the Act, and 19 CFR 351.221(b)(4).

Dated: January 23, 2026.

Christopher Abbott,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Order
- IV. Discussion of the Methodology
- V. Currency Conversion
- VI. Recommendation

Appendix II

Companies Rescinded From Administrative Review

1. BNSF Railway
2. CAI Rail Inc.
3. Canadian National Railway Company
4. Canadian Pacific Kansas City Limited
5. Chicago Freight Car Leasing Company
6. CIT Rail (First Citizens Bank)
7. CSX Transportation Corp.
8. Freightcar America, Inc.
9. GATX de Mexico
10. Mitsui de Mexico, S. de R.L. de C.V.
11. Modern Rail Capital
12. National Steel Car, Ltd.
13. Norfolk Southern Railway
14. Strato, Inc.
15. The Greenbrier Companies, Inc.
16. Trinity Rail Group LLC
17. TTX Company
18. Tubos Acero Mexico
19. Union Pacific Railroad
20. Union Tank Car Company
21. Wabtec Corporation
22. Wells Fargo Rail

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DEPARTMENT OF COMMERCE

International Trade Administration

Quarterly Update to Annual Listing of Foreign Government Subsidies on Articles of Cheese Subject to an In-Quota Rate of Duty

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Comments must be submitted by March 31, 2026.

ADDRESSES: The U.S. Department of Commerce (Commerce) encourages any person having information on foreign government subsidy programs which benefit articles of cheese subject to an in-quota rate of duty to submit such information in writing. All comments must be submitted through the Federal eRulemaking Portal at <https://www.regulations.gov>, Docket No. ITA-2020-0005. The materials in the docket will not be edited to remove identifying

¹⁷ In these preliminary results, Commerce applied the assessment rate calculation method adopted in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Duty Proceedings; Final Modification*, 77 FR 8101 (February 14, 2012) (*Final Modification for Reviews*).

¹⁸ See *Final Modification for Reviews*, 77 FR at 8103; see also 19 CFR 351.106(c)(2).

¹⁹ See *Order*, 88 FR at 78308; see also *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties*, 68 FR 23954 (May 6, 2003).

²⁰ See section 751(a)(2)(C) of the Act.

²¹ See *Order*, 88 FR at 78308.

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. All comments should be addressed to Christopher Abbott, Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance, at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Samuel Brummitt, 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.

SUPPLEMENTARY INFORMATION:

Background

On November 24, 2025, pursuant to section 702(h) of the Trade Agreements Act of 1979, as amended (the Act), Commerce published the quarterly update to the annual listing of foreign government subsidies on articles of cheese subject to an in-quota rate of duty covering the period April 1, 2025, through June 30, 2025.¹ In the *Second Quarter 2025 Update*, we requested that any party that had information on foreign government subsidy programs that benefited articles of cheese subject to an in-quota rate of duty submit such information to Commerce.² We received no comments, information, or requests for consultation from any party.

Pursuant to section 702(h) of the Act, we hereby provide Commerce’s update of subsidies on articles of cheese that were imported during the period July 1,

2025, through September 30, 2025. The appendix to this notice lists the country, the subsidy program or programs, and the gross and net amounts of each subsidy for which information is currently available. Commerce will incorporate additional programs which are found to constitute subsidies, and additional information on the subsidy programs listed, as the information is developed.

Notification to Interested Parties

This determination and notice are in accordance with section 702(a) of the Act.

Dated: January 22, 2026.

Christopher Abbott,
Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix

SUBSIDY PROGRAMS ON CHEESE SUBJECT TO AN IN-QUOTA RATE OF DUTY

Country	Program(s)	Gross ³ subsidy (\$/lb.)	Net ⁴ subsidy (\$/lb.)
27 European Union Member States ⁵	European Union Restitution Payments	\$0.00	\$0.00
Canada	Export Assistance on Certain Types of Cheese	0.47	0.47
Norway	Indirect (Milk) Subsidy	0.00	0.00
	Consumer Subsidy	0.00	0.00
	Total	0.00	0.00
Switzerland	Deficiency Payments	0.00	0.00

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration
[RTID 0648–XF333]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to U.S. Navy Ice Exercise Activities 2026 in the Arctic Ocean

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.
ACTION: Notice; issuance of incidental harassment authorization.

SUMMARY: In accordance with regulations implementing the Marine Mammal Protection Act (MMPA) as

amended, notification is hereby given that NMFS has issued an incidental harassment authorization (IHA) to the U.S. Department of the Navy (hereafter Navy) for authorization to take marine mammals incidental to Ice Exercise Activities 2026 (ICEX26) in the Arctic Ocean. The Navy’s activities are considered military readiness activities pursuant to the MMPA, as amended by the National Defense Authorization Act for Fiscal Year 2004 (2004 NDAA).

DATES: This authorization is effective from February 18, 2026, through April 30, 2026.

ADDRESSES: Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities>. In case of problems accessing

these documents, please call the contact listed below.

FOR FURTHER INFORMATION CONTACT: Alyssa Clevensine, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:
MMPA Background and Determinations

The MMPA prohibits the “take” of marine mammals, with certain exceptions. Among the exceptions is section 101(a)(5)(D) of the MMPA (16 U.S.C. 1361 *et seq.*) which directs the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking by harassment of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and the public has an opportunity to comment on the proposed IHA.

¹ See *Quarterly Update to Annual Listing of Foreign Government Subsidies on Articles of Cheese Subject to an In-Quota Rate of Duty*, 90 FR 52916 (November 24, 2025) (*Second Quarter 2025 Update*).

² *Id.*

³ Defined in 19 U.S.C. 1677(5).

⁴ Defined in 19 U.S.C. 1677(6).

⁵ The 27 member states of the European Union are: Austria, Belgium, Bulgaria, Croatia, Cyprus,

Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden.

Specifically, NMFS will issue an IHA if it finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other “means of effecting the least [practicable] adverse impact” on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stocks for taking for certain subsistence uses (referred to here as “mitigation”). NMFS must also prescribe requirements pertaining to the monitoring and reporting of such takings. The definitions of key terms, such as “take,” “harassment,” and “negligible impact,” can be found in the MMPA and the NMFS’ implementing regulations (see 16 U.S.C. 1362; 50 CFR 216.103).

The 2004 NDAA (Pub. L. 108–136) removed the “small numbers” and “specified geographical region” limitations indicated above and amended the definition of “harassment” as applied to a “military readiness activity.” The activity for which incidental take of marine mammals is being requested qualifies as a military readiness activity.

On November 14, 2025, a notice of NMFS’ proposal to issue an IHA to the Navy for take of marine mammals incidental to submarine training and testing activities in the Arctic Ocean was published in the **Federal Register** (90 FR 51043). In that notice, NMFS indicated the estimated numbers, type, and methods of incidental take proposed for each species or stock, as well as the mitigation, monitoring, and reporting measures that would be required should the IHA be issued. The **Federal Register** notice also included analysis to support NMFS’ preliminary conclusions and determinations that the IHA, if issued, would satisfy the requirements of section 101(a)(5)(D) of the MMPA for issuance of the IHA. The **Federal Register** notice included web links to a draft IHA for review, as well as other supporting documents.

During the 30-day public comment period, NMFS received one comment letter from a private citizen. NMFS’ consideration of public comments, which we respond to below, did not result in changes to the analysis or findings in the **Federal Register** notice of proposed IHA or the required mitigation, monitoring, or reporting measures set forth in the proposed IHA. There are no changes to the specified

activity, the species taken, the proposed numbers, type, or methods of take, or the mitigation, monitoring, or reporting measures in the proposed IHA notice. No new information that would change any of the preliminary analyses, conclusions, or determinations in the proposed IHA notice has become available since that notice was published, and therefore, the preliminary analyses, conclusions, and determinations included in the proposed IHA are considered final.

Comment 1: The commenter asserted that Level A harassment cannot be wholly ruled out given the difficulty of detecting seals beneath ice and snow, and stated that this necessitates additional precautionary mitigation measures. The commenter provided five recommendations to enhance mitigation, monitoring, and reporting: seasonal restrictions on “high-intensity sound sources,” expanded shutdown and monitoring zones, implementation of passive acoustic monitoring (PAM), avoidance of ringed seal lair-rich areas, and enhanced reporting requirements.

Response: As discussed in the notice of the proposed IHA, Level A harassment is not likely to occur as a result of the specified activity, and the commenter provided no information that would invalidate this determination. Modeling for three previous ICEXs (2018, 2020, and 2022), which employed similar acoustic sources, did not result in any estimated takes by permanent threshold shift (PTS) (Level A harassment), and NMFS anticipates that the density of ringed seals is actually much lower than estimated in those previous analyses, further reducing the likelihood of Level A harassment. In addition, at close ranges and high sound levels approaching those that could cause auditory injury, seals would likely avoid the area immediately around the sound source. In consideration of the fact that total takes were likely overestimated for previous ICEX activities given the density information used in the analyses and the similarity between those activities and the activities planned for ICEX26, NMFS does not expect, and did not authorize, take by Level A harassment of ringed seal.

Regarding the recommendation to seasonally restrict sound sources, as described in the notice of proposed IHA, the dates and duration of the planned activity, along with the seasonal mitigation to minimize impacts to ringed seal lair construction and use of lairs, are expected to reduce potential acoustic impacts to ringed seals in the Study Area. As such, NMFS disagrees with the commenter that limiting

acoustic transmissions during periods when seals rely most heavily on lairs would substantially reduce disturbance.

Regarding the other four recommendations from the commenter, two of these were included as proposed measures and are required by the IHA: implementation of PAM and avoidance of lair-rich areas; therefore, these measures are not discussed further.

The commenter recommended expanded shutdown and monitoring zones but did not provide specific recommendations for zone sizes or provide any information that could be used to assess expansion of shutdown and monitoring zones. The proposed IHA and this final IHA require that Navy personnel must conduct PAM during all active sonar use, and must delay or shut down active acoustic transmissions and exercise torpedo launches if a marine mammal is detected. The IHA does not specify a distance for delaying or shutting down active acoustic sources following a marine mammal detection; any marine mammal detected with PAM would result in a shutdown of the active sonar source. As such, it is not possible to expand shutdown and monitoring zones as recommended by the commenter as these zones already extend to the farthest distance that marine mammals can be detected visually or acoustically.

Finally, the commenter did not provide specific reporting details that it considers to be enhanced from what was proposed and is required under the IHA. Therefore, we cannot further consider the recommendation. The monitoring and reporting measures required by the IHA satisfy the requirements of the MMPA.

Comment 2: The commenter stated the potential impacts from ICEX26 must also be considered alongside cumulative effects as part of the negligible impact determination required by the MMPA. Separately, the commenter also stated that NMFS should explicitly disclose how it interprets “small numbers” in this context and justify how the proposed take aligns with the requirement that take must be negligible relative to overall population size.

Response: NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.*, population-level effects). An estimate of the number of takes alone is not enough information

on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be “taken” through harassment, NMFS considers other factors, such as the likely nature of any impacts or responses (*e.g.*, intensity, duration), the context of any impacts or responses (*e.g.*, critical reproductive time or location, foraging impacts affecting energetics), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status.

Neither the MMPA nor NMFS’ codified implementing regulations call for consideration of other unrelated activities and their impacts on marine mammal populations. The preamble for NMFS’ implementing regulations (54 FR 40338, September 29, 1989) states in response to comments that the impacts from other past and ongoing anthropogenic activities are to be incorporated into the negligible impact analysis via their impacts on the baseline. Consistent with that direction, NMFS has factored into its negligible impact analysis the impacts of other past and ongoing anthropogenic activities via their impacts on the baseline, *e.g.*, as reflected in the density, distribution, and status of the species, population size and growth rate, and other relevant stressors. The 1989 final rule for the MMPA implementing regulations also addressed public comments regarding cumulative effects from future, unrelated activities. There, NMFS stated that such effects are not considered in making findings under MMPA section 101(a)(5) concerning negligible impact.

Section 101(a)(5)(D) of the MMPA requires NMFS to make a determination that the take incidental to a “specified activity” will have a negligible impact on the affected species or stocks of marine mammals. NMFS’ implementing regulations 50 CFR 216.104(a)(1) require applicants to include in their request a detailed description of the specified activity or class of activities that can be expected to result in incidental taking of marine mammals. Thus, the “specified activity” for which incidental take coverage is being sought under section 101(a)(5)(D) is generally defined and described by the applicant. Here, the Navy was the applicant for the IHA, and we are responding to the specified activity as described in that application and making the necessary findings on that basis.

Regarding the “small numbers” interpretation, as stated in the

Background section of the **Federal Register** notice of proposed IHA, the 2004 NDAA amended section 101(a)(5) of the MMPA for military readiness activities to remove the “small numbers” provision. ICEX26 qualifies as a military readiness activity and, as such, the “small numbers” provision does not apply.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our proposed action (*i.e.*, the issuance of an IHA) with respect to potential impacts on the human environment.

This action is consistent with categories of activities identified in Categorical Exclusion B4 (IHAs with no anticipated serious injury or mortality) of the Companion Manual for NAO 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS has determined that the issuance of this IHA qualifies to be categorically excluded from further NEPA review.

Endangered Species Act

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA) (16 U.S.C. 1531 *et seq.*) requires that each Federal agency ensures that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally whenever we propose to authorize take for endangered or threatened species, in this case with NMFS’ Alaska Regional Office (AKR).

There is one marine mammal species (Alaska stock of ringed seals) with confirmed occurrence in the project area that is listed under the ESA. The NMFS AKR issued a Biological Opinion under section 7 of the ESA, on the issuance of an IHA to the Navy under section 101(a)(5)(D) of the MMPA by the NMFS Office of Protected Resources. The Biological Opinion concluded that the proposed action is not likely to jeopardize the continued existence of ringed seals.

Authorization

Accordingly, consistent with the requirements of section 101(a)(5)(D) of

the MMPA, NMFS has issued an IHA to the Navy for authorization to take marine mammals incidental to submarine training and testing activities in the Arctic Ocean.

Dated: January 28, 2026.

Kimberly Damon-Randall,

*Director, Office of Protected Resources,
National Marine Fisheries Service.*

[FR Doc. 2026–01911 Filed 1–29–26; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Technical Information Service

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Revision of Currently Approved Information Collection; Comment Request; Limited Access Death Master File Certification Program Forms

AGENCY: National Technical Information Service (NTIS), Department of Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public’s reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before March 31, 2026.

ADDRESSES: Interested persons are invited to submit written comments by mail to Monica Voigt, IT Project Manager, Office of Program Management, National Technical Information Service, Department of Commerce or by email to mvoigt@ntis.gov or PRAComments@doc.gov. Please reference OMB Control Number 0692–0013 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Monica Voigt, IT Project Manager, Office of Program Management, National Technical Information Service,

Department of Commerce, 5301 Shawnee Road, Alexandria, VA 22312, email: mvoigt@ntis.gov or telephone: 703-605-6142.

SUPPLEMENTARY INFORMATION:

I. Abstract

Title of Information Collection: Limited Access Death Master File (LADMF) Certification Program Forms.

OMB Control Number: 0692-0013.

Form Number(s): NTIS FM161, NTIS FM101, NTIS FM100A, and NTIS FM100B:

- (A) Limited Access Death Master File Certification Form (Certification Form) (NTIS FM 161)
- (B) Limited Access Death Master File Accredited Conformity Assessment Body Application for Firewalled Status (Firewalled Status Application Form). (NTIS FM101)
- (C) Limited Access Death Master File (LADMF) Accredited Conformity Assessment Body Systems Safeguards Attestation Form (ACAB Systems Safeguards Attestation Form) (NTIS FM100A)
- (D) Limited Access Death Master File (LADMF) State or Local Government Auditor General (AG) or Inspector General (IG) Systems Safeguards Attestation Form (AG or IG Systems Safeguards Attestation Form) (NTIS FM100B)

This notice informs the public that the National Technical Information Service (NTIS) is requesting approval for revision of the above information collection for use in connection with the final rule for the "Certification Program for Access to the Death Master File," 15 CFR part 1110. Under this revision, NTIS is requesting approval to consolidate its information collection instruments used in conjunction with the LADMF Certification Program. The Firewalled Status Application Form (NTIS FM101; OMB Control Number 0692-0015), the ACAB Systems Safeguards Attestation Form (NTIS FM100A; OMB Control Number 0692-0016), and the AG or IG Systems Safeguards Attestation Form (NTIS FM100B; OMB Control Number 0692-0016) will be consolidated with the Certification Form (NTIS FM161) under OMB Control Number 0692-0013 with a revised information collection title of "Limited Access Death Master File (LADMF) Certification Program Forms." NTIS intends to submit requests to discontinue the use of OMB Control Number 0692-0015 and OMB Control Number 0692-0016 after this revision is approved. There are no substantive changes to the forms under this revision.

The final rule for the LADMF Certification Program was promulgated under Section 203 of the Bipartisan Budget Act of 2013, Public Law 113-67 (Act) and published on June 1, 2016 (81 FR 34882). The rule became effective on November 28, 2016 (15 CFR part 1110).

The Act prohibits the Secretary of Commerce (Secretary) from disclosing Death Master File (DMF) information during the three-year period following an individual's death (Limited Access DMF or LADMF), unless the person requesting the information has been certified to access the Limited Access DMF pursuant to certain criteria in a program that the Secretary establishes. The Secretary delegated the authority to carry out Section 203 to the Director of NTIS. The final rule requires that:

a. a Person, as defined in 15 CFR 1110.2, seeking access to the LADMF establish a legitimate fraud prevention interest or legitimate business purpose pursuant to a law, governmental rule, regulation, or fiduciary duty. The Certification Form (NTIS FM161) collects information that NTIS will use to evaluate whether the respondent qualifies to receive the LADMF under the rule.

b. a Person seeking certification or a Certified Person seeking renewal of a certification must submit a written attestation from an "Accredited Conformity Assessment Body" (ACAB), as defined in 15 CFR 1110.2, that such Person or Certified Person has information security systems, facilities and procedures in place to protect the security of the Limited Access DMF, as required under 15 CFR 1110.102(a)(2). The ACAB Systems Safeguards Attestation Form (NTIS FM100A) collects information based on an assessment by the ACAB conducted within three years prior to the date of the Person or Certified Person's submission of a completed certification statement under 15 CFR 1110.101(a). This collection includes specific requirements of the final rule, which the ACAB must certify are satisfied, and the provision of specific information by the ACAB, such as the date of the assessment and the auditing standard(s) used for the assessment.

c. the ACAB must be independent of the Person or Certified Person seeking certification, unless it is a conformity assessment body which qualifies for "firewalled status" pursuant to 15 CFR 1110.502.

The Firewalled Status Application Form (NTIS FM101) collects information that NTIS will use to evaluate whether the respondent qualifies for "firewalled status" under the rule, and, therefore, can provide a

written attestation in lieu of an independent ACAB's attestation. This information includes specific requirements of 15 CFR 1110.502(b), which the respondent ACAB must certify are satisfied, and the provision of specific information by the respondent ACAB, such as the identity of the Person or Certified Person that would be the subject of the attestation and the basis upon which the certifications were made.

d. under 15 CFR 1110.501(a)(2), a state or local government office of Auditor General (AG) or Inspector General (IG) and a Person or Certified Person that is a department or agency of the same state or local government, respectively, are not considered to be owned by a common "parent" entity under 15 CFR 1110.501(a)(1)(ii) for the purpose of determining independence, and attestation by the AG or IG is possible. The AG or IG Systems Safeguards Attestation Form (NTIS FM100B) is for the use of a state or local government AG or IG to attest on behalf of a state or local government department or agency Person or Certified Person. The AG or IG Systems Safeguards Attestation Form requires the state or local government AG or IG to attest that a Person seeking certification or a Certified Person seeking renewal of certification has information security systems, facilities and procedures in place to protect the security of the Limited Access DMF, as required under 15 CFR 1110.102(a)(2). The AG or IG Systems Safeguards Attestation Form collects information based on an assessment by the state or local government AG or IG conducted within three years prior to the date of the Person or Certified Person's submission of a completed certification statement under 15 CFR 1110.101(a). This collection includes specific requirements of the final rule, which the state or local government AG or IG must certify are satisfied, and the provision of specific information by the state or local government AG or IG, such as the date of the assessment.

II. Method of Collection

Electronic.

III. Data

OMB Control Number: 0692-0013.

Form Number(s): NTIS FM 161, NTIS FM101, NTIS FM100A, and NTIS FM100B.

Type of Review: Revision of a current information collection.

Affected Public: Individuals, households, or any Person seeking certification or a Certified Person seeking renewal of certification under

the final rule for the “Certification Program for Access to the Death Master File,” and ACABs and state or local government Auditors General or Inspectors General attesting that a	Person seeking certification or a Certified Person seeking renewal of certification under the final rule for the “Certification Program for Access to the Death Master File” has information	security systems, facilities and procedures in place to protect the security of the Limited Access DMF, as required by the final rule.

	NTIS FM161	NTIS FM101	NTIS FM100A	NTIS FM100B
Estimated Number of Respondents	260	65	250	30.
Estimated Time per Response	3 hours	1 hour	3 hours	3 hours.
Estimated Total Annual Burden Hours	780	65	750	90.
Estimated Total Annual Cost to Public	\$888,160	\$39,910	\$232,500	\$24,750.

Respondent’s Obligation: Voluntary.

Legal Authority: Section 203 of the Bipartisan Budget Act of 2013, Public Law 113–67; 15 CFR part 1110.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms 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 Information Collection Review (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.

Sheleen Dumas,
Departmental PRA Compliance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2026–01839 Filed 1–29–26; 8:45 am]
BILLING CODE 3510–04–P

CONSUMER FINANCIAL PROTECTION BUREAU

[Docket No. CFPB–2026–0005]

Agency Information Collection Activities: Comment Request

AGENCY: Consumer Financial Protection Bureau.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Consumer Financial Protection Bureau (CFPB or Bureau) requests the Office of Management and Budget’s (OMB’s) extension of an information collection titled “Consumer Response Intake Form.”

DATES: Written comments are encouraged and must be received on or before March 2, 2026 to be assured of consideration.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. In general, all comments received will become public records, including any personal information provided. Sensitive personal information, such as account numbers or Social Security numbers, should not be included.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Anthony May, Paperwork Reduction Act Officer, at (202) 435–7278, or email: CFPB_PRA@cfpb.gov. If you require this document in an alternative electronic format, please contact CFPB_Accessibility@cfpb.gov. Please do not submit comments to these email boxes.

SUPPLEMENTARY INFORMATION:
Title of Collection: Consumer Response Intake Form.

OMB Control Number: 3170–0011.

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

Affected Public: Individuals or households.

Estimated Number of Respondents: 6,000,000.

Estimated Total Annual Burden Hours: 1,123,334.

Abstract: The Consumer Response Intake Form is designed to aid consumers in the submission of complaints, inquiries, and feedback and to help the Bureau fulfill its statutory requirements. Consumers (also referred to as respondents) will be able to complete and submit information through the Intake Form electronically on the Bureau’s website. Alternatively, respondents may request that the Bureau mail a paper copy of the Intake Form and then mail it back to the Bureau or call to submit a complaint by telephone. The questions within the Intake Form prompt respondents for a description of, and key facts about, the complaint at issue, the desired resolution, contact and account information, information about the company they are submitting a complaint about, and previous action taken to attempt to resolve the complaint.

Request for Comments: The CFPB published a 60-day **Federal Register** notice on November 28, 2025 (90 FR 54643) under Docket Number: CFPB–2025–0042. The CFPB is publishing this notice and soliciting comments on: (a) Whether the collection of information is necessary for the proper performance of the functions of the CFPB, including whether the information will have practical utility; (b) The accuracy of the CFPB’s estimate of the burden of the collection of information, including the validity of the methods and the assumptions used; (c) Ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be reviewed by OMB as part of its review of this request. All comments will become a matter of public record.

Anthony May,

Paperwork Reduction Act Officer, Consumer Financial Protection Bureau.

[FR Doc. 2026–01895 Filed 1–29–26; 8:45 am]

BILLING CODE 4810-AM-P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2017–0044]

Agency Information Collection Activities; Extension of Collection; Safety Standard for Clothing Storage Units

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of Information Collection; Request for comment.

SUMMARY: As required by the Paperwork Reduction Act of 1995 (PRA), the Consumer Product Safety Commission (CPSC or Commission) announces that the Commission has submitted to the Office of Management and Budget (OMB) a request for extension of approval of information collection requirements associated with the Safety Standard for Clothing Storage Units. OMB previously approved the collection of information under control number 3041–0191. OMB’s most recent extension of approval will expire on February 28, 2026. On November 28, 2025, CPSC published a notice in the **Federal Register** to announce the agency’s intention to seek extension of approval of the collection of information. The Commission received one public comment in support of this information collection. Therefore, by publication of this notice, the Commission announces that CPSC has submitted to OMB a request for extension of approval of that collection of information.

DATES: Submit comments on the collection of information by March 2, 2026.

ADDRESSES: Submit comments about this request by email: OIRA_submission@omb.eop.gov or fax: 202–395–6881. Comments by mail should be sent to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the CPSC, Office of Management and Budget, Room 10235, 725 17th Street NW, Washington, DC 20503. Written comments that are sent to OMB also should be submitted

electronically at <http://www.regulations.gov>, under Docket No. CPSC–2017–0044.

FOR FURTHER INFORMATION CONTACT: Cynthia Gillham, Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814; (301) 504–7791, or by email to: pra@cpsc.gov.

SUPPLEMENTARY INFORMATION: CPSC seeks to renew the following currently approved collection of information:

Title: Safety Standard for Clothing Storage Units.

OMB Number: 3041–0191.

Type of Review: Renewal of collection.

Frequency of Response: On occasion.

Affected Public: Manufacturers and importers of clothing storage units.

General Description of Collection: Pursuant to 15 U.S.C. 2056f, CPSC promulgated a consumer product safety standard to protect against tip-over of clothing storage units (CSUs). 16 CFR part 1261. That standard incorporates by reference ASTM F2057–23, *Standard Safety Specification for Clothing Storage Units*. *Id.* 1261.2. A CSU is defined as a “furniture item with drawers and/or hinged doors intended for the storage of clothing typical with bedroom furniture.” Section 3.1.3, ASTM F2057–23. The standard’s requirements include warning labels that contain certain statements and pictograms. These requirements fall within the definition of “collection of information,” as defined in 44 U.S.C. 3502(3).

Identification and labeling requirements provide information to consumers and regulators needed to locate and recall noncomplying products. Identification and labeling requirements include content such as the name and address of the manufacturer. In addition, CSUs must contain warning labels. Warning labels or markings provide information to consumers on hazards and risks associated with product use. The CSU warning label must state: “Children have died from furniture tipover.” Section 10.2.3.1, ASTM F2057–23.

Estimated Number of Respondents: CPSC estimates that approximately 2,122 respondents will design and update the CSU label annually.¹ CPSC estimates that there are approximately

¹ According to 2023 County Business Patterns data published by the U.S. Census Bureau there were between 2,075 and 3,955 establishments manufacturing household furniture: Table CB2300CBP; Upper bound NAICS 33712 (Household and institutional furniture manufacturing), lower bound NAICS 337122 (Nonupholstered wood household furniture manufacturing).

20,103,360 CSU units that will need to be labeled annually.

Estimated Time per Response: The burden associated with the standard includes time spent updating/designing the labeling or marking for a CSU model and time spent attaching the label to a CSU. CPSC estimates that it could take an hour to update/design the labeling or marking for a CSU model. CPSC estimates it could take 0.06 minutes (3.6 seconds or 1,000 labels per hour) to attach the label to the CSU.

Total Estimated Annual Burden: CPSC estimates that it could take an hour to update/design the labeling or marking for a CSU model, therefore, the annual burden is 2,122 hours (based on 2,122 respondents). CPSC estimates that attaching the label to CSUs would amount to an annual burden of 20,103 hours [(0.06 min × 20,103,360 CSUs)/60 mins per hour]. The total estimated annual burden is 22,225 hours.

Total Estimated Annual Cost to Respondents: The total compensation cost per hour worked for private industry workers in goods-producing industries was \$47.00 (March 2025, Table 4, https://www.bls.gov/news.release/archives/ecec_06132025.pdf). Based on this analysis, CPSC estimates that the labor cost of respondent burden is approximately \$1 million annually [(2,122 hours + 20,103 hours) × \$47.00 per hour = \$1,044,575].

In addition to the labor burden costs addressed above, the labeling requirement imposes additional annualized costs. These costs include capital costs for adhesive paper used for each label to be placed on the CSUs. CPSC estimates the cost of the printed label will be about \$0.01. Therefore, the total cost of materials to industry would be about \$200,000 per year (\$0.01 × 20,103,360 units = \$201,033.60).

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2026–01885 Filed 1–29–26; 8:45 am]

BILLING CODE 6355-01-P

COUNCIL OF THE INSPECTORS GENERAL ON INTEGRITY AND EFFICIENCY

Privacy Act of 1974; System of Records

AGENCY: Council of Inspectors General on Integrity and Efficiency (CIGIE).

ACTION: Notice of modified systems of records.

SUMMARY: CIGIE proposes to modify two systems of records that are subject to the

Privacy Act of 1974. CIGIE established these systems of records pursuant to Public Law 116–136, in furtherance of the statutory mandate of CIGIE’s Pandemic Response Accountability Committee (PRAC) to promote transparency and conduct and support oversight of covered funds and the Coronavirus response, as defined in the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Public Law 116–136; 134 Stat. 533, Section 15010, as amended. The Consolidated Appropriations Act of 2021, Public Law 116–260, 134 Stat. 1182, Division O, Title VIII, Section 801(b), and the Consolidated Appropriations Act, 2022, Public Law 117–103, 136 STAT 307, Division E, Title VII, Section 750, further amended the definition of “covered funds” to clarify PRAC’s authorities. The One Big Beautiful Bill Act (OBBA) extended the PRAC’s jurisdiction to include all funds provided in the OBBA, amended Section 15010(a)(6) of the CARES Act to include the OBBA under the definition of “covered funds,” and extended PRAC’s sunset date to September 30, 2034. An Act to Provide for Reconciliation Pursuant to title II of H. Con. Res. 14, Public Law 119–21, Section 90102 (July 4, 2025)(OBBA). This modification of the two SORNs CIGIE established in furtherance of the PRAC’s statutory mandate will bring both SORNs into alignment with the PRAC’s jurisdiction, to include its expanded jurisdiction. CIGIE also proposes to modify the Routine Uses in these SORNs to comply with Executive Order (E.O.) 14249, Protecting America’s Bank Account Against Fraud, Waste, and Abuse, and Office of Management and Budget (OMB) Memorandum M–25–32, Preventing Improper Payments and Protecting Privacy Through Do Not Pay. CIGIE proposes deleting the reference to “Officials of CIGIE” in the Routine Uses, as the Privacy Act permits disclosures to internal agency employees; therefore, such disclosures are not considered routine uses.

DATES: The public may submit comments on this notice by March 2, 2026. This system of records will be effective without further notice, with the exception of the new or modified routine uses, which will become effective March 2, 2026, unless CIGIE determines that changes are necessary due to public comment.

ADDRESSES: Submit comments identified by “CIGIE–5” and/or “CIGIE–6” by any of the following methods:

1. *Federal Rulemaking Portal:* <http://www.regulations.gov>. Submit comments via the Federal eRulemaking portal by

searching for CIGIE–5 and/or CIGIE–6. Select the link “Comment Now” that corresponds with “CIGIE–5” and/or “CIGIE–6.” Follow the instructions provided on the screen. Please include your name, company name (if any), and “CIGIE–5” and/or “CIGIE–6” on your attached document.

2. *Mail:* Council of Inspectors General on Integrity and Efficiency, 1750 H Street NW, Suite 400, Washington, DC 20006. ATTN: Virginia Grebasch/CIGIE–5 (and/or CIGIE–6, as appropriate), Notice of New System of Records.

3. *Email:* comments@cigie.gov.

FOR FURTHER INFORMATION CONTACT:

Virginia Grebasch, Senior Counsel, Pandemic Response Accountability Committee, Council of the Inspectors General on Integrity and Efficiency, (202) 292–2600, or comments@cigie.gov.

SUPPLEMENTARY INFORMATION: One Big Beautiful Bill Act (OBBA) extended the PRAC’s jurisdiction to include all funds provided in the OBBA, amended Section 15010(a)(6) of the CARES Act to include the OBBA under the definition of “covered funds,” and extended PRAC’s sunset date to September 30, 2034. An Act to Provide for Reconciliation Pursuant to title II of H. Con. Res. 14, Public Law 119–21, Section 90102 (July 4, 2025). This Modification will align the two CIGIE Systems of Records Notices with the PRAC’s expanded jurisdiction. The modification to the two systems that were established in furtherance of the PRAC’s statutory mandate will enable the PRAC to carry out its statutory mandate, including PRAC’s expanded jurisdiction pursuant to the OBBA.

CIGIE proposes modifying the Purpose section of the existing SORNs and modifying the body of the existing SORNs by changing all references to “Coronavirus Funds” to “covered funds,” including in Routine Uses. This modification of the two SORNs CIGIE established in furtherance of the PRAC’s statutory mandate will bring both SORNs into alignment with the PRAC’s jurisdiction, to include its expanded jurisdiction.

CIGIE proposes modifying the Categories of Individuals in the System in CIGIE–5 to include those receiving OBBA funds. Further, it proposes removing the caveat in CIGIE–5 concerning the applicability of the Privacy Act to records of individuals acting in their entrepreneurial/sole-proprietor capacity.

CIGIE proposes modifying the location of records to the new physical of CIGIE Headquarters, 1750 H St. NW, Suite 400, Washington, DC 20006.

CIGIE proposes changing the security classification marking for PDWS to

Controlled Unclassified Information to reflect the security marking protocols established by NARA pursuant to Executive Order 13556.

CIGIE proposes adding Routine Uses to comply with Executive Order (E.O.) 14249, Protecting America’s Bank Account Against Fraud, Waste, and Abuse, and Office of Management and Budget (OMB) Memorandum M–25–32, Preventing Improper Payments and Protecting Privacy Through Do Not Pay.

CIGIE proposes deleting the reference to “Officials of CIGIE” in the Routine Uses, as the Privacy Act permits disclosures to internal agency employees; therefore, such disclosures are not considered routine uses.

All other sections of the SORNs remain the same unless otherwise noted.

SYSTEM NAME AND NUMBER:

PRAC Data Warehouse System (PDWS)—CIGIE–5, and PRAC Accountability Data System (PADS)—CIGIE–6.

SECURITY CLASSIFICATION:

Controlled Unclassified Information.

SYSTEM LOCATION:

The location of paper records contained within the PWS and PADS is the headquarters of the Council of the Inspectors General on Integrity and Efficiency (CIGIE), 1750 H Street NW, Suite 400, Washington, DC 20006. Records maintained in electronic form are principally located in contractor-hosted data centers in the United States. Contact the System Manager identified below for additional information.

SYSTEM MANAGER(S):

Executive Director, Pandemic Response Accountability Committee, Council of the Inspectors General on Integrity and Efficiency, 1750 H St. NW, Suite 400, Washington, DC 20006, (202)292–2600, cigie.information@cigie.gov.

PURPOSE(S) OF THE SYSTEM:

To carry out the PRAC’s responsibilities to support oversight of funds provided in the OBBA and promote transparency and conduct and support oversight of covered funds and the Coronavirus response to prevent and detect fraud, waste, abuse, and mismanagement; and mitigate major risks that cut across program and agency boundaries.” The terms “covered funds” and “Coronavirus response” have the meaning defined in Section 10510(a)(6) and (a)(6), respectively, of the CARES Act, as amended.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The CIGIE-5 system contains records on individuals who relate to PRAC efforts undertaken in support of its mission to promote transparency and conduct and support oversight of covered funds and the Coronavirus response to prevent and detect fraud, waste, abuse, and mismanagement and mitigate major risks that cut across programs and agencies, and its statutory obligation in the OBBB to support oversight of the funds provided in the OBBB. Individuals include but are not limited to those who have applied for, sought, or received Federal funds.

The CIGIE-6 system contains records on individuals who relate to PRAC efforts undertaken in support of its efforts to promote transparency and conduct and support oversight of covered funds and the Coronavirus response to prevent and detect fraud, waste, abuse, and mismanagement and mitigate major risks that cut across programs and agencies, and to support oversight of the funds provided in the OBBB. Individuals include but are not limited to those who have applied for, sought, or received Federal funds. In addition, these individuals include:

(a) Individuals who are or have been the subject of investigations or other inquiries identified by or submitted to the PRAC;

(b) Individuals who are or have been witnesses, complainants, or informants in investigations or other inquiries identified by or submitted to the PRAC;

(c) Individuals who are or have been potential subjects or parties to an investigation or other inquiry identified by or submitted to the PRAC;

(d) Individuals who are or have been related to entities or individuals that are or have been a subject of, potential subject of, or party to an investigation or other inquiry identified by or submitted to the PRAC;

(e) Individuals who have or have had increased risk factors indicating they may have been involved with possible fraud, waste, abuse, mismanagement, or improper payments related to Federal funds; and

(f) Individuals who are or have been related to entities or individuals that have or have had increased risk factors indicating they may have been involved with possible fraud, waste, abuse, mismanagement, or improper payments related to Federal funds.

CATEGORIES OF RECORDS IN THE SYSTEM:

For CIGIE-5: The system maintains records that contribute to the transparency of covered funds and the Coronavirus response and effective

oversight of fraud, waste, abuse, and mismanagement and mitigation of major risks that cut across programs and agencies related to covered funds and the Coronavirus response, and to support oversight of the funds provided in the OBBB.

These records may include, but are not limited to, records concerning: Covered Funds, funds provided in the OBBB, and other Federal funding; the Coronavirus Response; individuals in their personal capacity or individuals who are employees or representatives of businesses, corporations, tribal governments, not-for-profit organizations, or other organizations that have applied for, sought, or received covered funds or have been involved in any capacity in the Coronavirus Response. Such records may include, but are not limited to these individuals' home addresses, telephone numbers, Social Security numbers or tax identifications numbers, company business addresses, business financial information and records, bank account information, payroll records, personal contact information, business affiliations, and employment history.

For CIGIE-6: The system maintains records that contribute to the transparency of covered funds and the Coronavirus response and effective oversight of fraud, waste, abuse, and mismanagement and mitigation of major risks that cut across programs and agencies related to covered funds and the Coronavirus response, and to support oversight of the funds provided in the OBBB. These records may include, but are not limited to, records concerning: covered funds, funds provided in the OBBB, and other Federal funding; the Coronavirus Response; individuals in their personal capacity or individuals who are employees or representatives of businesses, corporations, tribal governments, not-for-profit organizations, or other organizations that have applied for, sought, or received covered funds or have been involved in any capacity in the Coronavirus Response. Such records may include, but are not limited to, these individuals' home addresses, telephone numbers, Social Security numbers or tax identifications numbers, company business addresses, business financial information and records, bank account information, payroll records, personal contact information, business affiliations, and employment history.

The records may further include:

(a) Letters, memoranda, and other documents describing complaints, derogatory information, or alleged

criminal, civil, or administrative misconduct; and

(b) General intelligence and relevant data, leads for the PRAC or Offices of Inspector General (or other applicable oversight and law enforcement entities), reports of investigations and related exhibits, statements and affidavits, and records obtained or generated during an investigation or other inquiry, including but not limited to risk-based analytical research.

RECORD SOURCE CATEGORIES:

For CIGIE-5: Publicly and/or commercially available data sets and other source material; Federal agencies; and individuals and entities, including states and local jurisdictions, tribal governments, businesses, corporations, and other organizations, that have applied for, sought, or received covered funds or other Federal funds or have been involved in any capacity in the Coronavirus response, or funds provided in the OBBB.

For CIGIE-6: Publicly and/or commercially available data sets and other source material; Federal agencies; and individuals and entities, including states and local jurisdictions, tribal governments, businesses, corporations, and other organizations, that have applied for, sought, or received covered funds or other Federal funds or have been involved in any capacity in the Coronavirus response, or funds provided in the OBBB. The subjects of investigations and other inquiries; individuals and entities with which the subjects of investigations and other inquiries are associated; Federal, state, local, and foreign law enforcement and non-law enforcement agencies and entities; private citizens; witnesses; and informants.

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 portions of the records or information contained in this system may specifically be disclosed outside of CIGIE as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

A. To a Member of Congress in response to an inquiry from that Member made at the request of the individual. In such cases, however, the Member's right to a record is no greater than that of the individual.

B. If the disclosure of certain records to the Department of Justice (DOJ) is relevant and necessary to litigation, CIGIE may disclose those records to the DOJ. CIGIE may make such a disclosure if one of the following parties is

involved in the litigation or has an interest in the litigation:

1. CIGIE or any component thereof; or
2. Any employee or former employee of CIGIE in his or her official capacity; or

3. Any employee or former employee of CIGIE in his or her individual capacity when the DOJ has agreed to represent the employee; or

4. The United States, if CIGIE determines that litigation is likely to affect CIGIE or any of its components.

C. If disclosure of certain records to a court, adjudicative body before which CIGIE is authorized to appear, individual or entity designated by CIGIE or otherwise empowered to resolve disputes, counsel or other representative, party, or potential witness is relevant and necessary to litigation, CIGIE may disclose those records to the court, adjudicative body, individual or entity, counsel or other representative, party, or potential witness. CIGIE may make such a disclosure if one of the following parties is involved in the litigation or has an interest in the litigation:

1. CIGIE or any component thereof; or
2. Any employee or former employee of CIGIE in his or her official capacity; or

3. Any employee or former employee of CIGIE in his or her individual capacity when the DOJ has agreed to represent the employee; or

4. The United States, if CIGIE determines that litigation is likely to affect CIGIE or any of its components.

D. To the appropriate Federal, state, local, tribal, or foreign agency responsible for investigating, prosecuting, enforcing, or implementing a statute, rule, regulation, or order, if the information is relevant to a violation or potential violation of civil or criminal law or regulation within the jurisdiction of the receiving entity.

E. To officials and employees of any Federal agency to the extent the record contains information that is relevant to that agency's decision concerning the hiring, appointment, or retention of an employee; issuance of a security clearance; execution of a security or suitability investigation; or classification of a job.

F. To the National Archives and Records Administration (NARA) pursuant to records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

G. To contractors, grantees, consultants, volunteers, or other individuals performing or working on a contract, interagency agreement, service, grant, cooperative agreement, job, or other activity for CIGIE and who have a

need to access the information in the performance of their duties or activities for CIGIE.

H. To appropriate agencies, entities, and persons when: CIGIE suspects or has confirmed that there has been a breach of the system of records; CIGIE has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, CIGIE (including its information systems, programs, and operations), the Federal Government, or national security; and the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with CIGIE'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: CIGIE determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in responding to a suspected or confirmed breach; or 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 Federal agencies and independent certified public accounting firms that have a need for the information in order to audit the financial statements of CIGIE.

K. To an organization or an individual in the public or private sector if there is reason to believe the recipient is or could become the target of a particular criminal activity or conspiracy, or to the extent the information is relevant to the protection of life or property.

L. To CIGIE members and their employees who have need of the information in the performance of their duties.

M. To the Office of Personnel Management (OPM) in accordance with OPM's responsibility for evaluation and oversight of Federal personnel management.

N. To appropriate agencies, entities, and persons, to the extent necessary to respond to or refer correspondence.

O. To the news media and the public, unless it is determined that release of the specific information would constitute an unwarranted invasion of personal privacy.

P. To populate public-facing government websites to promote transparency of covered funds and the Coronavirus Response, unless it is determined that release of the specific information would constitute an

unwarranted invasion of personal privacy.

Q. To the U.S. Department of the Treasury when disclosure of the information is relevant to review payment and award eligibility through the Do Not Pay Working System for the purposes of identifying, preventing, or recouping improper payments to an applicant for, or recipient of, Federal funds, including funds disbursed by a state (meaning a state of the United States, the District of Columbia, a territory or possession of the United States, or a federally recognized Indian tribe) in a state-administered, federally funded program.

HISTORY:

CIGIE is modifying two SORNS, the PRAC Data Warehouse System (PDWS), CIGIE-5, 86 FR 7280 (Jan. 27, 2021), and the PRAC Accountability Data System (PADS), CIGIE-6, 86 FR 26704 (May 17, 2021).

Dated: January 27, 2026.

Andrew Cannarsa,

Executive Director of the Council of the Inspectors General on Integrity and Efficiency.

[FR Doc. 2026-01843 Filed 1-29-26; 8:45 am]

BILLING CODE P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD-2026-OS-0133]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Intelligence and Security (OUSD(I&S)), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995*, the Defense Counterintelligence and Security Agency (DCSA) announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: 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; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on

respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by March 31, 2026.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Director of Administration and Management, Privacy, Civil Liberties, and Transparency Directorate, Regulatory Division, 4800 Mark Center Drive, Mailbox #24, Suite 05F16, Alexandria, VA 22350-1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at <http://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Defense Counterintelligence and Security Agency, Freedom of Information and Privacy (FOIP) Office for Adjudications and Vetting, ATTN: Joy M. Greene, Fort George Meade, Maryland 20755, or call the FOIP Office for Adjudications and Vetting at 667-424-3667.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Freedom of Information/Privacy Act Request for Adjudication and Vetting Records; OMB Control Number 0704-0561.

Needs and Uses: The information collection is required to ensure needed information is collected to positively identify individuals who request records regarding themselves that are maintained by DCSA Personnel Vetting. These records will also be used in any Privacy Act appeals or related litigation. The Freedom of Information/Privacy Act Request for Adjudication and Vetting Records form will also be used to refer records under the release authority of another Federal Agency.

Affected Public: Individuals or households.

Annual Burden Hours: 84.

Number of Respondents: 1,005.

Responses per Respondent: 1.

Annual Responses: 1,005.

Average Burden per Response: 5 minutes.

Frequency: On occasion.

Dated: January 27, 2026.

Stephanie J. Bost,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2026-01815 Filed 1-29-26; 8:45 am]

BILLING CODE 6001-FR-P

DEPARTMENT OF EDUCATION

[Docket No.: ED-2025-SCC-0943]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Form for Maintenance of Effort Waiver Requests

AGENCY: Office of Elementary and Secondary Education (OESE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing an extension without change of a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before March 2, 2026.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be submitted within 30 days of publication of this notice. Click on this link www.reginfo.gov/public/do/PRAMain to access the site. Find this information collection request (ICR) by selecting "Department of Education" under "Currently Under Review," then check the "Only Show ICR for Public Comment" checkbox. Reginfo.gov provides two links to view documents related to this information collection request. Information collection forms and instructions may be found by clicking on the "View Information Collection (IC) List" link. Supporting statements and other supporting documentation may be found by clicking on the "View Supporting Statement and Other Documents" link.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Todd Stephenson, 202-205-1645.

SUPPLEMENTARY INFORMATION: The Department 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: Form for

Maintenance of Effort Waiver Requests.

OMB Control Number: 1810-0693.

Type of Review: An extension without change of a currently approved ICR.

Respondents/Affected Public: State, Local, and Tribal Governments *Total Estimated Number of Annual Responses:* 20.

Total Estimated Number of Annual Burden Hours: 1,600.

Abstract: Section 8521(a) of the Elementary and Secondary Education Act of 1965, as amended by the Every Student Succeeds Act (ESEA) provides that a local educational agency (LEA) may receive funds under Title I, Part A and other ESEA "covered programs" for any fiscal year only if the State educational agency (SEA) finds that either the combined fiscal effort per student or the aggregate expenditures of the LEA and the State with respect to the provision of free public education by the LEA for the preceding fiscal year was not less than 90 percent of the combined fiscal effort or aggregate expenditures for the second preceding fiscal year. This provision is the maintenance of effort (MOE) requirements for LEAs under the ESEA. If an LEA fails to meet the MOE requirement, under section 8521(b) of the ESEA, the SEA must reduce the amount of funds allocated under the programs covered by the MOE requirement in any fiscal year in the exact proportion by which the LEA fails to maintain effort by falling below 90 percent of either the combined fiscal effort per student or aggregate expenditures, if the LEA has also failed to maintain effort for 1 or more of the 5 immediately preceding fiscal years. In reducing an LEA's allocation because it failed to meet the MOE requirement, the SEA uses the measure most favorable to the LEA. Section 8521(c) gives the U.S. Department of Education (ED) the authority to waive the ESEA's MOE requirement for an LEA if it would be equitable to grant the waiver due to an exceptional or uncontrollable circumstance such as a natural disaster or a change in the organizational structure of the LEA or a precipitous decline in the LEA's financial resources.

If an MOE waiver is granted, the reduction required by section 8521(b) does not occur for that year. A request for a waiver of the MOE requirement is discretionary. Only an LEA that has failed to maintain effort and that believes its failure justifies a waiver would request one. To review an MOE waiver request, ED relies primarily on expenditure, revenue, and other data relevant to an LEA's request provided by the SEA. To assist an SEA with submitting this information, ED developed an MOE waiver form as part of the 2009 Title I, Part A Waiver Guidance, which covered a range of waivers that ED invited at that time. The purpose of this request is to renew approval for the MOE waiver form. This collection includes burden at the SEA level.

Ross Santy,

Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2026–01876 Filed 1–29–26; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2026–SCC–0166]

Agency Information Collection Activities; Comment Request; FERPA and PPRA E-Complaint Forms

AGENCY: Office of Planning, Evaluation and Policy Development (OPEPD), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing a reinstatement without change of a previously approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before MARCH 31, 2026.

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–2026–SCC–0166. 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 www.regulations.gov site is not available to the public for any reason, the Department 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 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 Student Privacy Policy Office, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Washington, DC 20202–1200.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Frank Miller, 202–453–6631.

SUPPLEMENTARY INFORMATION: The Department, 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. The Department is soliciting comments on the proposed information collection request (ICR) that is described below. The Department 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: FERPA and PPRA E-Complaint Forms.

OMB Control Number: 1880–0544.

Type of Review: A reinstatement without change of a previously approved ICR.

Respondents/Affected Public: Individuals and Households.

Total Estimated Number of Annual Responses: 500.

Total Estimated Number of Annual Burden Hours: 500.

Abstract: The Student Privacy Policy Office (SPPO) reviews, investigates, and processes complaints of alleged violations of Family Education Rights and Privacy Act (FERPA) and Protection of Pupil Rights Amendment (PPRA) filed by parents and eligible students.

SPPO's authority to investigate, review, and process complaints extends to allegations of violations of FERPA by any recipient of Unites States Department of Education (Department) funds under a program administered by the Secretary (e.g., schools, school districts, postsecondary institutions, state educational agencies, and other third parties that receive Department funds).

Ross Santy,

Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2026–01886 Filed 1–29–26; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98–1–000]

Records Governing Off-the-Record Communications; Public Notice

This constitutes notice, in accordance with 18 CFR 385.2201(b), of the receipt of prohibited and exempt off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive a prohibited or exempt off-the-record communication relevant to the merits of a contested proceeding, to deliver to the Secretary of the Commission, a copy of the communication, if written, or a summary of the substance of any oral communication.

Prohibited communications are included in a public, non-decisional file associated with, but not a part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become a part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such a request only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication shall serve the document on all parties listed on the official service list for the applicable

proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications are included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40

CFR 1501.6, made under 18 CFR 385.2201(e) (1) (v).

The following is a list of off-the-record communications recently received by the Secretary of the Commission. Each 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, please contact FERC Online Support at FERCOnlineSupport@ferc.gov or toll free at (866) 208-3676, or for TTY, contact (202) 502-8659.

Docket Nos.	File date	Presenter or requester
Prohibited: 1. CP25-233-000 2. EL25-49-000	1-15-2026 1-16-2026	FERC Staff. ¹ FERC Staff. ²
Exempt: None.		

¹ Memorandum of telephone communication dated 01/05/2025 with Berne Mosley from Magnum Gas Storage, LLC.

² Comments from Arushi Sharma Frank.

Dated: January 27, 2026.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2026-01846 Filed 1-29-26; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 9379-015]

Grenfell, LLC; Flat River Power, LLC: Notice of Transfer of Exemption

1. By letter filed November 13, 2025, Grenfell, LLC, and Flat River Power, LLC, informed the Commission that the exemption from licensing for the Belding Dam Project No. 9379, originally issued March 17, 1986,¹ has been transferred to Flat River Power, LLC. The project is located on the Flat River, Ionia County, Michigan. The transfer of an exemption does not require Commission approval.

2. Flat River Power, LLC is located at 813 Jefferson Hill Road, Nassau, New York 12123 is now the exemptee of Belding Dam Project No. 9379.

(Authority: 18 CFR 2.1.)

Dated: January 27, 2026.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2026-01916 Filed 1-29-26; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG26-137-000.

Applicants: Tip Top Solar Energy Center LLC.

Description: Tip Top Solar Energy Center LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 1/26/26.

Accession Number: 20260126-5298.

Comment Date: 5 p.m. ET 2/17/26.

Docket Numbers: EG26-138-000.

Applicants: Country Acres Clean Power LLC.

Description: Country Acres Clean Power LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 1/27/26.

Accession Number: 20260127-5030.

Comment Date: 5 p.m. ET 2/17/26.

Docket Numbers: EG26-139-000.

Applicants: Santa Teresa Solar, LLC.
Description: Santa Teresa Solar, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 1/27/26.

Accession Number: 20260127-5149.

Comment Date: 5 p.m. ET 2/17/26.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10-2126-012.

Applicants: Idaho Power Company.

Description: Notice of Non-Material Change in Status of Idaho Power Company.

Filed Date: 1/27/26.

Accession Number: 20260127-5157.

Comment Date: 5 p.m. ET 2/17/26.

Docket Numbers: ER10-2354-019.

Applicants: Midway-Sunset

Cogeneration Company.

Description: Notice of Non-Material Change in Status of Midway-Sunset Cogeneration Company.

Filed Date: 1/26/26.

Accession Number: 20260126-5325.

Comment Date: 5 p.m. ET 2/17/26.

Docket Numbers: ER26-283-001.

Applicants: Southern California Edison Company.

Description: Tariff Amendment: SCE Response to Deficiency Ltr re Unexecuted Sequoia LGIA (Re-File) to be effective 10/29/2025.

Filed Date: 1/27/26.

Accession Number: 20260127-5006.

Comment Date: 5 p.m. ET 2/17/26.

Docket Numbers: ER26-441-001.

Applicants: Clearlight Energy US Funding, LLC.

Description: Tariff Amendment: Deficiency Letter and Request for Expedited Comment Deadline to be effective 1/6/2026.

Filed Date: 1/26/26.

Accession Number: 20260126-5290.

Comment Date: 5 p.m. ET 2/5/26.

Docket Numbers: ER26-453-001.

Applicants: Gen IV Investment Opportunities, LLC.

Description: Tariff Amendment: Deficiency Letter and Request for Expedited Comment Deadline to be effective 1/7/2026.

Filed Date: 1/26/26.

Accession Number: 20260126-5292.

Comment Date: 5 p.m. ET 2/5/26.

Docket Numbers: ER26-559-001.

Applicants: Capacitor Borrower, LLC.
Description: Tariff Amendment: Deficiency Letter and Request for Expedited Comment Deadline to be effective 1/20/2026.

Filed Date: 1/26/26.

Accession Number: 20260126-5294.

Comment Date: 5 p.m. ET 2/5/26.

Docket Numbers: ER26-958-001.

¹ Grenfell Hydroelectric Associates, 34 FERC ¶ 62,524 (1986) (Order Granting Exemption from Licensing of a Small Hydroelectric Project of 5 Megawatts or Less).

Applicants: Mid-Atlantic Interstate Transmission, LLC.

Description: Tariff Amendment: PJM Interconnection, L.L.C. submits tariff filing per 35.17(b): Amendment to Amended IA, SA No. 4577 in ER26–958 to be effective 3/9/2026.

Filed Date: 1/27/26.

Accession Number: 20260127–5205.

Comment Date: 5 p.m. ET 2/17/26.

Docket Numbers: ER26–1133–000.

Applicants: Atlas VIII, LLC.

Description: Initial Rate Filing: Second Amended and Restated LGIA Co-Tenancy Agreement to be effective 1/28/2026.

Filed Date: 1/27/26.

Accession Number: 20260127–5035.

Comment Date: 5 p.m. ET 2/17/26.

Docket Numbers: ER26–1134–000.

Applicants: Atlas VIII, LLC.

Description: Initial rate filing: Second Amended and Restated Shared Facilities Common Ownership Agreement to be effective 1/28/2026.

Filed Date: 1/27/26.

Accession Number: 20260127–5037.

Comment Date: 5 p.m. ET 2/17/26.

Docket Numbers: ER26–1135–000.

Applicants: Atlas VIII, LLC.

Description: Initial rate filing: Shared Facilities Common Ownership Agreement Substation #1 to be effective 1/28/2026.

Filed Date: 1/27/26.

Accession Number: 20260127–5038.

Comment Date: 5 p.m. ET 2/17/26.

Docket Numbers: ER26–1136–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: Farmington Electric Utility System Stated Rate Filing to be effective 4/1/2026.

Filed Date: 1/27/26.

Accession Number: 20260127–5045.

Comment Date: 5 p.m. ET 2/17/26.

Docket Numbers: ER26–1137–000.

Applicants: Deseret Generation & Transmission Co-operative, Inc., Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: Southwest Power Pool, Inc. submits tariff filing per 35.13(a)(2)(iii): Deseret Generation & Transmission Co-operative, Inc. Stated Rate Filing to be effective 4/1/2026.

Filed Date: 1/27/26.

Accession Number: 20260127–5087.

Comment Date: 5 p.m. ET 2/17/26.

Docket Numbers: ER26–1139–000.

Applicants: 311SV 8me LLC.

Description: § 205(d) Rate Filing: Application for Market-Based Rate Authority to be effective 2/23/2026.

Filed Date: 1/27/26.

Accession Number: 20260127–5093.

Comment Date: 5 p.m. ET 2/17/26.

Docket Numbers: ER26–1140–000.

Applicants: Midcontinent

Independent System Operator, Inc., Big Rivers Electric Corporation.

Description: § 205(d) Rate Filing: Big Rivers Electric Corporation submits tariff filing per 35.13(a)(2)(iii): 2026–01–27 SA 4667 Big Rivers-OMU TIA to be effective 3/29/2026.

Filed Date: 1/27/26.

Accession Number: 20260127–5096.

Comment Date: 5 p.m. ET 2/17/26.

Docket Numbers: ER26–1141–000.

Applicants: Deseret Generation & Transmission Co-operative, Inc.

Description: § 205(d) Rate Filing: OATT Amendments—DGT RTO Expansion to be effective 4/1/2026.

Filed Date: 1/27/26.

Accession Number: 20260127–5101.

Comment Date: 5 p.m. ET 2/17/26.

Docket Numbers: ER26–1142–000.

Applicants: Santa Teresa Solar, LLC.

Description: § 205(d) Rate Filing: Application for Market-Based Rate Authority to be effective 3/3/2026.

Filed Date: 1/27/26.

Accession Number: 20260127–5116.

Comment Date: 5 p.m. ET 2/17/26.

Docket Numbers: ER26–1143–000.

Applicants: El Paso Electric Company.

Description: § 205(d) Rate Filing: Service Agreement No. 427, Simultaneous Exchange with Dynasty Power Inc. to be effective 4/1/2026.

Filed Date: 1/27/26.

Accession Number: 20260127–5138.

Comment Date: 5 p.m. ET 2/17/26.

Docket Numbers: ER26–1144–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: Revisions to Attachment AA Effective 20260401 to be effective 4/1/2026.

Filed Date: 1/27/26.

Accession Number: 20260127–5152.

Comment Date: 5 p.m. ET 2/17/26.

Docket Numbers: ER26–1145–000.

Applicants: Duke Energy Progress, LLC.

Description: § 205(d) Rate Filing: DEP–DEP E&P Agmt RS No. 485 to be effective 3/29/2026.

Filed Date: 1/27/26.

Accession Number: 20260127–5173.

Comment Date: 5 p.m. ET 2/17/26.

Docket Numbers: ER26–1146–000.

Applicants: Arizona Public Service Company.

Description: § 205(d) Rate Filing: Service Agreement No. 442—E&P w/El Rio Sol to be effective 12/29/2025.

Filed Date: 1/27/26.

Accession Number: 20260127–5226.

Comment Date: 5 p.m. ET 2/17/26.

The filings are accessible in the Commission's eLibrary system ([https://](https://elibrary.ferc.gov/idmws/search/fercgensearch.asp)

elibrary.ferc.gov/idmws/search/fercgensearch.asp) by querying the docket number.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) 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.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or OPP@ferc.gov.

Dated: January 27, 2026.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2026–01848 Filed 1–29–26; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 15392–000]

HGE Energy Storage 9, LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On January 21, 2025, HGE Energy Storage 9, LLC, filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the Whiskeytown Lake Pumped Storage Project to be located in Shasta County, California, adjacent to Whiskeytown Lake (reservoir), approximately 10 miles northwest of the city of Redding. The proposed project would occupy federal land managed by the National Park Service and the Bureau of Reclamation. The sole purpose of a preliminary permit is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters

owned by others without the owners' express permission.

The proposed pumped storage hydropower project would consist of: (1) the existing Whiskeytown Lake as a lower reservoir; (2) a new upper reservoir with a surface area of 36 acres and a storage volume of 3,600 acre-feet at a maximum water-surface elevation of 2,550 feet mean sea level (msl); (3) six 14,000-foot-long, 10-foot-diameter steel-lined penstocks to connect the reservoir to the powerhouse; (4) a 250-foot-long, 75-foot-wide, 100-foot-high, steel-reinforced concrete powerhouse constructed 100 feet below ground level, with six 200-megawatt (MW) reversible variable-speed pump-turbines, with a combined installed capacity of 1,200-MW; (5) a 100-foot-high, 30-foot-wide vertical access tunnel from ground level to the powerhouse; (6) a vertical intake structure to lead to the tailrace 100 feet below msl; (7) a 350-foot-long, 300-foot-wide concrete-lined tailrace; and (7) a 1.5-mile-long, 230-kilovolt line extending from the powerhouse to a planned AC-DC converter station. The estimated annual energy production of the project would be approximately 3,500,000 megawatt-hours.

Applicant Contact: Mr. Wayne Krouse, HGE Energy Storage 4 LLC, 2901 4th Avenue South #B 253, Birmingham, AL 35233; email: wayne@hgenergy.com; phone: (877) 556-6566.

FERC Contact: Shannon Archuleta; email: shannon.archuleta@ferc.gov; phone (503) 552-2739.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: on or before 5:00 p.m. Eastern Time on March 30, 2026. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502-6595 or OPP@ferc.gov.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, notices of intent, and competing applications using the Commission's eFiling system at <https://ferconline.ferc.gov/FERC.aspx>.

Commenters can submit brief comments up to 6,000 characters without prior registration using the eComment system at <https://ferconline.gov/QuickComment.aspx>. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov, (866) 208-3676 (toll-free), or (202) 502-8659 (TTY). Instead of electronic filing, you may submit a paper copy. Submissions

sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P-15392-000.

More information about this project, including a copy of the application, can be viewed on the Commission's website (<http://www.ferc.gov>) using the "eLibrary" link. Enter the docket number (P-15392) in the docket number field to access the document. For assistance, do not hesitate to get in touch with FERC Online Support.

(Authority: 18 CFR 2.1)

Dated: January 27, 2026.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2026-01925 Filed 1-29-26; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2373-016]

Midwest Hydro, LLC; 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 a subsequent license to continue to operate and maintain the Rockton Hydroelectric Project No. 2373 (project). The project is located on the Rock River in Winnebago County, Illinois. Commission staff has prepared an Environmental Assessment (EA) for the project.¹

The EA contains the staff's analysis of the potential environmental impacts of the project and 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.

The Commission provides all interested persons with an opportunity

to view and/or print the EA via the internet through the Commission's Home Page (<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, or at (866) 208-3676 (toll-free), or (202) 502-8659 (TTY).

You may also register online at <https://ferconline.ferc.gov/FERConline.aspx> 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 on or before 5:00 p.m. Eastern Time on February 26, 2026.

The Commission strongly encourages electronic filing. Please file comments using the Commission's eFiling system at <https://ferconline.ferc.gov/FERConline.aspx>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <https://ferconline.ferc.gov/Quick.aspx>. For assistance, please contact FERC Online Support. In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P-2373-016.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502-6595 or OPP@ferc.gov.

For further information, contact Laura Washington at (202) 502-6072 or by email at laura.washington@ferc.gov.

(Authority: 18 CFR 2.1)

Dated: January 27, 2026.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2026-01922 Filed 1-29-26; 8:45 am]

BILLING CODE 6717-01-P

¹ For tracking purposes under the National Environmental Policy Act, the unique identification number for documents relating to this environmental review is EAXX-019-20-000-1740141426.

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission**

[Project No. P-2266-102]

Nevada Irrigation District: Notice of Reasonable Period of Time for Water Quality Certification Application

On January 22, 2026, the California State Water Resources Control Board (Water Board) submitted to the Federal Energy Regulatory Commission (Commission), notice that it received a complete application for a Clean Water Act section 401(a)(1) water quality certification as defined in 40 CFR 121.5, from the above captioned project on December 29, 2025. Pursuant to section 5.23(b) of the Commission's regulations,¹ we hereby notify the Water Board of the following:

Date of Receipt of the Certification Request: December 29, 2025.

Reasonable Period of Time to Act on the Certification Request: December 29, 2026.

If the Water Board fails or refuses to act on the water quality certification request on or before the above date, then the certifying authority is deemed waived pursuant to section 401(a)(1) of the Clean Water Act, 33 U.S.C. 1341(a)(1).

(Authority: 18 CFR 2.1.)

Dated: January 27, 2026.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2026-01923 Filed 1-29-26; 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: RP26-406-000.
Applicants: Iroquois Gas Transmission System, L.P.
Description: § 4(d) Rate Filing: 1.26.26 Negotiated Rates—Emera Energy Services, Inc. H-2715-89 to be effective 1/26/2026.

Filed Date: 1/26/26.
Accession Number: 20260126-5269.
Comment Date: 5 p.m. ET 2/9/26.
Docket Numbers: RP26-407-000.
Applicants: Iroquois Gas Transmission System, L.P.

Description: § 4(d) Rate Filing: 1.26.26 Negotiated Rates—Mercuria Energy America, LLC H-7540-89 to be effective 1/26/2026.

Filed Date: 1/26/26.
Accession Number: 20260126-5273.
Comment Date: 5 p.m. ET 2/9/26.
Docket Numbers: RP26-408-000.
Applicants: Iroquois Gas Transmission System, L.P.

Description: § 4(d) Rate Filing: 1.26.26 Negotiated Rates—Trafigra Trading LLC H-8150-89 to be effective 1/27/2026.

Filed Date: 1/26/26.
Accession Number: 20260126-5275.
Comment Date: 5 p.m. ET 2/9/26.
Docket Numbers: RP26-409-000.
Applicants: Adelphia Gateway, LLC.
Description: § 4(d) Rate Filing: Adelphia Gateway Emergency Tariff Filing to be effective 1/26/2026.

Filed Date: 1/26/26.
Accession Number: 20260126-5311.
Comment Date: 5 p.m. ET 2/9/26.
Docket Numbers: RP26-410-000.
Applicants: Equitrans, L.P.
Description: § 4(d) Rate Filing: Negotiated Rate Agreements—1/24/2026 to be effective 1/24/2026.

Filed Date: 1/27/26.
Accession Number: 20260127-5002
Comment Date: 5 p.m. ET 2/9/26.
Docket Numbers: RP26-411-000.
Applicants: Transcontinental Gas Pipe Line Company, LLC.
Description: § 4(d) Rate Filing: Rate Schedule S-2 Tracker Filing Eff 2/1/2026 to be effective 2/1/2026.

Filed Date: 1/27/26.
Accession Number: 20260127-5040.
Comment Date: 5 p.m. ET 2/9/26.
Docket Numbers: RP26-412-000.
Applicants: Big Sandy Pipeline, LLC.
Description: Compliance filing: Big Sandy Fuel Filing Effective 3-1-2026 to be effective N/A.

Filed Date: 1/27/26.
Accession Number: 20260127-5143.
Comment Date: 5 p.m. ET 2/9/26.
Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding. The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercgensearch.asp>) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing

requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502-6595 or OPP@ferc.gov.

Dated: January 27, 2026.

Carlos D. Clay,
Deputy Secretary.

[FR Doc. 2026-01849 Filed 1-29-26; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission**

[Project No. 11730-029]

Black River Limited Partnership Notice of Availability of Environmental Assessment

The EA contains Commission staff's analysis of the potential environmental effects of the proposed amendment, alternatives to the proposed action, and concludes that the proposed amendment, would not constitute a major federal action that would affect the quality of the human environment.

The EA may be viewed on the Commission's website at <http://www.ferc.gov> using the "eLibrary" link. Enter the docket number (P-significantly 11730) in the docket number field to access the document. For assistance, contact FERC Online Support at FERCOnlineSupport@ferc.gov or toll-free at 1-866-208-3676, or for TTY, (202) 502-8659.

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.

All comments must be filed by February 26, 2026 5:00 p.m. Eastern Time.

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>. For assistance, please contact FERC Online Support. In lieu of

¹ 18 CFR 5.23(b).

electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P-11730-029.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202)502-6595 or *OPP@ferc.gov*.

For further information, contact Jeremy Jessup at 202-502-6779 or *Jeremy.Jessup@ferc.gov*.

(Authority: 18 CFR 2.1)

Dated: January 27, 2026.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2026-01915 Filed 1-29-26; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 4900-090]

Forestport Hydro, LLC; Notice of Reasonable Period of Time for Water Quality Certification Application

On January 16, 2026, the New York State Department of Environmental Conservation (New York DEC) submitted to the Federal Energy Regulatory Commission (Commission) notice that it received a request for a Clean Water Act section 401(a)(1) water quality certification as defined in 40 CFR 121.5, from Forestport Hydro, LLC, in conjunction with the above captioned project on January 16, 2026. Pursuant to the Commission's regulations,¹ we hereby notify New York DEC of the following dates.

Date of Receipt of the Certification Request: January 16, 2026.

Reasonable Period of Time to Act on the Certification Request: One year, January 16, 2027.

If New York DEC fails or refuses to act on the water quality certification request on or before the above date, then the certifying authority is deemed waived pursuant to section 401(a)(1) of the Clean Water Act, 33 U.S.C. 1341(a)(1).

(Authority: 18 CFR 2.1)

Dated: January 27, 2026.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2026-01918 Filed 1-29-26; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 4900-090]

Forestport Hydro, LLC; Notice of Intent To Prepare an Environmental Assessment

On February 27, 2025, Forestport Hydro, LLC filed a relicense application for the 3.3-megawatt Forestport Hydroelectric Project No. 4900. The project is located on the Black River in Oneida County, New York.

In accordance with the Commission's regulations, on November 20, 2025, Commission staff issued a notice that the project was ready for environmental analysis (REA notice). Based on the information in the record, including comments filed on the REA notice, staff does not anticipate that licensing the project would constitute a major federal action significantly affecting the quality of the human environment. Therefore, staff intends to prepare an environmental assessment (EA) on the application to relicense the project.¹

The EA will be issued and circulated for review by all interested parties. All comments filed on the EA will be analyzed by staff and considered in the Commission's final licensing decision.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502-6595 or *OPP@ferc.gov*.

The application will be processed according to the following schedule. The EA will be issued for a 30-day comment period. Revisions to the schedule may be made as appropriate.

Milestone	Target date
Commission issues EA	November 23, 2026.

Any questions regarding this notice may be directed to Rebecca Brodeur by telephone at (202) 502-8392 or by email at *rebecca.brodeur@ferc.gov*.

(Authority: 18 CFR 2.1)

¹ For tracking purposes under the National Environmental Policy Act, the unique identification number for documents relating to this environmental review is EAXX-019-20-000-1767605526.

Dated: January 27, 2026.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2026-01917 Filed 1-29-26; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 3407-088]

Big Wood Canal Company; Notice of Meeting

a. *Project Name and Number:* Magic Dam Hydroelectric Project No. 3407-088.

b. *Applicant:* Big Wood Canal Company.

c. *Date and Time of Meeting:* Wednesday, February 11, 2026 from 1:30 p.m. to 3:00 p.m. Eastern Time (11:30 a.m. to 1:00 p.m. Mountain Time).

d. *FERC Contact:* Ingrid Brofman at (202) 502-8347 or *ingrid.brofman@ferc.gov*.

e. *Purpose of Meeting:* Commission staff will hold a meeting with staff from the Idaho State Historic Preservation Office, U.S. Bureau of Land Management, and Big Wood Canal Company to discuss the Area of Potential Effects and other cultural resource related concerns for the Magic Dam Hydroelectric Project relicensing pursuant to section 106 of the National Historic Preservation Act. The meeting will be held virtually via Microsoft Teams.

f. A summary of the meeting will be placed in the public record of this proceeding. As appropriate, the meeting summary will include both a public, redacted version that excludes any information about the specific location of an archeological site or Native American cultural resource and an unredacted privileged version, if necessary.

(Authority: 18 CFR 2.1)

Dated: January 27, 2026.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2026-01919 Filed 1-29-26; 8:45 am]

BILLING CODE 6717-01-P

¹ 18 CFR 4.34(b)(5)(iii).

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission****[Docket No. CP26–73–000]****Equitrans, L.P.; Notice of Request Under Blanket Authorization and Establishing Intervention and Protest Deadline**

Take notice that on January 21, 2026, Equitrans, L.P. (Equitrans), 2200 Energy Drive, Canonsburg, Pennsylvania 15317, filed in the above referenced docket, a prior notice request pursuant to sections 157.205 and 157.216(b) of the Commission's regulations under the Natural Gas Act (NGA), and Equitrans' blanket certificate issued in Docket No. CP96–532–000, for authorization to abandon in place the West Fairfield Compressor Station, comprised of one 1,005 horsepower reciprocating compressor unit that was historically used to relay gas along the Allegheny Valley Connector System but is no longer needed for that purpose. All of the above facilities are located in Westmoreland County, Pennsylvania (West Fairfield Compressor Station Abandonment Project). The project will allow Equitrans to avoid unnecessary operations and maintenance expenses, because the West Fairfield Compressor Station is no longer required for Equitrans to meet its firm obligations on the Allegheny Valley Connector system. Equitrans estimates that there is no cost associated the abandonment in place, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (<http://www.ferc.gov>). From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

User assistance is available for eLibrary and the Commission's website during normal business hours from FERC Online Support at (202) 502–6652 (toll free at 1–866–208–3676) or email at ferconlinesupport@ferc.gov, or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the

Public Reference Room at public.referenceroom@ferc.gov.

Any questions regarding this application should be directed to Sarah A. Shaffer, Rates & Regulatory Director, Equitrans, L.P., 2200 Energy Drive, Canonsburg, Pennsylvania 15317, by phone at (412) 395–2580 or by email at sarah.shaffer@eqt.com.

Public Participation

There are three ways to become involved in the Commission's review of this project: you can file a protest to the project, you can file a motion to intervene in the proceeding, and you can file comments on the project. There is no fee or cost for filing protests, motions to intervene, or comments. The deadline for filing protests, motions to intervene, and comments is 5:00 p.m. Eastern Time on March 30, 2026. How to file protests, motions to intervene, and comments is explained below.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation (OPP) at (202) 502–6595 or OPP@ferc.gov.

Protests

Pursuant to section 157.205 of the Commission's regulations under the NGA,¹ any person² or the Commission's staff may file a protest to the request. If no protest is filed within the time allowed or if a protest is filed and then withdrawn within 30 days after the allowed time for filing a protest, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request for authorization will be considered by the Commission.

Protests must comply with the requirements specified in section 157.205(e) of the Commission's regulations,³ and must be submitted by the protest deadline, which is 5:00 p.m. Eastern Time on March 30, 2026. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

Interventions

Any person has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to

subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure⁴ and the regulations under the NGA⁵ by the intervention deadline for the project, which is 5:00 p.m. Eastern Time on March 30, 2026. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at <https://www.ferc.gov/resources/guides/how-to/intervene.asp>.

All timely, unopposed motions to intervene are automatically granted by operation of Rule 214(c)(1). Motions to intervene that are filed after the intervention deadline are untimely and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations. A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Comments

Any person wishing to comment on the project may do so. The Commission considers all comments received about the project in determining the appropriate action to be taken. To ensure that your comments are timely and properly recorded, please submit your comments on or before 5:00 p.m. Eastern Time on March 30, 2026. The filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding.

How To File Protests, Interventions, and Comments

There are two ways to submit protests, motions to intervene, and comments. In both instances, please reference the Project docket number CP26–73–000 in your submission.

¹ 18 CFR 157.205.

² Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

³ 18 CFR 157.205(e).

⁴ 18 CFR 385.214.

⁵ 18 CFR 157.10.

(1) You may file your protest, motion to intervene, and comments by using the Commission's eFiling feature, which is located on the Commission's website (www.ferc.gov) under the link to Documents and Filings. New eFiling users must first create an account by clicking on "eRegister." You will be asked to select the type of filing you are making; first select "General" and then select "Protest", "Intervention", or "Comment on a Filing"; or⁶

(2) You can file a paper copy of your submission by mailing it to the address below. Your submission must reference the Project docket number CP26–73–000.

To file via USPS: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To file via any other method: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of submissions (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or FercOnlineSupport@ferc.gov.

Protests and motions to intervene must be served on the applicant either by mail at: Sarah A. Shaffer, Rates & Regulatory Director, Equitrans, L.P., 2200 Energy Drive, Canonsburg, Pennsylvania 15317 or by email (with a link to the document) at sarah.shaffer@eqt.com. Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from OPP at (202) 502–6595 or on the FERC website at www.ferc.gov using the "eLibrary" link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of

time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to www.ferc.gov/docs-filing/esubscription.asp.

(Authority: 18 CFR 2.1)

Dated: January 27, 2026.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2026–01924 Filed 1–29–26; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2446–052]

STS Hydropower, LLC; 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 a new license to continue to operate and maintain the Dixon Hydroelectric Project No. 2446 (project). The project is located on the Rock River in Lee and Ogle Counties, Illinois. Commission staff has prepared an Environmental Assessment (EA) for the project.¹

The EA contains the staff's analysis of the potential environmental impacts of the project and 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.

The Commission provides all interested persons with an opportunity to view and/or print the EA via the internet through the Commission's Home Page (<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, or at (866) 208–3676 (toll-free), or (202) 502–8659 (TTY).

You may also register online at <https://ferconline.ferc.gov/FEROnline.aspx> 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 on or before 5:00 p.m. Eastern Time on February 26, 2026.

The Commission strongly encourages electronic filing. Please file comments using the Commission's eFiling system at <https://ferconline.ferc.gov/FEROnline.aspx>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <https://ferconline.ferc.gov/Quick.aspx>. For assistance, please contact FERC Online Support. In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P–2446–052.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or OPP@ferc.gov.

For further information, contact Laura Washington at (202) 502–6072 or by email at laura.washington@ferc.gov.

(Authority: 18 CFR 2.1)

Dated: January 27, 2026.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2026–01921 Filed 1–29–26; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2740–055]

Duke Energy Carolinas, LLC; Notice of Revised Procedural Schedule for Processing of Relicense Application

On July 14, 2025, as supplemented,¹ Duke Energy Carolinas, LLC filed an application for a new major license for the 1,400-megawatt Bad Creek Pumped Storage Project No. 2740 (Bad Creek Project, or project). On July 28, 2025, Commission staff issued a notice of

⁶ Additionally, you may file your comments electronically by using the eComment feature, which is located on the Commission's website at www.ferc.gov under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project.

¹ For tracking purposes under the National Environmental Policy Act, the unique identification number for documents relating to this environmental review is EAXX–019–20–000–1740141467.

¹ The final license application filed July 14, 2025, was supplemented on November 7, 2025, and December 19, 2025.

application tendered for filing with the Commission and establishing procedural schedule for relicensing the Bad Creek Project. The notice included

an anticipated schedule for issuing a Notice of Acceptance/Notice of Ready for Environmental Analysis by September 2025.

By this notice, Commission staff is updating the procedural schedule, as follows. Further revisions to the schedule may be made as appropriate.

Milestone	Target date
Issue Notice of Acceptance/Notice of Ready for Environmental Analysis	February 2026.

Any questions regarding this notice may be directed to Sarah Salazar at (202) 502–6863, or sarah.salazar@ferc.gov.

(Authority: 18 CFR 2.1)

Dated: January 27, 2026.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2026–01920 Filed 1–29–26; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL OPRM–FAD–207]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information 202–993–3272 or <https://www.epa.gov/nepa>. Weekly receipt of Environmental Impact Statements (EIS) Filed January 16, 2026 10 a.m. EST Through January 26, 2026 10 a.m. EST Pursuant to CEQ Guidance on 42 U.S.C. 4332.

Notice: Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA’s comment letters on EISs are available at: <https://cdxapps.epa.gov/cdx-enepa-II/public/action/eis/search>.

- EIS No. 20250192, Final, USAF, AK,* Proposed Mortar and Artillery Training at Richardson Training Area, Joint Base Elmendorf-Richardson, Alaska, Review Period Ends: 03/02/2026, Contact: David Martin 907–552–8151.
- EIS No. 20250193, Draft, USAF, HI,* Air Force Maui Optical and Supercomputing Site Small Telescope Research Facility, Comment Period Ends: 03/16/2026, Contact: Levi Davis 719–554–3731.
- EIS No. 20250194, Draft, VA, TX,* Proposed Relocation of the Veterans Affairs Medical Center (VAMC) San Antonio, Texas, Comment Period Ends: 03/16/2026, Contact: Glenn Elliott 202–360–1243.
- EIS No. 20250195, Final Supplement, USFWS, NE,* Final Supplemental Environmental Impact Statement for

the Nebraska Public Power District Revised R-Project Habitat Conservation Plan, Contact: Kassandra Karssen 308–216–2130.

Amended Notice

- EIS No. 20250141, Draft, FERC, WY,* Hydropower License re Seminole Pumped Storage Project, Comment Period Ends: 02/13/2026, Contact: Office of External Affairs 866–208–3372. Revision to FR Notice Published 11/21/2025; Extending the Comment Period from 01/02/2026 to 02/13/2026.
- EIS No. 20250188, Final, OSM, AL,* ADOPTION—Warrior Met Coal Mines, Contact: Allison Travers 202–501–9341. Revision to FR Notice Published on 1/23/2026. Corrected adopting agency from BLM to OSMRE.
- EIS No. 20250190, Draft, FHWA, MD,* Chesapeake Bay Crossing Study Tier 2 EIS, Comment Period Ends: 03/09/2026, Contact: Alexander Bienko 410–779–7148. Revision to FR Notice Published 1/23/2026; Correction to Comment Period Due Date from March 20, 2026 to March 9, 2026.

Dated: January 26, 2026.

Nancy Abrams,
Deputy Director, Federal Activities Division.

[FR Doc. 2026–01874 Filed 1–29–26; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[CG Docket No. 25–165; DA 25–1002; FR ID 327339]

Termination of Dormant Proceedings

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: In this document, the Consumer and Governmental Affairs Bureau announces the availability of the FCC order terminating, as dormant, certain docketed Commission proceedings.

DATES: The dockets are terminated as of January 30, 2026.

FOR FURTHER INFORMATION CONTACT: Zac Champ, Consumer Policy Division,

Consumer and Governmental Affairs Bureau, email at zac.champ@fcc.gov or by phone at (202) 418–1495.

SUPPLEMENTARY INFORMATION: The Commission’s Order, *Ninth Dormant Proceedings Termination Order*, DA 25–1002, adopted and released December 3, 2025, is available in CG Docket No. 25–165. The full text of document DA 25–1002 and the associated spreadsheet listing the proceedings terminated as dormant are available for public inspection on the Commission’s website at <https://www.fcc.gov/document/fcc-closes-more-2000-inactive-proceedings>. These documents and any documents filed in this matter may also be found by searching ECFs at: <https://www.fcc.gov/ecfs>. To request this document in accessible formats for people with disabilities (e.g., Braille, large print, electronic files, audio format) or to request reasonable accommodations (e.g., accessible format documents, sign language interpreters, CART), send an email to fcc504@fcc.gov or call the FCC’s Consumer and Governmental Affairs Bureau at (202) 418–0530.

Federal Communications Commission.

Robert Garza,
Legal Advisor, Consumer and Governmental Affairs Bureau.

[FR Doc. 2026–01831 Filed 1–29–26; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[DA 26–89; FR ID 328066]

Consumer Protection and Accessibility Advisory Committee; Announcement of Meeting

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: In this document, the Commission announces the second meeting of the current term of its Consumer Protection and Accessibility Advisory Committee (CPAAC or Committee).

DATES: Tuesday, February 24, 2026. The meeting will come to order at 9:00 a.m. Eastern Time.

ADDRESSES: The CPAAC meeting will be held in the Commission Meeting Room at Federal Communications Commission (FCC) Headquarters, located at 45 L Street NE, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT:

David M. Pérez or Joshua Mendelsohn, Designated Federal Officers, Federal Communications Commission, via email: CPAAC@fcc.gov.

SUPPLEMENTARY INFORMATION: This meeting is open to members of the general public. The in-person meeting will have sign language interpreters and open captioning. The meeting will be webcast with sign language interpreters and open captioning at: www.fcc.gov/live. In addition, a reserved amount of time will be available on the agenda for comments and inquiries from the public. Members of the public will be able to provide comments either in person if they are attending the meeting or by sending their questions or comments to livequestions@fcc.gov. These comments or questions may be addressed during the public comment period.

Requests for other reasonable accommodations or for materials in accessible formats for people with disabilities should be submitted via email to: fcc504@fcc.gov or by calling the Consumer and Governmental Affairs Bureau at (202) 418-0530. Such requests should include a detailed description of the accommodation needed and a way for the FCC to contact the requester if more information is needed to fill the request. Requests should be made as early as possible; last minute requests will be accepted but may not be possible to accommodate.

Proposed Agenda: The Committee members will discuss (i) working group reports; (ii) the full committee will consider and may vote on recommendations presented by the working groups; (iii) meeting schedules; and (iv) any other topics relevant to the CPAAC's work. The meeting agenda will be available at www.fcc.gov/cpaac and may be modified at the discretion of the CPAAC Co-Chairs and Designated Federal Officers.

(Authority: 5 U.S.C. 1009(a)(2).)

Federal Communications Commission.

Robert Garza,

Legal Advisor, Consumer and Government Affairs Bureau.

[FR Doc. 2026-01898 Filed 1-29-26; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060-1256; FR ID 327952]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning:

whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before March 31, 2026. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email PRA@fcc.gov and to nicole.ongele@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele, (202) 418-2991.

OMB Control Number: 3060-1256.

Title: Connect America Fund Phase II and Rural Digital Opportunity Fund Auction Support.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities, Not-for-profit institutions, and State, Local or Tribal governments.

Number of Respondents and Responses: 530 respondents and 530 responses.

Estimated Time per Response: 2 hours.

Frequency of Response: Annual reporting requirements.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection 47 U.S.C. 154, 214, 254 and 303(r) of the Communications Act of 1934, as amended.

Total Annual Burden: 1,060 hours.

Total Annual Cost: No Cost.

Needs and Uses:

Connect America Fund Phase II Auction

The Commission is requesting the Office of Management and Budget (OMB) approval for this revised information collection. On November 18, 2011, the Commission released the USF/ICC Transformation Order and Further Notice of Proposed Rulemaking, WC Docket No. 10-90 et al., FCC 11-161 (USF/ICC Transformation Order and/or FNPRM), which comprehensively reformed and modernized the high-cost program within the universal service fund to focus support on networks capable of providing voice and broadband services. Among other things, the Commission created the CAF and concluded that support in price cap areas would be provided through a combination of "a new forward-looking model of the cost of constructing modern multi-purpose networks" and a competitive bidding process (CAF Phase II auction or Auction 903). The Commission also sought comment in the accompanying USF/ICC Transformation FNPRM on proposed rules governing the CAF Phase II auction, including basic auction design and the application process.

In the CAF Phase II auction, service providers competed to receive support of up to \$1.98 billion over 10 years to offer voice and broadband service in unserved high-cost areas. The information collection requirements reported under this collection are the result of several Commission decisions to implement the reform adopted in the *USF/ICC Transformation Order* and move forward with conducting the CAF Phase II auction. In the *April 2014 Connect America Order*, WC Docket No. 10-90 et al., FCC 14-54, the

Commission adopted various rules regarding participation in the CAF Phase II auction, the term of support, and the eligible telecommunications carrier (ETC) designation process. In the *Phase II Auction Order*, WC Docket No. 10–90 et al., FCC 16–64, the Commission adopted rules to govern the CAF Phase II auction, including the adoption of a two-stage application process, which includes a pre-auction short-form application to be submitted by parties interested in bidding in the CAF Phase II auction and a post-auction long-form application that must be submitted by winning bidders seeking to become authorized to receive CAF Phase II auction support. The Commission concluded, based on its experience with auctions and consistent with the record, that this two-stage application process balances the need to collect information essential to conducting a successful auction and authorizing CAF Phase II support with administrative efficiency.

On January 30, 2018, the Commission adopted a public notice that established the final procedures for the CAF Phase II auction, including the long-form application disclosure and certification requirements for winning bidders seeking to become authorized to receive CAF Phase II auction support. *See Phase II Auction Procedures Public Notice*, WC Docket No. 17–182 et al., FCC 18–6. The Commission also adopted the *Phase II Auction Order on Reconsideration*, WC Docket No. 10–90 et al., FCC 18–5, which modified the Commission’s letter of credit rules to provide some additional relief for CAF Phase II auction support recipients by reducing the costs of maintaining a letter of credit. On January 19, 2023, WCB released a public notice announcing that the Commission had concluded its review of CAF Phase II auction long-form applications. *See WCB Concludes CAF II Application Review, Long-Forms Made Public*, AU Docket No. 17–182 et al., DA 23–49.

The Commission eliminated the information collection requirements related to the CAF Phase II auction FCC Form 683 now that its review of CAF Phase II auction long-form applications has concluded.

Rural Digital Opportunity Fund Auction

On February 7, 2020 the Commission released the *Rural Digital Opportunity Fund Order*, WC Docket Nos. 19–126, 10–90, FCC 20–5 which will commit up to \$20.4 billion over the next decade to support up to gigabit speed broadband networks in rural America. Funding was allocated through a multi-round,

reverse, descending clock auction that favored faster services with lower latency and encouraged intermodal competition in order to ensure that the greatest possible number of Americans will be connected to the best possible networks, all at a competitive cost.

To implement the Rural Digital Opportunity Fund auction (or Auction 904), the Commission adopted new rules for the Rural Digital Opportunity Fund auction, including the adoption of a two-stage application process. Like with the CAF Phase II auction, this process included a pre-auction short-form application submitted by parties interested in bidding in the Rural Digital Opportunity Fund auction (FCC Form 183) and a post-auction long-form application that must be submitted by winning bidders (or their designees) seeking to become authorized to receive Rural Digital Opportunity Fund support (FCC Form 683). The Commission received approval for the short-form application (FCC Form 183) in a separate collection under the OMB control number 3060–1252.

On September 30, 2025, the Commission adopted an order that conducted a comprehensive review of legacy requirements and determined that certain high-cost program rules no longer serve any operational purpose. *Delete, Delete Delete; Removal of Obsolete Regulations*; GN Docket No. 25–133, FCC 25–68 (rel. September 30, 2025) (*Delete, Delete, Delete*). This requested change results from the Commission’s decision in that proceeding. The Commission determined that 47 CFR 54.315(a)–(b) and 47 CFR 54.804(a)–(b) are outdated and obsolete, and unnecessary because all associated proposals using FCC Form 683 have concluded.

Therefore, the Commission proposes to remove the application requirement and retains only the limited ongoing requirements related to the annual maintenance of letters of credit under 47 CFR 54.315(c) CAF Phase II and 54.804(c) RDOF.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2026–01830 Filed 1–29–26; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies; Correction

In the **Federal Register** of January 8, 2026, FR Doc. 2026–00148, the notice

“Formations of, Acquisitions by, and Mergers of Bank Holding Companies” by the Federal Reserve Bank of Atlanta is corrected with respect to the application by CBS Banc-Corp., Russellville, Alabama, for the title to read “Notice of Proposals to Engage in or to Acquire Companies Engaged in Permissible Nonbanking Activities”, and for the first two paragraphs to read:

“The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR part 225) to engage de novo, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board’s Freedom of Information Office at <https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.”

The final paragraph is corrected to read “*CBS Banc-Corp., Russellville, Alabama*; to acquire TAG Bancshares Inc. and thereby indirectly acquire Citizens Bank & Trust, Inc., both of Trenton, Georgia, and thereby engage in operating a savings association pursuant to section 225.28(b)(4)(ii) of the Board’s Regulation Y.”

The comment period continues to end on February 9, 2026. Interested persons may continue to view the notice and submit comments as provided in 91 FR 712 (January 8, 2026) no later than February 9, 2026.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2026–01905 Filed 1–29–26; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM**Formations of, Acquisitions by, and Mergers of Bank Holding Companies**

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at <https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Benjamin W. McDonough, Deputy Secretary of the

Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than March 2, 2026.

A. Federal Reserve Bank of Philadelphia (William Spaniel, Senior Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105–1521. Comments can also be sent electronically to Comments.applications@phil.frb.org:

1. *OceanFirst Financial Corp., Toms River, New Jersey*; to merge with Flushing Financial Corporation, and thereby indirectly acquire Flushing Bank, both of Uniondale, New York.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2026–01904 Filed 1–29–26; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Administration for Children and Families**

[Office of Management and Budget #: 0970–0345]

Proposed Information Collection Activity; Temporary Assistance for Needy Families Financial Report, ACF–196T

AGENCY: Office of Family Assistance, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF) is requesting a 3-year extension of the Temporary Assistance for Needy Families (TANF) Financial Report, Form ACF–196T (Office of Management and Budget (OMB) #0970–0345, expiration 3/31/2026). ACF is not proposing updates to the form but is proposing

significant updates to streamline and improve the instructions. While the substance of the instructions remains the same, they are easier to read, with review time reduced by an estimated 33 percent.

DATES: *Comments due* March 31, 2026.

ADDRESSES: In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above. You can obtain copies of the proposed collection of information and submit comments by emailing infocollection@acf.hhs.gov. Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Grantees of the TANF program are required by statute to report financial data on a quarterly basis. Form ACF–196T is used by tribal agencies administering the TANF program to report these quarterly expenditure data and to request quarterly grant funds. Failure to collect the data would seriously compromise the Office of Family Assistance and ACF's ability to monitor TANF expenditures and compliance with statutory requirements. These data are also needed to estimate outlays and to prepare reports and budget submissions for Congress. The instructions have been edited for clarification and general improvements for respondents.

Respondents: Tribal agencies receiving a direct grant from OFA to administer a TANF program.

Annual Burden Estimates

Based on the edits to the instructions, the estimated time per response has been reduced 33 percent, from 1.5 hours to 1 hour. The number of agencies has been reduced to reflect current grant recipients. Overall, annual burden estimates have decreased from 306 hours to 200 hours.

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
TANF Financial Report, Form ACF–196T	50	4	1.0	200

Comments: The Department specifically requests comments 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) the quality, utility, and clarity of the information to be 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 within 60 days of this publication.

Authority: Social Security Act, Section 409; 45 CFR 286,245–286.285.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2026–01855 Filed 1–29–26; 8:45 am]

BILLING CODE 4184–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–0131]

FDA Rare Disease Innovation Hub Future Programming; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the following request for comments for a future public workshop series entitled “Rare disease Innovation, Science, and Exploration (RISE) Workshop.” The purpose of the public workshops is to focus on challenges that are common to multiple diseases or a class of diseases, and for which evolving science offers innovative solutions. The workshops will primarily focus on cross-cutting or common issues and will not be focused on any specific product under review by the Agency. The Agency further welcomes comments that highlight general rare disease-related issues of potential interest for the FDA Rare Disease Innovation Hub (Hub) to inform its future activities.

DATES: Submit either electronic or written comments by December 31, 2026. See the **SUPPLEMENTARY INFORMATION** section for comment deadlines corresponding to specific workshop sessions.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 31, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically,

including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your 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–2026–N–0131 for “FDA Rare Disease Innovation Hub Future Programming; Request for Comments.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the

claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Philipa Friedman, Center for Biologics Evaluation and Research, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–7911, RDInnovationHub@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The FDA is publishing this request for comments to obtain suggestions for topics for future RISE Workshops. The Hub supports the RISE Workshop series pursuant to its commitment to further advance regulatory science of rare disease therapies and the Agency’s PDUFA VII commitments to enhance regulatory science and expedite drug development and rare disease product review under the Food, Drug, and Cosmetic Act.

The Hub-sponsored RISE workshop series focuses on challenges that are common to multiple diseases or a class of diseases, and for which evolving science offers innovative solutions. The workshops are open to the public and designed for interaction and discourse between the various rare disease community members and perspectives, including drug developers, patient and disease organizations, academics, FDA regulators and reviewers, and relevant staff from other federal agencies. All workshops include coordination of the relevant medical product Centers and

address the Centers' approaches to the relevant issues. The workshops also include a discussion of the role of patients and patient/disease organizations in the design and implementation of innovative solutions. The workshops primarily focus on cross-cutting or common issues and will not be focused on any specific product under review by the Agency. Preference will be given to submissions that are germane to multiple disease states and/or that are submitted jointly by two or more entities.

For consideration for the summer RISE Workshop, FDA requests comments by February 28, 2026. For consideration for the fall RISE Workshop, FDA requests comments by May 31, 2026. The Agency requests that submissions include:

- A description of the proposed topic;
- Suggested speakers and/or subject matter experts;
- A description of the impact of the topic on the development and regulatory science of rare disease therapies;
- The disease state(s) affected by the challenge highlighted in the submission;
- If relevant, related FDA guidances or existing programs addressing the challenge highlighted in the submission.

Notice of this meeting series is given pursuant to 21 CFR 10.65.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-01903 Filed 1-29-26; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: HRSA AIDS Drug Assistance Program Data Report, OMB No. 0915-0345—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection

projects of the Paperwork Reduction Act of 1995, 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 March 31, 2026.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 13N82, 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 Samantha Miller, the HRSA Information Collection Clearance Officer, at (301) 443-3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: HRSA AIDS Drug Assistance Program (ADAP) Data Report, OMB No. 0915-0345 Extension

Abstract: HRSA's Ryan White HIV/AIDS Program (RWHAP) ADAP is authorized under Part B of the RWHAP statute, codified in sections 2611 to 2631 of the Public Health Service Act, which provides grants to U.S. states and territories. RWHAP ADAP is a state and territory administered program that provides Food and Drug Administration-approved medications to low-income people with HIV who have limited or no health coverage from private insurance, Medicaid, or Medicare. RWHAP ADAP funds may also be used to purchase health care coverage for eligible clients and for services that enhance access, adherence, and monitoring of drug treatments.

All 50 states, the District of Columbia, Puerto Rico, Guam, the U.S. Virgin Islands, and the five U.S. Pacific Territories or Associated Jurisdictions receive RWHAP Part B grant awards, including funds for RWHAP ADAP. RWHAP Part B requires the annual submission of an ADAP Data Report, which is composed of a Recipient Report and a Client Report. The Recipient Report is a collection of basic information about grant recipient

characteristics and policies including program administration, purchasing mechanisms, funding, and expenditures. The Client Report is a collection of de-identified client-level records (one record for each client enrolled in RWHAP ADAP), which includes the client's encrypted unique identifier, basic demographic data, enrollment and certification information, details on medication and/or health care coverage assistance received (including associated costs), and HIV clinical information.

HRSA is not proposing any changes to the collection, and there are no anticipated changes in the reporting burden.

Need and Proposed Use of the Information: The RWHAP statute mandates the submission of a biennial report by the Secretary of HHS to the appropriate committees of Congress concerning the coordination of federal HIV programs across HHS (42 U.S.C. 300ff-81(b)). HRSA uses the ADAP Data Report to evaluate the national impact of RWHAP ADAP by providing deidentified client-level data on individuals being served, services being delivered, and costs associated with these services. The client-level data is used to assess the health outcomes of people with HIV receiving services through RWHAP ADAP, monitor the use of RWHAP ADAP funds in addressing the HIV epidemic and its impact on communities, and track progress toward achieving the goals identified in ending the HIV epidemic in the United States.

Likely Respondents: State ADAPs of RWHAP Part B recipients.

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 use 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)	Total burden hours
Recipient Report	54	1	54	6	324
Client Report	54	1	54	81	4,374
Total	54		54		4,698

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. 2026-01883 Filed 1-29-26; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Heart, Lung, and Blood Advisory Council, April 9, 2026, 09:00 a.m. to April 10, 2026, 05:00 p.m., National Institute of Health, Rockledge II, Bethesda, MD 20892 which was published in the **Federal Register** on January 22, 2026, 91 FRN 2787.

The National Heart, Lung, and Blood Institute, Sleep Disorders Research Advisory Board meeting is being amended to add the registration links for each meeting date. Registration is required to attend the open portion of this meeting. To register for Day 1 April 9, 2026: 1:00 p.m. to 5:00 p.m. use the following link: <https://events.gcc.teams.microsoft.com/event/e4352ca7-12c8-47e2-9440-e1d675300cbc@14b77578-9773-42d5-8507-251ca2dc2b06>. To register for Day 2 April 10, 2026: 1:00 p.m. to 5:00 p.m. use the following link: <https://events.gcc.teams.microsoft.com/event/65acb0f8-d2c3-44c1-9351-e9d359e3bd0d@14b77578-9773-42d5-8507-251ca2dc2b06>.

The meeting is open to the public.

Dated: January 28, 2026.

Denise M. Santeufemio,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026-01881 Filed 1-29-26; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Neurological Disorders and Stroke Council.

The meeting will be open to the public as indicated below. Individuals who plan to participate and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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 Advisory Neurological Disorders and Stroke Council.

Date: March 10, 2026.

Open: March 10, 2026, 3:00 p.m. to 3:30 p.m.

Agenda: To discuss upcoming Concept Clearance Initiatives and other business of the Council. The meeting will be available via NIH Videocast. <https://videocast.nih.gov/>.

Closed: March 10, 2026, 3:30-6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6001 Executive Boulevard, Room 1131, Rockville, Maryland 20852 (Virtual Meeting).

Contact Person: Andrea Meredith Ph.D., Director, Extramural Activities, National Institute of Neurological Disorders and Stroke, NIH, 6001 Executive Blvd., 5th Floor, MSC 9531, Bethesda, MD 20892, (301) 496-9248, andrea.meredith@nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice at least 10 days in advance of the meeting. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: www.ninds.nih.gov, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS.)

Dated: January 27, 2026.

Rosalind M. Niamke,

Program Analyst Office of Federal Advisory Committee Policy.

[FR Doc. 2026-01837 Filed 1-29-26; 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 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Eye Council.

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/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant

applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Eye Council.

Date: March 20, 2026.

Time: 10:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Address: National Eye Institute, 6700B Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Hyo-Jung Anna Han, Acting Director, Division of Extramural Activities, National Eye Institute, 6700B Rockledge Drive, Bethesda, MD 20892, anna.han@nih.gov.

Information is also available on the Institute's/Center's home page: <https://www.nei.nih.gov/about/advisory-committees/national-advisory-eye-council-naec>, where an agenda and any additional information for the meeting will be posted when available.

Dated: January 28, 2026.

Rosalind M. Niamke,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026-01879 Filed 1-29-26; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; NIDDK Research Centers and Mentored Training.

Date: February 18, 2026.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Charlene J. Repique, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health,

Room 7347, 6707 Democracy Boulevard, Bethesda, MD 20892, (301) 451-3638, charlene.repique@nih.gov.

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Sensory-Motor Neuroscience Study Section.

Date: March 3-4, 2026.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Alena Valeryevna Savonenko, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1009J, Bethesda, MD 20892, (301) 594-3444, savonenkoa2@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Project: P Series: NEI Center Core Grant for Vision Research (P30).

Date: March 6, 2026.

Time: 11:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Lai Yee Leung, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1011D, Bethesda, MD 20892, (301) 827-8106, leungl2@csr.nih.gov.

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Skeletal Biology Structure and Regeneration Study Section.

Date: March 12, 2026.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Yanming Bi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, (301) 451-0996, ybi@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; NIH Director's New Innovator Award Program.

Date: March 17-18, 2026.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Marci Scidmore, Ph.D., Scientific Review Officer, Scientific Review Program, Natl Institute of Allergy & Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G76, Bethesda, MD 20892, (240) 627-3255, marci.scidmore@nih.gov.

Name of Committee: Oncology 1—Basic Translational Integrated Review Group; Biochemical and Cellular Oncogenesis Study Section.

Date: March 17-18, 2026.

Time: 9:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Jian Cao, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 827-5902, caojn@csr.nih.gov.

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Skeletal Biology Development and Disease Study Section.

Date: March 18, 2026.

Time: 9:00 a.m. to 9:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Vanessa Dawn Sherk, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 801C, Bethesda, MD 20892, (301) 594-3218, sherkv2@csr.nih.gov.

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group; Therapeutic Immune Regulation Study Section.

Date: March 19, 2026.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Yue Wu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 803C, Bethesda, MD 20892, (301) 867-5309, wuy25@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Projects: Lung and Sleep.

Date: March 19, 2026.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Melissa H. Nagelin, Ph.D., BS, Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6705 Rockledge Drive, Room 207-K, Bethesda, MD 20892, 301-827-7951, nagelinmh2@nhlbi.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA Panel: Small Grant Program for NHLBI K Award Recipients (R03).

Date: March 20, 2026.

Time: 9:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Dmitri V. Gnatenko, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 867-5309, gnatenkod2@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 27, 2026.

Rosalind M. Niamke,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026-01835 Filed 1-29-26; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Cell Biology Integrated Review Group; Biology and Development of the Eye Study Section.

Date: March 5-6, 2026.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Robert O'Hagan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (240) 909-6378, ohaganr2@csr.nih.gov.

Name of Committee: Applied Therapeutics for Cancer Integrated Review Group; Radiation Therapeutics and Biology Study Section.

Date: March 9, 2026.

Time: 8:30 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Bo Hong, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6194, MSC 7804, Bethesda, MD 20892, 301-996-6208, hongb@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics in Health Services Research: Maternal, Reproductive, and Child Health.

Date: March 10, 2026.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: June Lee Gin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480-2589, june.gin@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; NIH Director's New Innovator Award Program.

Date: March 10-11, 2026.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Sharon Isern, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 810J, Bethesda, MD 20892, (301) 435-0000, iserns2@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Training and Career Development: Gastroenterology and Related Disciplines.

Date: March 12, 2026.

Time: 8:30 a.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Jian Yang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594-7799, jian.yang@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; NIH Director's New Innovator Award Program.

Date: March 12-13, 2026.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Marcus Ferrone, PHARM D Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301-402-2371, marcus.ferrone@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Gastroenterology and Related Disciplines.

Date: March 12, 2026.

Time: 2:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Jian Yang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, Bethesda, MD 20892, (301) 594-7799, jian.yang@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 27, 2026.

Rosalind M. Niamke,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026-01836 Filed 1-29-26; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke, Interagency Pain Research Coordinating Committee Call for Committee Membership Nominations

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) (Department) has created the Interagency Pain Research Coordinating Committee (IPRCC) and is seeking nominations for this committee.

DATES: Nominations are due by COB February 27th, 2026.

ADDRESSES: Nominations must be submitted through the webform on the IPRCC website: <https://forms.office.com/g/T9cdDRH8nN>.

FOR FURTHER INFORMATION CONTACT: Carolyn Conlin, Email: Carolyn.Conlin@nih.gov or Phone: (240) 974-8244.

SUPPLEMENTARY INFORMATION: As specified in Public Law 111-148 ("Patient Protection and Affordable Care Act") the Committee will:

(A) develop a summary of advances in pain care research supported or conducted by the Federal agencies

relevant to the diagnosis, prevention, and treatment of pain and diseases and disorders associated with pain:

(B) identify critical gaps in basic and clinical research on the symptoms and causes of pain;

(C) make recommendations to ensure that the activities of the National Institutes of Health and other Federal agencies are free of unnecessary duplication of effort;

(D) make recommendations on how best to disseminate information on pain care; and (e) make recommendations on how to expand partnerships between public entities and private entities to expand collaborative, cross-cutting research.

Membership on the committee will include six (6) non-Federal members from among scientists, physicians, and other health professionals and six (6) non-Federal members of the general public who are representatives of leading research, advocacy, and service organizations for individuals with pain-related conditions. Members will serve overlapping three-year terms. It is anticipated that the committee will meet at least once a year.

Code of regulations (41 CFR 102–3.30(c)) stipulates that committee membership must be fairly balanced in its membership in terms of the points of view represented and the functions to be performed. Appointments shall be made free from discrimination on the basis of race, religion, color, national origin, age, disability, or sex.

The Department is soliciting nominations for non-federal members from among scientists, physicians, and other health professionals and for non-federal members of the public who represent a leading research, advocacy, or service organization for people with pain-related conditions. These candidates will be considered to fill positions open through completion of current member terms. Nominations are due by COB February 27th, 2026, using the IPRCC nomination webform: <https://forms.office.com/g/T9cdDRH8nN>.

Dated: December 19, 2025.

Walter J. Koroshetz,

Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health.

[FR Doc. 2026–01865 Filed 1–29–26; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Mentored Career Development Awards in Social and Community Research & Other Special Topics.

Date: February 12, 2026.

Time: 9:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Deborah Ismond, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–5633, deborah.ismond@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 28, 2026.

Rosalind M. Niamke,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–01877 Filed 1–29–26; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Heart, Lung, and Blood Advisory Council, April 9, 2026, 09:00 a.m. to April 10, 2026, 05:00 p.m., National Institute of Health, Rockledge I, Bethesda, MD 20892 which

was published in the **Federal Register** on January 22, 2026, 91 FRN 2787.

The National Heart, Lung, and Blood Institute, Sleep Disorders Research Advisory Board meeting is being amended to add the registration links for each meeting date. Registration is required to attend the open portion of this meeting. To register for Day 1 April 9, 2026: 1:00 p.m. to 5:00 p.m. use the following link: <https://events.gcc.teams.microsoft.com/event/e4352ca7-12c8-47e2-9440-e1d675300cbc@14b77578-9773-42d5-8507-251ca2dc2b06>. To register for Day 2 April 10, 2026: 9:30 p.m. to 2:00 p.m. use the following link: <https://events.gcc.teams.microsoft.com/event/65acb0f8-d2c3-44c1-9351-e9d359e3bd0d@14b77578-9773-42d5-8507-251ca2dc2b06>. The meeting is open to the public.

Dated: January 27, 2026.

Denise M. Santeufemio,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–01838 Filed 1–29–26; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2025–0113; OMB No. 1660–0073]

Agency Information Collection Activities: Submission for OMB Review, Comment Request; National Urban Search and Rescue Response System

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: 30-Day notice of extension with revision and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA) will submit the information collection abstracted below to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. FEMA invites the general public to take this opportunity to comment on an extension of a currently approved information collection. In accordance with the requirements of the Paperwork Reduction Act of 1995, this notice seeks comments concerning the National Urban Search and Rescue Response System to perform work on public or private lands essential to save lives and protect property, including search and

rescue and emergency medical care, and other essential needs.

DATES: Comments must be submitted on or before March 2, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: Catherine Deel, Chief, Finance and Administration Section, US&R Branch, FEMA, Response Directorate, Operations Division at catherine.deel@fema.dhs.gov or (202) 701-5566. You may contact the Information Management Division for copies of the proposed collection of information at email address: FEMA-Information-Collections-Management@fema.dhs.gov.

SUPPLEMENTARY INFORMATION: Section 303 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act), 42 U.S.C. 5144, authorizes the President of the United States to form emergency support teams of Federal personnel to be deployed to an area affected by a major disaster or emergency. Section 403(a)(3)(B) of the Stafford Act provides that the President may authorize Federal departments and agencies to perform work on public or private lands essential to save lives and protect property, including search and rescue and emergency medical care, and other essential needs. Section 327 of the Stafford Act further authorizes the National Urban Search and Rescue Response System ("the System") and outlines the Administrator's authorization to designate teams as well as outlines specific protections for System members. The information collection activity is authorized under the Office of Management and Budget's "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards" codified at 2 CFR part 200. The collection contains information from the programmatic and administrative activities of the Urban Search and Rescue Sponsoring Agencies relating to the Readiness and Response Cooperative Agreement awards.

Collection of Information

Title: National Urban Search and Rescue Response System.

Type of Information Collection: Extension, with change, of a currently approved information collection.

OMB Number: 1660-0073.

FEMA Forms: FEMA Form FF-104-FY-21-174 (formerly 089-0-10), Urban Search Rescue Response System Narrative Statement Workbook; FEMA Form FF-104-FY-21-175 (formerly 089-0-11), Urban Search Rescue Response System Semi-Annual Performance Report; FEMA Form FF-104-FY-21-176 (formerly 089-0-12), Urban Search Rescue Response System Amendment Form; FEMA Form FF-104-FY-21-179 (formerly 089-0-26), Vehicle Support Unit Purchase/Replacement/Disposal Justification.

Abstract: The information collection activity is the collection of program and administrative information from 28 established Urban Search and Rescue Sponsoring Agencies relating to the Readiness and Response Cooperative Agreement awards. This information includes a narrative statement used to evaluate grantees' proposed use of funds, progress reports to monitor progress on Cooperative Agreements, amendment requests to change scope and period of performance and approval for vehicle purchase.

Affected Public: State, Local, or Tribal Governments.

Estimated Number of Respondents: 98.

Estimated Number of Responses: 154.

Estimated Total Annual Burden Hours: 308.

Estimated Total Annual Respondent Cost: \$20,048.

Estimated Respondents' Operation and Maintenance Costs: \$0.

Estimated Respondents' Capital and Start-Up Costs: \$0.

Estimated Total Annual Cost to the Federal Government: \$141,873.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the Agency, including whether the information shall have practical utility; (b) 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; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) 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.

Russell Bard,

Acting Senior Director for Information Management, Office of the Chief Administrative Officer, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2026-01870 Filed 1-29-26; 8:45 am]

BILLING CODE 9111-54-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-6602-N-01]

Summit Lake Formula Area Expansion

ACTION: Notice.

SUMMARY: This notice advises the public of HUD's final determination on the Summit Lake Paiute Tribe's request to expand its formula area under the Indian Housing Block Grant (IHBG) program. Consistent with IHBG program regulations, HUD is announcing its final determination to expand the Summit Lake Paiute Tribe's formula area to include the balance of Humboldt County, Washoe County, Storey County, Pershing County, Churchill County, Douglas County, Mineral County, Lyon County, Esmeralda County, Clark County, Nye County, and Carson City County in the state of Nevada, for fiscal year 2026.

DATES: HUD's final determination is effective January 30, 2026.

FOR FURTHER INFORMATION CONTACT: Erna F. Reeves, Director, Office of Grants Management, Office of Native American Programs, Department of Housing and Urban Development, 451 Seventh Street SW, Room 4108, Washington, DC 20410, telephone 202-401-7914 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit: <https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs>.

SUPPLEMENTARY INFORMATION: The IHBG program allocation formula is authorized by section 302 of the Native American Housing Assistance and Self Determination Act of 1996 (25 U.S.C. 4101 *et seq.*) (NAHASDA). In accordance with 24 CFR part 1000, funds appropriated by Congress for the IHBG program are made available to eligible grant recipients by formula to ensure the equitable and fair distribution of funds. The formula has four components including Need. Need

is calculated using the seven factors listed at 24 CFR 1000.324, each based on a tribe's formula area. Should a tribe's formula area overlap with one or more other Indian Tribes, 24 CFR 1000.326 provides the procedure HUD will use to resolve potential or actual issues arising from the overlap. On August 1, 2025, the Summit Lake Paiute Tribe requested that its formula area be expanded to cover the balance of Humboldt County, Washoe County, Storey County, Pershing County, Churchill County, Douglas County, Mineral County, Lyon County, Esmeralda County, Clark County, and Nye County in the state of Nevada based on the Department of the Interior's Near Reservation Service Area Designation as listed in the **Federal Register** (FR Vol. 48, No. 174, September 7, 1983), and Carson City County in the state of Nevada based on the Department of the Interior's Near Reservation Service Area Designation as listed in the **Federal Register** (FR Vol. 60, No. 165, August 25, 1995). On August 13, 2025, HUD informed the Summit Lake Paiute Tribe of its preliminary decision to increase the formula area to include the balance of Humboldt County, Washoe County, Storey County, Pershing County, Churchill County, Douglas County, Mineral County, Lyon County, Esmeralda County, Clark County, Nye County, and Carson City County based on the Near Reservation Service Area Designations. Overlapping formula areas were created between the Summit Lake Paiute Tribe, Confederated Tribes of the Goshute Reservation, Duck Valley Shoshone-Paiute Tribes, Duckwater Shoshone Tribe, Ely Shoshone Tribe, Fallon Paiute Tribe, Fort McDermitt Paiute and Shoshone Tribes, Lovelock Paiute Tribe, Pyramid Lake Paiute Tribe, Reno-Sparks Indian Colony, Walker River Paiute Tribe, Washoe Tribe, Yerington Paiute Tribe, and Yomba Shoshone Tribe, as a result of this decision.

Whenever Tribes have overlapping formula areas, the Needs data for all the individual areas for all Tribes are combined and then apportioned among the Tribes in the overlap as outlined in 24 CFR 1000.326. Consistent with 24 CFR 1000.302, HUD is required to notify the affected Indian Tribes by certified mail and provide the Tribes with opportunity to comment for a period of not less than 90 days. HUD met this requirement with its August 13, 2025 letter to the Confederated Tribes of the Goshute Reservation, Duck Valley Shoshone-Paiute Tribes, Duckwater Shoshone Tribe, Ely Shoshone Tribe, Fallon Paiute Tribe, Fort McDermitt

Paiute and Shoshone Tribes, Lovelock Paiute Tribe, Pyramid Lake Paiute Tribe, Reno-Sparks Indian Colony, Walker River Paiute Tribe, Washoe Tribe, Yerington Paiute Tribe, and Yomba Shoshone Tribe.

Consistent with 24 CFR 1000.302, HUD must consider all comments received on its preliminary determination and publish the notice of final determination in the **Federal Register**. Because HUD provided notification to the affected Tribes on August 13, 2025, the 90-day period for affected Tribes to comment on the preliminary determination elapsed on November 11, 2025. HUD did not receive comments or feedback from the affected Indian Tribes on its preliminary determination within this 90-day period. Consequently, HUD is providing notice of its final determination to increase the formula area of the Summit Lake Paiute Tribe's to include the balance of Humboldt County, Washoe County, Storey County, Pershing County, Churchill County, Douglas County, Mineral County, Lyon County, Esmeralda County, Clark County, Nye County, and Carson City County in the state of Nevada, for fiscal year 2026.

Hilary Atkin,

Acting Deputy Assistant Secretary for Office of Native American Programs, Office of Public and Indian Housing.

[FR Doc. 2026-01867 Filed 1-29-26; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-7107-N-02 OMB Control No.: 2577-0301]

30-Day Notice of Proposed Information Collection: Capital Fund High Risk/Receivership/Substandard/Troubled Program

AGENCY: Office of Policy Development and Research, Chief Data Officer, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comments from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 30 days of public comment.

DATES: *Comments Due Date: March 2, 2026.*

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and

recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: John L. Murphy, PRA Compliance Officer, Paperwork Reduction Act Division, PRAD, Department of Housing and Urban Development, 451 7th Street SW, Room 8220, Washington, DC 20410; email at PaperworkReductionActOffice@hud.gov, ATTN: John L. Murphy telephone (202) 402-8084. This is not a toll-free number. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit <https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs>. Copies of available documents submitted to OMB may be obtained from Dr. Murphy.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A. The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on June 26, 2025 at 90 FR 27333.

A. Overview of Information Collection

Title of Information Collection: Capitol Fund High Risk/Receivership/Substandard/Troubled Program.

OMB Approval Number: 2577-0301.

Type of Request: Renewal of Approved Collection.

Form Number: Annual SF-425, Federal Financial Report; Annual SF-425, Federal Financial Report; SF-1199A; SF-1199A, Direct Deposit Sign-up; SF-1199A, HUD Form 53001, Actual Modernization Cost, Review of Final Narrative (Post-award reports).

Description of the need for the information and proposed use: This supporting statement renews the post-award information collection for competitive awards under the Capital Fund Program. Post-award information includes annual financial and performance reporting, audits, and award closeout. Reporting also includes compliance with the Award Term in Appendix A of 2 CFR part 170. Grantees must also adhere to the application submission requirements in the NOFO, including implementing the project

proposed with the application, including how use of funding will improve the targeted Asset Management Property (AMP). Further, grantees are required to maintain eligibility for the life of the award, including all program specific threshold eligibility requirements.

The pre-award information collection for the Capital Fund Program is removed from this control number and may be moved to OMB Control Number 2501-0044. The Capital Fund Program provides funding for costs associated with public housing asset improvement to Public Housing

Agencies (PHAs) that are either in receivership, designated troubled or substandard, or otherwise deemed high risk. Funding is focused on improving public housing asset management property performance in two core areas: Physical Condition and Occupancy.

Information collection	Number of respondents	Frequency of response per respondents	Total annual responses	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
Annual SF-425, Project Performance and Other Annual Reporting	5	4	20	1	5	55.15	275.75
SF-1199A	5	1	5	1	5	55.15	275.75
Closeout and Final Narrative	5	1	5	2	10	55.15	551.50
Record Retention	5	4	20	5	5	55.15	275.75
Totals	15		45		20		1,378.75

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(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;

(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 through the use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 2 of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507.

John L. Murphy,

*Compliance Officer, Department PRA
Compliance Officer, Office of Policy
Development and Research, Chief Data
Office.*

[FR Doc. 2026-01880 Filed 1-29-26; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-7107-N-03; OMB Control No.: 2577-0290]

30-Day Notice of Proposed Information Collection: Public Housing Flat Rent Exception Request Market Analysis

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comments from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 30 days of public comment.

DATES: *Comments Due Date:* March 2, 2026.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT:

Anna Guido, PRA Compliance Officer, Paperwork Reduction Act Division, PRAD, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410; email at PaperworkReductionActOffice@hud.gov, ATTN: telephone (202) 402-5535. This is not a toll-free number.

HUD welcomes and is prepared to receive calls on individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit <https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs>.

Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A. The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on September 15, 2025 at 90 FR 44387.

A. Overview of Information Collection

Title of Information Collection: Public Housing Flat Rent Exception Request Market Analysis.

OMB Approval Number: 2577-0290.

Type of Request: Extension.

Form Number: HUD-5880.

Description of the need for the information and proposed use: Form HUD-5880 streamlines the process and reduces burden on PHAs when submitting a market analysis as part of a flat rent exception request in accordance with Notice PIH 2022-33(HA), which implements Section 238 of Title II of Public Law 113-235, the Department of Housing and Urban Development Appropriations Act of 2015. Notice PIH 2022-33(HA) allows PHAs to request flat rents that are based on the local rental market conditions, when the PHA can demonstrate through a market analysis that the Fair Market

Rents (FMRs) are not reflective of the local market. This version of the form has been in use since FY2023. HUD is adjusting the average number of

respondents and hourly cost per response to reflect the average level of submissions in FY2023, FY2024, and FY2025 and higher wage estimates from

the Occupational Employment and Wage Statistics, but HUD is not proposing any changes to the form being renewed.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
HUD–5880—Flat Rent Market Analysis	57	1	57	8	456	\$28.06	\$12,795.36
Total	57	1	57	8	456	28.06	12,795.36

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(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;

(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 through the use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 2 of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507.

Anna Guido,

Department PRA Compliance Officer, Office of Policy Development and Research, Chief Data Officer.

[FR Doc. 2026–01869 Filed 1–29–26; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–HQ–NWRs–2025–1397; FXRS126109WSMU–267–FF09R24000; OMB Control Number 1018–NEW]

Agency Information Collection Activities; Interjurisdictional Invasive Species Rapid Response Team Program

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), we, the U.S. Fish and Wildlife Service (Service), are proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before March 31, 2026.

ADDRESSES: Send your comments on the information collection request (ICR) by one of the following methods (please reference 1018–InSRR in the subject line of your comments):

- *Internet (preferred):* <https://www.regulations.gov>. Follow the instructions for submitting comments on Docket No. FWS–HQ–NWRs–2025–1397.

- *Email:* Info_Coll@fws.gov.

- *U.S. mail:* Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, 5275 Leesburg Pike, MS: PRB (JAO/3W), Falls Church, VA 22041–3803.

FOR FURTHER INFORMATION CONTACT:

Madonna L. Baucum, Service Information Collection Clearance Officer, by email at Info_Coll@fws.gov, or by telephone at (703) 358–2503. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR part 1320, all information collections require approval. We may not conduct or sponsor, and you are not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number.

As part of our continuing effort to reduce paperwork and respondent

burdens, we are again inviting the public and other Federal agencies 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 especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this 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) How might the agency 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 response.

Comments that you submit in response to this notice are a matter of public record. 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 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.

Abstract: The Department of the Interior (DOI) developed the conceptual foundation for an Interjurisdictional Invasive Species Rapid Response Team (InSRRT) in 2023. Key authorities and

frameworks authorizing the IInSRRT include:

1. Executive Order (E.O.) 13112 (as amended by E.O. 13751)—This order directs Federal agencies, including DOI, to prevent the introduction of invasive species, detect and respond rapidly to new invasions, and control and eradicate established invasive species. It also mandates restoration of native species and habitats impacted by invasives.

2. National Invasive Species Council (NISC)—DOI is a leading member of NISC, which coordinates federal efforts to address invasive species. The Council provides national leadership and policy guidance to improve the efficiency and effectiveness of federal responses.

3. The Fish and Wildlife Act (16 U.S.C. 742a–742k)—This law establishes a policy for fish, shellfish, and wildlife resources in the U.S. It protects and directs their management to support sustainable use and prevent over-exploitation.

4. The National Invasive Species Act of 1996 (16 U.S.C. 4701 *et seq.*)—This law prevents the introduction and spread of nonindigenous aquatic nuisance species into the waters of the U.S. through mandated regulations.

5. DOI Invasive Species Strategic Plan (2021–2025)—This strategic plan outlines DOI's vision and coordinated approach to managing invasive species across its bureaus. It emphasizes prevention, early detection, rapid response, control, and restoration, while promoting collaboration with Federal, State, Tribal, and private partners.

6. Bureau-Specific Authorities—Each DOI bureau (e.g., U.S. Fish and Wildlife Service, Bureau of Land Management, National Park Service) has specific mandates and operational authority to manage invasive species on the lands and waters they oversee. These efforts include prevention, control, eradication, and restoration activities across more than 500 million acres of public lands.

7. Cross-Agency Coordination—DOI works closely with other Federal agencies (e.g., U.S. Department of Agriculture and Department of Defense), State and Tribal governments, Territorial governments, and nongovernmental partners to implement invasive species management strategies and share resources.

Efforts are now underway to put that concept into action. An IInSRRT coordinator will work across the DOI and with partners to further develop and implement the program for nationally significant incidents warranting rapid response.

Rapid response to an early detection of an invasive species is one of the most

effective ways to prevent these invasive species from becoming established and causing costly, long-term harm. Rapid response is defined as a process employed to eradicate the founding population of a non-native species from a specific location before it begins to reproduce or spreads so widely that eradication is no longer feasible. Capacity and funding to undertake rapid response can be limiting factors in implementing rapid response actions.

The purpose of the IInSRRT program is to build capacity for rapid response. The scope includes responding to new high-risk invasions of national significance or to species that have made a significant spatial jump from currently established locations, as appropriate to the DOI mission, and across multiple jurisdictions within DOI authorities. The program will increase resources available to support rapid response actions through interjurisdictional deployment teams and Incident Command System support. Importantly, this program builds on successful rapid response models within DOI such as the Service's Invasive Species Strike Teams and the National Park Service's Invasive Plant Management Teams while supporting work on and off DOI managed lands as requested by the lead resource management entity.

Response efforts will target new introductions to the U.S., including Alaska, Hawaii, and US territories, with a focus on aquatic and terrestrial invasive plants and animals that threaten nonagricultural systems. The focus also includes invasive species that have jumped significant spatial gaps or would lead to significant harm without intervention. Responses will not include pathogens at this time.

The program structure is composed of the IInSRRT coordinator, an IInSRRT guidance group, and deployment team members. The guidance group will provide guidance and support as needed and assist with planning, communications, and overall program operations. The deployment team will be composed of DOI employees that have technical skills in rapid response and relevant qualifications. The IInSRRT program will assist in achieving management objectives flowing from the National Early Detection and Rapid Response Framework and other local, regional, and national efforts.

Consideration of deployment will occur when the lead agency or agencies lack capacity and requests assistance. The application for assistance from a lead entity will require justification and is subject to approval by the IInSRRT

coordinator and IInSRRT guidance group. The criteria to determine what merits a response and the process to request the team will be developed by the IInSRRT coordinator and guidance group.

The IInSRRT program will request the following types of information via the two forms described below:

1. *Form 3–200–93, “Application for IInSRRT Incident Assistance” (New)*—The Service proposes to collect the following categories of information via Form 3–200–93:

A. *Requestor Information*—Affiliation and point of contact information, to include name, title, email, location, and phone number.

B. *Incident Response Narrative*—Narrative should include summaries of the proposed objectives of the incident response.

C. *Description of the Invasive Species*—The description should provide a comprehensive overview of the species, including both its common and scientific names. It should summarize the impact of the species, particularly any effects on culturally significant resources. The narrative should also include a brief history of the species' global invasion, highlighting where and how it has spread. Finally, it should indicate whether this is the first known occurrence of the species in the United States or specifically within the affected region.

D. *Location of Incident Response*—The response should include the date the invasive species was first detected, along with a summary of the survey methods used to assess the extent of the introduction. This should also note the number of surveys conducted. An approximate area, in acres, where the species was found should be provided, including the level of certainty regarding that estimate. The narrative should describe the characteristics of the incident response location, such as the types of habitats present. It should also state whether the requesting entity is the land management authority for the proposed response area and whether the area overlaps with any other land management jurisdictions.

E. *Response Details*—The response should indicate whether any rapid response plans are currently in place for either the invasive species or the specific incident response location. It should include a summary of the treatment or control methods proposed for managing the incident, such as mechanical, chemical, or biological tools. Additionally, the narrative should outline the resources available or needed—including tools, staffing, and

partner support—to effectively carry out the response.

An estimated timeframe for addressing the incident should be provided, along with the latest possible start date by which eradication is still considered feasible. This estimate should reflect the applicant's best judgment and include their level of certainty regarding that timeline.

F. Compliance with Rules and Regulations—The response should indicate whether any National Environmental Policy Act (NEPA) consultations have already been completed that are applicable to the proposed incident response. If so, relevant documentation should be attached. It should also state whether any NEPA Categorical Exclusions may apply to the proposed activities. Additionally, the narrative should address whether there are any federally listed species or habitats within the proposed incident response location. If applicable, the specific species and/or habitats should be named.

The response should also confirm whether there are any historic or potentially historic properties within the incident area that may require consideration under the National Historic Preservation Act or related laws. Finally, the narrative should identify any other applicable compliance requirements—such as federal, state, or tribal regulations—and describe any plans in place to address them.

G. Species Risk Level—The response should indicate whether the species involved in the proposed incident response has undergone any formal risk screenings or has been included in any horizon scans or watch lists. If applicable, the narrative should list the specific screenings or scans, along with their overall risk ratings (e.g., high risk, moderate risk, low risk). Copies of the relevant documents should be attached to the application to support the assessment.

H. Post-response Plans—The response should indicate whether the requesting entity has the resources and capacity to monitor the site following the incident response. It should also include a summary of the post-monitoring plan, outlining how the entity will assess whether the invasive species has been successfully eradicated. This may include details such as the frequency and duration of monitoring, survey methods, and criteria for confirming eradication.

We will use the information collected via Form 3–202–93 to consider the application for rapid response to new invasive species and whether the request is within the scope and feasibility for the IInSRRT program to activate.

2. Form 3–202–58, “Response Monitoring Report” (New)—The Service proposes to collect the following types of information via Form 3–202–58:

A. Background Information and Introduction—The response should

indicate a summary of the incident response, the dates of the reporting period, and the reporting entities information.

B. Post-response Monitoring Efforts—The response should summarize the survey efforts completed post incident response.

C. Post-response Summary—The response should summarize the current results from post-response monitoring efforts.

We will use the information collected via Form 3–202–58 to monitor the potential eradication of the target invasive species.

The public may request a copy of Forms 3–200–93 and 3–202–58 by sending a request to the Service Information Collection Clearance Officer (see **ADDRESSES**, above).

Title of Collection: Interjurisdictional Invasive Species Rapid Response Team Program.

OMB Control Number: 1018–New.

Form Number: FWS Forms 3–200–93 and 3–202–58.

Type of Review: New.

Respondents/Affected Public: State, local, and Tribal governments.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion for applications and monitoring reports.

Total Estimated Annual Nonhour Burden Cost: None.

Requirement	Average number of annual respondents	Average number of responses each	Average number of annual responses	Average completion time per response	Estimated annual burden hours
Form 3–200–93, “Application for IInSRRT Incident Assistance”					
Government	20	1	20	2	40
Form 3–202–58, “Response Monitoring Report”					
Government	2	2	4	60	240
Totals	22		24		280

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Madonna Baucum,

Information Collection Clearance Officer, U.S. Fish and Wildlife Service.

[FR Doc. 2026–01873 Filed 1–29–26; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–NWRS–2025–N039; FXRS126109WH000–267–FF09R23000; OMB Control Number 1018–0190]

Agency Information Collection Activities; Submission to the Office of Management and Budget; U.S. Fish and Wildlife Service Bison Donations Request Program

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the U.S. Fish and Wildlife Service (Service), are proposing to renew a currently approved information collection without change.

DATES: Interested persons are invited to submit comments on or before March 2, 2026.

ADDRESSES: Written comments and recommendations for the proposed

information collection should be sent within 30 days of publication of this notice to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. Please provide a copy of your comments to the Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS: PRB (JAO/3W), 5275 Leesburg Pike, Falls Church, VA 22041–3803 (mail); or by email to Info_Coll@fws.gov. Please reference “1018–0190” in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT:

Madonna L. Baucum, Service Information Collection Clearance Officer, by email at Info_Coll@fws.gov, or by telephone at (703) 358–2503. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. You may also view the information collection request at <https://www.reginfo.gov/public/do/PRAMain>.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act (PRA; 44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR part 1320, all information collections require approval under the PRA. We may not conduct or sponsor, and you are not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number.

On September 11, 2025, we published in the **Federal Register** (90 FR 44083) a notice of our intent to request that OMB approve this information collection. The Service published the **Federal Register** notice on [Regulations.gov](https://www.regulations.gov) (Docket No. FWS–HQ–NWR5–2025–0023) to provide the public with an additional method to submit comments (in addition to the typical email and U.S. mail submission methods). In that notice, we solicited comments for 60 days, ending on November 10, 2025. We received two comments in response to that notice; however, neither comment addressed the information collection requirements, and no response is required.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again inviting the public and other Federal agencies 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 especially interested in public comment addressing the following:

- (1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;
- (2) The accuracy of our estimate of the burden for this 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) How might the agency 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 response.

Comments that you submit in response to this notice are a matter of public record. 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 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.

Abstract: The Service’s “Bison Donations Transfer Protocol” (protocol) describes the process for the donation of the available surplus bison from the Service to eligible organizations, Tribes, or intertribal organizations as outlined in regulations at 50 CFR 30.1, as well as in Service Manual chapters 701 FW 5 and 701 FW 8. Surplus bison are offspring that exceed the ecological carrying capacity of the Service bison metapopulation. The primary purposes of donating these bison are to support conservation of the species as native North American wildlife and to assist in the restoration of bison herds on conservation partner lands, with special emphasis on restoring conservation herds to Tribal lands. Our authorities governing the Protocol include:

- National Wildlife Refuge System Administration Act, as amended (16 U.S.C. 668dd and 668ee);
- American Indian Religious Freedom Act (Pub. L. 95–341, as amended);
- Indian Self-Determination and Education Assistance Act (Pub. L. 93–638, as amended);
- Surplus Range Animals (50 CFR 30.1);
- Disposition of Surplus Range Animals (50 CFR 30.2);
- Native American Policy of the U.S. Fish and Wildlife Service (510 FW 1);
- Range-Limited American Plains Bison Management policy (701 FW 8); and
- Collections, Donations, and Disposals policy (701 FW 5).

In 2020, the U.S. Department of the Interior (DOI) Bison Working Group published the *Department of the Interior Bison Conservation Initiative 2020* (initiative), recognizing bison as a wildlife species in need of conservation. Consistent with this initiative, Service policy identifies the ecological and cultural values of bison as nationally and/or historically significant animals.

The *Bison Conservation Genetics Workshop: Report and Recommendations* (2010 report) identifies DOI bison herds as a valuable source with which to start new conservation herds proposed by other Federal, State/provincial, or Tribal governments. The *DOI Bison Report: Looking Forward* (2014 report) acknowledges the challenges to achieving bison restoration on DOI lands and emphasizes the importance of partnerships for achieving bison conservation and ecological restoration. Both the 2010 and 2014 reports also identify the potential for bison herds maintained by Indian Tribes to contribute to species conservation, and the Service recognizes that such bison may also support Tribal cultural rights and practices.

Periodic reduction in the size of Service bison herds is required to remain within the ecological carrying capacity of Service lands. Live bison capture and removal assist in the restoration of bison to Tribal lands, support the efforts of States and other conservation organizations, and ensure that the ecological needs of other species are met on refuges of limited size. To support maximum conservation of genetic diversity within and across Service herds, selection of young bison available for donation is coordinated across all refuges. From the surplus bison made available for donation from refuges, requests will be prioritized for bison restoration and conservation purposes.

We use Form 3–2555, “Bison Donations Request Form,” to request surplus bison. Respondents will generally be from Tribal governments and intertribal organizations, although we do expect to receive a small number of requests from States and private sector organizations (nonprofit and educational/research organizations). The request form provides details governing the protocol and collects the following information:

- Name of requesting Tribe, intertribal organization, State, or private sector organization.
- Documentation that the proposed project or program meets the definition of a conservation herd.
- Demonstration of the educational contribution of the donation to increasing public knowledge and appreciation of the wildlife values of bison (for educational and research organizations only).
- Total number (or percentage of total donation request) of bison and purpose of request:
 - Establish a free-ranging conservation herd;
 - Supplement or augment a free-ranging conservation herd;
 - Establish a self-sustaining herd for non-conservation purposes;
 - Supplement or augment a self-sustaining herd for non-conservation purposes;
 - Public display, educational purposes, and/or research;
 - Tribal spiritual or cultural purposes; or
 - A description if “Other” purpose.
- Signature of requesting Tribe, intertribal organization, State, or private sector organization official.

In addition to the completion of Form 3–2555, recipients of donated bison must inform the Service of the destination State for donated bison no fewer than 30 days prior to a scheduled bison capture operation, to allow the Service time to meet interstate transport regulatory testing requirements. Recipients of donated bison must also inform the Service of the physical destination address for donated bison no fewer than 10 days prior to scheduled bison loadout, to facilitate timely completion of required interstate veterinary permit applications and veterinary inspection certificates.

The public may request a copy of Form 3–2555 by sending a request to the Service Information Collection Clearance Officer (see **ADDRESSES**, above).

Title of Collection: U.S. Fish and Wildlife Service Bison Donations Request Program.

OMB Control Number: 1018–0190.

Form Number: 3–2555.

Type of Review: Extension without change of a currently approved collection.

Respondents/Affected Public: Private sector organizations and State/local/Tribal governments.

Respondent’s Obligation: Voluntary.

Total Estimated Number of Annual Responses: 22.

Total Estimated Number of Annual Responses: 33.

Estimated Completion Time per Response: Varies from 30 minutes to 1 hour, depending on activity.

Total Estimated Number of Annual Burden Hours: 22.

Frequency of Collection: On occasion.

Total Estimated Annual Nonhour Burden Cost: None.

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.*).

Madonna Baucum,

Information Collection Clearance Officer, U.S. Fish and Wildlife Service.

[FR Doc. 2026–01900 Filed 1–29–26; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

**[FWS–HQ–ES–2025–N041;
FXES11110900000–267–FF09E24000; OMB
Control Number 1018–0119]**

Agency Information Collection Activities; Submission to the Office of Management and Budget; Policy for Evaluation of Conservation Efforts When Making Listing Decisions (PECE)

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), we, the U.S. Fish and Wildlife Service (Service), are proposing to renew a currently approved information collection without change.

DATES: Interested persons are invited to submit comments on or before March 2, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to <https://www.reginfo.gov/>

[public/do/PRAMain](https://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. Please provide a copy of your comments to the Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS: PRB (JAO/3W), 5275 Leesburg Pike, Falls Church, VA 22041–3803 (mail); or by email to Info_Coll@fws.gov. Please reference “1018–0119” in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT:

Madonna L. Baucum, Service Information Collection Clearance Officer, by email at Info_Coll@fws.gov, or by telephone at (703) 358–2503. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. You may also view the information collection request at <https://www.reginfo.gov/public/do/PRAMain>.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act (PRA; 44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR part 1320, all information collections require approval under the PRA. We may not conduct or sponsor, and you are not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number.

On August 11, 2025, we published in the *Federal Register* (90 FR 38658) a notice of our intent to request that OMB approve this information collection. The Service published the *Federal Register* notice on *Regulations.gov* (Docket No. FWS–HQ–NWRs–2025–0023) to provide the public with an additional method to submit comments (in addition to the typical email and U.S. mail submission methods). In that notice, we solicited comments for 60 days, ending on October 10, 2025. We received the following comments in response to that notice:

Comment 1: Electronic comment received August 11, 2025 via *Regulations.gov* (FWS–HQ–ES–2025–0008–0002) from Jan Publie. The commenter did not address the information collection requirements.

Agency Response to Comment 1: No response required.

Comment 2: Anonymous electronic comment received September 22, 2025

via *Regulations.gov* (FWS–HQ–ES–2025–0008–0003). The commenter did not address the information collection requirements.

Agency Response to Comment 2: No response required.

Comment 3: Electronic comment received October 3, 2025 via *Regulations.gov* (FWS–HQ–ES–2025–0008–0004) from Michael B. Sloane, Director, on behalf of the New Mexico Department of Game and Fish. The commenter indicated their agency responded to previous requests for information regarding the listing decision process for a variety of species and their responses were prepared with minimal time requirements (1–4 hours per request). They also indicated they provided information to inform Species Status Assessments for a variety of species and participated in the development of conservation and management plans. For these activities, the commenter indicated the information collection activities were not burdensome and that the information collected is valuable and reflective of a good collaboration with State agencies and consideration of their perspectives and conservation work. The commenter expressed their appreciation for the opportunity to comment on the information collection process.

Agency Response to Comment 3: No response required.

Comment 4: Electronic comment received October 9, 2025 via *Regulations.gov* (FWS–HQ–ES–2025–0008–0005) from W. Laird Hamberlin, Chief Executive Officer, on behalf of the Safari Club International (SCI). The submission included the following comments:

The commenter indicated SCI supports PECE because it is consistent with the Endangered Species Act (ESA) and provides a thoughtful and structured method to consider conservation efforts that have not yet generated measurable results. However, they also indicated SCI feels PECE is incomplete and believes that PECE should explicitly include the efforts made by a foreign nation to protect species. SCI recommends that FWS develop a policy to specifically address considerations of efforts being made by foreign nations or political subdivisions of foreign nations to protect species.

Agency Response to Comment 4: We appreciate SCI's comment and recommendation for ways to expand our considerations of efforts being made by foreign nations to protect species; however, revisions to the PECE Policy are outside the scope of the currently approved information collection. We

will consider this suggestion in the future if we undertake a revision to the PECE Policy.

Comment 5: Electronic comment received October 10, 2025 via *Regulations.gov* (FWS–HQ–ES–2025–0008–0006) from Jennifer A. McIvor, EWAC Policy Chair, John M. Anderson, EWAC Executive Director, and Brooke Marcus, Nossaman LLP, on behalf of the Energy and Wildlife Action Coalition. The submission included the following comments:

EWAC encourages FWS to continue to incentivize and collect information on voluntary conservation efforts across the United States.

EWAC highlighted that voluntary conservation plays a critical role in species protection and can directly influence the Service's decision not to list species under the Endangered Species Act (ESA). EWAC did not provide any information on the information collection burden related to the PECE policy but stated that resources expended to collect information on voluntary conservation will help further national energy and grid reliability goals.

Agency Response to Comment 5: We appreciate EWAC's comment and support for the PECE Policy.

Comment 6: Electronic comment received October 10, 2025 via *Regulations.gov* (FWS–HQ–ES–2025–0008–0007) from Andrew Langer, Director, and Kiley McLeroy, Policy Analyst, on behalf of the Conservative Political Action Coalition (CPAC) Center for Regulatory Freedom (CRF). The submission included the following comments opposing the renewal of the information collection associated with PECE:

The CPAC–CRF stated that the PECE Policy is not based on the best reading of the statutory authority and should be rescinded. The CPAC–CRF contends that the Policy which allows FWS to consider voluntary conservation efforts when making listing decisions under the ESA misinterprets the ESA's intent, which they assert is focused on protecting species already classified as endangered or threatened—not those that might become so in the future.

Their comment also cited legal and procedural concerns they have with the information collection and PECE policy.

Further, CPAC–CRF's comment invokes Executive Order 14219 and the Supreme Court's 2024 decision in *Loper Bright Enterprises v. Raimondo*, which overturned *Chevron* deference. They argue that PECE relies on agency interpretation rather than the "best reading" of the ESA, making it legally

indefensible under current federal policy and judicial precedent.

Agency Response to Comment 6: We appreciate CPAC–CRF's comment, however, the concerns regarding the legality of the PECE Policy are outside the scope of the currently approved information collection.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again inviting the public and other Federal agencies 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 especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this 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) How might the agency 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 response.

Comments that you submit in response to this notice are a matter of public record. 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 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.

Abstract: Section 4 of the Endangered Species Act (ESA; 16 U.S.C. 1531 *et seq.*) outlines the process by which we can list a species as a threatened species or an endangered species. When we consider whether to list a species, the ESA requires us to take into account the efforts made by any State or any political subdivision of a State to protect such species. We also consider the

efforts made by other entities. States or other entities often formalize conservation efforts in conservation agreements, conservation plans, management plans, or similar documents. The conservation efforts recommended or described in such documents could prevent some species from becoming so imperiled that they meet the definition of a threatened species or an endangered species under the ESA.

The Policy for Evaluation of Conservation Efforts When Making Listing Decisions (PECE; 68 FR 15100, March 28, 2003) encourages the development of conservation agreements or plans and provides the standard that an individual conservation effort must meet in order for us to consider whether it is likely to make a difference in a species' status. PECE applies to formalized conservation

efforts that have not been implemented or have been implemented but have not yet demonstrated if they are effective at the time of a listing decision.

Under PECE, formalized conservation efforts are defined as conservation efforts (specific actions, activities, or programs designed to eliminate or reduce threats or otherwise improve the status of a species) identified in a conservation agreement, conservation plan, management plan, or similar document. To assist us in evaluating whether a formalized conservation effort meets the standard under PECE, we collect information such as conservation plans, monitoring results, and progress reports. The development of any agreement or plan is voluntary. The PECE is posted on our candidate conservation website at <https://www.fws.gov/library/collections/>

candidate-conservation-policies-regulations-and-guidance.

Title of Collection: Policy for Evaluation of Conservation Efforts When Making Listing Decisions (PECE).

OMB Control Number: 1018–0119.

Form Number: None.

Type of Review: Extension without change of a currently approved collection.

Respondents/Affected Public: Primarily State, local, or Tribal governments. However, individuals, businesses, and not-for-profit organizations also could develop agreements/plans or may agree to implement certain conservation efforts identified in a State agreement or plan.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion.

Total Estimated Annual Nonhour Burden Cost: None.

Activity	Estimated number of annual respondents	Average number of submissions each	Estimated number of annual responses	Completion time per response (hours)	Estimated annual burden hours
PECE—Reporting					
Individuals	1	1	1	120	120
Private Sector	1	1	1	120	120
Government	1	1	1	120	120
PECE—Monitoring					
Individuals	1	1	1	600	600
Private Sector	1	1	1	600	600
Government	1	1	1	600	600
PECE—Development of Conservation Plan/Agreement (One-Time Burden)					
Individuals	1	1	1	2,000	2,000
Private Sector	1	1	1	2,000	2,000
Government	1	1	1	2,000	2,000
Totals	9		9		8,160

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.*).

Madonna Baucum,

Information Collection Clearance Officer, U.S. Fish and Wildlife Service.

[FR Doc. 2026–01909 Filed 1–29–26; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–LE–2025–N042; FXLE18110900000–267–FF09L00000; OMB Control Number 1018–0092]

Agency Information Collection Activities; Submission to the Office of Management and Budget; Federal Fish and Wildlife Applications and Reports—Law Enforcement

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), we, the U.S. Fish and Wildlife

Service (Service), are proposing to renew an information collection without change.

DATES: Interested persons are invited to submit comments on or before March 2, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be submitted within 30 days of publication of this notice at <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. Please provide a copy of your comments to the Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS: PRB (JAO/3W),

5275 Leesburg Pike, Falls Church, VA 22041–3803 (mail); or by email to *Info_Coll@fws.gov*. Please reference “1018–0092” in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT:

Madonna L. Baucum, Service Information Collection Clearance Officer, by email at *Info_Coll@fws.gov*, or by telephone at (703) 358–2503. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR 1320.8(d)(1), all information collections require approval under the PRA. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number.

On September 11, 2025, we published in the **Federal Register** (90 FR 44091) a notice of notice of our intent to request that OMB approve this information collection. In that notice, we solicited comments for 60 days, ending on November 10, 2025. We received the following comments in response to that notice:

Comment 1: Anonymous electronic comment received 11/10/2025 via *Regulations.gov* (FWS–HQ–LE–2025–0572–0007). The commenter did not address the information collection requirements.

Agency Response to Comment 1: No response required.

Comment 2: Electronic comment received 11/10/2025 via *Regulations.gov* (FWS–HQ–LE–2025–0572–0008) from the Zoological Society of San Diego, doing business as the San Diego Zoo Wildlife Alliance (SDZWA). The submission included the following comments:

SDZWA emphasized the importance of this permit in supporting conservation programs such as the Species Survival Programs (SSP) and other recovery efforts. These programs require frequent movement of animals between institutions to maintain genetic diversity and population sustainability.

The organization provided several recommendations to improve the permit process:

1. *Necessity and Utility:* The permit is essential for managing wildlife transport and preventing illegal trade. It also helps reduce stress on animals by allowing the shortest and most direct travel routes.

2. *Burden Estimate Accuracy:* The current estimate of 1.25 hours to complete the form is often inaccurate, especially when specific scenarios require input from multiple experts, sometimes taking days.

3. *Quality and Clarity:* SDZWA suggests revising the application format to better align questions with the information USFWS needs. Clearer guidance would help applicants provide accurate and complete responses.

4. *Minimizing Burden:* The organization recommends transitioning to ePermits and accepting online payments, which would streamline the process and reduce reliance on paper checks.

5. *Conservation Impact:* Clarifying when the permit is required—particularly in relation to CITES and ESA protections—would enhance the effectiveness of the process. For instance, animals born in the U.S. and not listed under CITES or ESA may not require the permit, and such guidance should be made explicit.

The commenter concluded by reaffirming their commitment to wildlife conservation and expressed appreciation for the opportunity to contribute to the improvement of the permitting process.

Agency Response to Comment 2: The Service appreciates the comments from the SDZWA and acknowledges the variances of completion times when completing permit applications. The currently approved burden represents an estimate based on the variety of applicants and their comfort level completing the permit applications.

The Service is working to automate permits but is currently waiting on the new direction regarding electronic permitting processes expected to be developed by the Department of the Interior in the coming year.

We will also consider their recommendation for revisions and the development of improved guidance as we work to develop the proposed deregulatory action under RIN 1018–BF16, “Importation, Exportation, and Transportation of Wildlife; Updates to the Regulations” which is expected in late calendar year 2026.

Comment 3: Electronic comment received 11/10/2025 via *Regulations.gov* (FWS–HQ–LE–2025–0572–0009) from Dan Ashe, President and CEO, on behalf of the Association of Zoos and Aquariums (AZA). The submission

included the following key recommendations and observations:

1. *Necessity and Utility:* The permit is vital for enabling direct and efficient transport of wildlife, reducing stress on animals and supporting conservation goals. It also aids USFWS in managing wildlife trade and preventing illegal activities.

2. *Burden Estimate Accuracy:* The current estimate of 1.25 hours to complete the form is often inaccurate. The complexity of the application, especially when specific scenarios are required, can extend the process to several days.

3. *Clarity and Quality of Application:* AZA recommends revising the application format to better align questions with the information USFWS needs. A guided form or clearer questions would help applicants provide accurate and complete responses.

4. *Minimizing Burden:* AZA urges USFWS to digitize the permit process through ePermits and allow online payments, replacing the current paper-based system and mailed checks. This would reduce administrative burden for both applicants and agency staff.

The AZA concluded by expressing appreciation for USFWS’s commitment to wildlife protection and law enforcement, and emphasized the importance of continued collaboration to streamline processes that support the conservation and recovery of threatened and endangered species.

Agency Response to Comment 3: The Service appreciates the comments from the AZA and acknowledges the variances of completion times when completing permit applications. The currently approved burden represents an estimate based on the variety of applicants and their comfort level completing the permit applications.

The Service is working to automate permits but is currently waiting on the new direction regarding electronic permitting processes expected to be developed by the Department of the Interior in the coming year.

We will also take their remaining for revisions and the development of improved guidance contained in this collection of information under consideration as we work to develop the proposed deregulatory action under RIN 1018–BF16, “Importation, Exportation, and Transportation of Wildlife; Updates to the Regulations” which is expected in late calendar year 2026.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies 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 especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this 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) How might the agency 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 response).

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 information collection request. 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.

Abstract: The Endangered Species Act (ESA; 16 U.S.C. 1531 *et seq.*) makes it unlawful to import or export wildlife or

wildlife products for commercial purposes without first obtaining an import/export license (see 16 U.S.C. 1538(d)). The ESA also requires that fish or wildlife be imported into or exported from the United States only at a designated port, or at a nondesignated port under certain limited circumstances (see 16 U.S.C. 1538(f)). This information collection includes the following permit/license application forms:

Form 3–200–2, “Designated Port Exception Permit”

Under 50 CFR 14.11, it is unlawful to import or export wildlife or wildlife products at ports other than those designated in 50 CFR 14.12, unless you qualify for an exception. The following exceptions allow qualified individuals, businesses, or scientific organizations to import or export wildlife or wildlife products at a nondesignated port:

(a) To export the wildlife or wildlife products for scientific purposes;

(b) To minimize deterioration or loss; or

(c) To relieve economic hardship.

To request authorization to import or export wildlife or wildlife products at nondesignated ports, applicants must complete Form 3–200–2. Designated port exception permits can be valid for up to 2 years. We may require a permittee to file a report on activities conducted under authority of the permit.

Forms 3–200–3a, “Federal Fish and Wildlife Permit Application Form: Import/Export License—U.S. Entities,” and 3–200–3b, “Federal Fish and Wildlife Permit Application Form: Import/Export License—Foreign Entities” (Paper and Electronic)

It is unlawful to import or export wildlife or wildlife products for commercial purposes without first obtaining an import/export license (50 CFR 14.91). Applicants located in the United States must complete Form 3–

200–3a to request this license. Foreign applicants that reside or are located outside the United States must complete Form 3–200–3b to request this license.

We use the information collected on Forms 3–200–3a and 3–200–3b as an enforcement tool and management aid to (a) monitor the international wildlife market and (b) detect trends and changes in the commercial trade of wildlife and wildlife products. Import/export licenses are valid for up to 1 year. We may require a licensee to file a report on activities conducted under authority of the import/export license.

Form 3–200–44, “Permit Application Form: Registration of an Agent/Tannery Under the Marine Mammal Protection Act (MMPA)”

The information collected on Form 3–200–44 will be used by Service employees to confirm that an applicant has provided a written description of the procedures that they will use to receive, store, process, and ship marine mammal parts and products. The information collected will also be used to confirm the written description system of the bookkeeping and inventory that the applicant will use to receive, store, process and ship marine mammal parts and products, from Native Alaskans to Native Alaskans.

Form 3–200–44a, “Registered Agent/Tannery Bi-Annual Inventory Report”

The information collected on Form 3–200–44a will be used by Service employees to review the activities of the registered agent or registered tannery regarding the receipt and transfer of marine mammal parts and products from Native Alaskans to Native Alaskans.

Unless a form number is specified in the table below, we collect the following information on Forms 3–200–2, 3–200–3a, 3–200–3b, 3–200–44, and 3–200–44a:

We collect information on . . .	So that we can . . .
Name of the individual and personal identifying information such as date of birth, social security number, occupation, and address and contact information.	Identify the individual and the activity conducted by the applicant for which a license/permit is required.
Name of business, tax identification number or social security number, description of business, website, and name and contact information for the principal officer.	Identify the business and the activity conducted by the applicant for which a license/permit is required.
Name, street address, and contact information for each additional partner/principal officer (3–200–3a and 3b).	Identify all individuals or businesses associated with the entity requesting a license/permit.
Whether or not applicant has or has ever had any Federal fish and wildlife permits; if yes, number of current permit or permit to be renewed/reissued.	Identify prior or current activity under Federal wildlife permits. This helps in determining their knowledge of Service laws and regulations.
U.S. address for foreign applicant	Inspect records, as necessary.
Name, physical address, and telephone number of agent or location where business records will be maintained.	Inspect records, as necessary.
Street address and contact information for location where wildlife inventories will be kept (3–200–3a and 3b).	Provide Service Officers access to their facility to examine inventories of wildlife or wildlife products imported or to be exported.
Port(s) of entry where importation/exportation is requested (3–200–2)	Determine if port is appropriate to be requested. Determine if additional workload can be accommodated by staff presently available at the requested port.
Valid import/export license number (for commercial shipments) (3–200–2)	Establish compliance with commercial import/export requirements.

We collect information on . . .	So that we can . . .
Reason for requesting port exception (3–200–2)	Determine if there is a bona fide scientific purpose, potential deterioration or loss, or potential economic hardship that would occur from the issuance of the permit.
General description of wildlife or wildlife products	Determine workload burden.
Whether the applicant is applying for a registration under the Marine Mammal Protection Act (MMPA) as agent, tannery, or both (3–200–44).	Determine whether the business qualifies for a registration under the MMPA.
The species that the agent or tannery wishes to use in the transfer of marine mammal parts and products from Native Alaskans to Native Alaskans (3–200–44).	Determine that the species requested are eligible under the MMPA.
The procedure that the agent or tannery will use to receive, store, process, and ship marine mammal parts and products from Native Alaskans to Native Alaskans (3–200–44).	Determine that these procedures are sufficient to ensure the legitimate transfer of mammal parts and products from Native Alaskans to Native Alaskans.
The system of bookkeeping and inventory used to receive, store, process, and ship marine mammal parts and products from Native Alaskans to Native Alaskans (3–200–44).	Determine that the system of bookkeeping and inventory are sufficient to ensure the legitimate transfer of mammal parts and products from Native Alaskans to Native Alaskans.
A certification by the applicant that they will responsibly receive, store, process, and ship marine mammal parts and products from Native Alaskans to Native Alaskans to receive an exemption under the MMPA (3–200–44).	Confirm that the applicant is aware of the requirements in order to receive an exemption under the MMPA.
A description of the activities of the registered agent or registered tannery regarding the receipt and transfer of marine mammal parts and products from Native Alaskans to Native Alaskans (3–200–44a).	Confirm that the applicant is receiving, storing, processing, and shipping marine mammal parts and products from Native Alaskans to Native Alaskans.

Permittees and licensees must maintain records that accurately describe each importation or exportation of wildlife or wildlife products under the permit/license, and any subsequent sale or transfer of the wildlife or wildlife products. In addition, licensees must make these records and the corresponding inventory of wildlife or wildlife products available for our inspection at reasonable times, subject to applicable limitations of law. Any live wildlife possessed under a Service permit/license must be maintained under humane and healthful conditions. We believe the burden associated with these recordkeeping requirements is minimal because the records already exist.

Importers and exporters must complete Form 3–177 (Declaration for Importation or Exportation of Fish or Wildlife) for all imports or exports of wildlife or wildlife products. This form provides an accurate description of the imports and exports. OMB has approved the information collection for Form 3–177 and assigned OMB Control Number 1018–0012. Normal business practices should produce records (e.g., invoices or bills of sale) needed to document additional sales or transfers of the wildlife or wildlife products.

Generally, we do not require individuals and government entities to submit a report on activities conducted under the authority of a designated port exception permit. On an occasional basis, we may require entities to provide a report on activities conducted under a designated port exception permit or an import/export license.

The public may request a copy of any form contained in this information collection by sending a request to the Service Information Collection Clearance Officer (see **ADDRESSES**).

Title of Collection: Federal Fish and Wildlife Applications and Reports—Law Enforcement; 50 CFR parts 13 and 14.

OMB Control Number: 1018–0092.
Form Number: Forms 3–200–2, 3–200–3a, 3–200–3b, 3–200–44, and 3–200–44a.

Type of Review: Extension without change of a currently approved collection.

Respondents/Affected Public: Individuals, private sector, and State/local/Tribal entities.

Total Estimated Number of Annual Respondents: 11,933.

Total Estimated Number of Annual Responses: 11,953.

Estimated Completion Time per Response: Varies from 15 minutes to 1 hour 15 minutes, depending on activity.

Total Estimated Number of Annual Burden Hours: 13,431.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion for Forms 3–200–2, 3–200–3a, 3–200–3b, 3–200–44, and reporting requirements. Biannually for Form 3–200–44a.

Total Estimated Annual Nonhour Burden Cost: \$1,188,700. There is a \$100 fee associated with applications (Forms 3–200–2, 3–200–3a, and 3–200–3b) and a \$150 fee associated with applications (Form 3–200–44) received from individuals and the private sector. There is no fee for applications from government agencies or for processing reports.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Madonna Baucum,
Information Collection Clearance Officer, U.S. Fish and Wildlife Service.

[FR Doc. 2026–01910 Filed 1–29–26; 8:45 am]
BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

**[267A2100DD/AAKC001030/
A0A501010.000000]**

**Indian Entities Recognized by and
Eligible To Receive Services From the
United States Bureau of Indian Affairs**

AGENCY: Bureau of Indian Affairs,
Interior.

ACTION: Notice.

SUMMARY: This notice publishes the current list of 575 Tribal entities recognized by and eligible for funding and services from the Bureau of Indian Affairs (BIA) by virtue of their status as Indian Tribes.

DATES: The list is updated from the notice published on December 11, 2024 (89 FR 99899).

FOR FURTHER INFORMATION CONTACT: Ms. Shyla Joe, Bureau of Indian Affairs, Deputy Director, Office of Indian Services, Mail Stop 3645–MIB, 1849 C Street NW, Washington, DC 20240. Telephone number: (202) 513–0783.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to section 104 of the Federally Recognized Indian Tribe List Act of November 2, 1994 (Pub. L. 103–454; 108 Stat. 4791, 4792), in accordance with section 83.6(a) of part 83 of Title 25 of the Code of Federal Regulations, and in exercise of authority delegated to the Assistant Secretary—Indian Affairs under 25 U.S.C. 2 and 9 and 209 DM 8. Published below is an updated list of federally recognized Indian Tribes within the contiguous 48 states and Alaska. This list includes the addition of the Lumbee Tribe of North Carolina following the enactment of the National Defense Authorization Act for Fiscal Year 2026 on December 18, 2025. The legislation recognized the Lumbee

Tribe of North Carolina, while setting forth certain conditions on the Tribe's eligibility for services and benefits provided by the Federal government to federally recognized Indian Tribes. See Public Law 119–60, section 8803. Conditions include the Secretary of the Interior's verification of the Tribe's roll, the development of a determination of needs for services, and a general delay in the delivery of services until the third fiscal year following the date of enactment of Public Law 119–60. The enactment of legislation recognizing the Lumbee Tribe of North Carolina is consistent with the directive set forth in the Presidential Memorandum entitled "Federal Recognition of the Lumbee Tribe of North Carolina," signed by President Trump on January 23, 2025.

Other amendments to the list include formatting edits and name changes. To aid in identifying Tribal name changes, Tribes previously listed, former names, or also known as (aka) names are included in parentheses after the correct current Tribal name. The BIA will continue to list the Tribe's former or previously listed name for several years before dropping the former or previously listed name from the list.

The listed Indian entities are recognized to have the immunities and privileges available to federally recognized Indian Tribes by virtue of their Government-to-Government relationship with the United States as well as the responsibilities, powers, limitations, and obligations of such Indian Tribes. The BIA has continued the practice of listing the Alaska Native entities separately for the purpose of facilitating their identification.

William Henry Kirkland III,

Assistant Secretary—Indian Affairs.

Indian Tribal Entities Within the Contiguous 48 States Recognized by and Eligible To Receive Services From the United States Bureau of Indian Affairs

Absentee-Shawnee Tribe of Indians of Oklahoma
 Agua Caliente Band of Cahuilla Indians of the Agua Caliente Indian Reservation, California
 Ak-Chin Indian Community
 Alabama-Coushatta Tribe of Texas
 Alabama-Quassarte Tribal Town
 Alturas Indian Rancheria, California
 Apache Tribe of Oklahoma
 Assiniboine and Sioux Tribes of the Fort Peck Indian Reservation, Montana
 Augustine Band of Cahuilla Indians, California
 Bad River Band of the Lake Superior Tribe of Chippewa Indians of the Bad River Reservation, Wisconsin
 Bay Mills Indian Community, Michigan

Bear River Band of the Rohnerville Rancheria, California
 Berry Creek Rancheria of Maidu Indians of California
 Big Lagoon Rancheria, California
 Big Pine Paiute Tribe of the Owens Valley
 Big Sandy Rancheria of Western Mono Indians of California
 Big Valley Band of Pomo Indians of the Big Valley Rancheria, California
 Bishop Paiute Tribe
 Blackfeet Tribe of the Blackfeet Indian Reservation of Montana
 Blue Lake Rancheria, California
 Bridgeport Indian Colony
 Buena Vista Rancheria of Me-Wuk Indians of California
 Burns Paiute Tribe
 Cabazon Band of Cahuilla Indians (previously listed as Cabazon Band of Mission Indians, California)
 Cachil DeHe Band of Wintun Indians of the Colusa Indian Community of the Colusa Rancheria, California
 Caddo Nation of Oklahoma
 Cahto Tribe of the Laytonville Rancheria
 Cahuilla Band of Indians
 California Valley Miwok Tribe, California
 Campo Band of Diegueno Mission Indians of the Campo Indian Reservation, California
 Capitan Grande Band of Diegueno Mission Indians of California (Barona Group of Capitan Grande Band of Mission Indians of the Barona Reservation, California; Viejas (Baron Long) Group of Capitan Grande Band of Mission Indians of the Viejas Reservation, California)
 Catawba Indian Nation
 Cayuga Nation
 Cedarville Rancheria, California
 Chemehuevi Indian Tribe of the Chemehuevi Reservation, California
 Cher-Ae Heights Indian Community of the Trinidad Rancheria, California
 Cherokee Nation
 Cheyenne and Arapaho Tribes, Oklahoma
 Cheyenne River Sioux Tribe of the Cheyenne River Reservation, South Dakota
 Chickahominy Indian Tribe
 Chickahominy Indian Tribe—Eastern Division
 Chicken Ranch Rancheria of Me-Wuk Indians of California
 Chippewa Cree Indians of the Rocky Boy's Reservation, Montana
 Chitimacha Tribe of Louisiana
 Citizen Potawatomi Nation, Oklahoma
 Cloverdale Rancheria of Pomo Indians of California
 Cocopah Tribe of Arizona
 Coeur D'Alene Tribe
 Cold Springs Rancheria of Mono Indians of California
 Colorado River Indian Tribes of the Colorado River Indian Reservation, Arizona and California
 Comanche Nation, Oklahoma
 Confederated Salish and Kootenai Tribes of the Flathead Reservation
 Confederated Tribes and Bands of the Yakama Nation
 Confederated Tribes of Siletz Indians of Oregon
 Confederated Tribes of the Chehalis Reservation
 Confederated Tribes of the Colville Reservation

Confederated Tribes of the Coos, Lower Umpqua and Siuslaw Indians
 Confederated Tribes of the Goshute Reservation, Nevada and Utah
 Confederated Tribes of the Grand Ronde Community of Oregon
 Confederated Tribes of the Umatilla Indian Reservation
 Confederated Tribes of the Warm Springs Reservation of Oregon
 Coquille Indian Tribe
 Coushatta Tribe of Louisiana
 Cow Creek Band of Umpqua Tribe of Indians
 Cowlitz Indian Tribe
 Coyote Valley Band of Pomo Indians of California
 Crow Creek Sioux Tribe of the Crow Creek Reservation, South Dakota
 Crow Tribe of Montana
 Delaware Nation, Oklahoma
 Delaware Tribe of Indians
 Dry Creek Rancheria Band of Pomo Indians, California
 Duckwater Shoshone Tribe (previously listed as Duckwater Shoshone Tribe of the Duckwater Reservation, Nevada)
 Eastern Band of Cherokee Indians
 Eastern Shawnee Tribe of Oklahoma
 Eastern Shoshone Tribe of the Wind River Reservation, Wyoming
 Elem Indian Colony of Pomo Indians of the Sulphur Bank Rancheria, California
 Elk Valley Rancheria, California
 Ely Shoshone Tribe of Nevada
 Enterprise Rancheria of Maidu Indians of California
 Ewiiapaayp Band of Kumeyaay Indians (previously listed as Ewiiapaayp Band of Kumeyaay Indians, California)
 Federated Indians of Graton Rancheria, California
 Flandreau Santee Sioux Tribe of South Dakota
 Forest County Potawatomi Community, Wisconsin
 Fort Belknap Indian Community of the Fort Belknap Reservation of Montana
 Fort Bidwell Indian Community of the Fort Bidwell Reservation of California
 Fort Independence Indian Community of Paiute Indians of the Fort Independence Reservation, California
 Fort McDermitt Paiute and Shoshone Tribes of the Fort McDermitt Indian Reservation, Nevada and Oregon
 Fort McDowell Yavapai Nation, Arizona
 Fort Mojave Indian Tribe of Arizona, California & Nevada
 Fort Sill—Chiricahua—Warm Springs—Apache Tribe (previously listed as Fort Sill Apache Tribe of Oklahoma)
 Gila River Indian Community of the Gila River Indian Reservation, Arizona
 Grand Traverse Band of Ottawa and Chippewa Indians, Michigan
 Greenville Rancheria
 Grindstone Indian Rancheria of Wintun-Wailaki Indians of California
 Guidville Rancheria of California
 Habematolel Pomo of Upper Lake, California
 Hannahville Indian Community, Michigan
 Havasupai Tribe of the Havasupai Reservation, Arizona
 Ho-Chunk Nation of Wisconsin
 Hoh Indian Tribe
 Hoopa Valley Tribe, California

- Hopi Tribe of Arizona
Hopland Band of Pomo Indians, California
Houlton Band of Maliseet Indians
Hualapai Indian Tribe of the Hualapai Indian Reservation, Arizona
Iipay Nation of Santa Ysabel, California
Inaja Band of Diegueno Mission Indians of the Inaja and Cosmit Reservation, California
Ione Band of Miwok Indians of California
Iowa Tribe of Kansas and Nebraska
Iowa Tribe of Oklahoma
Jackson Band of Miwuk Indians
Jamestown S'Klallam Tribe
Jamul Indian Village of California
Jena Band of Choctaw Indians
Jicarilla Apache Nation, New Mexico
Kaibab Band of Paiute Indians of the Kaibab Indian Reservation, Arizona
Kalispel Indian Community of the Kalispel Reservation
Karuk Tribe
Kashia Band of Pomo Indians of the Stewarts Point Rancheria, California
Kaw Nation, Oklahoma
Keweenaw Bay Indian Community, Michigan
Kialegee Tribal Town
Kickapoo Traditional Tribe of Texas
Kickapoo Tribe of Indians of the Kickapoo Reservation in Kansas
Kickapoo Tribe of Oklahoma
Kiowa Tribe (previously listed as Kiowa Indian Tribe of Oklahoma)
Klamath Tribes
Kletsel Dehe Wintun Nation of the Cortina Rancheria (previously listed as Kletsel Dehe Band of Wintun Indians)
Koi Nation of Northern California
Kootenai Tribe of Idaho
La Jolla Band of Luiseno Indians, California
La Posta Band of Diegueno Mission Indians of the La Posta Indian Reservation, California
Lac Courte Oreilles Band of Lake Superior Chippewa Indians of Wisconsin
Lac du Flambeau Band of Lake Superior Chippewa Indians of the Lac du Flambeau Reservation of Wisconsin
Lac Vieux Desert Band of Lake Superior Chippewa Indians of Michigan
Las Vegas Tribe of Paiute Indians of the Las Vegas Indian Colony, Nevada
Little River Band of Ottawa Indians, Michigan
Little Shell Tribe of Chippewa Indians of Montana
Little Traverse Bay Bands of Odawa Indians, Michigan
Lone Pine Paiute-Shoshone Tribe
Los Coyotes Band of Cahuilla and Cupeno Indians, California
Lovelock Paiute Tribe of the Lovelock Indian Colony, Nevada
Lower Brule Sioux Tribe of the Lower Brule Reservation, South Dakota
Lower Elwha Tribal Community
Lower Sioux Indian Community in the State of Minnesota
Lumbee Tribe of North Carolina (See **SUPPLEMENTARY INFORMATION** *supra*, noting conditions on the Tribe's eligibility for Federal services)
Lummi Tribe of the Lummi Reservation
Lytton Rancheria of California
Makah Indian Tribe of the Makah Indian Reservation
Manchester Band of Pomo Indians of the Manchester Rancheria, California
Manzanita Band of Diegueno Mission Indians of the Manzanita Reservation, California
Mashantucket Pequot Indian Tribe
Mashpee Wampanoag Tribe
Match-E-Be-Nash-She-Wish Band of Pottawatomis (previously listed as Match-E-Be-Nash-She-Wish Band of Pottawatomis Indians of Michigan)
Mechoopda Indian Tribe of Chico Rancheria, California
Menominee Indian Tribe of Wisconsin
Mesa Grande Band of Diegueno Mission Indians of the Mesa Grande Reservation, California
Mescalero Apache Tribe of the Mescalero Reservation, New Mexico
Miami Tribe of Oklahoma
Miccosukee Tribe of Indians
Middletown Rancheria of Pomo Indians of California
Mi'kmaq Nation (previously listed as Aroostook Band of Micmacs)
Minnesota Chippewa Tribe, Minnesota (Six component reservations: Bois Forte Band (Nett Lake); Fond du Lac Band; Grand Portage Band; Leech Lake Band; Mille Lacs Band; White Earth Band)
Mississippi Band of Choctaw Indians
Moapa Band of Paiute Indians of the Moapa River Indian Reservation, Nevada
Modoc Nation
Mohegan Tribe of Indians of Connecticut
Monacan Indian Nation
Mooretown Rancheria of Maidu Indians of California
Morongo Band of Mission Indians, California
Muckleshoot Indian Tribe
Nansemond Indian Nation
Narragansett Indian Tribe
Navajo Nation, Arizona, New Mexico, & Utah
Nez Perce Tribe
Nisqually Indian Tribe
Nooksack Indian Tribe
Northern Arapaho Tribe of the Wind River Reservation, Wyoming
Northern Cheyenne Tribe of the Northern Cheyenne Indian Reservation, Montana
Northfork Rancheria of Mono Indians of California
Northwestern Band of the Shoshone Nation
Nottawaseppi Huron Band of the Pottawatomis, Michigan
Oglala Sioux Tribe
Ohkay Owingeh, New Mexico
Omaha Tribe of Nebraska
Oneida Indian Nation
Oneida Nation
Onondaga Nation
Otoe-Missouria Tribe of Indians, Oklahoma
Ottawa Tribe of Oklahoma
Paiute Indian Tribe of Utah (Cedar Band of Paiutes, Kanosh Band of Paiutes, Koosharem Band of Paiutes, Indian Peaks Band of Paiutes, and Shivwits Band of Paiutes)
Paiute-Shoshone Tribe of the Fallon Reservation and Colony, Nevada
Pala Band of Mission Indians
Pamunkey Indian Tribe
Pascua Yaqui Tribe of Arizona
Paskenta Band of Nomlaki Indians of California
Passamaquoddy Tribe
Pauma Band of Luiseno Mission Indians of the Pauma & Yuima Reservation, California
Pawnee Nation of Oklahoma
Pechanga Band of Indians (previously listed as Pechanga Band of Luiseno Mission Indians of the Pechanga Reservation, California)
Penobscot Nation
Peoria Tribe of Indians of Oklahoma
Picayune Rancheria of Chukchansi Indians of California
Pinoleville Pomo Nation, California
Pit River Tribe, California (includes XL Ranch, Big Bend, Likely, Lookout, Montgomery Creek, and Roaring Creek Ranches)
Poarch Band of Creek Indians
Pokagon Band of Potawatomi Indians, Michigan and Indiana
Ponca Tribe of Indians of Oklahoma
Ponca Tribe of Nebraska
Port Gamble S'Klallam Tribe
Potter Valley Tribe, California
Prairie Band Potawatomi Nation
Prairie Island Indian Community in the State of Minnesota
Pueblo of Acoma, New Mexico
Pueblo of Cochiti, New Mexico
Pueblo of Isleta, New Mexico
Pueblo of Jemez, New Mexico
Pueblo of Laguna, New Mexico
Pueblo of Nambe, New Mexico
Pueblo of Picuris, New Mexico
Pueblo of Pojoaque, New Mexico
Pueblo of San Felipe, New Mexico
Pueblo of San Ildefonso, New Mexico
Pueblo of Sandia, New Mexico
Pueblo of Santa Ana, New Mexico
Pueblo of Santa Clara, New Mexico
Pueblo of Taos, New Mexico
Pueblo of Tesuque, New Mexico
Pueblo of Zia, New Mexico
PuliklaTribe of Yurok People (previously listed as Resighini Rancheria, California)
Puyallup Tribe of the Puyallup Reservation
Pyramid Lake Paiute Tribe of the Pyramid Lake Reservation, Nevada
Quapaw Nation
Quartz Valley Indian Community of the Quartz Valley Reservation of California
Quechan Tribe of the Fort Yuma Indian Reservation, California & Arizona
Quileute Tribe of the Quileute Reservation
Quinault Indian Nation
Ramona Band of Cahuilla, California
Rappahannock Tribe, Inc.
Red Cliff Band of Lake Superior Chippewa Indians of Wisconsin
Red Lake Band of Chippewa Indians, Minnesota
Redding Rancheria, California
Redwood Valley or Little River Band of Pomo Indians of the Redwood Valley Rancheria California
Reno-Sparks Indian Colony, Nevada
Rincon Band of Luiseno Indians (previously listed as Rincon Band of Luiseno Mission Indians of Rincon Reservation, California)
Robinson Rancheria
Rosebud Sioux Tribe of the Rosebud Indian Reservation, South Dakota
Round Valley Indian Tribes, Round Valley Reservation, California
Sac & Fox Nation of Missouri in Kansas and Nebraska
Sac & Fox Nation, Oklahoma
Sac & Fox Tribe of the Mississippi in Iowa
Saginaw Chippewa Indian Tribe of Michigan

Saint Regis Mohawk Tribe
 Salt River Pima-Maricopa Indian Community of the Salt River Reservation, Arizona
 Samish Indian Nation
 San Carlos Apache Tribe of the San Carlos Reservation, Arizona
 San Juan Southern Paiute Tribe of Arizona
 San Pasqual Band of Diegueno Mission Indians of California
 Santa Rosa Band of Cahuilla Indians, California
 Santa Rosa Indian Community of the Santa Rosa Rancheria, California
 Santa Ynez Band of Chumash Mission Indians of the Santa Ynez Reservation, California
 Santee Sioux Nation, Nebraska
 Santo Domingo Pueblo
 Sauk-Suiattle Indian Tribe
 Sault Ste. Marie Tribe of Chippewa Indians, Michigan
 Scotts Valley Band of Pomo Indians of California
 Seminole Tribe of Florida
 Seneca Nation of Indians
 Seneca-Cayuga Nation
 Shakopee Mdewakanton Sioux Community of Minnesota
 Shawnee Tribe
 Sherwood Valley Rancheria of Pomo Indians of California
 Shingle Springs Band of Miwok Indians, Shingle Springs Rancheria (Verona Tract), California
 Shinnecock Indian Nation
 Shoalwater Bay Indian Tribe of the Shoalwater Bay Indian Reservation
 Shoshone-Bannock Tribes of the Fort Hall Reservation
 Shoshone-Paiute Tribes of the Duck Valley Reservation, Nevada
 Sisseton-Wahpeton Oyate of the Lake Traverse Reservation, South Dakota
 Skokomish Indian Tribe
 Skull Valley Band of Goshute Indians of Utah
 Snoqualmie Indian Tribe
 Soboba Band of Luiseno Indians, California
 Sokaogon Chippewa Community, Wisconsin
 Southern Ute Indian Tribe of the Southern Ute Reservation, Colorado
 Spirit Lake Tribe, North Dakota
 Spokane Tribe of the Spokane Reservation
 Squaxin Island Tribe of the Squaxin Island Reservation
 St. Croix Chippewa Indians of Wisconsin
 Standing Rock Sioux Tribe of North & South Dakota
 Stillaguamish Tribe of Indians of Washington
 Stockbridge Munsee Community, Wisconsin
 Summit Lake Paiute Tribe of Nevada
 Suquamish Indian Tribe of the Port Madison Reservation
 Susanville Indian Rancheria, California
 Swinomish Indian Tribal Community
 Sycuan Band of the Kumeyaay Nation
 Table Mountain Rancheria
 Tejon Indian Tribe
 Te-Moak Tribe of Western Shoshone Indians of Nevada (Four constituent bands: Battle Mountain Band; Elko Band; South Fork Band; and Wells Band)
 The Chickasaw Nation
 The Choctaw Nation of Oklahoma
 The Muscogee (Creek) Nation
 The Osage Nation
 The Seminole Nation of Oklahoma

Thlopthlocco Tribal Town
 Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota
 Timbisha Shoshone Tribe
 Tohono O'odham Nation of Arizona
 Tolowa Dee-ni' Nation
 Tonawanda Band of Seneca
 Tonkawa Tribe of Indians of Oklahoma
 Tonto Apache Tribe of Arizona
 Torres Martinez Desert Cahuilla Indians, California
 Tulalip Tribes of Washington
 Tule River Indian Tribe of the Tule River Reservation, California
 Tunica-Biloxi Indian Tribe
 Tuolumne Band of Me-Wuk Indians of the Tuolumne Rancheria of California
 Turtle Mountain Band of Chippewa Indians of North Dakota
 Tuscarora Nation
 Twenty-Nine Palms Band of Mission Indians of California
 United Auburn Indian Community of the Auburn Rancheria of California
 United Keetoowah Band of Cherokee Indians in Oklahoma
 Upper Mattaponi Tribe
 Upper Sioux Community, Minnesota
 Upper Skagit Indian Tribe
 Ute Indian Tribe of the Uintah & Ouray Reservation, Utah
 Ute Mountain Ute Tribe
 Utu Utu Gwaitu Paiute Tribe of the Benton Paiute Reservation, California
 Walker River Paiute Tribe of the Walker River Reservation, Nevada
 Wampanoag Tribe of Gay Head (Aquinnah)
 Washoe Tribe of Nevada & California (Carson Colony, Dresslerville Colony, Woodfords Community, Stewart Community, & Washoe Ranches)
 White Mountain Apache Tribe of the Fort Apache Reservation, Arizona
 Wichita and Affiliated Tribes (Wichita, Keechi, Waco, & Tawakonie), Oklahoma
 Wilton Rancheria, California
 Winnebago Tribe of Nebraska
 Winnemucca Indian Colony of Nevada
 Wiyot Tribe, California
 Wyandotte Nation
 Yankton Sioux Tribe of South Dakota
 Yavapai-Apache Nation of the Camp Verde Indian Reservation, Arizona
 Yavapai-Prescott Indian Tribe
 Yerington Paiute Tribe of the Yerington Colony & Campbell Ranch, Nevada
 Yocha Dehe Wintun Nation, California
 Yomba Shoshone Tribe of the Yomba Reservation, Nevada
 Ysleta del Sur Pueblo
 Yuhaaviatam of San Manuel Nation (previously listed as San Manuel Band of Mission Indians, California)
 Yurok Tribe of the Yurok Reservation, California
 Zuni Tribe of the Zuni Reservation, New Mexico

Native Entities Within the State of Alaska Recognized by and Eligible To Receive Services From the United States Bureau of Indian Affairs

Agdaagux Tribe of King Cove
 Akiachak Native Community
 Akiak Native Community
 Alatna Village

Algaaciq Native Village (St. Mary's)
 Allakaket Village
 Aleut Community of St. Paul Island (See Pribilof Islands Aleut Communities of St. Paul & St. George Islands) (previously listed as Saint Paul Island (See Pribilof Islands Aleut Communities of St. Paul & St. George Islands))
 Alutiiq Tribe of Old Harbor
 Angoon Community Association
 Anvik Village
 Arctic Village (See Native Village of Venetie Tribal Government)
 Asa'carsarmiut Tribe
 Beaver Village
 Birch Creek Tribe
 Central Council of the Tlingit & Haida Indian Tribes
 Chalkyitsik Village
 Cheesh-Na Tribe
 Chevak Native Village
 Chickaloon Native Village
 Chignik Bay Tribal Council
 Chignik Lake Village
 Chilkat Indian Village (Klukwan)
 Chilkoot Indian Association (Haines)
 Chinik Eskimo Community (Golovin)
 Chuloonawick Native Village
 Circle Native Community
 Craig Tribal Association
 Curyung Tribal Council
 Douglas Indian Association
 Egegik Village
 Eklutna Native Village
 Emmonak Village
 Evansville Village (aka Bettles Field)
 Gulkana Village Council
 Healy Lake Village
 Holy Cross Tribe
 Hoonah Indian Association
 Hughes Village
 Huslia Village
 Hydaburg Cooperative Association
 Igiugig Village
 Inupiat Community of the Arctic Slope
 Iqumgiut Traditional Council
 Ivanof Bay Tribe
 Kaguyak Village
 Kaktovik Village (aka Barter Island)
 Kasigluk Traditional Elders Council
 Kenaitze Indian Tribe
 Ketchikan Indian Community
 King Island Native Community
 King Salmon Tribe
 Klawock Cooperative Association
 Knik Tribe
 Kokhanok Village
 Koyukuk Native Village
 Levelock Village
 Lime Village
 Loudon Tribe (previously listed as Galena Village (aka Loudon Village))
 Manley Hot Springs Village
 Manokotak Village
 McGrath Native Village
 Mentasta Traditional Council
 Metlakatla Indian Community, Annette Island Reserve
 Naknek Native Village
 Native Village of Afognak
 Native Village of Akhiok
 Native Village of Akutan
 Native Village of Aleknagik
 Native Village of Ambler
 Native Village of Atka
 Native Village of Atqasuk

Native Village of Barrow Inupiat Traditional Government
 Native Village of Belkofski
 Native Village of Brevig Mission
 Native Village of Buckland
 Native Village of Cantwell
 Native Village of Chenega
 Native Village of Chignik Lagoon
 Native Village of Chitina
 Native Village of Chuathbaluk (Russian Mission, Kuskokwim)
 Native Village of Council
 Native Village of Deering
 Native Village of Diomedea (aka Inalik)
 Native Village of Eagle
 Native Village of Eek
 Native Village of Ekuk
 Native Village of Ekwok
 Native Village of Elim
 Native Village of Eyak (Cordova)
 Native Village of False Pass
 Native Village of Fort Yukon
 Native Village of Gakona
 Native Village of Gambell
 Native Village of Georgetown
 Native Village of Goodnews Bay
 Native Village of Hamilton
 Native Village of Hooper Bay
 Native Village of Kanatak
 Native Village of Karluk
 Native Village of Kiana
 Native Village of Kipnuk
 Native Village of Kivalina
 Native Village of Kluti Kaah (aka Copper Center)
 Native Village of Kobuk
 Native Village of Kongiganak
 Native Village of Kotzebue
 Native Village of Koyuk
 Native Village of Kwigillingok
 Native Village of Kwinhagak (aka Quinhagak)
 Native Village of Larsen Bay
 Native Village of Marshall (aka Fortuna Ledge)
 Native Village of Mary's Igloo
 Native Village of Mekoryuk
 Native Village of Minto
 Native Village of Nanwalek (aka English Bay)
 Native Village of Napaimute
 Native Village of Napakiak
 Native Village of Napaskiak
 Native Village of Nelson Lagoon
 Native Village of Nightmute
 Native Village of Nikolski
 Native Village of Noatak
 Native Village of Nuiqsut (aka Nooiksut)
 Native Village of Nunam Iqua
 Native Village of Nunapitchuk
 Native Village of Ouzinkie
 Native Village of Paimiut
 Native Village of Perryville
 Native Village of Pilot Point
 Native Village of Point Hope
 Native Village of Point Lay
 Native Village of Port Graham
 Native Village of Port Heiden
 Native Village of Port Lions
 Native Village of Ruby
 Native Village of Saint Michael
 Native Village of Savoonga
 Native Village of Scammon Bay
 Native Village of Selawik
 Native Village of Shaktoolik
 Native Village of Shishmaref
 Native Village of Shungnak
 Native Village of South Naknek (previously listed as South Naknek Village)

Native Village of Stevens
 Native Village of Tanacross
 Native Village of Tanana
 Native Village of Tatitlek
 Native Village of Tazlina
 Native Village of Teller
 Native Village of Tetlin
 Native Village of Tuntutuliak
 Native Village of Tununak
 Native Village of Tyonek
 Native Village of Unalakleet
 Native Village of Unga
 Native Village of Venetie Tribal Government (Arctic Village and Village of Venetie)
 Native Village of Wales
 Native Village of White Mountain
 Nenana Native Association
 New Koliganek Village Council
 New Stuyahok Village
 Newhalen Village
 Newtok Village
 Nikolai Village
 Ninilchik Village
 Nome Eskimo Community
 Nondalton Tribe (previously listed as Nondalton Village)
 Noorvik Native Community
 Northway Village
 Nulato Village
 Nunakauyarmiut Tribe
 Organized Village of Grayling (aka Holikachuk)
 Organized Village of Kake
 Organized Village of Kasaan
 Organized Village of Kwethluk
 Organized Village of Saxman
 Orutsarmiut Traditional Native Council
 Oscarville Traditional Village
 Pauloff Harbor Village
 Pedro Bay Village
 Petersburg Indian Association
 Pilot Station Traditional Village
 Pitka's Point Traditional Council
 Platinum Traditional Village
 Portage Creek Village (aka Ohgsenakale)
 Pribilof Islands Aleut Communities of St. Paul & St. George Islands (St. George Island and Saint Paul Island)
 Qagan Tayagungin Tribe of Sand Point
 Qawalangin Tribe of Unalaska
 Rampart Village
 St. George Island (See Pribilof Islands Aleut Communities of St. Paul & St. George Islands)
 Salamatof Tribe
 Seldovia Village Tribe
 Shageluk Native Village
 Sitka Tribe of Alaska
 Skagway Village
 Stebbins Community Association
 Sun'aq Tribe of Kodiak
 Takotna Village
 Tangirnaq Native Village
 Telida Village
 Traditional Village of Togiak
 Tuluksak Native Community
 Twin Hills Village
 Ugashik Village
 Umkumiut Native Village
 Village of Alakanuk
 Village of Anaktuvuk Pass
 Village of Aniak
 Village of Atmautluak
 Village of Bill Moore's Slough
 Village of Chefornak
 Village of Clarks Point

Village of Crooked Creek
 Village of Dot Lake
 Village of Iliamna
 Village of Kalskag
 Village of Kaltag
 Village of Kotlik
 Village of Lower Kalskag
 Village of Ohogamiut
 Village of Red Devil
 Village of Sleetmute
 Village of Solomon
 Village of Stony River
 Village of Venetie (See Native Village of Venetie Tribal Government)
 Village of Wainwright
 Wrangell Cooperative Association
 Yakutat Tlingit Tribe
 Yupiit of Andreafski

[FR Doc. 2026–01899 Filed 1–29–26; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[OMB Control Number 1076–0164;
 267A2100DD/AAKP300000/
 A0A501010.000000]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Homeliving Programs and School Closure and Consolidation

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Bureau of Indian Education (BIE), are proposing to renew an information collection without change.

DATES: Interested persons are invited to submit comments. To be considered, your comments must be received on or before March 2, 2026.

ADDRESSES: Send your written comments and recommendations for the proposed information collection request (ICR) to the Office of Information and Regulatory Affairs (OIRA) through https://www.reginfo.gov/public/do/PRA/ocrPublicCommentRequest?ref_nbr=202508-1076-001 or by visiting <https://www.reginfo.gov/public/do/PRAMain> and selecting “Currently under Review—Open for Public Comments” and then scrolling down to the “Department of the Interior.”

FOR FURTHER INFORMATION CONTACT: Steven Mullen, Information Collection Clearance Officer, Office of Regulatory Affairs and Collaborative Action—Indian Affairs, U.S. Department of the Interior, 1001 Indian School Road NW, Suite 229, Albuquerque, New Mexico 87104; comments@bia.gov; (202) 924–

2650. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. You may also view the ICR at <https://www.reginfo.gov/public/Forward?SearchTarget=PRA&textfield=1076-0164>.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (PRA, 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), 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.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on September 22, 2025 (90 FR 45403). No comments were received.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again soliciting comments from the public and other Federal agencies on the proposed ICR that is described below. We are especially interested in public comment addressing the following:

- (1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;
- (2) The accuracy of our estimate of the burden for this 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) How might the agency 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 response.

Comments that you submit in response to this notice are a matter of public record. 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.

Abstract: The regulations at 25 CFR part 36, subpart G, “Homeliving Programs,” implement section 1122 of the Native American Education Improvement Act of 2001 (Pub. L. 95–561, title XI, sec. 1120, as added Pub. L. 107–110, title X, sec. 1042, Jan. 8, 2002, 115 Stat. 2007). These regulations require BIE to implement national standards for homeliving situations in all BIE-funded residential schools. The BIE must collect information from all BIE-funded residential schools in order to assess each school's progress in meeting the national standards. Submission of this information allows BIE to ensure that minimum academic standards for the education of Indian children and criteria for dormitory situations in BIE-operated schools and Indian-controlled contract schools are met.

Title of Collection: Homeliving Programs and School Closure and Consolidation.

OMB Control Number: 1076–0164.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Parents and guardians; federally recognized Indian Tribes.

Total Estimated Number of Annual Respondents: 594.

Total Estimated Number of Annual Responses: 594 per year, on average.

Estimated Completion Time per Response: Varies from 15 minutes to 40 hours.

Total Estimated Number of Annual Burden Hours: 1,039 hours.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: Annual or on occasion, depending on the activity.

Total Estimated Annual Nonhour Burden Cost: None.

Authority

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.*).

Steven Mullen,

*Information Collection Clearance Officer,
Office of Regulatory Affairs and Collaborative
Action—Indian Affairs.*

[FR Doc. 2026–01908 Filed 1–29–26; 8:45 am]

BILLING CODE 4337–15–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1770
(Preliminary)]

Fresh Winter Strawberries From Mexico; Revised Schedule for the Subject Investigation

AGENCY: United States International Trade Commission.

ACTION: Notice.

DATES: January 23, 2026.

FOR FURTHER INFORMATION CONTACT:

Caitlyn Costello (202–205–2610), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (<https://www.usitc.gov>). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>.

SUPPLEMENTARY INFORMATION: On December 31, 2025, the Commission established a schedule for the conduct of the preliminary phase of the subject investigation (91 FR 380, January 6, 2026). On January 20, 2026, the Department of Commerce (“Commerce”) extended the deadline for its initiation determination to February 9, 2026 (91 FR 2910, January 23, 2026). The Commission, therefore, is revising its schedule to conform with Commerce's new schedule as follows: the deadline for filing postconference briefs and for written statements from any person who has not entered an appearance as a party is January 30, 2026.

The Commission must reach preliminary determinations within 25 days after the date on which the Commission receives notice from Commerce of initiation of the investigation, and the Commission's views must be transmitted to Commerce within five business days thereafter.

For further information concerning this proceeding, see the Commission's notice cited above and the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and B (19 CFR part 207).

Authority: This investigation is being conducted under authority of title VII of

the Tariff Act of 1930; this notice is published pursuant to § 207.12 of the Commission's rules.

By order of the Commission.

Issued: January 27, 2026.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2026–01812 Filed 1–29–26; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–626 and 731–TA–1452 (Review)]

Certain Collated Steel Staples From China; Determinations

On the basis of the record¹ developed in the subject five-year reviews, the United States International Trade Commission (“Commission”) determines, pursuant to the Tariff Act of 1930 (“the Act”), that revocation of the countervailing and antidumping duty orders on certain collated steel staples from China would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

Background

The Commission instituted these reviews on June 2, 2025 (90 FR 23364) and determined on September 5, 2025, that it would conduct expedited reviews (90 FR 58308, December 16, 2025).

The Commission made these determinations pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)). It completed and filed its determinations in these reviews on January 27, 2026. The views of the Commission are contained in USITC Publication 5698 (January 2026), entitled *Certain Collated Steel Staples from China: Investigation Nos. 701–TA–626 and 731–TA–1452 (Review)*.

By order of the Commission.

Issued: January 27, 2026.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2026–01840 Filed 1–29–26; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1232 (Enforcement II)]

Certain Chocolate Milk Powder and Packaging Thereof; Notice of a Commission Determination Not To Review an Initial Determination Granting a Motion for Summary Determination of Violation of the General Exclusion Order and Cease and Desist Orders; Request for Briefing on the Recommended Remedy for Violation of the Cease and Desist Orders

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 enforcement initial determination (“EID”) (Order No. 9) of the presiding administrative law judge (“ALJ”) granting a motion for summary determination of violation of the General Exclusion Order (“GEO”) and Cease and Desist Orders (“CDOs”). The Commission requests written submissions from the parties, interested government agencies, and other interested persons on the recommended remedy for violation of the CDOs, under the schedule set forth below.

FOR FURTHER INFORMATION CONTACT: Panyin Hughes, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3042. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email EDIS3Help@usitc.gov. General information concerning the Commission may also be obtained by accessing its internet server at <https://www.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted the original investigation on December 1, 2020, based on a complaint filed on behalf of Meenaxi Enterprise Inc. (“Meenaxi”) of Edison, New Jersey. 85 FR 77237–38 (Dec. 1, 2020). The complaint alleged violations of section 337 of the Tariff Act of 1930, 19 U.S.C. 1337, based upon the importation into the United States,

the sale for importation, and the sale within the United States after importation of certain chocolate milk powder and packaging thereof by reason of infringement of U.S. Trademark Registration No. 4,206,026 (“the ‘026 mark”). The Commission's notice of investigation named several respondents, including but not limited to Bharat Bazar Inc. of Union City, California (“Bharat Bazaar”); Coconut Hill Inc. d/b/a Coconut Hill of Sunnyvale, California (“Coconut Hill”); Organic Food d/b/a Namaste Plaza Indian Super Market (“Organic Food”) of Fremont, California; and New India Bazar Inc. d/b/a New India Bazar of San Jose, California (“New India”). *Id.* at 77237. The Office of Unfair Import Investigations (“OUII”) was also a party to the investigation. *Id.*

In the underlying investigation, all respondents were found in default. *See* Order No. 6 (Feb. 10, 2021), *unreviewed by* Comm'n Notice (Mar. 2, 2021); Order No. 23 (May 19, 2022), *unreviewed by* Comm'n Notice (Jun. 14, 2022). On May 24, 2021, Meenaxi moved for summary determination of violation of section 337 by the respondents found in default by Order No. 6 and requested a GEO. On December 1, 2021, the former chief administrative law judge granted the motion as an initial determination (“ID”) (Order No. 15), but noted discrepancies with respect to respondent Organic Food, calling into question whether that respondent was ever properly served with the complaint and notice of investigation and with the CALJ's order to show cause why the respondents should not be found in default, Order No. 5 (Jan. 13, 2021). *See* Order No. 15 at 1, n.1. No petitions for review of the ID were filed. The Commission determined *sua sponte* to review Order No. 15 and ordered reconsideration of Order No. 6 as to Organic Food and/or any other respondents who may not have been properly served with documents in the underlying investigation. *See* Comm'n Notice at 3 (Jan. 18, 2022). The Commission remanded the investigation to an ALJ for further proceedings. *Id.*

On remand, the current chief administrative law judge (“CALJ”) issued Order No. 18, granting Meenaxi's unopposed motion for leave to amend the complaint and notice of investigation to (i) substitute Organic Food with proposed respondent Organic Ingredients Inc. d/b/a Namaste Plaza Indian Super Market (“Organic Ingredients”) of San Diego, California; (ii) correct the address of respondent New India; (iii) correct the address of respondent Bharat Bazar; and (iv) supplement the complaint with Exhibits

¹ The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

9-a, 9-b, and 9-c, concerning Organic Food and/or Organic Ingredients. Order No. 18 at 1–5 (Mar. 11, 2022), *unreviewed by* Comm’n Notice (Apr. 12, 2022); *see also* 87 FR 22940–41 (Apr. 18, 2022). Meenaxi also demonstrated that Bharat Bazar actually had been served with all of the documents in the investigation (prior to remand) despite incorrectly spelling Bharat Bazar’s address as being on “Niled Road” instead of “Niles Road.” *See* Order No. 18 at 4.

The CALJ conducted remand proceedings as to Organic Ingredients and New India to respond to the amended complaint and notice of investigation, and then ordered them to respond to an order to show cause why they should not be found in default. *See* Order No. 19 (Mar. 11, 2022); Order No. 21 at 2–3 (May 3, 2022). On May 19, 2022, the CALJ issued an ID finding Organic Ingredients and New India in default. Order No. 23 (May 19, 2022), *unreviewed by* Comm’n Notice (June 14, 2022). Accordingly, the Commission found all respondents in default (collectively with the respondents previously found in default, the “Defaulting Respondents”).

Subsequently, on June 15, 2022, following the remand determination of default, Meenaxi again moved for summary determination of violation by the Defaulting Respondents and requested a GEO. On July 6, 2022, OUII filed a response supporting the motion.

On August 3, 2022, the CALJ issued a remand ID (“RID”) (Order No. 27), granting the second motion for summary determination and finding a violation of section 337 with respect to the ‘026 mark. The RID found that all Defaulting Respondents met the importation requirement and that Meenaxi satisfied the domestic industry requirement. *See* 19 U.S.C. 1337(a)(1–3). No party petitioned for review of the ID.

On September 19, 2022, the Commission determined not to review the RID. *See* 87 FR 58130–32 (Sept. 23, 2022). On November 15, 2022, the Commission issued a final determination finding a violation, issuing a GEO prohibiting the unlicensed importation of chocolate milk powder and packaging thereof that infringe the ‘026 mark, and terminating the investigation. *See* 87 FR 70864–66 (Nov. 21, 2022). The GEO prohibits the unlicensed importation of “chocolate milk powder in consumer-sized container with the Bournvita label.” *Id.* That same day, the Commission issued an opinion explaining the basis for its final determination.

On November 9, 2023, the Commission determined to institute an

enforcement proceeding (“Enforcement I”) under Commission Rule 210.75 to investigate alleged violations of the GEO by four respondents: (1) Organic Ingredients; (2) New India; (3) Bharat Bazar; and (4) Coconut Hill (collectively the “Enforcement Respondents”). *See* 88 FR 78786–87 (Nov. 16, 2023); 89 FR 15220 (Mar. 1, 2024). OUII was also named as a party. *Id.*

On January 10, 2024, the presiding ALJ issued an order directing the Enforcement Respondents to show cause why they should not be found in default and why judgment should not be rendered against them for failing to respond to the enforcement complaint and notice of investigation. *See* Enforcement I, Order No. 6 (Jan. 10, 2024). Enforcement I, Order No. 6, directed the Enforcement Respondents to make any showing of good cause by no later than February 2, 2024. *Id.* at 3. No party responded to Order No. 6. *See* Enforcement I, Order No. 8 at 1 (Feb. 13, 2024).

On March 14, 2024, the Commission determined that the four Enforcement Respondents were in default. *See* Order No. 8 (Feb. 13, 2024), *unreviewed by* Comm’n Notice (Mar. 14, 2024). On March 15, 2024, Meenaxi filed a motion requesting summary determination of violation of the GEO and the issuance of CDOs against the four Enforcement Respondents. *See* Enforcement I, Initial Determination (“EID–1”) at 5.

On August 16, 2024, the ALJ granted Meenaxi’s motion and recommended issuance of CDOs. *See* Enforcement I, Order No. 9 (Aug. 16, 2024). On November 18, 2024, the Commission issued a final determination finding that all four Enforcement Respondents had violated the GEO and issued CDOs against each of the four Enforcement Respondents. 89 FR 92,722–723 (Nov. 18, 2024).

On February 24, 2025, Meenaxi filed a complaint requesting that the Commission institute a second enforcement proceeding to investigate alleged violations of the GEO and CDOs by the same four Enforcement Respondents: (1) Organic Ingredients; (2) New India; (3) Bharat Bazar; and (4) Coconut Hill Inc. *See* EID at 5. On March 26, 2025, the Commission determined to institute an enforcement proceeding under Commission Rule 210.75 to investigate alleged violations of the GEO and CDOs by the four Enforcement Respondents. *See* 90 FR 14,381–382 (Apr. 1, 2025). OUII is also named as a party. *Id.* Meenaxi filed proof that the notice was served on each of the four Enforcement Respondents. *See* July 29, 2025 Letter from Anil

Gandhi to Secretary Barton, EDIS Doc. ID 857933.

On May 9, 2025, the ALJ issued an order directing the Enforcement Respondents to show cause why they should not be found in default and why judgment should not be rendered against them for failing to respond to the second enforcement complaint and notice of investigation. Enforcement II, Order No. 5 (May 9, 2025). Order No. 5 directed the Enforcement Respondents to make any showing of good cause by no later than June 13, 2025. *Id.* at 3. No party responded to Order No. 5, the show-cause order. Meenaxi filed proof that Order No. 5 was served on each of the four Enforcement Respondents. *See* May 19, 2025 Letter from Anil Gandhi to Secretary Barton, EDIS Doc. ID 851448, 851447. On July 15, 2025, the Commission determined that the four Enforcement Respondents were in default. Order No. 6 (June 16, 2025), *unreviewed by* Comm’n Notice (July 15, 2025). Meenaxi filed proof that Order No. 6 was served on each of the four Enforcement Respondents. *See* July 29, 2025 Letter from Anil Gandhi to Secretary Barton, EDIS Doc. ID 857933.

On July 10, 2025, Meenaxi filed a motion for summary determination of violation of the GEO and CDOs by the four Enforcement Respondents and requested issuance of civil penalties against the four Enforcement Respondents. *See* EID at 6. Meenaxi argued that the Enforcement Respondents have violated the Commission’s GEO and CDOs by continuing to import, sell for importation, advertise, market, distribute, offer to sell, and sell the “Bournvita” products that infringe the ‘026 mark. EID at 18.

On December 15, 2025, the presiding ALJ issued the subject EID (Order No. 9), granting Meenaxi’s motion and recommending issuance of the requested civil penalties. The ALJ concluded that the un rebutted evidence demonstrates that the Enforcement Respondents have imported and/or sold after importation chocolate milk powder products bearing the “Bournvita” label in violation of the GEO and CDOs. No party filed a petition seeking review of EID.

Having reviewed the record of the investigation, including the enforcement complaint, EID, and the parties’ submissions to the ALJ, the Commission has determined not to review the ALJ’s findings that the Enforcement Respondents have violated the GEO and CDOs.

In connection with the final disposition of this enforcement proceeding, the statute authorizes

issuance of civil penalties for violation of CDOs. 19 U.S.C. 1337(f)(2); *see also*, *Certain Two-Way Glob. Satellite Comm’n Devices, Sys. & Components Thereof*, Inv. No. 337–TA–854 (Enforcement), Comm’n Op. at 26 (July 1, 2014); *Certain Ink Cartridges & Components Thereof*, Inv. No. 337–TA–565 (Enforcement), Comm’n Op. at 17 (Aug. 28, 2009). When calculating a proportionate penalty, the Commission considers, *inter alia*, the six factors set forth in *Certain Erasable Programmable Read Only Memories (“EPROMs”)*, Inv. No. 337–TA–276 (Enforcement), Comm’n Op. at 23–24, 26 (July 19, 1991). Accordingly, the Commission is interested in receiving written submissions that address the form of remedy and the amount of civil penalties, if any, that should be ordered.

Written Submissions: The parties to the investigation are requested to file written submissions on the form of remedy and the amount of any civil penalty to be imposed for the violation of the CDOs by the defaulting four Enforcement Respondents. The parties’ submissions should cite all evidence in support of such amounts and shall address the factors set forth in *EPROMs*. The parties’ submissions regarding the *EPROMs* public interest factor should discuss the potential effect of a civil penalty on the public health and welfare. Parties are also requested to provide detailed information regarding sales of infringing products after the effective date of the CDOs relevant to calculating the amount of civil penalties and the total number of days in violation of the CDOs. Specifically, for each day of sale after violation of the CDOs, please provide the following information: (1) identity of the products sold; (2) number of products sold; and (3) value of the products sold. The written submissions must be filed no later than close of business on February 10, 2025. Reply submissions must be filed no later than the close of business on February 17, 2025. No further submissions on these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above pursuant to 19 CFR 210.4(f). Submissions should refer to the investigation number (“Inv. No. 337–TA–1232 Enforcement II”) in a prominent place on the cover page and/or the first page. (*See Handbook for Electronic Filing Procedures*, https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf). Persons with questions regarding filing should contact the Secretary, (202) 205–2000.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. Any non-party wishing to submit comments containing confidential information must serve those comments on the parties to the investigation pursuant to the applicable Administrative Protective Order. A redacted non-confidential version of the document must also be filed with the Commission and served on any parties to the investigation within two business days of any confidential filing. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

The Commission’s vote on this determination took place on January 27, 2026.

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: January 27, 2026.

Lisa Barton,
Secretary to the Commission.
[FR Doc. 2026–01816 Filed 1–29–26; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Air Act

On January 27, 2026, the Department of Justice lodged a proposed amendment to the Consent Decree entered on June 11, 2018 by the United States District Court for the Western District of Louisiana in the lawsuit entitled *United States et al. v. Columbian Chemical Company*, (W.D. La.), Civil Action No. 6:17–cv–01661.

The proposed Consent Decree amendment revises the Consent Decree’s deadlines for the Defendant, Columbian Chemical Company (now known as Birla Carbon U.S.A., Inc.) to install and begin continuously operating certain air pollution control equipment at its carbon black manufacturing facilities in North Bend, Louisiana, and Hickok, Kansas. The proposed Consent Decree amendment also revises the Consent Decree’s deadlines for the Defendant to achieve and continuously maintain certain limits on emissions of sulfur dioxide, nitrogen oxides, and particulate matter from its facilities.

The publication of this notice opens a period for public comment on the proposed Consent Decree amendment. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States et al. v. Columbian Chemical Company* (W.D. La.), D.J. Ref. No. 90–5–2–1–10943. 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:

<i>To submit comments:</i>	<i>Send them to:</i>
By email	pubcomment-ees.enrd@usdoj.gov .
By mail	Assistant Attorney General, U.S. DOJ–ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Any comments submitted in writing may be filed by the United States in whole or in part on the public court docket without notice to the commenter.

During the public comment period, the proposed Consent Decree amendment may be examined and downloaded at this Justice Department website: <http://www.usdoj.gov/enrd/consent-decrees>. If you require assistance accessing the Consent Decree amendment, you may request assistance by email or by mail to the addresses

provided above for submitting comments.

Thomas Carroll,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2026–01813 Filed 1–29–26; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

[OMB Number 1121–0259]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of a Previously Approved Collection; Claims Public Safety Officer Medal of Valor Application

AGENCY: Office of Justice Programs, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Office of Justice Programs, Department of Justice (DOJ), will be 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: Comments are encouraged and will be accepted for 60 days until March 31, 2026.

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 Michelle Martin, U.S. Department of Justice, 999 N. Capitol St NE, Washington DC 20044–0146, at (202) 598–9288 or michelle.a.martin@usdoj.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 Bureau of Justice Statistics, 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.

Abstract: Information collection form for individuals applying for compensation under the Radiation Exposure Compensation Act.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a previously approved collection.

2. *The Title of the Form/Collection:* Public Safety Officer Medal of Valor Application.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* OMB #1121–0259 DOJ Component: Office of Justice Programs.

4. Affected public who will be asked or required to respond, as well as a brief abstract: The information that is being collected is solicited from federal, state, local and tribal public safety agencies, who wish to nominate their personnel to receive the Public Safety Officer Medal of Valor (MOV). This information is provided on a voluntary basis, includes agency and nominee information along with details about the events for which the nominees are to be considered when determining who will be recommended to receive the MOV.

5. *Obligation to Respond:* Voluntary.

6. *Total Estimated Number of Respondents:* Approximately 550 nominations.

7. *Estimated Time per Respondent:* 25 minutes.

8. *Frequency:* Once.

9. *Total Estimated Annual Time Burden—*57.29 hours.

10. *Total Estimated Annual Other Costs Burden—*\$0.

If additional information is required contact: Darwin Arceo, Department Clearance Officer, United States Department of Justice, Justice Management Division, Enterprise Portfolio Management, Two Constitution Square, 145 N Street NE, 4W–218, Washington, DC.

Dated: January 28, 2026.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2026–01906 Filed 1–29–26; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF JUSTICE

[OMB Number 1140–0010]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Title—Application To Transport Interstate or To Temporarily Export Certain NFA Firearms—ATF Form 5320.20

AGENCY: Bureau of Alcohol, Tobacco, Firearms, and Explosives; Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF), will be 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: ATF encourages comments on this information collection. You may submit written comments for 30 days, until midnight on March 2, 2026.

ADDRESSES: Submit written comments and recommendations for this information collection to the following website: www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function and entering either the title of the information collection or the OMB control number: 1140–0010.

FOR FURTHER INFORMATION CONTACT: If you have questions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact: Meghan Tisserand, either by mail at National Firearms Act Division; Division Staff Office; 244 Needy Road; Martinsburg, WV 25405, by email at Meghan.tisserand@atf.gov, or by telephone at 304–616–3219.

SUPPLEMENTARY INFORMATION: . The proposed information collection was previously published in the **Federal Register**, 90 FR 54761, on Friday, November 28, 2025, allowing a 60-day comment period. We encourage written comments and suggestions from the public and affected agencies concerning the proposed information collection. Your comments should address one or more of the following four points:

- Evaluate whether the proposed information collection is necessary to properly perform the identified functions of the Bureau, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the proposed information

collection's burden, including the validity of the methodology and assumptions used;

- Evaluate whether, and if so how, the agency can enhance the quality, utility, and clarity of the information being collected; and
- Minimize the information collection's burden 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 responses to be submitted electronically.

You may view this information collection request at www.reginfo.gov. Follow the instructions to view Department of Justice information collections currently under review by OMB and look for 1140–0010.

DOJ seeks PRA authorization for this information collection for three years. OMB authorization for an ICR cannot be for more than three years without renewal. DOJ notes that information collection requirements submitted to OMB for existing ICRs receive a month-to-month extension while they undergo review.

Overview of This Information Collection

1. *Type of information collection:* Revising a previously approved collection.

2. *Title of the form/collection:* Application to Transport Interstate or to Temporarily Export Certain NFA Firearms.

3. *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* ATF Form 5320.20.

Component: Bureau of Alcohol, Tobacco, Firearms, and Explosives; U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Affected public: federal government; state, local, and tribal governments; individuals or households; private sector for-profit institutions.

Abstract: Persons who wish to transport certain NFA firearms (machine guns, short-barreled rifles, short-barreled shotguns, or destructive devices) out of the state in which they registered the firearm, for certain temporary or permanent domestic purposes or for temporary export, must submit Form 20 to ATF before they may transport the items. 18 U.S.C. 922(a)(4), 27 CFR 478.28.

5. *Obligation to respond:* voluntary and required to obtain or retain benefits.

6. *Total estimated number of respondents:* 12,878 respondents.

7. *Estimated time per respondent:* 0.167 hours.

8. *Frequency:* Once annually.

9. *Total estimated annual time burden:* 2,151 total hours.

10. *Total estimated annual other costs burden:* \$0.

Revisions to This Information Collection

Information Collection (IC) OMB 1140–0010 is being revised to make it electronically fillable, enabling it to be submitted by email. ATF has also made the second copy automatically auto-fill. Additionally, ATF will have included this form on its eForms platform online by the time this ICR completes the renewal process, all of which results in full electronic submission. Other edits to this form include changes to make it easier to read along with a slight title revision to clarify the types of transportation covered. There has also been a decrease in respondents, resulting in a decrease in total annual burden hours, and a consequential decrease in the monetized time value for this information collection request (ICR).

Public Comments

ATF received 53 comments on this information collection. Four commenters supported the proposed changes, noting that electronic submission would reduce the public's time burden. The majority of the remaining comments revolved around respondents' desire to abolish the notification requirement entirely for all lawful owners. Additionally, they stated that although a digital process "is an improvement over paper, the requirement to file Form 5320.20 violates the Second Amendment and the right to travel." One respondent wrote that the AG should acknowledge the unconstitutional nature of the current process and "order the ATF not to enforce the rule, pardon anyone who had been convicted under these rules, and, in lieu of a court ruling, issue a second document signed by the AG authorizing blanket approval for any individual lawfully possessing an NFA item to cross state lines with it 'for all lawful purposes' with no expiration and no form required."

Another comment focused on ways to reduce burden on both the public and agency. The commenter suggested possibly "limiting the ATF Form 20 submission and approval requirement only to scenarios involving the permanent transport of an item across state lines or involving the temporary

export of the item outside of the United States." If the agency determines that it "cannot completely eliminate the Form 20 requirement for interstate transports," the commenter asked that "ATF consider the option of converting the ATF Form 20 submission in these instances (and potentially others) to a notification-only process, eliminating the requirement for owners to wait for approval prior to transportation."

ATF appreciates the feedback from these commenters on the proposed changes. It is helpful to receive feedback, positive or negative, from persons impacted by our processes so we can make them more user-friendly and efficient. In response to the four commenters who voiced their support for offering a digital submission option, we believe the following information will be helpful. In addition to allowing electronic signatures, ATF is also making its NFA forms electronically fillable as the ICRs come up for renewal, and it expects to move to solely electronic forms over the next year. The proposed changes to these forms reflect larger revisions the agency has been making to its NFA processes and other NFA forms.

ATF is not aware of a court that has held that the approval process under 18 U.S.C 922(a)(4) violates the Second Amendment and an individual's right to travel with National Firearms Act firearms. However, ATF is currently reviewing the approval process for NFA firearm transport requests to propose ways to relieve potential administrative burdens in that request process for an individual to travel with a NFA firearm. Among ATF's considerations are options similar to those suggested by the commenters.

If you need additional information, contact: Darwin Arceo, Department Clearance Officer, Enterprise Portfolio Management, Justice Management Division; United States Department of Justice; Two Constitution Square, 145 N Street NE, 4W–218, Washington, DC 20530.

Dated: January 28, 2026.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2026–01858 Filed 1–29–26; 8:45 am]

BILLING CODE 4410-FY-P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts

30-Day Notice for the “Application for International and Domestic Indemnification”; Proposed Collection; Comment Request

ACTION: Notice.

SUMMARY: The National Endowment for the Arts, on behalf of the Federal Council on the Arts and the Humanities, will submit the following public information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995: Application for International Indemnification. Copies of this ICR, with applicable supporting documentation, may be obtained by visiting www.reginfo.gov.

DATES: Written comments must be submitted to the office listed in the address section below within 30 days from the date of this publication in the **Federal Register**.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this Notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection request by selecting “National Endowment for the Arts” under “Currently Under Review;” then check “Only Show ICR for Public Comment” checkbox. Once you have found this information collection request, select “Comment,” and enter or upload your comment and information. Alternatively, comments can be sent to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the National Endowment for the Arts, Office of Management and Budget, Room 10235, Washington, DC 20503, or call (202) 395-7316, within 30 days from the date of this publication in the **Federal Register**.

SUPPLEMENTARY INFORMATION: The Office of Management and Budget (OMB) is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- 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;

- Enhance the quality, utility and clarity of the information to be collected; 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 the electronic submissions of responses.

Agency: National Endowment for the Arts.

Title: Application for International and Domestic Indemnification.

OMB Number: 3135-0094.

Frequency: Renewed every three years.

Affected Public: Nonprofit, tax exempt organizations, and governmental units.

Estimated Number of Respondents: 10 per year (Domestic); 15 per year (International).

Estimated Time per Respondent: 50 hours (Domestic); 55 hours (International).

Estimated Cost per Respondent: \$1,590.

Total Burden Hours: 1,325 hours.

Total Annualized Capital/Startup Costs: 0.

Total Annual Costs (Operating/Maintaining Systems or Purchasing Services): \$270,507.

Description: This application form is used by nonprofit, tax-exempt organizations (primarily museums), and governmental units to apply to the Federal Council on the Arts and the Humanities (through the National Endowment for the Arts) for indemnification of eligible works of art and artifacts, borrowed from lenders: within the United States for domestic exhibition; or abroad for exhibition in the United States, from within the United States when the foreign works of art are integral to the exhibition; or sent from the United States for exhibition abroad. The indemnity agreement is backed by the full faith and credit of the United States. In the event of loss or damage to an indemnified object, the Federal Council on the Arts and the Humanities certifies the validity of the claim and requests payment from Congress. 20 U.S.C. 973 *et seq.* requires such an application and specifies information which must be supplied. This statutory requirement is implemented by regulation at 45 CFR 1160.4.

Dated: January 28, 2026.

Daniel Beattie,

Director, Office of Guidelines & Panel Operations, National Endowment for the Arts.
[FR Doc. 2026-01894 Filed 1-29-26; 8:45 am]

BILLING CODE 7537-01-P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities: Comment Request; National Science Foundation Research Traineeship Program Monitoring System

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 the 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.

DATES: Written comments on this notice must be received by March 31, 2026 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, Randolph Building, 401 Dulany Street, Alexandria, VA 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: National Science Foundation Research Traineeship (NRT) Monitoring System.

OMB Number: 3145-0263.

Expiration Date of Approval: December 31, 2026.

Type of Request: Intent to seek approval to renew an information collection.

Proposed Project: The National Science Foundation’s (NSF’s) Directorate for STEM Education (EDU) administers the NSF Research Traineeship (NRT) program. The NRT program is designed to encourage the development and implementation of bold, new, and potentially

transformative models for STEM graduate education training. The NRT program seeks to ensure that graduate students in research-based master's and doctoral degree programs develop the skills, knowledge, and competencies needed to pursue a range of STEM careers. NRT is dedicated to the effective training of STEM graduate students in high-priority interdisciplinary or convergent research areas through the use of a comprehensive traineeship model that is innovative, evidence-based, and aligned with changing workforce and research needs. In support of national efforts to prepare the next generation of the advanced STEM workforce, the program anticipates publishing a revised notice of funding opportunity in spring 2026 for new research traineeship projects. These new research traineeship awards, alongside existing awards, will continue to use the NRT monitoring system.

Until 2021, NRT awardees provided NSF with information on their activities through periodic research performance progress reports. Beginning in 2021, the NRT monitoring system (also referred to as the NRT reporting system) has replaced these reports with a tailored program monitoring system that uses a web-based data collection system to collect, review, and validate specific data on NRT awards. EDU is committed to ensuring the efficient and effective means for the reporting and analysis of data generated by funded projects within the NRT program.

The NRT monitoring system includes subsets of questions aimed at the different project participants (*i.e.*, Principal Investigators (PIs), and trainees) and allows for data analysis and data report generation by authorized NSF staff. The collection generally includes three categories of descriptive data: (1) Staff and project participants (data that are necessary to determine individual-level treatment and control groups for future third-party study or for internal evaluation); (2) project implementation characteristics (also necessary for future use to identify well-matched comparison groups); and (3) project outputs (necessary to measure baseline for pre- and post-NSF-funding-level impacts). NRT awardees will be required to report data on an annual basis for the life of their award.

Use of the Information: NSF will primarily use the data from this collection for program planning, management, performance and audit purposes to respond to queries from the Congress, the public, NSF's external merit reviewers who serve as advisors,

the NSF's Office of the Inspector General, and as a basis for either internal or third-party evaluations of individual programs. This information is required for effective administration, communication, program and project monitoring and evaluation, and for measuring attainment of NSF's program, project, and strategic goals, and as identified by the President's Accountability in Government Initiative; GPRA, and the NSF's Strategic Plan. The Foundation's Strategic Plan is available at <https://www.nsf.gov/about/performance/strategic-plan>.

Since this collection will primarily be used for accountability and evaluation purposes, a census, rather than sampling design, typically is necessary. At the individual project level, funding can be adjusted based on individual project responses to some of the surveys. Some data collected under this collection will serve as baseline data for separate research and evaluation studies.

NSF-funded contract or grantee researchers and internal or external evaluators in part may identify control, comparison, or treatment groups for NSF's education and training portfolio using some of the descriptive data gathered through this collection to conduct well-designed, rigorous research and portfolio evaluation studies.

Burden on the Public: Estimated at 82 hours per award for 120 awards for a total of 9,840 hours (per year).

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.

Dated: January 27, 2026.

Suzanne H. Plimpton,
Reports Clearance Officer, National Science Foundation.

[FR Doc. 2026-01827 Filed 1-29-26; 8:45 am]

BILLING CODE 7555-01-P

NUCLEAR REGULATORY COMMISSION

[NRC-2025-2062]

State of Wyoming: NRC Staff Assessment of a Proposed Amendment to the Agreement Between the Nuclear Regulatory Commission and the State of Wyoming

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed amendment to state agreement; request for comment.

SUMMARY: As required by Section 274e. of the Atomic Energy Act of 1954, as amended (AEA), the U.S. Nuclear Regulatory Commission (NRC or Commission) is publishing the proposed Agreement for public comment (Appendix A). The NRC is also publishing the summary of a draft assessment by the NRC staff of the State of Wyoming's regulatory source material program. Comments are requested on the proposed amendment to the Agreement and its effect on public health and safety. Comments are also requested on the draft staff assessment, the adequacy of the State of Wyoming's source material program, and the adequacy of the staffing of the State's program, as discussed in this document.

DATES: Submit comments by March 2, 2026. 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; however, the NRC encourages electronic comment submission through the Federal Rulemaking website:

- **Federal Rulemaking Website:** Go to <https://www.regulations.gov> and search for Docket ID NRC-2025-2062. Address questions about Docket IDs in *Regulations.gov* to Bridget Curran; telephone: 301-415-1003; email: Bridget.Curran@nrc.gov. For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION**

CONTACT section of this document.

- **Mail Comments to:** Office of Administration, Mail Stop: TWFN-5-A85, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Program Management, Announcements and Editing Staff.

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

FOR FURTHER INFORMATION CONTACT: Allyce Bolger, telephone: 301-415-

0855; email: Allyce.Bolger@nrc.gov and Huda Akhavannik, telephone: 301-415-5253; email: Huda.Akhavannik@nrc.gov. Both are staff of the Office of Nuclear Material Safety and Safeguards at the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC-2025-2062 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-2025-2062.
- **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 ADAMS Public Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, at 301-415-4737, or by email to PDR.Resource@nrc.gov. For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the "Availability of Documents" section.
- **NRC's PDR:** The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1-800-397-4209 or 301-415-4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal Rulemaking website (<https://www.regulations.gov>). Please include Docket ID NRC-2025-2062 in your comment submission.

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

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

SUPPLEMENTARY INFORMATION: By letter dated August 5, 2025, Governor Mark Gordon of the State of Wyoming requested that the U.S. Nuclear Regulatory Commission (NRC or Commission) amend its Agreement with the State of Wyoming as authorized by Section 274b. of the Atomic Energy Act of 1954, as amended (AEA). Under the proposed amendment to the Agreement, the Commission would discontinue, and the State of Wyoming would assume, regulatory authority over source material recovered from any mineral resources processed primarily for purposes other than its uranium or thorium content. Since 2018, Wyoming's existing Agreement allows the State to assume regulatory authority over byproduct materials as defined in Section 11e.(2) of the AEA, and source materials involved in the extraction or concentration of uranium or thorium in source material and ores at milling facilities.

II. Additional Information on Agreements Entered Under Section 274 of the AEA

Under the proposed amended Agreement, the NRC would discontinue its authority over source material recovered from any mineral resources processed primarily for purposes other than its uranium or thorium content and would transfer its regulatory authority to the State of Wyoming. There is currently one NRC licensee that would be transferred to the State of Wyoming under this proposed amended Agreement. The NRC periodically reviews the performance of the Agreement States to assure compliance with the provisions of Section 274.

Section 274e. of the AEA requires that the terms of the proposed Agreement be published in the **Federal Register** for public comment once each week for four consecutive weeks. This document is being published in fulfillment of that requirement.

III. Proposed Amended Agreement With the State of Wyoming

Background

(a) Section 274b. of the AEA provides the mechanism for a State to assume regulatory authority from the NRC over certain radioactive materials and activities that involve use of these materials. The radioactive materials, sometimes referred to as "Agreement materials," are byproduct materials as defined in Sections 11e.(1), 11e.(2), 11e.(3), and 11e.(4) of the AEA; source material as defined in Section 11z. of the AEA; and special nuclear material as defined in Section 11aa. of the AEA, restricted to quantities not sufficient to form a critical mass.

The State of Wyoming has requested authority over a subcategory of source material in this amendment to its Agreement, specifically:

(a) source material recovered from any mineral resources processed primarily for purposes other than its uranium or thorium content.

(b) The proposed amended Agreement contains articles that:

- (i) Specify the materials and activities over which authority was transferred in 2018 and in this amendment;
- (ii) Specify the materials and activities over which the Commission will retain regulatory authority;
- (iii) Continue the authority of the Commission to safeguard special nuclear material, protect restricted data, and protect common defense and security;
- (iv) Commit the State of Wyoming and the NRC to exchange information as necessary to maintain coordinated and compatible programs;
- (v) Provide for the reciprocal recognition of licenses;
- (vi) Provide for the suspension or termination of the amended Agreement; and
- (vii) Specify the effective date of the proposed amended Agreement.

The Commission reserves the option to modify the terms of the proposed amendment to the Agreement in response to comments, to correct errors, and to make editorial changes. The final text of the proposed amended Agreement, with the effective date, will be published after the amended Agreement is approved by the Commission and signed by the NRC Chairman and the Governor of Wyoming.

(c) The regulatory program is authorized by law under the Wyoming Environmental Quality Act, Wyoming Statutes §§ 35-11-2001 through 2004, §§ 35-11-101 *et seq.*, and §§ 16-3-101 *et seq.*, which provides the Governor with the authority to enter into an Agreement with the Commission. The State of Wyoming law contains

provisions for the orderly transfer of regulatory authority over affected licenses from the NRC to the State. In a letter dated August 5, 2025, Governor Gordon certified that the State of Wyoming has a program for the control of radiation hazards that is adequate to protect public health and safety within the State of Wyoming for the materials and activities specified in the proposed amended Agreement, and that the State desires to assume regulatory responsibility for these materials and activities. After the effective date of the amended Agreement, the license issued by the NRC would continue in effect as a State of Wyoming license until the license expires or is replaced by State-issued license.

(d) The draft staff assessment finds that the Wyoming Department of Environmental Quality's Source Material Program is adequate to protect public health and safety and is compatible with the NRC's regulatory program for the regulation of source material recovered from any mineral resources processed primarily for purposes other than its uranium or thorium content.

Summary of the Draft NRC Staff Assessment of the State of Wyoming's Program for the Regulation of Source Material

The NRC staff has examined the State of Wyoming's request for an amended Agreement with respect to the ability of the State's radiation control program to regulate source material recovered from any mineral resources processed primarily for purposes other than its uranium or thorium content. The examination was based on the Commission's Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement," (46 FR 7540, January 23, 1981, as amended by Policy Statements published at 46 FR 36969, July 16, 1981, and at 48 FR 33376, July 21, 1983) (Policy Statement), and the Office of Nuclear Material Safety and Safeguards Procedure SA-700, "Processing an Agreement" and its associated Handbook. The Policy Statement has 28 criteria that serve as the basis for the NRC staff's assessment of the State of Wyoming's request for an amended Agreement. The following section will reference the appropriate criteria numbers from the Policy Statement that apply to each section. Criteria 9b, 15, and 22 do not apply to the proposed Agreement since Wyoming's authority will be limited to the regulation of uranium recovery facilities and source

material recovered from any mineral resources processed primarily for purposes other than its uranium or thorium content.

(a) *Organization and Personnel.* The NRC staff reviewed these areas under Criteria 1, 2, 20, and 24 in the draft staff assessment. The State of Wyoming's proposed amended Agreement program for the regulation of source material is called the "Source Material Program," and will be located within the Land Quality Division in the Department of Environmental Quality along with the existing Agreement program that regulates uranium recovery facilities.

The educational requirements for the Source Material Program staff are specified in the State of Wyoming's personnel position descriptions and meet the NRC criteria with respect to formal education or combined education and experience requirements. All current staff members meet the requirements of a bachelor's degree in the physical, life science, or engineering; or an equivalent combination of education and experience has been substituted for the degree. All have training and work experience in radiation protection. Supervisory level staff each have at least 20 years of working experience in radiation protection.

The State of Wyoming performed an analysis of the expected workload under the proposed amended Agreement. Based on the NRC staff review of the State of Wyoming's analysis, the State has an adequate number of staff to regulate source material under the terms of the proposed amended Agreement. The State of Wyoming will employ the equivalent of 3 full-time equivalent professional and technical staff to support the Source Material Program.

The State of Wyoming has indicated that the Source Material Program has an adequate number of trained and qualified staff in place. The State of Wyoming has developed qualification procedures for license reviewers and inspectors that are similar to the NRC's procedures. The Source Material Program staff has accompanied the NRC staff on inspections of the NRC licensee in Wyoming. The Source Material Program staff is also actively supplementing its experience through meetings, discussions, and through self-study, in-house training, and formal training.

Overall, the NRC staff concluded that the Source Material Program staff identified by the State of Wyoming to participate in the Agreement program has sufficient knowledge and experience in radiation protection, the use of radioactive materials, the

standards for the evaluation of applications for licensing, and the techniques of inspecting licensed users of source materials.

(b) *Legislation and Regulations.* The NRC staff reviewed these areas under Criteria 1–9a, 10–14, 17, 19, 21, and 23–28 in the draft staff assessment. Wyoming Statutes §§ 35–11–2001 provide the authority to enter into the amended Agreement and establish the Wyoming Department of Environmental Quality as the lead agency for the State's Source Material Program. The Department has the requisite authority to promulgate regulations under the Wyoming Statutes §§ 35–11–2002(b) for protection against radiation. Wyoming Statutes §§ 35–11–2003 and 2004 provide the Source Material Program the authority to issue licenses and orders; conduct inspections; and enforce compliance with regulations, license conditions, and orders. Wyoming Statute § 35–11–2003(d) requires licensees to provide access to inspectors.

The NRC staff verified that the State of Wyoming adopted by reference the relevant NRC regulations in parts 19, 20, 40, 61, 71, and 150 of title 10 of the *Code of Federal Regulations* (10 CFR) into the Wyoming Source Material Rules and Regulations Chapters 1–9. The State of Wyoming is currently revising its source material regulations to address NRC comments. The revised regulations, expected to be finalized by the end of 2025, were reviewed by NRC staff and address all NRC comments. Therefore, the State of Wyoming will adopt an adequate and compatible set of radiation protection regulations that apply to source material recovered from any mineral resources processed primarily for purposes other than its uranium or thorium content. The NRC staff also verified that the State of Wyoming will not attempt to enforce regulatory matters reserved to the Commission.

(c) *Storage and Disposal.* The NRC staff reviewed these areas under Criteria 8, 9a, and 11 in the draft staff assessment. The State of Wyoming has adopted NRC compatible requirements for the handling and storage of radioactive material, including regulations equivalent to the applicable standards contained in 10 CFR part 20, which address the general requirements for waste disposal, and 10 CFR part 61, which addresses waste classification and form. These regulations are applicable to all licensees covered under this proposed amended Agreement.

(d) *Transportation of Radioactive Material.* The NRC staff reviewed this

area under Criteria 10 in the draft staff assessment. The State of Wyoming has adopted compatible regulations to the NRC regulations in 10 CFR part 71. Part 71 contains the requirements licensees must follow when preparing packages containing source material for transport. Part 71 also contains requirements related to the licensing of packaging for use in transporting source material.

(e) *Recordkeeping and Incident Reporting.* The NRC staff reviewed this area under Criteria 1 and 11 in the draft staff assessment. The State of Wyoming has adopted compatible regulations to the sections of the NRC regulations that specify requirements for licensees to keep records and to report incidents or accidents involving the State's regulated Agreement materials specified in the proposed amended Agreement.

(f) *Evaluation of License Applications.* The NRC staff reviewed this area under Criteria 1, 7, 8, 9a, 13, 14, 20, 23, and 25 in the draft staff assessment. The State of Wyoming has adopted compatible regulations to the NRC regulations that specify the requirements to obtain a license to possess or use source material. The State of Wyoming has also developed licensing procedures and adopted NRC licensing guides for specific uses of source material for use by the program staff when evaluating license applications.

(g) *Inspections and Enforcement.* The NRC staff reviewed these areas under Criteria 1, 16, 18, 19, and 23 in the draft staff assessment. The State of Wyoming has adopted a schedule providing for the inspection of licensees as frequently as, or more frequently than, the inspection schedule used by the NRC. The State of Wyoming's source material program has adopted procedures for the conduct of inspections, reporting of inspection findings, and reporting inspection results to the licensees. Additionally, the State of Wyoming has also adopted procedures for the enforcement of regulatory requirements.

(h) *Regulatory Administration.* The NRC staff reviewed this area under Criterion 23 in the draft staff assessment. The State of Wyoming is bound by requirements specified in its State law for rulemaking, issuing licenses, and taking enforcement actions. The State of Wyoming has also adopted administrative procedures to ensure fair and impartial treatment of license applicants. The State of Wyoming law prescribes standards of ethical conduct for State employees.

(i) *Cooperation With Other Agencies.* The NRC staff reviewed this area under Criteria 25, 26, and 27 in the draft staff assessment. The State of Wyoming law

provides for the recognition of existing NRC and Agreement State licenses and the State has a process in place for the transition of the active NRC license. Upon the effective date of the amended Agreement, the active NRC license for materials covered by the amended Agreement will be recognized as a Wyoming Department of Environmental Quality license.

The State of Wyoming also provides for "timely renewal." This provision affords the continuance of licenses for which an application for renewal has been filed more than 30 days prior to the date of expiration of the license.

The State of Wyoming regulations in the Source Material Rules and Regulations Chapters 1–9 provide exemptions from the State's requirements for the NRC, and the U.S. Department of Energy contractors or subcontractors. The proposed amended Agreement commits the State of Wyoming to use its best efforts to cooperate with the NRC and the other Agreement States in the formulation of standards and regulatory programs for the protection against hazards of radiation, and to assure that the State's program will continue to be compatible with the Commission's program for the regulation of Agreement materials. The proposed amended Agreement specifies the desirability of reciprocal recognition of licenses and commits the Commission and the State of Wyoming to use their best efforts to accord such reciprocity. Consistent with NRC requirements, the State of Wyoming would be able to recognize the licenses of other jurisdictions by general license, as appropriate.

Staff Conclusion

Section 274d. of the AEA provides that the Commission shall enter into an Agreement under Section 274b. with any State if:

(a) The Governor of that State certifies that the State has a program for the control of radiation hazards adequate to protect the public health and safety with respect to the materials within the State covered by the proposed Agreement, and that the State desires to assume regulatory responsibility for such materials; and

(b) The Commission finds that the State program is in accordance with the requirements of Subsection 274o. and in all other respects compatible with the Commission's program for the regulation of such materials and is adequate to protect public health and safety with respect to the materials covered by the proposed Agreement.

The NRC staff has reviewed the proposed amended Agreement, the

certification of Wyoming Governor Gordon, and the supporting information provided by the Source Material Program of the Wyoming Department of Environmental Quality. Based upon this review, the NRC staff concludes that the State of Wyoming source material program satisfies the Section 274d. criteria as well as the criteria in the Commission's Policy Statement "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement." The NRC staff also concludes that the proposed State of Wyoming source material program to regulate source material recovered from any mineral resources processed primarily for purposes other than its uranium or thorium content, as comprised of statutes, regulations, procedures, and staffing, is compatible with the Commission's program and is adequate to protect the public health and safety with respect to the materials covered by the proposed amended Agreement. Therefore, the proposed amended Agreement meets the requirements of Section 274 of the AEA.

IV. Executive Order Reviews

Executive Order (E.O.) 12866

The Office of Information and Regulatory Affairs has determined that this proposed amendment to Wyoming's Agreement is not a significant regulatory action under E.O. 12866.

E.O. 13132

This action does not have federalism implications, as defined in Executive Order 13132. It will not significantly limit the rights, roles, and responsibilities of State or local governments.

E.O. 14300

On May 23, 2025, President Donald J. Trump signed E.O. 14300, "Ordering the Reform of the Nuclear Regulatory Commission." Section 5, "Reforming and Modernizing the NRC's Regulations," requires the NRC to undertake a review and wholesale revision of its regulations and guidance documents as guided by the policies set forth in section 2 of the E.O. The NRC is currently in the process of implementing the direction in E.O. 14300. When the NRC finalizes its rules during the implementation of E.O. 14300, the Agreement States will need to update their own regulations, as necessary, to maintain compatibility with the NRC's program within a specific timeframe.

V. Availability of Documents

The documents identified in the following table are available to

interested persons through one or more of the following methods, as indicated.

Document description	ADAMS accession No.
Wyoming Final Application to Amend Agreement, dated August 2025	ML25227A230 (Package).
Wyoming Final Amended Application Supplemental Information	ML25267A041 (Package).
Letter from Governor Mark Gordon, Wyoming, to Chairman Wright requesting amended agreement be established between the NRC and State of Wyoming, dated August 5, 2025.	ML25227A232.
Staff Requirements Memorandum for SECY-23-0075 "Wyoming's Proposal to Amend the Existing Agreement to Regulate the Processing of Source Material to Extract Mineral Resources Other Than the Uranium or Thorium Content," dated September 19, 2023.	ML23262B163.
SECY-23-075 "Wyoming's Proposal to Amend the Existing Agreement to Regulate the Processing of Source Material to Extract Mineral Resources Other Than the Uranium or Thorium Content," dated August 24, 2023.	ML23172A212.
Draft Assessment of the Proposed Wyoming Program	ML25237A057.
State Agreement (SA) 700 "Processing an Agreement," dated June 15, 2022	ML22138A414.
SA-700 Handbook for Processing an Agreement Procedure, dated June 17, 2022	ML22140A396.

Dated: January 28, 2026.

For the Nuclear Regulatory Commission.

Dafna Silberfeld,

Acting Director, Division of Materials Safety, Security, State, and Tribal Programs, Office of Nuclear Material Safety and Safeguards.

Appendix A

An Amended Agreement Between the United States Nuclear Regulatory Commission and the State of Wyoming for the Discontinuance of Certain Commission Regulatory Authority and Responsibility Within the State Pursuant to Section 274 of the Atomic Energy Act of 1954, as Amended

Whereas, The United States Nuclear Regulatory Commission (hereinafter referred to as "the Commission") is authorized under Section 274 of the Atomic Energy Act of 1954, as amended, 42 U.S.C. 2011 *et seq.* (hereinafter referred to as "the Act"), to enter into an agreement with the Governor of the State of Wyoming (hereinafter referred to as "the State") providing for discontinuance of the regulatory authority of the Commission within the State under Chapters 6, 7, and 8, and Section 161 of the Act with respect to byproduct material as defined in Section 11e.(2) of the Act, source material involved in the extraction or concentration of uranium or thorium in source material or ores at milling facilities, and source material recovered from any mineral resources processed primarily for purposes other than its uranium or thorium content; and,

Whereas, The Governor of the State of Wyoming is authorized under Wyoming Statute Section 35-11-2001 to enter into this Agreement with the Commission; and,

Whereas, The Commission entered into an Agreement with the State of Wyoming under Section 274 of the Act, which became effective on September 30, 2018 (hereinafter referred to as the "September 30, 2018 Agreement"), and provided for discontinuance of the regulatory authority of the Commission within the State under Chapters 6, 7, and 8, and Section 161 of the Act with respect to byproduct materials as defined in Section 11e.(2) of the Act, and source materials involved in the extraction or concentration of uranium or thorium in source material and ores at milling facilities; and,

Whereas, The Governor of the State of Wyoming submitted a letter of intent on February 21, 2023, to the Commission to pursue this amended Agreement which would allow the State to assume regulatory authority for source material recovered from any mineral resources processed primarily for purposes other than its uranium or thorium content in addition to the materials covered under the September 30, 2018 Agreement; and,

Whereas, The Governor of the State of Wyoming certified on August 5, 2025, that the State has a program for the control of radiation hazards that is also adequate to protect public health and safety with respect to the materials within the State covered by this amended Agreement and that the State desires to assume regulatory responsibility for such materials; and,

Whereas, The Commission found on [date], that the program of the State of Wyoming for the regulation of the materials covered by this amended Agreement is compatible with the Commission's program for the regulation of such materials and is adequate to protect the public health and safety; and,

Whereas, The State of Wyoming and the Commission recognize the desirability and importance of cooperation between the Commission and the State in the formulation of standards for protection against hazards of radiation and in assuring that State and Commission programs for protection against hazards of radiation will be coordinated and compatible; and,

Whereas, The Commission and the State of Wyoming recognize the desirability of the reciprocal recognition of licenses, and of the granting of limited exemptions from licensing of those materials subject to this Agreement; and,

Whereas, This Agreement is entered into pursuant to the provisions of the Act;

Now, therefore, it is hereby agreed between the Commission and the Governor of the State of Wyoming acting on behalf of the State that this amended Agreement supersedes the September 30, 2018, Agreement as follows:

Article I

Subject to the exceptions provided in Articles II, IV, and V, the Commission shall discontinue, as of the effective date of this

Agreement, the regulatory authority of the Commission in the State under Chapters 6, 7, and 8, and Section 161 of the Act with respect to the following materials:

A. Byproduct material as defined in Section 11e.(2) of the Act;

B. Source material involved in the extraction or concentration of uranium or thorium in source material or ores at uranium or thorium milling facilities (hereinafter referred to as "source material associated with milling activities"); and

C. Source material recovered from any mineral resources processed primarily for purposes other than obtaining the source material content.

Article II

A. This Agreement does not provide for the discontinuance of any authority, and the Commission shall retain authority and responsibility, with respect to:

1. Byproduct material as defined in Section 11e.(1) of the Act;
2. Byproduct material as defined in Section 11e.(3) of the Act;
3. Byproduct material as defined in Section 11e.(4) of the Act;
4. Source material except for source material as defined in Article I.B. and I.C. of this Agreement;

5. Special nuclear material;

6. The regulation of the land disposal of byproduct, source, or special nuclear material received from other persons, excluding 11e.(2) byproduct material or source material described in Article I.A. and B. of this Agreement;

7. The evaluation of radiation safety information on sealed sources or devices containing byproduct, source, or special nuclear material and the registration of the sealed sources or devices for distribution, as provided for in regulations or orders of the Commission;

8. The regulation of the construction, operation, and decommissioning of any production or utilization facility or any uranium enrichment facility;

9. The regulation of the export from or import into the United States of byproduct, source, or special nuclear material, or of any production or utilization facility;

10. The regulation of the disposal into the ocean or sea of byproduct, source, or special

nuclear material waste as defined in regulations or orders of the Commission;

11. The regulation of the disposal of such other byproduct, source, or special nuclear material as the Commission determines by regulation or order should, because of the hazards or potential hazards thereof, not to be so disposed without a license from the Commission;

12. The regulation of activities not exempt from Commission regulation as stated in 10 CFR part 150;

13. The regulation of laboratory facilities that are not located at facilities licensed under the authority relinquished under Article I.A. and B. of this Agreement; and,

14. Notwithstanding this Agreement, the Commission shall retain regulatory authority over the American Nuclear Corporation license (License No. SUA-667; Docket No. 040-04492).

B. Notwithstanding this Agreement, the Commission retains the following authorities pertaining to byproduct material as defined in Section 11e.(2) of the Act:

1. Prior to the termination of a State license for such byproduct material, or for any activity that results in the production of such material, the Commission shall have made a determination that all applicable standards and requirements pertaining to such material have been met.

2. The Commission reserves the authority to establish minimum standards governing reclamation, long-term surveillance or maintenance, and ownership of such byproduct material and of land used as its disposal site for such material. Such reserved authority includes:

a. The authority to establish terms and conditions as the Commission determines necessary to assure that, prior to termination of any license for such byproduct material, or for any activity that results in the production of such material, the licensee shall comply with decontamination, decommissioning, and reclamation standards prescribed by the Commission and with ownership requirements for such material and its disposal site;

b. The authority to require that prior to termination of any license for such byproduct material or for any activity that results in the production of such material, title to such byproduct material and its disposal site be transferred to the United States or the State at the option of the State (provided such option is exercised prior to termination of the license);

c. The authority to permit use of the surface or subsurface estates, or both, of the land transferred to the United States or a State pursuant to paragraph 2.b. in this section in a manner consistent with the provisions of the Uranium Mill Tailings Radiation Control Act of 1978, provided that the Commission determines that such use would not endanger public health, safety, welfare, or the environment;

d. The authority to require, in the case of a license for any activity that produces such byproduct material (which license was in effect on November 8, 1981), transfer of land and material pursuant to paragraph 2.b. in this section taking into consideration the status of such material and land and interests

therein and the ability of the licensee to transfer title and custody thereof to the United States or a State;

e. The authority to require the Secretary of the United States Department of Energy, other Federal agency, or State, whichever has custody of such byproduct material and its disposal site, to undertake such monitoring, maintenance, and emergency measures as are necessary to protect public health and safety and other actions as the Commission deems necessary; and,

f. The authority to enter into arrangements as may be appropriate to assure Federal long-term surveillance or maintenance of such byproduct material and its disposal site on land held in trust by the United States for any Indian Tribe or land owned by an Indian Tribe and subject to a restriction against alienation imposed by the United States.

Article III

With the exception of those activities identified in Article II, A.8 through A.11, this Agreement may be amended, upon application by the State and approval by the Commission to include one or more of the additional activities specified in Article II, A.1 through A.7, whereby the State may then exert regulatory authority and responsibility with respect to those activities.

Article IV

Notwithstanding this Agreement, the Commission may from time to time by rule, regulation, or order, require that the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct, source, or special nuclear material shall not transfer possession or control of such product except pursuant to a license or an exemption for licensing issued by the Commission.

Article V

This Agreement shall not affect the authority of the Commission under Subsection 161b. or 161i. of the Act to issue rules, regulations, or orders to promote the common defense and security, to protect restricted data, or to guard against the loss or diversion of special nuclear material.

Article VI

The Commission will cooperate with the State and other Agreement States in the formulation of standards and regulatory programs of the State and the Commission for: (a) protection against hazards of radiation; and (b) to assure that Commission and State programs for protection against the hazards of radiation will be coordinated and compatible.

The State agrees to cooperate with the Commission and other Agreement States in the formulation of standards and regulatory programs of the State and the Commission for: (a) protection against the hazards of radiation; and (b) to assure that the State's program will continue to be compatible with the program of the Commission for the regulation of materials covered by this Agreement.

The State and the Commission agree to keep each other informed of proposed changes in their respective rules and regulations and to provide each other with

the opportunity for early and substantive contribution to the proposed changes.

The State and the Commission agree to keep each other informed of events, accidents, and licensee performance that may have generic implication or otherwise be of regulatory interest.

Article VII

The Commission and the State agree that it is desirable to provide reciprocal recognition of licenses for the materials listed in Article I licensed by the other party or by any other Agreement State.

Accordingly, the Commission and the State agree to develop appropriate rules, regulations, and procedures by which reciprocity will be accorded.

Article VIII

The Commission, upon its own initiative after reasonable notice and opportunity for hearing to the State or upon request of the Governor of Wyoming, may terminate or suspend all or part of this Agreement and reassert the licensing and regulatory authority vested in it under the Act if the Commission finds that (1) such termination or suspension is required to protect the public health and safety, or (2) the State has not complied with one or more of the requirements of Section 274 of the Act. Pursuant to Section 274j. of the Act, the Commission may, after notifying the Governor, temporarily suspend all or part of this Agreement without notice or hearing if, in the judgment of the Commission, an emergency situation exists with respect to any material covered by this Agreement creating danger which requires immediate action to protect public health and safety of persons either within or outside the State, and the State has failed to take steps necessary to contain or eliminate the cause of the danger within a reasonable time after the situation arose. The Commission shall periodically review actions taken by the State under this Agreement to ensure compliance with Section 274 of the Act, which requires a State program to be adequate to protect the public health and safety with respect to the materials covered by this Agreement and to be compatible with the Commission's program.

Article IX

In the licensing and regulation of byproduct material as defined in Section 11e.(2) of the Act, or of any activity that results in production of such material, the State shall comply with the provisions of Section 274o. of the Act, if in such licensing and regulation, the State requires financial surety arrangements for reclamation or long-term surveillance and maintenance of such material.

The total amount of funds the State collects for such purposes shall be transferred to the United States if custody of such material and its disposal site is transferred to the United States upon termination of the State license for such material or any activity that results in the production of such material. Such funds include, but are not limited to, sums collected for long-term surveillance or maintenance. Such funds do not, however, include monies held as surety where no

default has occurred and the reclamation or other bonded activity has been performed; and, such surety or other financial requirements must be sufficient to ensure compliance with those standards established by the Commission pertaining to bonds, sureties, and financial arrangements to ensure adequate reclamation and long-term management of such byproduct material and its disposal site.

Article X

This Agreement shall supersede the September 30, 2018 Agreement and become effective on [date], and shall remain in effect unless and until such time as it is terminated pursuant to Article VIII.

Done at [City, State], in triplicate, this [date] day of [month], [year].

For the United States Nuclear Regulatory Commission.

Ho K. Nieh,
Chairman for the U.S. Nuclear Regulatory Commission.

For the State of Wyoming.

Mark Gordon,
Governor.

[FR Doc. 2026-01850 Filed 1-29-26; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[NRC-2024-0191]

Information Collection: NRC Insider Threat Program for Licensees and Other Requiring Access to Classified Information

AGENCY: The U.S. 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 Insider Threat Program for Licensees and Other Requiring Access to Classified Information.”

DATES: Submit comments by March 2, 2026. 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: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to <https://www.reginfo.gov/public/do/PRAMain>. Find this

particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT:

Heather Dempsey, Acting NRC Clearance Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-0856; email: Infocollects.Resource@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC-2024-0191 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-2024-0191.

- **NRC’s Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1-800-397-4209, at 301-415-4737, or by email to PDR.Resource@nrc.gov. A copy of the collection of information and related instructions may be obtained without charge by accessing ADAMS Accession Nos. ML25013A287 and ML25013A290. The supporting statement is available in ADAMS under Accession No. ML25224A258.

- **NRC’s PDR:** The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1-800-397-4209 or 301-415-4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

- **NRC’s Clearance Officer:** A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC’s Acting Clearance Officer, Heather Dempsey, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-0856; email: Infocollects.Resource@nrc.gov.

B. Submitting Comments

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function.

The 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 Insider Threat Program for Licensees and Other Requiring Access to Classified Information.” 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 June 9, 2025, 90 FR 24303.

1. **The title of the information collection:** NRC Insider Threat Program for Licensees and Other Requiring Access to Classified Information.

2. **OMB approval number:** 3150-0251.

3. **Type of submission:** Reinstatement.

4. **The form number, if applicable:** Not applicable.

5. **How often the collection is required or requested:** Annually or as events occur.

6. **Who will be required or asked to respond:** All licensees or stakeholders

who have been granted access to classified information under part 95 of title 10 of the *Code of Federal Regulations* “Facility Security Clearance and Safeguarding of National Security Information and Restricted Data.”

7. *The estimated number of annual responses:* 72.

8. *The estimated number of annual respondents:* 19.

9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 3,189.5 hours (2,272.5 reporting + 917 recordkeeping).

10. *Abstract:* The NRC-regulated facilities and their contractors who are authorized to access and possess classified matter are required to provide information and maintain records to demonstrate they have established and are maintaining an Insider Threat Program to identify and protect classified information against a potential insider threat.

Dated: January 28, 2026.

For the Nuclear Regulatory Commission.

Kristen Benney,

NRC’s Acting Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2026–01857 Filed 1–29–26; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2026–152; K2026–152]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission’s consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* February 4, 2026.

ADDRESSES: Submit comments electronically via the Commission’s Filing Online system at <https://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:

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II. Public Proceeding(s)

III. Summary Proceeding(s)

I. Introduction

Pursuant to 39 CFR 3041.405, the Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to Competitive negotiated service agreement(s). The request(s) may propose the addition of a negotiated service agreement from the Competitive product list or the modification of an existing product currently appearing on the Competitive product list.

The public portions of the Postal Service’s request(s) can be accessed via the Commission’s website (<http://www.prc.gov>). Non-public portions of the Postal Service’s request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.¹

Section II identifies the docket number(s) associated with each Postal Service request, if any, that will be reviewed in a public proceeding as defined by 39 CFR 3010.101(p), the title of each such request, the request’s acceptance date, and the authority cited by the Postal Service for each request. For each such request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 and 39 CFR 3000.114 (Public Representative). Section II also establishes comment deadline(s) pertaining to each such request.

The Commission invites comments on whether the Postal Service’s request(s) identified in Section II, if any, are consistent with the policies of title 39. Applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3041. Comment deadline(s) for each such request, if any, appear in Section II.

Section III identifies the docket number(s) associated with each Postal Service request, if any, to add a standardized distinct product to the Competitive product list or to amend a standardized distinct product, the title of each such request, the request’s acceptance date, and the authority cited by the Postal Service for each request. Standardized distinct products are negotiated service agreements that are variations of one or more Competitive products, and for which financial models, minimum rates, and classification criteria have undergone advance Commission review. *See* 39

¹ See Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

CFR 3041.110(n); 39 CFR 3041.205(a). Such requests are reviewed in summary proceedings pursuant to 39 CFR 3041.325(c)(2) and 39 CFR 3041.505(f)(1). Pursuant to 39 CFR 3041.405(c)–(d), the Commission does not appoint a Public Representative or request public comment in proceedings to review such requests.

II. Public Proceeding(s)

1. *Docket No(s):* MC2026–152 and K2026–152; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 1480 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* January 27, 2026; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Kenneth Moeller; *Comments Due:* February 4, 2026.

III. Summary Proceeding(s)

None. *See* Section II for public proceedings.

This Notice will be published in the **Federal Register**.

Parvaneh Higareda,

Alternate Federal Register Liaison.

[FR Doc. 2026–01851 Filed 1–29–26; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–104695; File No. SR–FINRA–2026–002]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing of a Proposed Rule Change To Amend FINRA Rules 5110 (Corporate Financing Rule—Underwriting Terms and Arrangements) and 5123 (Private Placements of Securities)

January 27, 2026.

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 January 22, 2026, the Financial Industry Regulatory Authority, Inc. (“FINRA”) 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 FINRA. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to amend FINRA Rules 5110 (Corporate Financing Rule—Underwriting Terms and Arrangements) and 5123 (Private Placements of Securities). The proposed amendments to Rule 5110 would improve and clarify the valuation method for securities considered underwriting compensation, add new exclusions from underwriting compensation that codify exemptions FINRA staff has issued, and include minor changes to improve the operation of the rule. The proposed amendments to Rule 5123 would expand available exemptions to include offerings sold to investors meeting the categories of accredited investor for certain family offices and certain entities with assets under management in excess of \$5,000,000, consistent with the Commission's treatment of those categories.

The text of the proposed rule change is available on FINRA's website at <http://www.finra.org> and at the principal office of FINRA.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA 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. FINRA 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

The ability of small and large businesses to raise capital efficiently is critical to job creation and economic growth. Rule 5110 has played an important role in the capital raising process by prohibiting unfair underwriting terms and arrangements in connection with the public offering of securities. Moreover, Rule 5110 continues to be important to promoting investor protection and market integrity through effective and efficient regulation that facilitates vibrant capital markets.

Rule 5110 requires a member that participates in a public offering to file

documents and information with FINRA about the underwriting terms and arrangements.³ FINRA's Corporate Financing Department ("Department") reviews this information prior to the commencement of the offering to determine whether the underwriting compensation and other terms and arrangements meet the requirements of the applicable FINRA rules.⁴

The unregistered offering market also is an important source of capital for American businesses, including small and midsize companies. Rule 5123 plays a critical role in providing information that assists FINRA in the identification of potential trends and rule violations in the private placement market.

In general, Rule 5123 requires members to file with FINRA any private placement memorandum, term sheet or other offering document, and any retail communication that promotes or recommends a private placement, including any material amended versions thereof, used in connection with a private placement of securities within 15 calendar days of the date of first sale, unless the member can rely on an applicable exemption from the rule. Rule 5123 contains an exemption from filing for offerings sold to certain types of sophisticated institutional investors that qualify as "accredited investors" under Rule 501 of the Securities Act of 1933 ("Securities Act").⁵ These

³ The following are examples of public offerings that are routinely filed: (1) initial public offerings ("IPOs"); (2) follow-on offerings; (3) shelf offerings; (4) rights offerings; (5) offerings by direct participation programs as defined in FINRA Rule 2310(a)(4) (Direct Participation Programs); (6) exchange offers; (7) offerings pursuant to SEC Regulation A; and (8) offerings by closed-end funds.

⁴ FINRA does not approve or disapprove an offering; rather, the review relates solely to the FINRA rules governing underwriting terms and arrangements and does not purport to express any determination of compliance with any federal or state laws, or other regulatory or self-regulatory requirements regarding the offering. A member may proceed with a public offering only if FINRA has provided an opinion that it has no objection to the proposed underwriting terms and arrangements. See Rule 5110(a)(1)(C)(ii).

⁵ These "institutional" accredited investors are: banks and savings and loan associations; registered broker-dealers; investment advisers; insurance companies; investment companies; business development companies; Small Business Investment Companies; Rural Business Investment Companies; state employee benefit plans with assets in excess of \$5 million; or ERISA employee benefit plans, if the investment decision is made by a plan fiduciary, which is either a bank, savings and loan association, insurance company, or registered investment adviser, or if the employee benefit plan has total assets in excess of \$5 million, or if a self-directed plan, with investment decisions made solely by persons that are accredited investors (see Rule 501(a)(1)); private business development companies (see Rule 501(a)(2)); organizations described in Section 501(c)(3) of the Internal Revenue Code, corporation, Massachusetts or

institutional accredited investors have sufficient sophistication to warrant an exemption from the rule.

In 2020, the SEC amended the definition of accredited investor to include two additional types of institutional entities.⁶ The amendments updated the definition of accredited investor to more effectively identify institutional and individual investors that have the knowledge and expertise to participate in private capital markets.

Overview of Proposed Amendments

The proposed amendments to Rule 5110 would improve and clarify parts of the rule covering the valuation method for securities deemed underwriting compensation. The proposed amendments would also include new exclusions from underwriting compensation that codify exemptions FINRA staff has issued and clarifications of other provisions, all of which would further promote capital formation without lessening investor or issuer protection. In addition, the proposed amendments would include several minor changes to improve the operation of the rule and address common questions encountered during the review process.

The proposed amendments to Rule 5123 would add two types of entities that would qualify under the existing filing exemption under Rule 5123, consistent with the Commission's treatment of the accredited investor definition.

Rule 5110 Proposed Amendments

Valuation Method for Securities Acquisitions Considered Underwriting Compensation

Currently, when participating members⁷ acquire securities that are deemed underwriting compensation, the value of the securities is based on either the public offering price per security or the price paid per security on the date of acquisition if a "bona fide public

similar business trust, partnership, or limited liability company, not formed for the specific purpose of acquiring the securities offered, with total assets in excess of \$5 million (see Rule 501(a)(3)); and trusts with total assets in excess of \$5 million, not formed for the specific purpose of acquiring the securities offered, whose purchase is directed by a sophisticated person as described in Rule 506(b)(2)(ii) (see Rule 501(a)(7)).

⁶ See Accredited Investor Definition, Securities Exchange Act Release 89669 (August 26, 2020), 85 FR 64234 (October 9, 2020), including new categories of accredited investor under Rule 501(a)(9) and (a)(12).

⁷ The term "participating member" means any FINRA member that is participating in a public offering, any affiliate or associated person of the member, and any immediate family, but does not include the issuer. See Rule 5110(j)(15).

market” exists for the security.⁸ The definition of “bona fide public market” requires that the securities be traded on a national securities exchange and relies on SEC Regulation M’s definitions of average daily trading volume and public float.⁹ FINRA understands that members have experienced challenges determining whether a security had a “bona fide public market” on the acquisition date using this complex, multipart definition. When a security does not meet the definition, and does not have a public offering price, it cannot be valued under the rule and is therefore considered indeterminate compensation, which is prohibited under Rule 5110(g)(1).

The proposed rule change would amend Rule 5110(c)(2) and (3) by replacing “bona fide public market” with a valuation method in which the calculation is more predictable, based on the closing market price of a security traded on a registered national securities exchange or a “designated offshore securities market”¹⁰ on the date of acquisition. Using this readily available market data would greatly simplify application of the rule.

Exclusions From Underwriting Compensation for Certain Securities Acquisitions

The proposed rule change is intended to foster capital raising by providing additional exclusions from underwriting compensation for certain types of investments by participating members in anticipation of, or concurrently with, a public offering. These proposed amendments cover (1) debt-for-equity exchanges; (2) capital investments for direct participation programs (“DPPs”)¹¹ and unlisted real estate investment trusts (“REITs”);¹² and (3) non-convertible preferred securities, and describe factors FINRA has considered regarding whether to exclude securities acquisitions from being deemed underwriting compensation when such acquisitions are in connection with bona fide financing that would benefit the issuer and investors. Each proposed amendment is discussed below.

Debt-for-Equity Exchanges

Rule 5110 does not now provide an exclusion from underwriting compensation for securities acquired by affiliates of underwriters in connection with debt-for-equity exchange

transactions. Debt-for-equity exchanges have increasingly occurred in recent years and provide favorable tax treatment and economic benefits to issuers.¹³ A debt-for-equity exchange is composed of a series of transactions in which a lender acquires equity securities of the issuer, often referred to as exchange shares, in return for a cash loan. The exchange shares are subsequently or concurrently registered and offered by underwriters in a public offering. The offering proceeds are used, in whole or part, as repayment of the loan. When the lender is an affiliate of an underwriter, it falls within the definition of participating member, and the equity securities acquired by the affiliated lender for making the loan fall within the definition of underwriting compensation.

The proposed rule change would add new Supplementary Material .01(b)(23) to provide relief from such exchanges being deemed underwriting compensation if the equity acquired is part of a transaction that provides economic and tax benefits to the issuer and meets the following conditions:

- the affiliated member subsequently offered all of the equity securities the lender acquired in a firm commitment offering following the debt exchange;¹⁴
- the parties determined the terms of the debt exchange and the subsequent equity issued through arms’ length negotiations based on the market price of the equity;¹⁵ and
- the affiliated member negotiated customary compensation for the subsequent equity offering.

The proposed rule change would facilitate capital formation by providing consistent regulatory treatment of a common financing strategy issuers employ.

Capital Investments for DPPs and REITs

Rule 5110 does not now provide an exclusion from underwriting compensation for capital investments in exchange for an equity stake made by affiliates of underwriters concurrently

with or in advance of a public offering. Such investments are common in DPP and REIT offerings to provide the initial or subsequent equity capital or financing needed by an issuer.

The proposed rule change would add new Supplementary Material .01(b)(24) to provide relief from such transactions by setting out the conditions for excluding capital investments from being deemed underwriting compensation. Supplementary Material .01(b)(24) would work as a self-operating exclusion and would not limit when the transactions could occur. The conditions for Supplementary Material .01(b)(24) apply to securities acquired before or during the distribution of an offering by a participating member in the issuer or an affiliated entity and would require that:

- the capital investments are disclosed in the prospectus;
- the offering and the securities acquired in the capitalization transaction are valued and priced based on net asset value (“NAV”);¹⁶
- the offering is subject to the requirements of Rule 2310 (Direct Participation Programs); and
- the securities acquired are restricted for a period of 180 days following the commencement of sales.

These conditions are intended to promote transparency, ensure fair valuation, and address potential conflicts of interest in these transactions.

Non-Convertible Preferred Securities

Rule 5110 provides that non-convertible or non-exchangeable debt securities and derivative instruments acquired by any participating member in a transaction related to a public offering at a fair price¹⁷ are considered underwriting compensation but have no compensation value.¹⁸ Because both non-convertible debt and non-convertible preferred securities cannot be converted to common stock and provide predetermined payments to holders, resulting in fixed sources of income, FINRA views them as

¹³ Pursuant to Rule 5110(i), FINRA received 15 exemption requests for debt-for-equity transactions from 2022 through 2024.

¹⁴ Typically, lenders and affiliated members coordinate to satisfy this condition. However, even if they do not coordinate, the affiliated member can satisfy the condition with the subsequent offering.

¹⁵ Past exemptions that have been granted consistent with the conditions of this proposed Supplementary Material involved operating companies with equity listed on a national securities exchange with a market price and did not involve an IPO or a spinoff. Member firms intending to participate in transactions that do not align with the terms of this Supplementary Material may, as with any transaction subject to Rule 5110, request exemptive relief pursuant to FINRA Rule 5110(i) and the Rule 9600 Series.

¹⁶ Capitalization transactions occurring before the issuer has material assets would be deemed to occur at or above NAV.

¹⁷ See Rule 5110.06(b).

¹⁸ See Rules 5110(c)(5) and 5110.06. As a general rule, compensation that cannot be valued is prohibited. See Rule 5110(g)(1). Under this exclusion, treating these transactions as compensation without value permits the participating member to receive the securities (as long as they are received at a fair price) while still allowing FINRA the ability to review the transactions to determine whether they were, indeed, received at a fair price. If they were not, the value of underwriting compensation that is attributed to these securities is the difference between their fair price and their actual price.

⁸ See Rule 5110(c).

⁹ See Rule 5121(f)(3).

¹⁰ See Securities Act Rule 902(b).

¹¹ See Rule 2310(a)(4).

¹² See Rule 2231(d)(4).

equivalent for purposes of the Rule 5110 exclusion and, accordingly, the proposed rule change would treat them in a comparable manner as long as non-convertible preferred securities are acquired at a fair price. This rule change would facilitate capital formation by providing members with predictable regulatory treatment and benefit issuers through the capital investments made in exchange for non-convertible preferred securities from affiliates of members that participate in public offerings.

Changes To Improve Operation of Rule 5110

The proposed rule change would make other minor modifications to Rule 5110 based on FINRA's experience reviewing filings that FINRA believes would improve the operation of the rule and reduce the number of questions raised by filers during the review process. For example, Rule 5110(g)(5)(B) permits termination fees or the receipt of compensation in the form of rights of first refusal in connection with a public offering that is terminated when specific requirements are met that protect the issuer (*i.e.*, they are not deemed to be prohibited unreasonable terms or arrangements). Increasingly, members negotiate payments often described as "tail fees" in engagement letters that are similar to the terms and requirements for termination fees or rights of first refusal. Because tail fees provide compensation in the event of a subsequent financing from investors introduced by a member following the termination of an agreement, these payments are comparable to termination fees for purposes of Rule 5110. The proposed rule change would amend Rule 5110(g)(5)(B) to clarify that the same requirements would apply to such fees.¹⁹ If these requirements are not met, tail fees would constitute unreasonable arrangements under Rule 5110.

¹⁹ These requirements are that: (i) the agreement specifies that the issuer has a right of "termination for cause," which shall include the participating member's material failure to provide the underwriting services contemplated in the written agreement; (ii) an issuer's exercise of its right of "termination for cause" eliminates any obligations with respect to the payment of any termination fee or provision of any right of first refusal; (iii) the amount of any termination fee must be reasonable in relation to the underwriting services contemplated in the agreement and any fees arising from underwriting services provided under a right of first refusal must be customary for those types of services; and (iv) the issuer shall not be responsible for paying the termination fee unless an offering or other type of transaction (as set forth in the agreement) is consummated within two years of the date the engagement is terminated by the issuer. See Rule 5110(g)(5)(B).

Proposed Amendments to Rule 5123

The proposed rule change would add two types of entities to the filing exemption under Rule 5123, consistent with the Commission's treatment of the accredited investor definition. As stated above, in August 2020, the Commission adopted amendments to the definition of "accredited investor" under Rule 501²⁰ to more effectively identify institutional and individual investors that have the knowledge and expertise to participate in private capital markets. These changes included:

- any entity, of a type not listed in paragraphs (a)(1), (2), (3), (7), or (8) of Rule 501, not formed for the specific purpose of acquiring the securities offered, owning investments in excess of \$5,000,000;²¹ and
- any "family office" with assets under management in excess of \$5,000,000, that is not formed for the specific purpose of acquiring the securities offered and its prospective investment is directed by a person who has such knowledge and experience in financial and business matters that such family office is capable of evaluating the merits and risks of the prospective investment.²²

Adding these two types of entities to the existing exemption would establish consistency with the purpose of Rule 5123. FINRA believes that the investors described above possess a level of sophistication and expertise that is similar to the institutional accredited investors currently exempted under Rule 5123 and generally do not need the additional protections and oversight provided through the filing requirements. FINRA notes that qualified purchasers, which currently are covered in another exemption from Rule 5123's filing requirements, are defined under the Investment Company Act of 1940 and the rules thereunder ("Investment Company Act") to include natural persons or certain companies that own not less than \$5,000,000 in investments.²³ The two entities above have a similar financial threshold, which indicates an equivalently high level of sophistication to justify exemption from Rule 5123.²⁴

²⁰ See SEC Accredited Investor Definition Release, *supra* note 6.

²¹ See 17 CFR 230.501(a)(9).

²² See 17 CFR 230.501(a)(12).

²³ See Investment Company Act Section 2(a)(51).

²⁴ The Commission's August 2020 accredited investor amendments promulgated additional categories of accredited investors, including natural persons holding professional certifications and designations or other credentials, knowledgeable employees of private funds, and certain family clients, which FINRA is not proposing to add in these amendments.

If the Commission approves the proposed rule change, FINRA will announce the effective date of the proposed rule change in a *Regulatory Notice*.

2. Statutory Basis

FINRA believes that the proposed rule changes are consistent with the provisions of Section 15A(b)(6) of the Act,²⁵ which requires, among other things, that FINRA rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest.

The proposed amendments to Rules 5110 would enhance the efficiency of FINRA rules and further support capital formation. For example, the proposed amendments to Rule 5110 would improve and clarify the application of Rule 5110 and align the rule with current practices relating to underwriting compensation. The proposed amendments to Rule 5110 regarding valuation of securities that are considered underwriting compensation would replace a valuation process that members have stated is unnecessarily complex and cumbersome with a simpler, more straightforward valuation process, which would provide predictability and efficiency to members' valuation processes. The proposed amendments to Rule 5110 regarding new exclusions from underwriting compensation that codify exemptions FINRA staff has issued would provide additional flexibility and clarity for member firms that would reduce the need for and cost associated with certain participating members requesting exemptions from FINRA, reduce the amount of time for FINRA's review of these filings, allow issuers to access capital markets faster, and enhance the transparency and efficiency of the regulatory process.²⁶ The codification of these exemptions as exclusions may lead some members that would not request an exemption under the baseline to use an exclusion, generating additional or greater investments in issuers, thereby increasing access and options to capital raising.

The proposed amendments to Rule 5110 also would maintain important protections for issuers and investors

²⁵ 15 U.S.C. 78o-3(b)(6).

²⁶ FINRA received 21 requests for exemptions for capital investments and debt-for-equity transactions from 2022 through 2024. Each request required substantial analysis by FINRA staff and discussions with the member firm, resulting in a longer review of a potential offering in order to consider the request.

participating in offerings. The proposed valuation method would continue to ensure that securities that are acquired by underwriters are valued fairly. In addition, the proposed exclusions are narrowly tailored and based on exemptive relief FINRA has provided, which have worked well for issuers and investors.²⁷ The proposed rule change also would not decrease FINRA's ability to oversee underwriting terms and arrangements. In totality, the proposed rule change would reduce the administrative and operational burdens for members and FINRA, promote regulatory efficiency, and enhance market functioning while maintaining issuer and investor protection.

The proposed amendments to Rules 5123 also would enhance the efficiency of FINRA rules and further support capital formation. By expanding the scope of private placements that are exempt from the requirement of Rule 5123, members that participate in these offerings would no longer be required to comply with Rule 5123.

In addition, the proposed amendments to Rule 5123 would not diminish investor protection. The institutional investors who would be covered by the filing exemption possess a level of sophistication and expertise that is similar to the institutional accredited investors currently exempted under Rule 5123 and generally do not need the additional protections and oversight provided through the filing requirements. Non-institutional accredited investors who may not possess the same level of sophistication and expertise as institutional investors would continue to receive the protections of the Rule 5123 filing requirement, with FINRA reviewing private placement offerings sold to these investors and helping detect misconduct in the private placement process, thereby promoting investor protection.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule changes will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Economic Impact Assessment

FINRA has undertaken an economic impact assessment to analyze the regulatory need for the proposed rule change, its potential economic impacts, including anticipated costs, benefits, and distributional and competitive

effects, relative to the current baseline, and the alternatives FINRA considered in assessing how best to meet FINRA's regulatory objectives.

Regulatory Need

As discussed earlier, the current approach to valuation of securities that are considered underwriting compensation under current Rule 5110 can be complex, creating unnecessary burdens for members and uncertainty on whether they are permitted to acquire certain securities or required to receive a different form of compensation. The proposed rule change would provide a simpler, more straightforward approach. In addition, certain transactions require participating members to request exemptions from FINRA. This approval process can increase the amount of time for issuers to access capital markets. By codifying existing FINRA staff positions, the proposed rule change would reduce such requests by replacing existing requirements with more practical and transparent alternatives. The proposed rule change would also expand the exemptions available in Rule 5123 and better align FINRA rules with SEC rules relating to the treatment of institutional accredited investors.

Economic Baseline

The economic baseline for the proposed rule changes is the existing regulation framework of public offerings and private placements subject to regulatory oversight under Rules 5110 and 5123 and their interpretations and implementation by FINRA. The economic baseline also includes industry practices relating to and compliance with these existing regulations and other relevant regulatory frameworks.

With respect to public offerings subject to Rules 5110, FINRA evaluated filing information to assess members' participation in public offerings required to be filed with FINRA. FINRA notes that the observations addressed here do not include observations in which members may have relied on a filing exemption under Rule 5110(h)(1). FINRA received 3,711 new filings under Rule 5110 during 2022–2024. The annual number of new filings ranged from 1,398 in 2022 to 1,209 in 2024, with an average number of 1,237 filings per year. These filings represented underwriting, allocation, distribution, advisory and other investment banking services in connection with a public offering conducted by 333 members, to the extent the member's participation in the public offering is required to be provided. The average and median

number of filings in which a member participated was 15 and three during the period, respectively. The aggregate amount of offering proceeds in association with these filings was over \$781 billion, with a median value of approximately \$50 million per filing.

Certain proposed changes to Rule 5110 specifically relate to public offerings with capital investments for DPPs and REITs, debt-for-equity transactions, and securities acquired by a participating member without a "bona fide public market." FINRA collected information on exemption requests submitted by members in non-shelf filings related to these three sets of acquisitions. An analysis of this data finds that among the 2,402 new non-shelf offerings filed under Rule 5110 during 2022–2024, six (0.25 percent) offerings requested exemptions relating to capital investments for DPPs and REITs, 15 (0.62 percent) offerings requested exemptions relating to debt-for-equity transactions, and 12 (0.5 percent) offerings requested exemptions relating to valuing securities without a bona fide public market.²⁸ A majority of these exemptions were granted after FINRA took into consideration all relevant factors.

With respect to private placement offerings under Rule 5123, FINRA collected information detailing 8,485 unique filings under Rule 5123 submitted by 525 members during the above period. The annual number of unique filings ranged from 3,807 in 2022 to 2,344 in 2024, with an average number of 2,828 filings per year. Among the 8,485 unique filings, 7,599 (90 percent) had projected proceeds totaling \$388 billion with a median value of \$10 million per filing. Projected proceeds were reported as unknown for the remaining filings. The average and median number of these filings submitted per participating member during the above period were 15 and three, respectively.

Economic Impact

The proposed rule change would directly impact members, issuers and investors that participate in public offerings and private placements. This economic impact analysis considers the significant impacts associated with specific rule changes relating to

²⁸ See Rule 5110(i). "Pursuant to the Rule 9600 Series, FINRA, for good cause shown after taking into consideration all relevant factors, may conditionally or unconditionally grant an exemption from any provision of this Rule to the extent that such exemption is consistent with the purposes of the Rule, the protection of investors, and the public interest."

²⁷ Rule 5110.01(b)(23)–(24) codifies the factors and factual circumstances FINRA has consistently considered when granting these exemptions.

underwriting compensation and private placement offerings.

Anticipated Benefits of Proposed Amendments to Rule 5110

Overall, the proposed changes to Rule 5110 would simplify and clarify the application of Rule 5110 and align the rule with current practice relating to underwriting compensation. The additional flexibility in the proposed changes would facilitate negotiation between members and issuers of underwriting terms and arrangements that comply with Rule 5110. The proposed changes would also reduce the need for certain participating members to request exemptions from FINRA, reduce the amount of time for FINRA's review of these filings, allow issuers to access capital markets faster, and enhance the transparency and efficiency of the regulatory process. The codification of the exemptions as exclusions may lead some members that would not request an exemption under the baseline to use an exclusion, generating additional or greater investments in issuers thereby increasing access and options to capital raising.

The proposed amendments related to the valuation method for securities acquisitions would increase the options participating members have for receiving underwriting compensation, which may include convertible and non-convertible securities. Currently, participating members in these offerings experience challenges using the market price on the date of the acquisition because a "bona fide public market" does not exist. Because a value cannot be determined, participating members must either negotiate to be compensated in cash or request an exemption from FINRA because the receipt of such securities would constitute an unreasonable term or arrangement under Rule 5110(g)(1).

Under current Rule 5110, transactions involving capital investments made by affiliates of underwriters in DPPs and REITs as well as securities acquired by affiliates of underwriters in connection with debt-for-equity exchange transactions are deemed underwriting compensation. Hence, participating members must either find alternative financing options or request exemptive relief from the presumption that these transactions may be deemed underwriting compensation.

The proposed changes to codify these exemptions would reduce compliance costs for participating members insofar as they reduce the time and expense incurred by members' employees and outside legal counsel in seeking such

exemptions. The proposed changes may also create new financing opportunities for issuers and members and reduce costs associated with such exemptions. The benefits may also extend to offerings exempt from the filing requirements in Rule 5110(h)(1), but otherwise subject to compliance.

Participating members that acquire non-convertible preferred securities in connection with a public offering at a fair price will benefit from the proposed amendments to treat non-convertible preferred securities equivalently to non-convertible or non-exchangeable debt securities. FINRA believes that these proposed changes would provide participating members additional flexibility and clarity with respect to the applicable requirements for such securities acquisitions under Rule 5110.

Anticipated Costs of Proposed Amendments to Rule 5110

As discussed earlier, the proposed amendments would codify prior positions taken by FINRA staff that have not imposed costs on issuers and investors. To the extent that codification allows for greater use of the flexibilities provided, capital formation may be enhanced at limited additional risk to investors. FINRA does not expect this change to affect overall underwriting compensation or negatively affect investors, given FINRA's oversight and competitive pressure among underwriters. Therefore, the proposed changes are not expected to increase costs to issuers and investors that participate and invest in public offerings.

Anticipated Benefits and Costs of Proposed Amendments to Rule 5123

The proposed changes would expand the scope of private placements that are exempt from the requirement of Rule 5123. The proposed exemptions relate to private placements sold to two additional types of institutional entities that were included in the SEC's amended definition of accredited investor in 2020 (*i.e.*, certain entities owning investment in excess of \$5,000,000 and certain family offices with assets under management in excess of \$5,000,000).²⁹ Members in these offerings would no longer incur the costs to comply with Rule 5123, whereas the regulatory protection provided through the filings requirement is not necessary because the two new categories of accredited investors are considered to have sufficient sophistication to appropriately evaluate the risks and

rewards of the investment and therefore warrant an exemption from Rule 5123.

The extent of the cost savings for members cannot be estimated in aggregate because FINRA does not collect the information that would identify the private placement offerings sold exclusively to the above two types of specified institutional entities. The expected cost savings would likely be greater for members that participate in these offerings more frequently or members that seek to expand their private placement activities.

Alternatives Considered

FINRA considered several alternatives in developing the proposed rule change. One alternative FINRA considered was to expand the types of securities that are eligible to be valued under the proposed rule to also include over-the-counter ("OTC") equity securities. While this alternative would provide participating members with additional compensation options, FINRA notes that there can be material differences in the frequency and volume of trading among OTC equity securities, which may impact the availability of information for use in performing valuations for such securities.

Although FINRA has not incorporated this alternative into the current proposed rule change, FINRA is continuing to evaluate whether additional types of securities could be eligible for valuation under Rule 5110. In the interim, FINRA believes the proposed rule change as drafted achieves an appropriate balance between supporting capital formation and maintaining adequate issuer and investor protection. Under current Rule 5110, securities that trade only OTC in the U.S., including securities of foreign issuers, may nonetheless qualify as underwriting compensation. Further, foreign ordinary shares, including those traded OTC in the U.S., may be eligible for the designated offshore securities market provision proposed in this rule, and thus such securities would be eligible to be valued under the current proposal.³⁰

³⁰ FINRA estimates that, from February 1, 2025 to July 29, 2025, 9,435 out of 18,927 issuers with securities traded on the U.S. OTC market also have equity securities traded in foreign markets. These issuers account for most of total OTC market capitalization, with the dollar trade volume representing 89% of the total U.S. OTC equity market during the referenced six months period. The estimation is based on the American Depository Receipts, Global Depository Receipts, and foreign ordinary shares classification and market capitalization data for issuers for which this data is available.

²⁹ See *supra* note 6.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

In December 2024, FINRA published *Regulatory Notice 24-17* (the “*Notice*”), requesting comment on the proposed rule change (the “*Notice Proposal*”). Six comments were received in response to the *Notice*. A copy of the *Notice* is available on FINRA's website at <http://www.finra.org>. A list of the commenters in response to the *Notice* and copies of the comment letters received in response to the *Notice* are available on FINRA's website.³¹

Most commenters were overall supportive of the direction of the proposed rule changes in the *Notice*, but not all commenters supported every aspect of the *Notice Proposal*. Some commenters sought clarifications or changes to specific rule provisions. FINRA has considered the concerns raised by commenters and, as discussed in detail below, has addressed many of the concerns noted by commenters in response to the *Notice Proposal*. The comments and FINRA's responses are set forth in detail below.

Valuation Method Under Rule 5110(c)

While the ABA expressed broad support for FINRA's efforts to continue to modernize its rules, simplify compliance and codify additional exclusions from underwriting compensation, the ABA expressed concern about the drafting of proposed FINRA Rule 5110(c) in the *Notice Proposal*. According to the ABA, because FINRA proposed to delete the words “or to a security with a bona fide public market” without substituting alternative language referring to “a security traded on a U.S. exchange or designated offshore market,” the new valuation methods in paragraphs (c)(2)(A) and (c)(3)(B) for securities traded on U.S. exchanges and offshore markets “will be without effect.”³²

In response to the comments, FINRA has modified the proposed rule language to clarify that a security can be accurately valued “using any method in this paragraph (c).” This includes the valuation of a security traded on a national securities exchange that is registered under Section 6(a) of the Exchange Act or a designated offshore securities market as defined under Securities Act Rule 902(b). If the security can be accurately valued, it

would not be subject to the prohibition in paragraph (g)(1), which precludes receipt of any underwriting compensation for which a value cannot be determined.

The ABA also suggested that FINRA expand the types of securities that are eligible to be valued under the rule to also include certain OTC equity securities, which are not traded on national securities exchanges. While FINRA has not incorporated this suggestion into the current proposed rule change, FINRA is continuing to evaluate whether additional types of securities could be eligible for valuation under Rule 5110.

Debt-for-Equity Exchanges

In general, FINRA received positive feedback and support for these proposed changes.³³ The ABA sought clarification that an affiliated member would not be prohibited from placing a portion of the equity securities acquired by the lender in its investment account if it is unable to sell that portion in the offering. In FINRA's view, the rule language in the *Notice Proposal* does not foreclose placing a portion of the equity securities acquired by the lender in its investment account if it is unable to sell that portion in the offering.

SIFMA sought clarification that the safe harbor would apply when the transaction is structured to provide economic and tax benefits to a direct or indirect shareholder of issuer. In FINRA's view, the definition of “issuer” is broad enough to capture significant shareholders.³⁴

Capital Investments for DPPs and REITs

In general, FINRA received positive feedback and support for these proposed changes.³⁵ The ABA sought more guidance as to application of the exclusion in the *Notice Proposal*. The ABA, ADISA, and IPA also raised questions about whether the investments must be made before an offering, as the use of the word “seed” may imply before the offering. FINRA did not intend to limit the capital investments to before the offering in the *Notice Proposal*. Accordingly, FINRA has replaced references to “seed capital” with “capital investments” and confirms that the amendments are agnostic to the timing of the acquisition.

IPA suggested that the principles-based approach FINRA proposed in the *Notice* should instead be a self-operating exclusion to provide regulatory certainty. FINRA agrees that

the exclusion for capital investments would operate most efficiently as a self-operating exclusion instead of a principles-based approach and has replaced Supplementary Material .05 with new Supplementary Material .01(b)(24) to include these capital investments as an example of payments not deemed to be underwriting compensation.

ADISA recommended that the conditions in the proposed capital investments exclusion to underwriting compensation in the *Notice Proposal* should fully align with the North American Securities Administrators Association (NASAA) REIT Guidelines. According to ADISA, the proposed conditions for this exclusion do not provide that securities may be transferred to an affiliate of the sponsor, which is allowable pursuant to Section II.A.2. of the NASAA REIT Guidelines. ADISA suggested adding language to the rule text that “the securities acquired and excluded may be transferred to other affiliated entities, which transfer would not be deemed to constitute an economic disposition of the securities during the 180 day period.”³⁶ In FINRA's view, this additional language is unnecessary, as the capital provided and transferred would already be excluded under FINRA Rule 5110(e)(2)(b), which permits the transfer of any security to any member participating in the offering and its officers or partners, its registered persons or affiliates, if all transferred securities remain subject to the lock-up restriction in paragraph (e)(1) for the remainder of the 180-day lock-up period.³⁷

ADISA also recommended that for the purposes of calculating the lockup restriction period in the *Notice Proposal*, FINRA should use the definitive date of effectiveness of the offering as a measurement rather than commencement of sales. In FINRA's view, replacing the date of commencement of sales with the date of effectiveness could result in an unreasonably short lockup period, as a prospectus may become effective long before the commencement of sales. Accordingly, FINRA did not accept this suggestion.

IPA suggested that FINRA clarify that a capitalization transaction occurring before the issuer has material assets will be deemed to occur at or above NAV, as a NAV determination should not be necessary in connection with a capital

³¹ See SR-FINRA-2026-002 (Form 19b-4, Exhibits 2b and 2c) for a list of abbreviations assigned to commenters (available on FINRA's website at <http://www.finra.org>).

³² See ABA letter.

³³ See ABA, SIFMA letters.

³⁴ See Rule 5110(j)(12).

³⁵ See ABA, ADISA, IPA letters.

³⁶ See ADISA letter.

³⁷ See Rule 5110(e)(2)(b).

transaction.³⁸ FINRA agrees that a capitalization transaction occurring before the issuer has material assets would be deemed to occur at or above NAV.

Non-Convertible Preferred Securities

The ABA was generally supportive of treating non-convertible or non-exchangeable preferred securities the same as non-convertible or non-exchangeable debt or derivative instruments.³⁹ However, the ABA sought clarification that reliance on this exclusion in the *Notice* Proposal would not be prohibited where the otherwise non-convertible preferred securities convert into the class of securities to be sold to the public as part of a recapitalization or other reorganization in preparation for an IPO. FINRA views this comment as beyond the scope of the proposed rule change.

Changes To Improve Operation of the Rule

The ABA was generally supportive of this proposed change, however the ABA suggested further clarification in the rule text defining “tail fee.”⁴⁰ FINRA does not think it is necessary to define “tail fee,” as “tail fee” is a commonly understood term and FINRA does not define other fees under the rule (e.g., termination fees, rights of first refusal). As FINRA stated in the *Notice* Proposal, tail fees provide compensation in the event of a subsequent financing from investors introduced by a member, following the termination of an agreement. Moreover, FINRA would review these fees based on the facts and circumstances of how they are structured.

Rule 5123

Several commenters, including SIFMA and ADISA, supported the Rule 5123 amendments in the *Notice* Proposal. However, Intellivest suggested that FINRA include all accredited investors under Rule 5123’s filing exemption.⁴¹ FINRA notes that the overwhelming majority of private placements are sold to accredited investors only. During 2022–2024, less than 4% of the private placements filed under Rule 5123 permitted sales to non-accredited investors. FINRA does not believe exempting review and oversight of the vast majority of private placements, including those that are offered and sold to all accredited investors, would be appropriate. First,

retail accredited investors generally do not have the same level of sophistication and expertise as institutional accredited investors. Second, exempting review and oversight of the vast majority of private placements could impede FINRA’s ability to detect misconduct in the private placement market, increasing risk exposure to retail investors. Third, FINRA notes that there are proposals in Congress and the SEC regarding the definition of accredited investor that we will monitor and consider in relation to Rule 5123 as they develop.

Intellivest also suggested that FINRA provide a safe harbor for a member that has a written agreement with another member to submit on its behalf the required 5123 filing, so a member would not need to follow up to ensure the other firm has met its filing obligations. FINRA views this comment as beyond the scope of 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 (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization 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 is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission’s internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-FINRA-2026-002 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-FINRA-2026-002. This file number should be included on the

subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission’s internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of FINRA. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to File Number SR-FINRA-2026-002 and should be submitted on or before February 20, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁴²

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2026-01825 Filed 1-29-26; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[OMB Control No. 3235-0766]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Extension: Rule 17a-14 and Form CRS

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549-2736

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (“SEC” or “Commission”) is submitting to the Office of Management and Budget (“OMB”) this request for extension of the proposed collection of information provided for in Rule 17a-14 (17 CFR 240.17a-14) and Form CRS (17 CFR 249.640), under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*).

Rule 17a-14 and Form CRS require a broker-dealer that offers services to retail investors to prepare and file with the Commission through WebCRD, post to the broker-dealer’s website (if it has one), and deliver to retail investors a relationship summary. The relationship summary can assist retail investors in making an informed choice about whether to hire or retain a broker-dealer,

⁴² 17 CFR 200.30-3(a)(12).

³⁸ See IPA letter.

³⁹ See ABA letter.

⁴⁰ See *supra* note 39.

⁴¹ See Intellivest letter.

as well as what types of accounts and services are appropriate for their needs.

The information that must be collected pursuant to Rule 17a–14 and Form CRS is necessary to provide broker-dealer retail customers, prospective retail customers, and the Commission with information about the relationships and services the firm offers to retail investors, fees and costs that the retail investor will pay, specific conflicts of interest and standards of conduct, legal or disciplinary history, and how to obtain additional information about the firm. The Commission uses the information to manage its regulatory and examination programs. Retail investors can use the information required in the relationship summary to determine whether to hire or retain a broker-dealer, as well as what types of accounts and services are appropriate for their needs. The information will therefore help establish a framework that protects investors and promotes efficiency, competition, and capital formation.

The aggregate annual hour burden for all respondents to comply with the information collection requirements of Rule 17a–14 and Form CRS is estimated to be approximately 7,424,299 hours per year. Under Rule 17a–14 and Form CRS, respondents will also incur cost burdens. The aggregate annual initial cost burden for all respondents is estimated to be approximately \$142,554 per year.

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 public may view and comment on this information collection request at: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202511-3235-004 or email comment to MBX.OMB.OIRA.SEC_desk_officer@omb.eop.gov within 30 days of the day after publication of this notice, by March 2, 2026.

Dated: January 28, 2026.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–01889 Filed 1–29–26; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 35918; 812–15958]

Carillon Series Trust and Carillon Tower Advisers, Inc.

January 27, 2026.

AGENCY: Securities and Exchange Commission (“Commission” or “SEC”).

ACTION: Notice.

Notice of an application under Section 6(c) of the Investment Company Act of 1940 (“Act”) for an exemption from Section 15(c) of the Act.

SUMMARY OF APPLICATION: The requested exemption would permit a Trust’s board of trustees to approve new sub-advisory agreements and material amendments to existing sub-advisory agreements without complying with the in-person meeting requirement of Section 15(c) of the Act.

APPLICANTS: Carillon Series Trust and Carillon Tower Advisers, Inc.

FILING DATES: The application was filed on December 18, 2025.

HEARING OR NOTIFICATION OF HEARING:

An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing on any application by emailing the SEC’s Secretary at Secretaries-Office@sec.gov and serving the Applicants with a copy of the request by email, if an email address is listed for the relevant Applicant below, or personally or by mail, if a physical address is listed for the relevant Applicant below. The email should include the file number referenced above. Hearing requests should be received by the Commission by 5:30 p.m., Eastern time, on February 23, 2026, and should be accompanied by proof of service on the Applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer’s interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission’s Secretary.

ADDRESSES: The Commission: Secretaries-Office@sec.gov. Applicants: Susan L. Walzer, Carillon Series Trust, susan.walzer@carillontower.com, with a copy to: Kathy Kresch Ingber, Esq., K&L Gates LLP, Kathy.Ingber@klgates.com.

FOR FURTHER INFORMATION CONTACT: Trace W. Rakestraw, Senior Special

Counsel, at (202) 551–6825 (Division of Investment Management, Chief Counsel’s Office).

SUPPLEMENTARY INFORMATION: For Applicants’ representations, legal analysis, and conditions, please refer to Applicants’ application, dated December 18, 2025, which may be obtained via the Commission’s website by searching for the file number at the top of this document, or for an Applicant using the Company name search field, on the SEC’s EDGAR system. The SEC’s EDGAR system may be searched at <https://www.sec.gov/search-filings>.

You may also call the SEC’s Office of Investor Education and Advocacy at (202) 551–8090.

For the Commission, by the Division of Investment Management, under delegated authority.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–01829 Filed 1–29–26; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[OMB Control No. 3235–0444]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Extension: Rule 10b–10

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (“SEC” or “Commission”) is submitting to the Office of Management and Budget (“OMB”) this request for extension of the proposed collection of information provided for in Rule 10b–10 (17 CFR 240.10b–10) under the Securities and Exchange Act of 1934 (15 U.S.C. 78a *et seq.*).

Rule 10b–10 requires broker-dealers to disclose specified information to customers regarding their securities transactions. The information required by the rule includes the date and time of the transaction, the identity and number of shares bought or sold, and whether the broker-dealer acts as agent for the customer or as principal for its own account. In addition, depending on whether the broker-dealer acts as agent for the customer or as principal for its own account, the rule requires the disclosure of commissions and, under

specified circumstances, mark-up and mark-down information. For transactions in debt securities (other than U.S. savings bonds and municipal securities) the rule requires the disclosure of redemption and yield information. For transactions in securities futures products in a futures account, the rule permits the disclosure of alternative information. This alternative information includes: the date the transaction was executed; the identity and number of shares bought or sold; the price, the delivery month, and the exchange on which the transaction was executed; the source and amount of any remuneration received or to be received by the broker-dealer in connection with the transaction; whether the broker receives payment for order flow for such transactions; and the fact that other specified information, including whether the broker-dealer is acting as agent or principal, will be available upon written request. Rule 10b-10 also requires broker-dealers to inform their customers if they are not members of the Securities Investor Protection Corporation ("SIPC").

The confirmation has long been a customary document in the securities industry, and it serves several functions, which include: broker-dealers use it as a billing statement; it serves as a customer invoice; it informs customers of the details of transactions and facilitates their checking for errors or misunderstandings; it provides information that helps investors evaluate the cost and quality of services provided by broker-dealers; it discloses conflicts of interest that may arise between investors and broker-dealers; and it safeguards against fraud by helping customers detect problems with transactions.

Rule 10b-10 potentially applies to all the approximately 3,292 broker-dealers that are registered with the Commission and that effect transactions for or with customers. Based on information provided by registered broker-dealers to the Commission in annual Form X-17a-5 Schedule I FOCUS Reports filed from January 1, 2022 to December 31, 2024, the Commission staff estimates that on average, registered broker-dealers process approximately 36,202,574,610 order tickets per year for transactions for or with customers. Each order ticket representing a transaction effected for or with a customer generally results in one confirmation. Therefore, the Commission staff estimates that approximately 36,202,574,610 confirmations are sent to customers annually. Based on information provided by industry participants, Commission staff estimates that it takes

approximately 30 seconds to generate and send a confirmation. As a result, the Commission staff estimates that the annual burden to brokers-dealers to comply with the confirmation delivery requirements of Rule 10b-10 would be approximately 301,688,122 hours (36,202,574,610 confirmation $\times$ 0.5 minutes/confirmation $\times$ 1 hour/60 minutes).

Based on informal discussions with securities industry representatives, as well as representations made in requests for exemptive and no-action letters, Commission staff estimates that broker-dealers use electronic confirmations as their sole confirmations for approximately 35 percent of transactions. Commission staff estimates that broker-dealers continue to send paper confirmations for the remaining 65 percent of transactions. Accordingly, approximately 23,531,673,497 paper confirmations are mailed to customers each year (36,202,574,610 $\times$ 0.65) and 12,670,901,114 wholly electronic confirmations are sent each year (36,202,574,610 $\times$ 0.35).

According to information provided by industry participants, the Commission staff estimates that the average cost for a paper confirmation is 85 cents and the average cost for a wholly electronic confirmation is 40 cents. Accordingly, the Commission staff estimates that the total annual cost associated with generating and mailing paper confirmations is approximately \$20,001,922,473 (23,531,673,497 paper confirmations $\times$ \$0.85 per confirmation) and the total annual cost associated with generating and sending wholly electronic confirmations is approximately \$5,068,360,446 (12,670,901,114 electronic confirmations $\times$ \$0.40 per confirmation). Accordingly, Commission staff estimates that the total annual cost associated with generating and delivering to investors the information required under Rule 10b-10 is approximately \$25,070,282,919 (\$20,001,922,473 + \$5,068,360,446).

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 public may view and comment on this information collection request at: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202511-3235-005 or email comment to MBX.OMB.OIRA.SEC_desk_officer@omb.eop.gov within 30 days of the day after publication of this notice, by March 2, 2026.

Dated: January 28, 2026.

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2026-01890 Filed 1-29-26; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-104694; File No. SR-BOX-2026-02]

Self-Regulatory Organizations; BOX Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend BOX Rule 5050 (Series of Options Contracts Open for Trading) To Permit the Listing of Up to Two Monday and Wednesday Expirations for Options on Certain Individual Stocks or Exchange-Traded Fund Shares

January 27, 2026.

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 January 20, 2026, BOX Exchange LLC ("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 from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend BOX Rule 5050 (Series of Options Contracts Open for Trading). Specifically, the Exchange proposes to amend BOX IM-5050-6 (Short Term Option Series Program) to permit the listing of up to two Monday and Wednesday expirations for options on certain individual stocks or Exchange-Traded Fund Shares. The text of the proposed rule change is available from the principal office of the Exchange, at the Commission's Public Reference Room and also on the Exchange's internet website at <https://rules.boxexchange.com/rulefilings>.

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,

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

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 self-regulatory organization 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 BOX Rule 5050 (Series of Options Contracts Open for Trading). Specifically, the Exchange proposes to amend BOX IM-5050-6 (Short Term Option Series Program) to permit the listing of up to two Monday and Wednesday expirations for options on certain individual stocks or Exchange-Traded Fund Shares. This is a competitive filing that is based on a proposal submitted by Nasdaq ISE, LLC ("Nasdaq ISE") and approved by the Commission.³

Specifically, the Exchange proposes to permit the listing of up to two Monday and Wednesday expirations for options on certain individual stocks or Exchange-Traded Fund Shares (collectively "Qualifying Securities"). Currently, as set forth in IM-5050-6, after an option class has been approved for listing and trading on the Exchange as a Short Term Option Series pursuant to BOX Rule 100(a)(66),⁴ the Exchange may open for trading on any Thursday or Friday that is a business day ("Short Term Option Opening Date") series of options on that class that expire at the close of business on each of the next five Fridays that are business days and are not Fridays in which standard

expiration options series, Monthly Options Series, or Quarterly Options Series expire ("Friday Short Term Option Expiration Dates"). The Exchange may have no more than a total of five Short Term Option Expiration Dates ("Short Term Option Weekly Expirations"). Further, if the Exchange is not open for business on the respective Thursday or Friday, the Short Term Option Opening Date for Short Term Option Weekly Expirations will be the first business day immediately prior to that respective Thursday or Friday. Similarly, if the Exchange is not open for business on a Friday, the Short Term Option Expiration Date for Short Term Option Weekly Expirations will be the first business day immediately prior to that Friday.

Additionally, the Exchange may open for trading series of options on the symbols provided in Table 1 of IM-5050-6 that expire at the close of business on each of the next two Mondays, Tuesdays, Wednesdays, and Thursdays, respectively, that are business days beyond the current week and are not business days in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire ("Short Term Option Daily Expirations").⁵ For those symbols listed in Table 1, the Exchange may have no more than a total of two Short Term Option Daily Expirations beyond the current week for each of Monday, Tuesday, Wednesday, and Thursday expirations, as applicable, at one time.

Proposal

At this time, the Exchange proposes to expand the Short Term Option Series Program to permit certain Qualifying Securities to list up to two Monday and Wednesday expirations in addition to the Friday weekly expiration. The Exchange proposes to define Qualifying Securities as eligible individual stocks or Exchange-Traded Fund Shares, which are separate and apart from the symbols listed in Table 1, that have received approval to list additional expiries on specific symbols, that meet the following criteria on a quarterly basis:

(1) an underlying security, as measured on the last day of the prior calendar quarter, must have:

(A) a market capitalization of greater than 700 billion dollars for an individual stock based on the closing price,⁶ or

(B) Assets under Management ("AUM") greater than 50 billion dollars for an Exchange-Traded Fund Share based on net asset value ("NAV");

(2) monthly options volume, as measured by sides traded in the last month preceding the quarter end, of greater than 10 million options;

(3) a position limit of at least 250,000 contracts; and

(4) participate in the Penny Interval Program.

Each calendar quarter, the Exchange will apply the above criteria to individual stocks and Exchange-Traded Fund Shares to determine eligibility for the following quarter as a Qualifying Security. Beginning on the second trading day in the first month of each calendar quarter, the market capitalization of individual stocks shall be calculated based on the closing price established on the primary exchange on the last trading day of the prior calendar quarter and the AUM for Exchange-Traded Fund Shares shall be calculated based on the NAV established on the primary exchange on the last trading day of the prior calendar quarter. The data establishing the volume thresholds will be established by using data from the last month of the prior calendar quarter from The Options Clearing Corporation. For options listed on the first trading day of a given calendar quarter, the volume shall be calculated using the last month of the quarter prior to that calendar quarter.⁷ BOX will make the list of Qualifying Securities available by close of business on the first trading day of the quarter.⁸

Eligible Qualifying Securities would be permitted to list two Short Term Option Expiration Dates beyond the current week for each Monday and Wednesday expiration at one time. For Qualifying Securities, the Exchange would not list an expiry on a day when there will be an Earnings Announcement⁹ that takes place after market close. For purposes of this rule proposal, earnings announcements shall include official public quarterly or

³ See Securities Exchange Act Release No. 104624 (January 16, 2026) (SR-ISE-2025-15) (Order Approving a Proposed Rule Change, as Modified by Amendment No. 1, to Amend the Short Term Option Series Program to List Qualifying Securities) ("Nasdaq ISE Filing").

⁴ Rule 100(a)(66) provides that the term "Short Term Option Series" means a series in an option class that is approved for listing and trading on BOX in which the series is opened for trading on any Monday, Tuesday, Wednesday, Thursday or Friday that is a business day and that expires on the Monday, Tuesday, Wednesday, Thursday, or Friday of the next business week, or, in the case of a series that is listed on a Friday and expires on a Monday, is listed one business week and one business day prior to that expiration. If a Tuesday, Wednesday, Thursday or Friday is not a business day, the series may be opened (or shall expire) on the first business day immediately prior to that Tuesday, Wednesday, Thursday or Friday, respectively. For a series listed pursuant to this section for Monday expiration, if a Monday is not a business day, the series shall expire on the first business day immediately following that Monday.

⁵ As set forth in Table 1 of IM-5050-6, the Exchange currently permits expirations in SPY, IWM, QQQ on Mondays, Tuesdays, Wednesdays and Thursdays. Also, the Exchange permits expirations in GLD, SLV and TLT on Mondays and Wednesdays. Finally, the Exchange permits expirations in USO and UNG on Wednesdays.

⁶ The closing price and the opening price shall be that of the primary exchange where the security is listed.

⁷ OCC data becomes available for the end of a quarter on the first trading day of a new quarter. For example, if the Exchange were to list Qualifying Securities in Q3 of 2025, BOX would look at the volume, measured in sides, for the last month of Q2 2025 or June 2025.

⁸ BOX will make this information available on BOX's website. This information will be freely accessible to the public.

⁹ An Earnings Announcement is an official public statement of a company's profitability for a specific period, typically a quarter or a year.

yearly earnings filed with the Commission ("Earnings Announcement").¹⁰ Not listing an expiry for a Qualifying Security on a day where there is an Earnings Announcement that takes place after market close will avoid permitting an additional expiry on a day where post-close price volatility may be impacted due to the Earnings Announcement.

Qualifying Securities that do not continue to meet the above criteria would no longer be permitted to list Monday and Wednesday expiries beginning on the second day of the following quarter.¹¹

The proposed Monday Qualifying Securities expirations will be similar to the current Monday Expirations in SPY, QQQ, and IWM (among other symbols that may list a Monday Expiration) in Short Term Option Daily Expirations set forth in IM-5050-6, such that the Exchange may open for trading on any Friday or Monday that is a business day (beyond the current week) series of options on Qualifying Securities to expire on any Monday of the month that is a business day and is not a Monday in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire, provided that Monday expirations that are listed on a Friday must be listed at least one business week and one business day prior to the expiration ("Monday Qualifying Securities Expirations").¹² In the event Qualifying Securities would expire on a Monday and that Monday is the same day that a standard expiration options series, Monthly Options Series, or Quarterly Options Series expires, the Exchange would skip that week's listing and instead list the following week; the two weeks of Monday Qualifying Securities Expirations would therefore not be consecutive. Today, Monday expirations in SPY, QQQ, and IWM similarly skip the weekly listing in the event the weekly listing would expire on the same day in the same class as a standard expiration options series, Monthly Options Series, or Quarterly Options Series.

The proposed Wednesday Qualifying Securities expirations will be similar to the current Wednesday SPY, QQQ, and IWM (among other symbols that may list a Wednesday Expiration) in Short Term

Option Daily Expirations set forth in IM-5050-6, such that the Exchange may open for trading on any Tuesday or Wednesday that is a business day (beyond the current week) series of options on Qualifying Securities to expire on any Wednesday of the month that is a business day and is not a Wednesday in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire ("Wednesday Qualifying Securities Expirations").¹³ In the event Qualifying Securities would expire on a Wednesday and that Wednesday is the same day that a standard expiration options series, Monthly Options Series, or Quarterly Options Series expires, the Exchange would skip that week's listing and instead list the following week; the two weeks of Wednesday Qualified Securities Expirations would therefore not be consecutive. Today, Wednesday expirations in SPY, QQQ, and IWM similarly skip the weekly listing in the event the weekly listing would expire on the same day in the same class as a standard expiration options series, Monthly Options Series, or Quarterly Options Series.

The interval between strike prices for the proposed Monday and Wednesday Qualifying Securities Expirations will be the same as those currently applicable for SPY, QQQ, and IWM Monday and Wednesday Expirations (among other symbols that may list a Monday or Wednesday Expiration) in the Short Term Option Series Program.¹⁴ Specifically, the Monday and Wednesday Qualifying Securities Expirations will have a strike interval of (i) \$0.50 or greater for strike prices below \$100, and \$1 or greater for strike prices between \$100 and \$150 for all option classes that participate in the Short Term Option Series Program, (ii) \$0.50 for option classes that trade in one dollar increments in Related non-short Term Options and are in the Short Term Option Series Program, or (iii) \$2.50 or greater for strike prices above \$150.¹⁵ As is the case with other equity options series listed pursuant to the Short Term Option Series Program, the Monday and Wednesday Qualifying Securities Expirations series will be P.M.-settled.

Pursuant to Rule 100(a)(66), with respect to the Short Term Option Series Program, if a Monday is not a business day, the series shall expire on the first business day immediately following that

Monday. Also, pursuant to Rule 100(a)(66), with respect to the Short Term Option Series Program, a Wednesday expiration series shall expire on the first business day immediately prior to that Wednesday, e.g., Tuesday of that week if the Wednesday is not a business day.

Currently, for each option class eligible for participation in the Short Term Option Series Program, the Exchange is limited to opening thirty (30) series for each expiration date for the specific class.¹⁶ The thirty (30) series restriction does not include series that are open by other securities exchanges under their respective weekly rules; the Exchange may list these additional series that are listed by other options exchanges.¹⁷ With the proposed changes, this thirty (30) series restriction would apply to Monday and Wednesday Qualifying Securities Expirations as well. In addition, the Exchange will be able to list series that are listed by other exchanges, assuming they file similar rules with the Commission to list Monday and Wednesday Qualifying Securities Expirations.

With this proposal, Monday and Wednesday Qualifying Securities Expirations would be treated similar to existing SPY, QQQ, and IWM Monday and Wednesday Expirations. With respect to standard expiration option series, Monday and Wednesday Qualifying Securities Expirations will be permitted to expire in the same week in which standard expiration option series on the same class expire.¹⁸ Not listing Monday and Wednesday Qualifying Securities Expirations for one week every month because there was a standard options series on that same class on the Friday of that week would create investor confusion.

Further, as with SPY, QQQ, and IWM Monday and Wednesday Expirations, the Exchange would not permit Monday and Wednesday Qualifying Securities Expirations to expire on a business day in which standard expiration option series, Monthly Options Series, or Quarterly Options Series expire.¹⁹ Therefore, all Monday and Wednesday Qualifying Securities Expirations would expire at the close of business on each of the next two Mondays and Wednesdays, respectively, that are business days and are not business days in which standard expiration option series, Monthly Options Series, or Quarterly Options Series expire. The

¹⁰ For purposes of this rule proposal, pre-announcements or "guidance" shall not be considered an Earnings Announcement.

¹¹ The Exchange has noted the additional expiries in a proposed Table 2 in IM-5050-6 along with the criteria for a Qualifying Security.

¹² They may also trade on Fridays, as is the case for all options series in the Short Term Option Series Program.

¹³ See *id.*

¹⁴ See BOX IM-5050-6. The Exchange notes that equity options which have an expiration of more than twenty-one days from the listing date would also be subject to the intervals as noted within IM-5050-6. See also IM-5050-11.

¹⁵ See *id.*

¹⁶ See BOX IM-5050-6.

¹⁷ See *id.*

¹⁸ See *id.*

¹⁹ See BOX IM-5050-6.

Exchange believes that it is reasonable to not permit two expirations on the same day in which a standard expiration option series, Monthly Options Series, a Quarterly Options Series would expire because those options would be duplicative of each other.

The Exchange does not believe that any market disruptions will be encountered with the introduction of Monday and Wednesday Qualifying Securities Expirations. The Exchange currently trades P.M.-settled Short Term Option Series that expire Monday, Tuesday, Wednesday and Thursday on several symbols²⁰ and has not experienced any market disruptions nor issues with capacity.²¹ Today, the Exchange has surveillance programs in place to support and properly monitor trading in Short Term Option Series that expire Monday, Tuesday, Wednesday and Thursday on several symbols.²² The Exchange believes that it has the necessary capacity and surveillance programs in place to support and properly monitor trading in the proposed Monday and Wednesday Qualifying Securities Expirations.

2. Statutory Basis

The Exchange believes that the proposal is consistent with the requirements of Section 6(b) of the Securities Exchange Act of 1934 (the “Act”),²³ in general, and Section 6(b)(5) of the Act,²⁴ 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 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.

Similar to Monday expirations in SPY, QQQ, and IWM, the proposal to permit Monday and Wednesday Qualifying Security Expirations, subject to the proposed limitation of two expirations beyond the current week, would protect investors and the public interest by providing the investing public and other market participants more choice and flexibility to closely tailor their investment and hedging decisions in these options and allow for a reduced premium cost of buying portfolio protection, thus allowing them to better manage their risk exposure.

The Exchange believes that the proposed criteria for Qualifying Securities requires individual stocks and Exchange-Traded Fund Shares to be highly liquid. A market capitalization measured on the last day of the prior calendar quarter based on the closing price of the underlying, of greater than 700 billion dollars for an individual stock, or AUM of 50 billion dollars for an Exchange-Trade Fund Share, in conjunction with the monthly options volume requirement of greater than 10 million options as measured by sides traded in the last month preceding the quarter end, is very restrictive. As provided in the ISE filing, this requirement represents substantially less than 1% of individual stocks (only eight (8) individual stocks currently exist as of January 1, 2025) and substantially less than 1% of Exchange-Traded Fund Shares (only seven (7) Exchange-Traded Fund Shares currently exist as of January 1, 2025, pursuant to Rule 5020, to trade additional expiries) traded.²⁵ Therefore, an individual stock or Exchange-Traded Fund Share that meets the aforementioned market capitalization and volume requirements are highly liquid and could be viewed as stable securities, as evidenced by the very low average realized volatility experienced by the Sample Qualifying Securities in the last 30 minutes of trading before the close in 2024 as compared to any security that traded an average of more than 100 options contracts per day.²⁶

The Exchange notes that with respect to position limits, Rule 3120(d)(5) provides, that “[t]o be eligible for the 250,000 contract limit, either the most recent six (6) month trading volume of the underlying security must have totaled at least 100 million shares or the most recent six-month trading volume of the underlying security must have totaled at least seventy-five (75) million shares and the underlying security must have at least 300 million shares currently outstanding.” The 250,000 contract position limit is the highest position limit with the exception of certain products listed in IM-3120-2. Options that qualify for the 250,000 position (and exercise) limit are highly liquid securities that have met the stringent requirements noted in Rule 3120(d)(5) to qualify for the highest position limit.

Finally, a Qualifying Security must participate in the Penny Interval Program. In order to qualify for the Penny Interval Program, an options class must be among the 300 most actively traded multiply listed option classes overlying securities priced below \$200.²⁷ The most actively traded options classes are included in the Penny Interval Program based on certain objective criteria (trading volume thresholds and initial price tests).

The number of individual stocks currently meeting all four criteria for a Qualifying Security is eight (8) and the number of Exchange-Traded Fund Shares currently meeting all four criteria for a Qualifying Security that do not already have Monday and Wednesday expirations is one (1) as of June 27, 2025. Both totals represent less than 0.2% of all securities with options listed. The Exchange believes that since individual stocks are the dominant constituents of the broad-based indexes (e.g., S&P 500 Index and Nasdaq-100 Index), the improvement in price transparency brought about by Monday and Wednesday trading will offer Market Makers and investors better volatility pricing which will inform trading on the related products to these indexes. The Exchange believes that the proposed criteria for Qualifying Securities is consistent with the protection of investors and the general public because the criteria targets the most liquid individual stocks and Exchange-Traded Fund Shares.

The Exchange would not list an expiry on a Qualifying Security on a day where there will be an Earnings

²⁰ See *supra* note 5.

²¹ In its filing to permit the listing of up to two Monday and Wednesday expirations for options on certain Qualifying Securities, ISE provided charts and analysis demonstrating the percentage of weekly listings in the options industry compared to monthly, quarterly, and Long-Term Options Series for a twelve-month period ending on February 11, 2025. The information includes time averaged data (the number of strikes by maturity date divided from the number of trading days) for all 18 options markets through February 11, 2025. The ISE Filing provides further that the Sample Qualifying Securities (selected based on January 2025 data) have an average annualized closing volatility of generally less than 20% and are more volatile than SPY, QQQ and IWM, but given that these are individual stocks it is reasonable to expect that they have idiosyncratic characteristics (increasing their volatility) relative to broad based Exchange-Traded Fund Shares like SPY, QQQ and IWM. ISE sourced this information, which are estimates, from OCC. See Securities Exchange Act Release No. 103434 (July 10, 2025), 90 FR 31716 (July 15, 2025) (SR-ISE-2025-15) (Notice of Filing of Amendment No. 1 to a Proposed Rule Change to Amend the Short Term Option Series Program to List Qualifying Securities).

²² See *supra* note 5.

²³ 15 U.S.C. 78f(b).

²⁴ 15 U.S.C. 78f(b)(5).

²⁵ See Securities Exchange Act Release No. 103434 (July 10, 2025), 90 FR 31716 (July 15, 2025) (SR-ISE-2025-15) (Notice of Filing of Amendment No. 1 to a Proposed Rule Change to Amend the Short Term Option Series Program to List Qualifying Securities).

²⁶ *Id.*

²⁷ See BOX Rule 7260. Each December OCC ranks all multiply listed option classes based on National Cleared Volume for the six full calendar months from June 1 through November 30 for determination of the most actively traded option classes.

Announcement that takes place after market close to avoid post-close price volatility that may arise from the Earnings Announcement and which may impact exercise and/or assignment decisions.

Qualifying Securities that do not continue to meet the above criteria would no longer be permitted to list Monday and Wednesday expiries in the following quarter, although the Qualifying Security would potentially have two weeks of strikes already listed which will persist. These remaining listings could continue to be traded until they expire.

With this proposal, overall, the Exchange would add a small number of Monday and Wednesday Qualifying Security Expirations by limiting the addition of two Monday expirations and two Wednesday expirations beyond the current week. The addition of Monday and Wednesday Qualifying Security Expirations would remove impediments to and perfect the mechanism of a free and open market by encouraging Market Makers to continue to deploy capital more efficiently and improve displayed market quality.²⁸ The Exchange believes that the proposal will allow Participants to expand hedging tools and tailor their investment and hedging needs more effectively in Qualifying Securities as these funds are most likely to be utilized by market participants to hedge the underlying asset classes.

Similar to SPY, QQQ, and IWM Monday and Wednesday Expirations, the introduction of Monday and Wednesday Qualifying Security Expirations is consistent with the Act as it will, among other things, expand hedging tools available to market participants and allow for a reduced premium cost of buying portfolio protection. The Exchange believes that Monday and Wednesday Qualifying Security Expirations will allow market participants to purchase options on Qualifying Securities based on their timing as needed and allow them to tailor their investment and hedging needs more effectively, thus allowing them to better manage their risk exposure. Today, BOX lists other Monday and Wednesday expirations.²⁹

In particular, the Exchange believes the Short Term Option Series Program has been successful to date and that Monday and Wednesday Qualifying Security Expirations should simply expand the ability of investors to hedge risk against market movements

stemming from economic releases or market events that occur throughout the month in the same way that the Short Term Option Series Program has expanded the landscape of hedging.

There are no material differences in the treatment of SPY, QQQ and IWM Monday and Wednesday Expirations compared to the proposed Monday and Wednesday Qualifying Security Expirations. Given the similarities between SPY, QQQ and IWM Monday and Wednesday Expirations and the proposed Monday and Wednesday Qualifying Security Expirations, the Exchange believes that applying the provisions in IM-5050-6 that currently apply to SPY, QQQ and IWM Monday and Wednesday Expirations is justified. The ISE Filing provided that, related to calls in SPY on April 2, 2025, the vast majority of open contracts (over 90%) were liquidated by customers prior to the close. Of the remaining open contracts, a substantial portion were rationally abandoned. In considering what constitutes rational activity on the part of a market participant in determining whether to exercise, especially in the strike near the 5:00 p.m. price, it must be taken into account that some market participants may elect to hold a contract given the illiquidity of the time period, and the desire for long exposure despite a trade price that may be lower. In other words, it cannot be assumed that customers are unaware of the market conditions, or their ability to liquidate. Also, it cannot be assumed that the customer would always liquidate in these circumstances. As provided in the ISE Filing, customers with calls in SPY on April 2, 2025 had a very high liquidation ratio which is evidenced by comparing the unabandoned contracts to the entire pool of long contracts throughout the day. With respect to the put data for SPY on April 2, 2025, the ISE Filing provides that out-of-the-money options were either liquidated or exercised. Only a small percentage of put options went unexercised. Additionally, it can be observed that very few puts remained unexercised at the higher strikes where opportunity for profit and less risk exists. This is in contrast to puts on lower strikes where opportunity for profit relative to the risk of the short is greater. In particular, with respect to the risk exposure of put writers, the exposure to an event similar to April 2, 2025 for the proposed Wednesday expirations would be substantially similar to the current risk that a put writer is exposed to with Friday expirations. In other words, the day of the expiry does not increase or decrease

the amount of risk of a put writer, but for the premium difference. Additionally, the Exchange believes that since the rational abandonment and out-of-the-money exercise rates were so high, as evidenced in the ISE Filing, it is clear that customers are largely aware of the exposure between 4:00 and 5:00 p.m. ET and therefore, the risk from the unliquidated position is undertaken knowingly.

Additionally, market participants that elect to utilize options receive a copy of the ODD which explains the risks inherent in options trading. Also, broker-dealers must have a reasonable basis to believe that a recommended transaction or investment strategy involving a security or securities is suitable for the customer.³⁰ Suitability rules are intended to distinguish the trading of customers with those of professional traders who are likely to have distinct risk/reward profiles, risk tolerance and capital. Regardless of whether the account is self-directed or options are being recommended, broker-dealers must perform due diligence on the customer and collect information about the customer to support a determination that options trading is appropriate for the customer. Options accounts are subject to specific supervisory reviews, including, among others, reviewing the compatibility of options transactions with investment objectives and with the types of transactions for which the account was approved, and are subject to other FINRA rules that apply when opening customer accounts, including among others, customer identification requirements under anti-money laundering rules.³¹ Therefore, the Exchange does not believe that listing of up to two Monday and Wednesday expirations for options on certain individual stocks or Exchange-Traded Fund Shares is inconsistent with the Act.

BOX represents that it has an adequate surveillance program in place to detect manipulative trading in the proposed option expirations, in the same way that it monitors trading in the current Short Term Option Series for Monday and Wednesday SPY, QQQ and IWM expirations. The Exchange also represents that it has the necessary system capacity to support the new expirations. Finally, the Exchange does not believe that any market disruptions will be encountered with the introduction of these option expirations. As discussed above, the Exchange

²⁸ Today, Market Makers are required to quote a specified time in their assigned options series. See BOX Rule 8050.

²⁹ See BOX IM-5050-6 at Table 1.

³⁰ See FINRA Rule 2111.

³¹ See <https://www.finra.org/rules-guidance/notices/21-15>.

believes that its proposal is a modest expansion of weekly expiration dates for Monday and Wednesday Qualifying Security Expirations given that it will be limited to two Monday expirations and two Wednesday expirations beyond the current week.

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. In this regard and as indicated above, the Exchange notes that the rule change is being proposed as a competitive response to a filing submitted by Nasdaq ISE that was recently approved by the Commission.³²

While the proposal will expand the Short Term Options Expirations to allow Monday and Wednesday Qualifying Security Expirations to be listed on BOX, the Exchange believes that this limited expansion for Monday and Wednesday expirations for options on Qualifying Securities will not impose an undue burden on competition; rather, it will meet customer demand. The Exchange would uniformly apply the Qualifying Security criteria to options in individual stocks and Exchange-Traded Fund Shares. The Exchange believes that Participants will continue to be able to expand hedging tools and tailor their investment and hedging needs more effectively in the Qualifying Securities.

Similar to SPY, QQQ and IWM Monday and Wednesday Expirations, the introduction of Monday and Wednesday Qualifying Security Expirations does not impose an undue burden on competition. The Exchange believes that it will, among other things, expand the hedging tools available to market participants and allow for a reduced premium cost of buying portfolio protection. The Exchange believes that Monday and Wednesday Qualifying Security Expirations will allow market participants to purchase options on Qualifying Securities based on their timing as needed and allow them to tailor their investment and hedging needs more effectively.

Further, not adding an expiry for a Qualifying Security on a day where there will be an Earnings Announcement that takes place after market close does not impose an undue burden on competition as the Exchange would uniformly apply this practice to the listing of all Qualifying Securities.

The Exchange does not believe the proposal will impose any burden on

inter-market competition, as nothing prevents other options exchanges from proposing similar rules to list and trade Monday and Wednesday Qualifying Security Expirations. Further, the Exchange does not believe the proposal will impose any burden on intra-market competition, as all market participants will be treated in the same manner under this proposal.

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 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 prior to 30 days from the date on which it 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)(iii) of the Act³³ and Rule 19b-4(f)(6) thereunder.³⁴

A proposed rule change filed under Rule 19b-4(f)(6)³⁵ normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b-4(f)(6)(iii),³⁶ 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. According to the Exchange, waiver of the operative delay would allow the Exchange to compete with one other exchange that has approval to list and trade the same option series.³⁷ The Commission believes that the proposed rule change presents no novel issues and that waiver of the 30-day operative delay is consistent with the protection

of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.³⁸

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 under Section 19(b)(2)(B)³⁹ 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 (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-BOX-2026-02 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-BOX-2026-02. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer

³³ 15 U.S.C. 78s(b)(3)(A)(iii).

³⁴ 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, 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.

³⁵ 17 CFR 240.19b-4(f)(6).

³⁶ 17 CFR 240.19b-4(f)(6)(iii).

³⁷ See *supra* note 3.

³⁸ 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).

³⁹ 15 U.S.C. 78s(b)(2)(B).

³² See *supra* note 3.

to file number SR–BOX–2026–02 and should be submitted on or before February 20, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁴⁰

Sherry R. Haywood,
Assistant Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–104696; File No. SR–NYSEAMER–2026–05]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Modify the NYSE American Options Fee Schedule To Waive the Combined Cap on Floor Broker Credits Paid for QCC Trades and Rebates Paid Through the Manual Billable Rebate Program for the Months of January and February 2026

January 27, 2026.

Pursuant to Section 19(b)(1) ¹ of the Securities Exchange Act of 1934 (“Act”) ² and Rule 19b–4 thereunder, ³ notice is hereby given that, on January 21, 2026, NYSE American LLC (“NYSE American” 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 self-regulatory organization. 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 modify the NYSE American Options Fee Schedule (“Fee Schedule”) to waive the maximum combined Floor Broker credits paid for QCC trades and rebates paid through the Manual Billable Rebate Program for the months of January and February 2026. The proposed rule change is available on the Exchange’s website at www.nyse.com and at the principal office of the Exchange.

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 purpose of this filing is to amend the Fee Schedule to waive the maximum combined Floor Broker credits paid for QCC trades and rebates paid through the Manual Billable Rebate Program for the months of January and February 2026.

The Exchange imposes a limit on the maximum combined Floor Broker credits paid for QCC trades and rebates paid through the Manual Billable Rebate Program per month per Floor Broker firm (the “Cap”).⁴ The Exchange recently filed a proposed rule change to increase the amount of the Cap from \$3,000,000 to \$4,000,000 based on sustained, elevated open outcry volumes in 2025.⁵ Because open outcry volumes on the Exchange remain elevated, the Exchange proposes to waive the Cap for the months of January and February 2026 and to use the period during which the Cap is waived to evaluate further adjustments to the amount of the Cap.⁶

As with previous waivers,⁷ the proposed waiver is being adopted in anticipation of Floor Broker firms

reaching the Cap before month’s end and potentially redirecting their order flow away from the Exchange. In the absence of the proposed waiver, Floor Broker firms may choose to re-direct such order flow to a competing market. Accordingly, the purpose of the proposal is to encourage Floor Broker firms to continue to direct open outcry transactions to the Exchange, despite increasing industry volumes making it less difficult to reach the Cap (even at the Cap’s newly increased amount).

Although the Exchange cannot predict with certainty how many Floor Broker firms would be impacted by this change, the Exchange believes that the proposed changes would incent Floor Brokers to continue to direct their order flow to the Exchange, thus increasing liquidity to the benefit of all market participants.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,⁸ in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,⁹ 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 changes to the Fee Schedule are reasonable, equitable, and not unfairly discriminatory. As a threshold matter, the Exchange is subject to significant competitive forces in the market for options securities transaction services that constrain its pricing determinations in that market. 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.”¹⁰

There are currently 18 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based options, no single exchange has more than 16% of the market share of

⁴ See Fee Schedule, Sections I.F. and III.E.1 (providing, in relevant part, that Floor Broker credits paid for QCC trades and rebates paid through the Manual Billable Rebate Program shall not combine to exceed \$4,000,000 per month per Floor Broker firm).

⁵ See SR–NYSEAMER–2026–03, available at <https://www.nyse.com/publicdocs/nyse/markets/nyse-american/rule-filings/filings/2026/SR-NYSEAMER-2026-03.pdf>.

⁶ See proposed Fee Schedule, Sections I.F. and III.E.1.

⁷ See Securities Exchange Act Release Nos. 102890 (April 18, 2025), 90 FR 17273 (April 24, 2025) (SRNYSEAMER–2025–26); 102985 (May 2, 2025), 90 FR 19584 (May 8, 2025) (SR–NYSEAMER–2025–27); 103623 (August 1, 2025), 90 FR 37905 (August 6, 2025) (SR–NYSEAMER–2025–46); 104258 (November 25, 2025), 90 FR 55186 (December 1, 2025) (SR–NYSEAMER–2025–65).

⁸ 15 U.S.C. 78f(b).

⁹ 15 U.S.C. 78f(b)(4) and (5).

¹⁰ See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (S7–10–04) (“Reg NMS Adopting Release”).

⁴⁰ 17 CFR 200.30–3(a)(12) and (59).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b–4.

executed volume of multiply-listed equity and ETF options trades.¹¹ Therefore, currently no exchange possesses significant pricing power in the execution of multiply-listed equity and ETF options order flow. More specifically, in November 2025, the Exchange had 8.58% market share of executed volume of multiply-listed equity and ETF options trades.¹² In such a low-concentrated and highly competitive market, no single options exchange possesses significant pricing power in the execution of options order flow. 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.

The proposed waiver of the Cap is reasonable because it is designed to encourage the role performed by Floor Brokers in facilitating the execution of orders via open outcry, a function that the Exchange wishes to support for the benefit of all market participants, and would allow the Exchange time to evaluate further changes to the amount of the Cap. Absent the proposed waiver, the Exchange believes that as soon as Floor Brokers reach the Cap, they are likely to re-direct order flow away from the Exchange, which may adversely impact other market participants trading on the Exchange. To the extent that the proposed waiver encourages Floor Brokers to facilitate transactions on the Exchange instead of on a competing market, all market participants participating on the Exchange would benefit from the increased liquidity. The Exchange believes the proposed waiver should continue to incent Floor Brokers to encourage market participants to aggregate their executions at the Exchange as a primary execution venue. To the extent that the proposed change achieves its purpose in attracting more volume to the Exchange, this increased order flow would continue to make the Exchange a more competitive venue for order execution, thus improving market quality for all market participants.

The Exchange believes the proposed waiver of the Cap is an equitable allocation of its fees and credits and is

not unfairly discriminatory because the proposal is based on the amount and type of business transacted on the Exchange. Floor Brokers are not obligated to execute manual transactions and QCCs to earn rebates and credits applied toward the Cap. However, the proposed waiver is designed to continue to encourage the role performed by Floor Brokers in facilitating the execution of orders via open outcry, a function that the Exchange wishes to support for the benefit of all market participants.

To the extent that the proposed waiver of the Cap continues to attract manual transactions and QCCs to the Exchange, this increased order flow would continue to make the Exchange a more competitive venue for order execution. Thus, the Exchange believes the proposed waiver would improve market quality for all market participants on the Exchange and attract more order flow to the Exchange, thereby improving market-wide quality and price discovery. The resulting increased volume and liquidity would provide more trading opportunities and tighter spreads to all market participants and thus would promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, protect investors and the public interest.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act, the Exchange does not believe that the proposed rule change would 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 all market participants. 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."¹³

Intramarket Competition. The proposed waiver of the Cap would apply equally to all similarly-situated Floor Brokers. To the extent that there is an additional competitive burden on non-Floor Brokers, the Exchange believes that any such burden would be appropriate because Floor Brokers serve an important function in facilitating the execution of orders in open outcry and price discovery for all market participants.

Intermarket Competition. The Exchange operates in a highly competitive market in which market participants can readily favor one of the other 17 competing options exchanges if they deem the Exchange's fee levels to be excessive. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and to attract order flow to the Exchange. Based on publicly-available information, and excluding index-based options, no single exchange has more than 16% of the market share of executed volume of multiply-listed equity and ETF options trades.¹⁴ Therefore, currently no exchange possesses significant pricing power in the execution of multiply-listed equity and ETF options order flow. More specifically, in November 2025, the Exchange had 8.58% market share of executed volume of multiply-listed equity and ETF options trades.¹⁵

The Exchange believes that the proposed waiver of the Cap reflects this competitive environment because it is designed to continue to incent Floor Brokers to direct manual and QCC transactions to the Exchange, to provide liquidity and to attract order flow. To the extent that Floor Brokers are encouraged to utilize the Exchange as a primary trading venue for all transactions, all Exchange market participants stand to benefit from the improved market quality and increased opportunities for price improvement. The Exchange notes that it operates in a highly competitive market in which market participants can readily favor

¹³ See Reg NMS Adopting Release, *supra* note 10, at 37499.

¹⁴ The OCC publishes options and futures volume in a variety of formats, including daily and monthly volume by exchange, available here: <https://www.theocc.com/Market-Data/Market-Data-Reports/Volume-and-Open-Interest/Monthly-Weekly-Volume-Statistics>.

¹⁵ Based on a compilation of OCC data for monthly volume of equity-based options and monthly volume of equity-based ETF options, *see id.*, the Exchange's market share in equity-based options increased from 6.09% for the month of November 2024 to 8.58% for the month of November 2025.

¹¹ The OCC publishes options and futures volume in a variety of formats, including daily and monthly volume by exchange, available here: <https://www.theocc.com/Market-Data/Market-Data-Reports/Volume-and-Open-Interest/Monthly-Weekly-Volume-Statistics>.

¹² Based on a compilation of OCC data for monthly volume of equity-based options and monthly volume of equity-based ETF options, *see id.*, the Exchange's market share in equity-based options increased from 6.09% for the month of November 2024 to 8.58% for the month of November 2025.

competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and credits to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

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) ¹⁶ of the Act and subparagraph (f)(2) of Rule 19b-4 ¹⁷ 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) ¹⁸ 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 (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-NYSEAMER-2026-05 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-NYSEAMER-2026-05. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-NYSEAMER-2026-05 and should be submitted on or before February 20, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁹

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2026-01824 Filed 1-29-26; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-104693; File No. SR-NASDAQ-2025-072]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing of a Proposed Rule Change, as Modified by Amendment No. 2, To Amend the Exchange's Rules To Enable the Trading of Securities on the Exchange in Tokenized Form

January 27, 2026.

On September 8, 2025, The Nasdaq Stock Market LLC ("Nasdaq" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "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 amend the Exchange's rules to enable the trading of securities on the Exchange in tokenized form. The proposed rule change was published for comment in the **Federal Register** on September 22, 2025.³ On November 3, 2025, pursuant

to Section 19(b)(2) of the Act,⁴ the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.⁵ On December 12, 2025, the Commission instituted proceedings under Section 19(b)(2)(B) of the Act,⁶ to determine whether to approve or disapprove the proposed rule change.⁷ On December 29, 2025, the Exchange filed Amendment No. 1 to the proposed rule change, which replaced and superseded the original filing in its entirety. On January 20, 2026, the Exchange filed Amendment No. 2 to the proposed change, which replaced and superseded the proposed rule change, as modified by Amendment No. 1, in its entirety. The proposed rule change, as modified by Amendment No. 2, is described in Items I and II below, which Items have been substantially prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change, as modified by Amendment No. 2, 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 Exchange's rules to enable the trading of securities on the Exchange in tokenized form during the pendency of a pilot program to be operated by the Depository Trust Company ("DTC") pursuant to the terms of a December 11, 2025 Commission No-Action Letter.⁸ Specifically, proposed rules Equity 1, Section 1 and Equity 4, Rules 4756, 4757, and 4758 will clarify how Nasdaq trades tokenized securities under this pilot program. This Amendment No. 2 supersedes the original filing, as amended by Amendment No. 1, in its entirety.⁹

are available at: <https://www.sec.gov/comments/sr-nasdaq-2025-072/srnasdaq2025072.htm>.

⁴ 15 U.S.C. 78s(b)(2).

⁵ See Securities Exchange Act Release No. 104173, 90 FR 51424 (November 17, 2025). The Commission designated December 21, 2025, as the date by which the Commission shall approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change.

⁶ 15 U.S.C. 78s(b)(2)(B).

⁷ See Securities Exchange Act Release No. 104384, 90 FR 58646 (December 17, 2025).

⁸ No-Action Letter Request Related to The Depository Trust Company's Development of the DTCC Tokenization Services, dated December 11, 2025, at <https://www.sec.gov/files/tm/no-action/dtc-nal-121125.pdf> (the "No-Action Letter" or the "Letter").

⁹ See Securities Exchange Act Release No. 103989 (September 16, 2025), 90 FR 45426 (September 22, 2025) (SR-NASDAQ-2025-072), as amended on January 20, 2026.

¹⁶ 15 U.S.C. 78s(b)(3)(A).

¹⁷ 17 CFR 240.19b-4(f)(2).

¹⁸ 15 U.S.C. 78s(b)(2)(B).

¹⁹ 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. 103989 (September 16, 2025), 90 FR 45426 ("Notice"). Comments received on the proposed rule change

The text of the proposed rule change is detailed below; proposed new language is italicized and proposed deletions are in brackets.

* * * * *

The NASDAQ Stock Market LLC Rules

* * * * *

Equity Rules

Equity 1 Equity Definitions

Section 1 Equity Definitions

(a) When used in the Equity Rules, unless the context otherwise requires:

(1) No change.

(2) “Security” Unless the context requires otherwise, the term “security” shall mean a “security,” *as that term is defined in section 3(a)(10) of the Securities Exchange Act of 1934, as amended, that is either listed on the Exchange or traded on the Exchange pursuant to unlisted trading privileges. A security may be traded in the Nasdaq Market Center in either traditional form (a digital representation of ownership and rights, but without utilizing distributed ledger (“blockchain” technology)) or, for the duration and under the terms of a pilot program operated by the Depository Trust Company (“DTC”), in tokenized form (a digital representation of ownership and rights which utilizes blockchain technology). Under the terms of a Securities and Exchange Commission No-Action Letter issued to DTC, dated December 11, 2025, only a subset of securities traded on Nasdaq will be eligible for trading in tokenized form (“DTC Eligible Securities”). Nasdaq will publish Equity Trader Alerts periodically to identify for DTC Eligible Participants (as that term is defined in Equity 4, Rule 4756(a)(5)) a current list of those DTC Eligible Securities that may trade in tokenized form on the Exchange. A share of a tokenized DTC Eligible Security shall be tradable in the Nasdaq Market Center together with, on the same Order Book as, and with the same execution priority as, its traditional counterpart, but only if the tokenized security is fungible with, shares the same CUSIP number with and trading symbol, and affords its shareholders the same rights and privileges as does a share of an equivalent class of the traditional security.*

* * * * *

Equity 4 Equity Trading Rules

* * * * *

4756. Entry and Display of Quotes and Orders

(a) Entry of Orders—Participants can enter orders into the System, subject to the following requirements and conditions:

(1)–(4) No change.

(5) *A market participant that is eligible to participate in the Depository Trust Company’s (“DTC’s”) three-year tokenization pilot program, pursuant to its terms and those of the Securities and Exchange Commission No-Action Letter, dated December 11, 2025 (the “No-Action Letter”) (each such market participant, a “DTC Eligible Participant”), and which wishes for its order in a DTC Eligible Security (as that term is defined in Equity 1, Section 1(a)(2)) to clear and settle in tokenized form as part of the DTC tokenization pilot program shall notate its preference upon entry of the order in the System by selecting a flag that the Exchange designates for this purpose, in accordance with the Exchange’s procedures. The flag will indicate the DTC Eligible Participant’s preference as to what form the security will take (i.e., token or traditional) and it also may include other information or instructions that DTC may require the DTC Eligible Participant to enter, in accordance with DTC’s rules, policies, and procedures, and the terms of the No-Action Letter, to effectuate the flag, such as the DTC Eligible Participant’s selection of a blockchain and a digital wallet address for a tokenized DTC Eligible Security (the Exchange will issue an Equity Trader Alert prior to requiring a DTC Eligible Participant to enter any such information or instructions to the flag, other than its tokenization preference). When a DTC Eligible Participant enters an order for a DTC Eligible Security with the tokenization flag selected, the Exchange, as an agent or designee of such DTC Eligible Participant, will communicate the DTC Eligible Participant’s flag, and any associated information or instructions to DTC. DTC will then carry out the DTC Eligible Participant’s tokenization preference, as set forth in the flag, as well as any instructions attendant thereto (as discussed herein) to the extent that the flag or instruction is executable in accordance with DTC’s rules, policies, and procedures, and the terms of the No-Action Letter. Nasdaq’s systems will not determine whether a market participant is a DTC Eligible Participant or whether a security is a DTC Eligible Security at the time of order entry and selection of the tokenization flag. Nasdaq also will not determine whether DTC is able to*

execute a tokenization order for other reasons, including because the DTC Eligible Participant wishes to mint the token to a blockchain that is not compatible with the DTC pilot tokenization program or to a digital wallet that is not registered with DTC. Thus, if at the time of order entry, a market participant is not a DTC Eligible Participant, the security selected for tokenization is not a DTC Eligible Security, or there are other reasons why DTC cannot execute a tokenization preference or instruction, then the order will remain in traditional (non-tokenized) form, in accordance with DTC’s rules, policies, and procedures. It is the sole responsibility of market participants to determine for themselves whether they are DTC Eligible Participants, if the securities subject to an order are DTC Eligible Securities, if the blockchains and wallets to which they wish to mint tokens are compatible with DTC’s pilot tokenization program, or whether the tokenization instruction is otherwise consistent with the terms of that program and the No Action Letter.

(b) Entry of Quotes—Nasdaq Market Makers and Nasdaq ECNs can enter Quotes into the System from 4:00 a.m. to 8:00 p.m. Eastern Time. Quotes will be processed as Attributable Orders, with such time-in-force designation as the Nasdaq Market Maker or Nasdaq ECN may assign. Entry of Quotes will be subject to the requirements and conditions set forth in section (a) above.

* * * * *

4757. Book Processing

(a) Orders on the Nasdaq Book shall be presented for execution against incoming Orders in the order set forth below:

(1)–(4) No change.

(5) *The mere fact that an order contains tokenized securities or indicates a preference of a DTC Eligible Participant to clear and settle DTC Eligible Securities in token form shall not affect the priority in which the Exchange executes that order.*

* * * * *

4758. Order Routing

(a) Order Routing Process

(1) The Order Routing Process shall be available to Participants during System Hours, unless otherwise noted in these rules, and shall route orders as described below. All routing of orders shall comply with Rule 611 of Regulation NMS under the Exchange Act.

(A) The System provides a variety of routing options. Routing options may be

combined with all available Order Types and Times-in-Force, with the exception of Order Types and Times-in-Force whose terms are inconsistent with the terms of a particular routing option. *When the Exchange routes an order for a DTC Eligible Security that a DTC Eligible Participant has designated for clearing and settlement in token form, in accordance with Rule 4756(a)(5), the Exchange will communicate this tokenization instruction to DTC upon receiving an execution for an order that was routed to another trading venue.* The System will consider the quotations only of accessible markets. The term “System routing table” refers to the proprietary process for determining the specific trading venues to which the System routes Orders and the Order in which it routes them. Nasdaq reserves the right to maintain a different System routing table for different routing options and to modify the System routing table at any time without notice. The System routing options are:

* * * * *

(b) Not applicable.

(c) Not applicable.

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 III 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 establish clearly that Nasdaq's member firms and investors that are eligible to participate in the DTC tokenization pilot program (“DTC Eligible Participants”) may trade tokenized versions of those equity securities and exchange traded products (“ETPs”) on the Exchange that are eligible for tokenization as part of the DTC tokenization pilot program (“DTC Eligible Securities”), pursuant to the terms of the No Action Letter. The filing describes and applies to one method by which DTC Eligible Securities can trade on Nasdaq within the current national

market system, using DTC to clear and settle trades in token form, per order handling instructions that DTC Eligible Participants may select upon entering their orders for DTC Eligible Securities on Nasdaq.¹⁰

Background

Over time, U.S. equity markets have thrived while absorbing successive waves of technological innovations. Nasdaq ushered in the first wave in the 1970s. Before that time, shares of equity securities existed only in paper form as stock certificates, and stocks were quoted, traded, and physically transferred among buyers and sellers through manual processes. Nasdaq—originally an acronym which stood for the National Association of Securities Dealers Automated Quotations—revolutionized the markets by quoting and trading equity securities electronically (digitally) and in an automated fashion. Subsequent waves of technological innovation followed that were no less revolutionary. Advances in computing technologies led to the rise of sophisticated algorithmic trading strategies, high-volume proprietary trading firms, and electronic market making. Meanwhile, advances in telecommunications enabled trade execution times to shrink from hours to microseconds, and for the dissemination of market data to shift from daily distributions of basic prices lists to lighting fast and efficient disseminations of rich and actionable market insights using modern data transfer infrastructure, cloud computing, and other technical innovations.

Securities tokenization is another new technology with potential applications for the securities markets. Put simply, tokenization enables aspects of securities transactions (which again, already are digital) to be recorded on a blockchain—a digital ledger that is encrypted, distributed among its users, and maintained, validated, and secured collectively by its users to ensure its integrity and security and to resist tampering. Today, by contrast, the securities markets employ various distinct and independent parties to perform these tasks, including trade matching, transferring, clearing, settlement, and custody services. These independent parties are highly regulated and trusted to protect investors. Today's system works extraordinarily well, it is

¹⁰Nasdaq is actively assessing multiple methods of tokenization and trading of tokenized securities. If the Exchange plans to adopt any particular alternative to the DTC approach, then to the extent necessary, it will file rule proposals with the Commission before doing so.

already highly efficient and reliable, and it operates at little or no commission cost to retail investors.

Although tokenization technology presents novel capabilities by which to record evidence of securities ownership and transactions, the trading of tokenized securities can, and it must, occur largely as Congress prescribed when it enacted and subsequently amended the Act. That is, Nasdaq believes such trading must occur in regulated markets, namely national securities exchanges, alternative trading systems, and at FINRA regulated broker-dealers. Nasdaq also believes that it must occur within the context of an interconnected national market system, rather than in siloed trading venues where investors would have no consolidated sense of best market-wide prices and no assured access to such prices. Furthermore, in Nasdaq's view, such trading should occur in markets that feature independent and regulated intermediaries to manage the links in the securities transaction chain safely, soundly, and in a disinterested manner.¹¹

The existing regulatory structure mandated by Congress applies to tokenized securities, regardless of whether such securities have certain unique properties (like the ability to be settled on a blockchain), much like it did when the SEC allowed securities to be decimalized and electrified and when exchange traded funds and other novel securities were approved decades ago. As in those cases, no significant exemptions or parallel market structure constructs are needed for tokenized securities to trade alongside other securities. As Commissioner Peirce stated recently, “[t]okenized securities are still securities” and “market participants must consider—and adhere to—the federal securities laws when transacting in these instruments.”¹² It is within this context that Nasdaq offers its proposal to trade tokenized securities.

¹¹Section 11A of the Act states that “[t]he linking of all markets for qualified securities . . . will foster efficiency, enhance competition, increase the information available to brokers, dealers, and investors, facilitate the offsetting of investors' orders, and contribute to best execution of such orders” such that Congress directed the Commission to “use its authority under this chapter to facilitate the establishment of a national market system for securities (which may include subsystems for particular types of securities with unique trading characteristics) in accordance with the findings and to carry out the objectives set forth in paragraph (1) of this subsection.” 15 U.S.C. 78K–1(a).

¹²Commissioner Hester M. Peirce, “Enchanting, but Not Magical: A Statement on the Tokenization of Securities,” available at <https://www.sec.gov/newsroom/speeches-statements/peirce-statement-tokenized-securities-070925>.

The Exchange believes the markets can use tokenization while continuing to provide the benefits and protections of the national market system. Wholesale exemptions from the national market system and related protections are neither necessary to achieve the goal of accommodating tokenization, nor are they in investors' best interests. To the contrary, they would harm investors and the markets since investors would lose access to portions of the market if platforms were not required to connect to the national market system or report trades. This would erode the National Best Bid and Offer ("NBBO"), a long-standing concern of many, including the SEC, increase fragmentation with liquidity pools not accessible to investors outside these platforms, and result in greater price dislocation.¹³ Thus, the markets, the issuers, and investors would be blind to activity occurring on these platforms, which would hinder issuer's ability to understand stock price movements and even daily trading volume. It would also impact questions of best execution and investor protection.¹⁴ Additionally, issuers would have no understanding of the total shares traded in any given day in their company's stock, further diminishing the strength of the public markets.¹⁵

¹³ Indeed, a recent news report validates these concerns as to tokens tracking two widely-held stocks—Apple and Amazon. These tokens experienced extreme price dislocations from the prices of their underlying stocks—a result that creates opportunities for retail investor exploitation as well as insider trading and manipulation. See Alexander Osipovich and Vicky Ge Huang, "Want to Trade Amazon on Crypto Exchange? The Price Might Be Off by 300%," Wall Street Journal, July 15, 2025, available at <https://www.wsj.com/finance/stocks/tokenized-stocks-prices-crypto-exchanges-856ea114>.

¹⁴ That lack of transparency is the current reality in Europe, which EU regulators are currently attempting to address with the creation of a consolidated tape. They view the US as a best-in-class example of providing a complete picture for issuers and investors of the trading activity and related price discovery in any given day, and they are now seeking to replicate our model. It would be detrimental to the underpinnings of our national market system to abandon that core aspect of our markets.

¹⁵ As an operator of a primary listing exchange, Nasdaq is also concerned by the impact of tokenization on securities issuers. In Europe, trading of tokenized stocks is occurring in a manner that raises numerous concerns. For example, we understand that some digital asset trading platforms are offering shares of U.S. equities to European investors without the prior knowledge or consent of the issuers of those securities. When issuers list securities on national securities exchanges, they do so with the expectation that those securities will trade in a certain form and on certain markets. Nasdaq believes that tokenizing securities should not occur in a manner that deprives issuers of their ability to determine where and how their shares trade. Nasdaq is limited in its ability to afford issuers a choice as to whether their shares are or become tokenized by other markets. Nevertheless,

Finally, we note that in Europe, trading of tokenized stocks is occurring in a manner that raises investor concerns. A few trading platforms are purporting to offer investors access to tokenized U.S. "equities," but they are not providing investors with actual shares in U.S. companies. Instead (and likely contrary to the understanding of unsophisticated investors), they are providing investors with digitally tradable rights to traditional digital shares that the platforms themselves purchase and hold in their own accounts. These digital rights do not comprise the full extent of the rights to which owners of traditional digital shares are entitled, including voting rights and the rights to corporate assets upon liquidation; instead, they merely convey economic rights associated with shares—the right to realize appreciation and depreciation in the value of the shares.¹⁶ Thus, a purchaser of these tokenized rights receives less value for their money than do purchasers of traditional digital securities.¹⁷

Although trading tokenized securities outside of the national market system would pose significant risks to the markets and investors, such risks need not occur. Nasdaq submits, as evidenced by this proposal, that only minor changes to existing rules and practice are necessary to accommodate the trading of tokenized securities and that granting broad exemptions would be unwarranted.¹⁸

Nasdaq's Flexible Approach

To tackle the challenge of trading tokenized equities, Nasdaq offers a simple and safe proposal that accommodates an approach to tokenization that DTC is pursuing in a tokenization pilot program, which the SEC approved in its No Action Letter. This approach leverages existing structures and players and rules, rather than experimenting with radical new models that are untested in the context

we encourage the Commission to consider the issue as it develops a new regulatory regime for tokenized securities.

¹⁶ See "Kraken Launches xStocks for 24/5 Trading of 60 US Stocks," Alinvest, June 30, 2025, available at <https://www.alinvest.com/news/kraken-launches-xstocks-24-5-trading-60-stocks-2506/>.

¹⁷ As the Commission ponders whether to permit similarly structured products to be offered in the United States, Nasdaq encourages the Commission consider whether such products should be marketable as "equities," "shares," or "stock" or whether instead they should be labeled more accurately as derivative instruments or depository rights to avoid investor confusion.

¹⁸ Nasdaq has previously noted the limitations inherent in the Commission's exemptive authority. See J. Zecca, "Digital Assets Sandbox," dated June 6, 2025, at 6–7, available at <https://www.sec.gov/files/digital-assets-sandbox-comment-060625.pdf>.

of listed securities and potentially detrimental to investors,' issuers,' and the markets' best interests.¹⁹

As noted above, Nasdaq proposes to trade DTC Eligible Securities within the confines of existing securities laws and rules. In Nasdaq's proposal to trade tokenized securities, Nasdaq believes that all existing Commission and Nasdaq rules that currently apply to trading non-tokenized securities on the Nasdaq Stock Market will continue to apply, without modification, except as follows.

Order Entry and Processing

First, the Exchange proposes to amend its definition of a security, at Equity 1, Section 1, to announce that DTC Eligible Participants may trade DTC Eligible securities in token form on the Exchange during the duration of, and pursuant to the terms of the DTC tokenization pilot program, as authorized by the No-Action Letter. The proposed rule change also clarifies that the term "tokenized" in this instance refers to digital representations of paper securities that utilize digital ledger or blockchain technology, as opposed to "traditional" securities, which are also digital representations of paper securities, but do not utilize blockchain technology. The proposal describes how the Exchange will trade DTC Eligible Securities in token form, noting that as long as DTC Eligible Securities are fungible with, have the same CUSIP number and trading symbol as, and afford their holders the same rights and privileges as do traditional securities of an equivalent class, then the Exchange will trade DTC Eligible Securities in token form together with traditional securities on the same Order Book and according to the same execution priority rules. A tokenized DTC Eligible Security would be deemed to provide the same rights and privileges as a traditional security if, among other things, it conveys an equity interest in an underlying company, a right to receive any dividends that the company issues to its shareholders, a right to exercise any voting rights that shareholders are due, and a right to receive a share of the residual assets of the company upon liquidation. The Exchange will not treat tokenized instruments to be equivalent to their traditional counterparts if they do not convey such rights or share the

¹⁹ See J. Zecca, "What's in a Name? A Stock by Any Other Name . . ." Nasdaq Inc.'s Response to "There Must Be Some Way Out of Here," April 25, 2025, at 19–21, available at <https://www.sec.gov/files/ctf-written-input-nasdaq-042525.pdf> (discussing the risks of trading digital assets in Vertically Integrated and Direct-to-retail digital asset markets).

same CUSIP and trading symbol, but instead the Exchange will treat these instruments as distinct (e.g., derivative securities or ADRs).²⁰ The proposed amended rule text is as follows, with proposed changes underlined:

(2) “Security” Unless the context requires otherwise, the term “security” shall mean a “security,” *as that term is defined in section 3(a)(10) of the Securities Exchange Act of 1934, as amended, that is either listed on the Exchange or traded on the Exchange pursuant to unlisted trading privileges. A security may be traded in the Nasdaq Market Center in either traditional form (a digital representation of ownership and rights, but without utilizing distributed ledger (“blockchain” technology)) or, for the duration and under the terms of a pilot program operated by the Depository Trust Company (“DTC”), in tokenized form (a digital representation of ownership and rights which utilizes blockchain technology). Under the terms of a Securities and Exchange Commission No-Action Letter issued to DTC, dated December 11, 2025, only a subset of securities traded on Nasdaq will be eligible for trading in tokenized form (“DTC Eligible Securities”). Nasdaq will publish Equity Trader Alerts periodically to identify for DTC Eligible Participants (as that term is defined in Equity 4, Rule 4756(a)(5)) a current list of those DTC Eligible Securities that may trade in tokenized form on the Exchange. A share of a tokenized DTC Eligible Security shall be tradable in the Nasdaq Market Center together with, on the same Order Book as, and with the same execution priority as, its traditional counterpart, but only if the tokenized security is fungible with, shares the same CUSIP number with and trading symbol, and affords its shareholders the same rights and privileges as does a share of an equivalent class of the traditional security.*

Second, the Exchange proposes to amend its Order Entry Rule, at Equity 4, Rule 4756, to describe how a DTC Eligible Participant can communicate its desire to clear and settle a DTC Eligible Security in tokenized form. The proposed amended Rule states that a DTC Eligible Participant that wishes for its order in a DTC Eligible Security to clear and settle in tokenized form must notate its preference upon entry of the order in the System by selecting a flag that the Exchange designates for this

purpose, in accordance with the Exchange’s procedures. When a DTC Eligible Participant enters an order for a DTC Eligible Security with the tokenization flag selected, the Exchange will communicate the DTC Eligible Participant’s tokenization preference to DTC (on a post-trade basis). The flag will indicate the DTC Eligible Participant’s preference as to what form the security will take (i.e., token or traditional) and it also may include other information or instructions that DTC may require the DTC Eligible Participant to enter, in accordance with DTC’s rules, policies, and procedures, and the terms of the No-Action Letter, to effectuate the flag, such as the DTC Eligible Participant’s selection of a blockchain and a digital wallet address for a tokenized DTC Eligible Security (the Exchange will issue an Equity Trader Alert prior to requiring a DTC Eligible Participant to enter any such information or instructions to the flag, other than its tokenization preference). DTC will then carry out the DTC Eligible Participant’s tokenization preference, as set forth in the flag, as well as any instructions attendant thereto (as discussed herein) to the extent that the flag or instruction is executable in accordance with DTC’s rules, policies, and procedures, and the terms of the No Action Letter.

Nasdaq’s systems will not determine whether a Participant is a DTC Eligible Participant or whether a security is a DTC Eligible Security at the time of order entry and selection of the tokenization flag. Nasdaq also will not determine whether DTC is able to execute a tokenization order for other reasons, including because the DTC Eligible Participant wishes to mint the token to a blockchain that is not compatible with the DTC pilot tokenization program or deposit it into a wallet that is not registered with DTC.²¹ Thus, if at the time of order

²¹ According to the No-Action Letter, any DTC participant would be permitted—at the DTC participant’s election—to participate in the DTC pilot tokenization services with an exception (i.e., participants for which DTC has U.S. tax withholding or reporting obligations, or a Treasury International Capital reporting obligation). As of October 31, 2025, DTC states that it has U.S. tax withholding and reporting obligations, or a TIC reporting obligation, for approximately 11 percent of its participants. Once DTC resolves outstanding tax and TIC compliance questions, it envisions offering the services to these participants as well. See n.8, *supra*.

Additionally, the No-Action Letter states that DTC will not execute a tokenization instruction if a DTC Eligible Participant cannot pass DTC’s risk management and compliance controls. See *id.* If a transaction would result in a participant breaching its Net Debit Cap, then the control would not allow that transaction to process until it could do so without breaching the cap. See *id.*

entry, a market participant is not a DTC Eligible Participant, the security selected for tokenization is not a DTC Eligible Security, or there are other reasons why DTC cannot execute a tokenization flag or instruction, DTC will settle the executed order in traditional (non-tokenized) form, in accordance with DTC’s rules, policies, and procedures. It is the sole responsibility of market participants to determine for themselves whether they are DTC Eligible Participants, if the securities subject to an order are DTC Eligible Securities, if the blockchains to which they wish to mint tokens are compatible with DTC’s pilot tokenization program, or whether the tokenization instruction is otherwise consistent with the terms of that program and the No Action Letter. That said, Nasdaq intends to develop functionality that would allow for it to check for eligibility at order entry, and it will submit a rule proposal to effectuate that functionality at the appropriate time. Third, Nasdaq proposes to amend its Book Processing Rule, at Equity 4, Rule 4757, to clarify that the mere fact that an order contains tokenized securities or indicates a preference to clear and settle securities in token form will not affect the priority in which the Exchange executes that order.

Fourth and finally, the Exchange proposes to amend its Order Routing Rule, at Equity 4, Rule 4758, to note that when the Exchange routes orders in DTC Eligible Securities that DTC Eligible Participants have designated for clearing and settlement in token form, in accordance with the Exchange’s order entry rules and procedures, then the Exchange will communicate this tokenization instruction to DTC upon receiving an execution for an order that was routed to another trading venue.

Apart from the above, as far as Nasdaq’s systems and matching engine are concerned, the Exchange’s trading procedures and behavior will be the same regardless of whether a DTC Eligible Participant opts to trade tokenized or traditional shares of a DTC Eligible Security.²² Among other things, the following aspects of Nasdaq’s trading system and procedures will not change when trading tokenized securities:

- All Exchange order types and attributes will be available for use by tokenized securities.

²² Nasdaq’s pricing structure and rates will not vary depending upon whether a transaction involves a share of a tokenized stock.

²⁰ This rule proposal does not address whether and how Nasdaq may choose to trade these non-fungible tokenized instruments in the future pursuant to a proposed Rule change.

- All Exchange routing strategies will be available for orders in tokenized securities.

- Orders in tokenized securities may participate in all of the Exchange's trading sessions as well as in its Opening and Closing Crosses, subject to generally applicable eligibility criteria.

- Participants may utilize their existing connectivity to enter orders in tokenized securities.

- The Exchange's fee schedule will not vary based upon whether shares that Participants execute are tokenized or traditional in nature.

- Market data feeds will not differentiate between tokenized and traditional shares.

- The Exchange will comply with any Commission requirements to report tokenization data to the Consolidated Audit Trail.

- Market surveillance of tokenized and traditional securities will rely upon the same underlying data, which will continue to be accessible by Nasdaq and FINRA.

- Trades in tokenized securities handled by DTC will continue to settle on a T+1 basis.

- Nasdaq's clearly erroneous and risk management measures will cover tokenized securities.

- Trading of tokenized securities under this proposal is not expected to alter the existing proxy distribution process.²³

A key benefit of Nasdaq's proposal is that it will readily allow for trading in tokenized DTC Eligible Securities to occur within the context of the national market system. The Exchange's proposal will allow for tokenized DTC Eligible Securities to trade on its market in a transparent manner, without degrading the NBBO, without further fragmenting the national market system, without causing price dislocations or facilitating market manipulation, and without undermining the investor protections that existing securities law provide.

Tokenization and Post-Trade Processing

This proposal to offer trading in tokenized securities will become effective once the requisite infrastructure and post-trade settlement services have been established by DTC. Nasdaq understands that DTC is

working to develop the necessary infrastructure, services, and procedures to facilitate such tokenization and the related post-trade settlement infrastructure and services.²⁴ On December 11, 2025, the Commission issued a No-Action Letter that enables DTC to begin providing services that support the Exchange's proposal as soon as this development is complete.²⁵

The details of DTC's planned service for settling traditional securities in token form and tokenized securities in traditional form are set forth in the No-Action Letter, a letter from DTC to the Commission requesting no-action relief, attached thereto, and on DTC's website.²⁶ Nasdaq refers readers to those documents for a fulsome description of the DTC pilot tokenization program.

By way of summary, Nasdaq understands that the DTC pilot tokenization program will operate as follows, in conjunction with Nasdaq. First, to be eligible to trade tokenized securities on Nasdaq, and for DTC to settle traditional securities in tokenized form or vice versa, one must be a DTC Eligible Participant. A DTC Eligible Participant must register with the DTC and obtain or more wallet addresses on a DTC approved blockchain. DTC also indicates that its ability to execute tokenization and de-tokenization instructions will be limited by both the blockchains to which its tokenization service connects as well as the universe of securities that will be eligible for its services. According to DTC, only blockchains that meet DTC's standards for such things as transaction reversal and resiliency, will be supported by its service. DTC represents that it expects that its tokenization service will support multiple blockchains, and it expects to publish its blockchain standards, and its list of supported blockchains, in the coming months.

According to DTC, securities that are DTC Eligible Securities—meaning that they are eligible for tokenization and de-tokenization as part of the DTC tokenization pilot program, will be limited to the following, for purposes of this proposal: (i) securities in the Russell 1000 Index at the time the service launches as well as any

additions to the index thereafter and notwithstanding the subsequent removal of any securities from the index; and (ii) ETFs that track major indices, such as the S&P 500 index and Nasdaq-100 index. These categories of DTC Eligible Securities will be the only tokenized equities that are available to trade on Nasdaq under this proposal.

If a DTC Eligible Participant wants to settle a DTC Eligible Security in token form, then the DTC Eligible Participant will submit an order handling instruction to the Exchange upon order entry. The DTC Eligible Participant will do so by selecting a flag designated by the Exchange for this purpose. The Exchange will then convey it to DTC for execution on a post-trade basis. Nasdaq understands that the DTC process is expected to include transfer of the Participant's designated book-entry position from the Participant's DTC account to a DTC control account and then conversion to a corresponding position in token form that DTC would mint and deliver to the Participant's DTC-registered digital wallet on a blockchain, which DTC would track and reconcile against the control account.²⁷ We also note that insofar as a DTC Eligible Participant's trades are settled on a net basis, and the DTC Eligible Participant's net position in a DTC Eligible Security is less than what the DTC Eligible Participant specified in its tokenization instruction, then DTC will adjust the instruction to tokenize the DTC Eligible Security to the extent of the net position.

DTC states that it will provide tokenization services on a pilot basis, as described above, for a period of three years after launch, after which time DTC will sunset the service.²⁸ Thus, Nasdaq will revisit this rule proposal when it knows what, if anything, will replace the service after it sunsets.

Nasdaq will alert its Members in an Equity Trader Alert at least 30 calendar days before the Exchange begins trading DTC Eligible Securities in tokenized form on its market.

Illustrative Example of Trading Tokenized Invesco QQQ on the Exchange

The following illustrates how Nasdaq will trade tokenized securities on its system. For purposes of this illustration, the Exchange uses the example of the Invesco QQQ TrustSM ETP (the "QQQ

²³ According to DTC, a DTC Eligible Participant may need to issue a de-tokenization instruction or DTC may need to force conversion of the Tokenized Entitlement into a Book-Entry Entitlement in order to receive a distribution or replacement security or to issue instructions in relation to the corporate action. In such situations, DTC would, to the extent feasible, provide the relevant participants with advance notice of the need to provide such instruction or DTC's need to take such action. See n.8, *supra*.

²⁴ Multiple other forms of tokenization and clearance and settlement are under discussion. The proposed rule change is specific to the process that Nasdaq understands DTC is developing. However, Nasdaq will explore additional solutions as they develop, with the objective of accommodating as much tokenization technology as possible as efficiently as possible. To the extent that Nasdaq elects to pursue any alternatives to this Proposal, it will do so pursuant to a separate filing.

²⁵ See n.8, *supra*.

²⁶ See *id.*; see also <https://www.dtcc.com/digital-assets/tokenization#Tokenization>.

²⁷ Nasdaq understands that the DTC process may be available in the second half of 2026. See DTCC, No Action Letter and DTC Tokenization Service FAQ, at 2, available at <https://www.dtcc.com/-/media/Files/Downloads/digital-assets/dtc-tokenization-service-faq.pdf>.

²⁸ See *id.*, at 1.

ETF” or “QQQ”), the shares of which its sponsor, Invesco Capital Management LLC (“Invesco”), intends to offer in tokenized form.²⁹

An Exchange member that is properly registered with DTC and eligible to participate in the DTC tokenization pilot program wishes to place a displayed limit order in a tokenized share of QQQ on behalf of an investor. The Exchange member would provide instructions to that effect when it enters the order into Nasdaq’s system, as it otherwise would do. The Exchange would then process that order consistent with how it processes all orders in QQQ shares in terms of order entry protocols, order handling, priority, order matching, and trade reporting. All Exchange Order Types and Attributes that are otherwise available to a traditional QQQ order in a given scenario would likewise be available to the tokenized QQQ order. The Exchange would generate market data about the order in the same way that it does now. The tokenized QQQ order would be available to match contra orders for either tokenized or traditional shares of QQQ and would do so without any special priority relative to other orders in QQQ on the Exchange book. When a trade occurs involving the order in tokenized QQQ, the Exchange will report trade information to the SIP as it does now. Until Nasdaq implements its plan to enable securities to trade on its market on a 23/5 basis, tokenized shares of QQQ will not be available for trading on Nasdaq outside of regular and extended trading hours.

The post-trade settlement services, including the eligibility of a member’s orders to be settled in tokenized form, will be determined by DTC’s policies and procedures and the No Action Letter.

2. Statutory Basis

Nasdaq’s proposal offers a means by which market participants can utilize the DTC pilot tokenization program when trading on the Exchange. The Exchange believes that its proposal is consistent with Section 6(b) of the Act,³⁰ in general, and furthers the objectives of Section 6(b)(5) of the Act,³¹ 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.

It is consistent with the Act to permit members of the Exchange to trade tokenized securities. As explained above, investors increasingly demand the ability to own and trade tokenized versions of financial assets, including securities. Such capabilities are available increasingly in other jurisdictions and to more a limited extent, in the United States. Thus far, and as compared with other available solutions, Nasdaq submits that its proposal offers a means of trading tokenized securities that is consistent with Congressional intent—in that it will provide for trading to occur within the framework of the national market system—while serving the best interests of issuers, investors, and the markets.

Most importantly, the proposal will involve trading tokenized securities on Nasdaq—the world’s leading and most trusted market operator and provider of market technology. This means that Nasdaq believes that the trading of tokenized securities that occurs on Nasdaq will be subject to the full panoply of SEC regulatory obligations and oversight, as well as Nasdaq rules, which together help to ensure that trading of all securities on Nasdaq is transparent, fair, orderly, equitable, and in the best interests of investors. Due to the application of the national market system rules, the prices of tokenized securities trading on Nasdaq will be transparent and they will both contribute to and account for the NBBO. Market makers on Nasdaq will provide two-sided liquidity, even in times of market stress. Broker-dealer members of the Exchange will have best execution obligations to investors when they execute trades of tokenized securities on Nasdaq. The Exchange itself will be subject to the rigors of Reg SCI to help ensure that tokenized securities trading occurs in a manner that is secure, dependable, and resilient as well as to ensure that Nasdaq is accountable for any failures to do so. Nasdaq’s systems have a track record of reliably processing transactions in microseconds, even during recent periods of record-high volatility and message traffic. Nasdaq’s world-class surveillance and enforcement capabilities—which are unique to national securities exchanges—also will be brought to bear to detect and address fraud and manipulation, should it occur.

Nasdaq’s proposal will also avoid risks inherent in other tokenization approaches that would potentially

fragment liquidity and isolate it to particular trading platforms and blockchain technologies that are not interoperable. In such scenarios, tokenized securities would not trade freely across markets as they do now or access better prices. Moreover, the markets could suffer to the extent that isolated liquidity no longer links to the national market system and contributes to the NBBO.

This proposal to trade tokenized securities on Nasdaq will require Nasdaq to change very little from its existing structure and practices, which the Commission has approved and oversees. As noted above, the tokenization services that DTC will provide in support of Nasdaq’s proposal have been reviewed by the Commission and are subject to the terms of the No-Action Letter.

B. Self-Regulatory Organization’s Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange’s proposal to trade tokenized securities on its market are neither intended to nor will they adversely impact competition. If anything, the Exchange expects that the proposed changes will promote competition by providing for the Nasdaq Stock Market to accommodate the demand for tokenized DTC Eligible Securities among listed companies and DTC Eligible Participants. Nasdaq believes that its proposal will be particularly attractive because it will provide for the trading of tokenized DTC Eligible Securities in a manner that is familiar to market participants and investors and which is consistent with existing laws and rules. Indeed, under Nasdaq’s proposal, the extent to which market participants (other than DTC) will need to modify their back-end systems and practices to accommodate tokenized securities trading should be minimal—meaning that those systems may simply need to account for the availability of the new flag and be set up to provide any information that the flag requires to Nasdaq. Nasdaq notes that market participants on the Exchange will remain free to trade, clear and settle securities in traditional form, including both DTC Eligible Securities and other securities.

In any event, the Exchange operates in a highly competitive market in which market participants can readily choose between competing venues if they deem participation in the Exchange’s market to no longer be desirable or if they do

²⁹ Although Nasdaq discusses herein the trading of the Invesco QQQ ETF on the Exchange, this rule proposal would allow Nasdaq to trade other tokenized versions of securities. We anticipate that Invesco will file separately with the Commission to obtain any permission or exemptive relief necessary to have tokenized QQQ shares traded on the Exchange.

³⁰ 15 U.S.C. 78f(b).

³¹ 15 U.S.C. 78f(b)(5).

not wish to trade tokenized securities. In such an environment, the Exchange must carefully consider the impact that any change it proposes may have on market participants, understanding that it will likely lose them to the extent a change is viewed as unfavorable by them. Because competitors are free to modify the functionality and structure of their markets, including by availing themselves of the same capabilities that are being developed to trade tokenized securities, the Exchange believes that the degree to which its proposal imposes any burden on competition is limited. Last, to the extent the proposed change is successful in attracting additional market participants or additional activity by existing Participants, the Exchange also believes that the proposed change will promote competition among trading venues by making the Exchange a more attractive trading venue for Participants and investors.

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. 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. 2, is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-NASDAQ-2025-072 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-2025-072. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable

information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-NASDAQ-2025-072 and should be submitted on or before February 20, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.³²

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026-01823 Filed 1-29-26; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-104692; File No. SR-NYSEARCA-2026-04]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Rules 5.32-O and 5.35-O Related to Flexible Exchange Options

January 27, 2026.

Pursuant to Section 19(b)(1)¹ of the Securities Exchange Act of 1934 ("Act"),² and Rule 19b-4 thereunder,³ notice is hereby given that on January 15, 2026, 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 self-regulatory organization. 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 Rules 5.32-O and 5.35-O related to Flexible Exchange ("FLEX") Options. Specifically, the Exchange proposes to allow for cash-settlement of certain FLEX Equity Options. The proposed rule change is available on the Exchange's website at www.nyse.com and at the principal office of the Exchange.

³² 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

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 amend Rules 5.32-O and 5.35-O related to FLEX Options. The proposal is substantially identical to approved rules on NYSE American LLC.⁴

FLEX Options are customized equity or index contracts that allow investors to tailor contract terms for exchange-listed equity and index options. The Exchange proposes to amend NYSE Arca Rule 5.32-O(f) to allow for cash settlement of certain FLEX Equity Options.⁵ Generally, FLEX Equity Options are settled by physical delivery of the underlying security,⁶ while all FLEX Index Options are currently settled by delivery in cash.⁷ As proposed, "FLEX ETF Options" where the underlying security is an Exchange-Traded Fund Share would be permitted to be settled by delivery in cash if the underlying security meets prescribed criteria, which criteria has been approved by the Securities and Exchange Commission ("SEC" or "Commission").⁸

To permit cash settlement of certain FLEX ETF Options, the Exchange

⁴ See NYSE American Rules 903G(c)(3)(iii) and 906G. See also Securities and Exchange Release No. 88131 (February 5, 2020), 85 FR 7806 (February 11, 2020) (SR-NYSEAMER-2019-38) (Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Allow Certain Flexible Equity Options To Be Cash Settled) (the "American FLEX Approval Order").

⁵ A "FLEX Equity Option" is an option on a specified underlying equity security or Exchange-Traded Fund Share. See Rule 5.30-O(b)(5).

⁶ See Rule 5.32-O(f)(3)(i).

⁷ See Rules 5.32-O (e)(2) and (3). Pursuant to Exchange rules, Binary Return Derivatives ("ByRDs") are also settled in cash. See Rule 5.82-O(b). As discussed below, cash settlement is also permitted in the over-the-counter ("OTC") market.

⁸ See generally American FLEX Approval Order, *supra* note 4.

proposes new paragraph (f)(3)(ii) to Rule 5.32–O. Proposed Rule 5.32–O(f)(3)(ii) would provide that the exercise settlement for a FLEX ETF Option may be by physical delivery of the underlying security or by delivery in cash if the underlying security, measured over the prior six-month period, has an average daily notional value of \$500 million or more and a national average daily volume (ADV) of at least 4,680,000 shares.⁹

The Exchange also proposes new subparagraph (A) to Rule 5.32–O(f)(3)(ii), which would provide that the Exchange will determine bi-annually the underlying securities that satisfy the notional value and trading volume requirements in Rule 5.32–O(f)(3)(ii) by using trading statistics for the previous six-months.¹⁰ The proposed rule would further provide that the Exchange will permit cash settlement as a contract term on no more than 50 underlying ETFs that meet the criteria in Rule 5.32–O(f)(3)(ii), and that if more than 50 underlying ETFs satisfy the notional value and trading volume requirements, the Exchange would select the top 50 ETFs that have the highest average daily volume.¹¹

Proposed new subparagraph (B) to Rule 5.32–O(f)(3)(ii) would further provide that if the Exchange determines pursuant to the bi-annual review that an underlying ETF ceases to satisfy the requirements under Rule 5.32–O(f)(3)(ii), any new positions overlying such ETF entered into will be required to have exercise settlement by physical delivery and any open cash-settled FLEX ETF Option positions may be traded only to close the position.¹²

⁹ See proposed Rule 5.32–O(f)(3)(ii). The Exchange also proposes a non-substantive amendment to Rule 5.32–O to renumber current Rule 5.32–O(f)(3)(ii) as new Rule 5.32–O(f)(3)(iii).

¹⁰ See proposed Rule 5.32–O(f)(3)(ii)(A). The Exchange plans to conduct the bi-annual review on January 1 and July 1 of each year. The results of the bi-annual review will be announced via Trader Update and any new securities that qualify would be permitted to have cash settlement as a contract term beginning on February 1 and August 1 of each year.

¹¹ See proposed Rule 5.32–O(f)(3)(ii)(A). The Exchange notes that, according to Rule 5.32–O(f)(1), it will not authorize for trading a FLEX Equity Option class (either cash-settled or physically-settled) on the iShares Bitcoin Trust (IBIT), the Grayscale Bitcoin Trust (GBTC), the Grayscale Bitcoin Mini Trust (BTC), and the Bitwise Bitcoin ETF (BITB). If the Exchange determines to allow FLEX trading on such options at a later date, it will do so by submitting a 19b–4 rule filing with the Commission.

¹² See proposed Rule 5.32–O(f)(3)(ii)(B). An OTP Holder or OTP Firm that is acting as a Market Maker may enter into an opening transaction in order to facilitate closing transactions of another market participant in option series that are restricted to closing-only transactions. See <https://www.nyse.com/publicdocs/nyse/markets/arca->

The Exchange believes it is appropriate to introduce cash settlement as an alternative contract term to the select group of ETFs because they are among the most highly liquid and actively-traded securities. As described more fully below, the Exchange believes that the deep liquidity and robust trading activity in the ETFs identified by the Exchange as meeting the criteria mitigate against historic concerns regarding susceptibility to manipulation.

Characteristics of ETFs

ETFs are funds that have their value derived from assets owned. The net asset value (“NAV”) of an ETF is a daily calculation that is based off the most recent closing prices of the assets in the fund and an actual accounting of the total cash in the fund at the time of calculation. The NAV of an ETF is calculated by taking the sum of the assets in the fund, including any securities and cash, subtracting out any liabilities, and dividing that by the number of shares outstanding.

Additionally, each ETF is subject to a creation and redemption mechanism to ensure the price of the ETF does not fluctuate too far away from its NAV—which mechanisms reduce the potential for manipulative activity. Each business day, ETFs are required to make publicly available a portfolio composition file that describes the makeup of their creation and redemption “baskets” (*i.e.*, a specific list of names and quantities of securities or other assets designed to track the performance of the portfolio as a whole). ETF shares are created when an Authorized Participant, typically a market maker or other large institutional investor, deposits the daily creation basket or cash with the ETF issuer. In return for the creation basket or cash (or both), the ETF issues to the Authorized Participant a “creation unit” that consists of a specified number of ETF shares. For instance, IWM is designed to track the performance of the Russell 2000 Index. An Authorized Participant will purchase all the Russell 2000 constituent securities in the exact same weight as the index prescribes, then deliver those shares to the ETF issuer. In exchange, the ETF issuer gives the Authorized Participant a block of

options/rule-interpretations/2017/NYSE%20Arca%20Options%20RB%2017-01.pdf. Consistent with a Market Maker’s duty to maintain fair and orderly markets under Rule 6.32–O, the Exchange will provide guidance to reflect that an OTP Holder or OTP Firm acting as a Market Maker in cash-settled FLEX ETF Options can enter into an opening transaction to facilitate closing only transactions of another market participant in cash-settled FLEX ETF Option series that are restricted to closing-only transactions.

equally valued ETF shares, on a one-for-one fair value basis. This process can also work in reverse. A redemption is achieved when the Authorized Participant accumulates a sufficient number of shares of the ETF to constitute a creation unit and then exchanges these ETF shares with the ETF issuer, thereby decreasing the supply of ETF shares in the market.

The principal, and perhaps most important, feature of ETFs is their reliance on an “arbitrage function” performed by market participants that influences the supply and demand of ETF shares and, thus, trading prices relative to NAV. As noted above, new ETF shares can be created and existing shares redeemed based on investor demand; thus, ETF supply is open-ended. This arbitrage function helps to keep an ETF’s price in line with the value of its underlying portfolio, *i.e.*, it minimizes deviation from NAV. Generally, in the Exchange’s view, the higher the liquidity and trading volume of an ETF, the more likely the price of the ETF will not deviate from the value of its underlying portfolio, making such ETFs less susceptible to price manipulation.

Trading Data for the ETFs Proposed for Cash Settlement

The Exchange believes that average daily notional value is an appropriate proxy for selecting underlying securities that are not readily susceptible to manipulation for purposes of establishing a settlement price. Average daily notional value considers both the trading activity and the price of an underlying security. As a general matter, the more expensive an underlying security’s price, the less cost-effective manipulation could become. Further, manipulation of the price of a security encounters greater difficulty the more volume that is traded. To calculate average daily notional value (provided in the table below), the Exchange summed the notional value of each trade for each symbol (*i.e.*, the number of shares times the price for each execution in the security) and divided that total by the number of trading days in the six-month period (from January 1, 2025 through June 30, 2025) reviewed by the Exchange.

Further, the Exchange proposes that qualifying ETFs also meet an ADV standard. The purpose for this second criteria is to prevent unusually expensive underlying securities from qualifying under the average daily notional value standard while not being one of the most actively traded securities. The Exchange believes an ADV requirement of 4,680,000 shares a

day is appropriate because it represents average trading in the underlying ETF of 200 shares per second. While no security is immune from all manipulation, the Exchange believes that the combination of average daily notional value and ADV as prerequisite requirements would limit cash settlement of FLEX ETF Options to those underlying ETFs that would be

less susceptible to manipulation in order to establish a settlement price.

The Exchange believes that the proposed objective criteria would ensure that only the most robustly traded and deeply liquid ETFs would qualify to have cash settlement as a contract term. As provided in the table below, as of August 1, 2025, the Exchange would be able to provide cash

settlement as a contract term for FLEX ETF Options on 50 underlying ETFs, as each of these securities currently meets the requirement of \$500 million or more average daily notional value and a minimum ADV of 4,680,000 shares. The table below provides the list of the 50 ETFs that, as of February 2, 2026, would be eligible to have cash settlement as a contract term.

Symbol	Security name	Average daily notional value (in dollars) (7/1/25–12/31/25)	Average daily volume (in shares) (7/1/25–12/31/25)
AGG	iShares Core U.S. Aggregate Bond ETF	851,736,628	8,537,106
ARKK	ARK Innovation ETF	790,660,256	10,002,331
BIL	State Street SPDR Bloomberg 1–3 Month T-Bill ETF	811,729,500	8,864,004
BND	Vanguard Total Bond Market	525,248,363	7,091,622
EEM	iShares MSCI Emerging Markets ETF	1,314,535,887	25,104,296
EFA	iShares MSCI EAFE ETF	1,400,802,545	15,047,336
EMB	iShares J.P. Morgan USD Emerging Markets Bond ETF	645,590,199	6,808,789
EWZ	iShares MSCI Brazil ETF	832,406,524	27,539,581
FXI	iShares China Large-Cap ETF	1,162,022,779	29,637,240
GDX	VanEck Gold Miners ETF	1,650,929,132	23,308,008
GLD	SPDR Gold Trust, SPDR Gold Shares	4,679,648,415	13,106,089
HYG	iShares iBoxx \$ High Yield Corporate Bond ETF	3,009,053,280	37,348,764
IAU	iShares Gold Trust	663,013,049	9,038,878
IBIT	iShares Bitcoin Trust ETF	3,302,762,948	54,804,815
IEF	iShares 7–10 Year Treasury Bond ETF	776,595,411	8,065,323
IEFA	iShares Core MSCI EAFE ETF	944,372,956	10,887,444
IEMG	iShares Core MSCI Emerging Markets ETF	707,399,002	10,864,418
IJH	iShares Core S&P Mid-Cap ETF	557,473,063	8,591,757
IVV	iShares Core S&P 500 ETF	4,916,301,448	7,366,354
IWM	iShares Russell 2000 ETF	9,107,195,726	38,334,860
KRE	State Street SPDR S&P Regional Banking ETF	1,010,867,367	16,149,904
KWEB	KraneShares CSI China Internet ETF	758,561,614	19,787,877
LQD	iShares iBoxx \$ Investment Grade Corporate Bond ETF	3,250,822,405	29,383,282
NVDL	GraniteShares ETF Trust GraniteShares 2x Long NVDA Daily ETF	1,108,697,601	12,675,065
QQQ	Invesco QQQ Trust, Series 1	30,818,923,154	51,850,964
RSP	Invesco S&P 500 Equal Weight ETF	2,762,810,864	14,703,142
SGOV	iShares 0–3 Month Treasury Bond ETF	1,388,081,321	13,809,327
SLV	iShares Silver Trust	1,678,176,062	35,288,580
SMH	VanEck Semiconductor ETF	2,469,068,633	7,678,563
SOXL	Direxion Daily Semiconductor Bull 3X Shares	3,006,888,191	87,729,942
SOXS	Direxion Daily Semiconductor Bear 3X Shares	1,190,447,220	242,272,959
SPY	SPDR S&P 500 ETF Trust	49,479,496,319	75,099,335
SPYM	State Street SPDR Portfolio S&P 500 ETF	832,289,521	10,428,634
SQQQ	ProShares UltraPro Short QQQ	2,097,799,624	101,252,728
TLT	iShares 20+ Year Treasury Bond ETF	3,020,168,090	34,177,787
TNA	Direxion Daily Small Cap Bull 3x Shares	550,895,018	13,028,336
TQQQ	ProShares UltraPro QQQ	5,470,244,126	64,643,171
TSLI	Direxion Shares ETF Trust Direxion Daily TSLA Bull 2X Shares	2,097,868,817	128,729,316
VCIT	Vanguard Intermediate-Term Corporate Bond ETF	908,984,288	10,872,165
VEA	Vanguard FTSE Developed Markets ETF	757,435,926	12,639,446
VOO	Vanguard S&P 500 ETF	4,849,283,165	7,967,852
XBI	State Street SPDR S&P Biotech ETF	1,018,437,196	9,948,285
XLB	State Street Materials Select Sector SPDR ETF	575,590,829	7,068,027
XLE	State Street Energy Select Sector SPDR ETF	1,323,649,507	16,857,476
XLF	State Street Financial Select Sector SPDR ETF	2,039,032,835	38,456,638
XLI	State Street Industrial Select Sector SPDR ETF	1,600,951,720	10,508,948
XLK	State Street Technology Select Sector SPDR ETF	2,227,341,881	8,716,285
XLP	State Street Consumer Staples Select Sector SPDR ETF	1,157,734,148	14,561,414
XLU	State Street Utilities Select Sector SPDR ETF	927,003,728	11,908,503
XLV	State Street Health Care Select Sector SPDR ETF	1,840,490,851	12,949,393

The Exchange believes that permitting cash settlement as a contract term for FLEX ETF Options for the ETFs in the above table would broaden the base of investors that use FLEX Options to

manage their trading and investment risk, including investors that currently trade in the over-the-counter (“OTC”) market for customized options, where settlement restrictions do not apply.

Today, equity options are settled physically at The Options Clearing Corporation (“OCC”), *i.e.*, upon exercise, shares of the underlying security must be assumed or delivered.

Physical settlement possesses certain risks with respect to volatility and movement of the underlying security at expiration against which market participants may need to hedge. The Exchange believes cash settlement may be preferable to physical delivery in some circumstances as it does not present the same risk. If an issue with the delivery of the underlying security arises, it may become more expensive (and time consuming) to reverse the delivery because the price of the underlying security would almost certainly have changed. Reversing a cash payment, on the other hand, would not involve any such issue because reversing a cash delivery would simply involve the exchange of cash. Additionally, with physical settlement, market participants that have a need to generate cash would have to sell the underlying security while incurring the costs associated with liquidating their position as well as the risk of an adverse movement in the price of the underlying security.

The Exchange notes that the SEC has previously approved or noticed for immediate effectiveness rule filings of other exchanges that allowed for the trading of cash-settled options,¹³ and specifically, cash-settled FLEX ETF Options.¹⁴

¹³ See e.g., PHLX FX Options traded on Nasdaq PHLX and S&P 500® Index Options traded on Cboe Options Exchange. The SEC noticed for immediate effectiveness, on a pilot basis, the listing and trading of RealDay™ Options on the SPDR S&P 500 Trust on the BOX Options Exchange LLC (“BOX”). See Securities Exchange Act Release No. 79936 (February 2, 2017), 82 FR 9886 (February 8, 2017) (“RealDay Pilot Program”). The RealDay Pilot Program was extended until February 2, 2019. See Securities Exchange Act Release No. 82414 (December 28, 2017), 83 FR 577 (January 4, 2018) (SR-BOX-2017-38). The RealDay Pilot Program was never implemented and RealDay™ Options on the SPDR S&P 500 Trust never traded on BOX. See also Securities Exchange Act Release Nos. 56251 (August 14, 2007), 72 FR 46523 (August 20, 2007) (SR-Amex-2004-27) (Order approving listing of Fixed Return Options (“FROs”)); and 71957 (April 16, 2014), 79 FR 22563 (April 22, 2014) (SR-NYSEMKT-2014-06) (Order approving name change from FROs to ByRDs and re-launch of these products, with certain modifications).

¹⁴ See Securities Exchange Act Release Nos. 102839 (April 11, 2025), 90 FR 16410 (April 17, 2025) (SR-BOX-2025-07) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 5055 To Allow for Cash Settlement of Certain FLEX Equity Options); 98044 (August 2, 2023), 88 FR 53548 (August 8, 2023) (SR-CBOE-2023-036) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Allow Certain Flexible Exchange Equity Options To Be Cash Settled); and 101720 (November 22, 2024), 89 FR 94986 (November 29, 2024) (SR-ISE-2024-12) (Notice of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Adopt Rules To List and Trade FLEX Options). See also Securities Exchange Act Release Nos. 88131 (February 5, 2020), 85 FR 7806 (February 11, 2020) (SR-NYSEAMER-2019-38) (Order Approving a

With respect to position and exercise limits, cash-settled FLEX ETF Options would be subject to the position limits set forth in Rule 5.35–O. Accordingly, the Exchange proposes new Rule 5.35–O(b)(ii), which would provide that a position in FLEX Equity Options where the underlying security is an ETF and that is settled in cash pursuant to Rule 5.32–O(f)(3)(ii) would be subject to the position limits set forth in Rule 6.8–O, and subject to the exercise limits set forth in Rule 6.9–O. The proposed rule further states that positions in such cash-settled FLEX Equity Options shall be aggregated with positions in physically-settled options on the same underlying ETF for the purpose of calculating the position limits set forth in Rule 6.8–O, and the exercise limits set forth in Rule 6.8–O.¹⁵ Given that each of the underlying ETFs that would currently be eligible to have cash-settlement as a contract term have established position and exercise limits applicable to physically-settled options, the Exchange believes it is appropriate for the same position and exercise limits to also apply to cash-settled options. Accordingly, of the 50 underlying securities that would currently be eligible to have cash settlement as a contract term, 34 would have a position limit of 250,000 contracts pursuant to Rule 6.9–O, Commentary .06(e).¹⁶ Further, pursuant to Rule 6.8–O, Commentary .06(f), 10 would have a position limit of 500,000 contracts; four (EEM, EFA, FIX and IWM) would have a position limit of 1,000,000 contracts; one (QQQ) would have a position limit of 1,800,000 contracts; and one (SPY) would have a position limit of 3,600,000 contracts.¹⁷

Proposed Rule Change, as Modified by Amendment No. 1, to Allow Certain Flexible Equity Options To Be Cash Settled; and 97231 (March 31, 2023), 88 FR 20587 (April 6, 2023) (SR-NYSEAMER-2023-22) (Notice of Filing and Immediate Effectiveness of Proposed Change to Make a Clarifying Change to the Term Settlement Style Applicable to Flexible Exchange Options).

¹⁵ See proposed Rule 5.35–O(b)(ii). The aggregation of position and exercise limits would include all positions on physically settled FLEX Equity Options and Non-FLEX Equity Options on the same underlying ETFs. The Exchange also proposes a non-substantive amendment to Rule 5.35–O to renumber current Rule 5.35–O(b)(ii) as new Rule 5.35–O(b)(iii).

¹⁶ Rule 6.8–O, Commentary .06(e) provides that the position limit shall be 250,000 contracts for options: (i) on an underlying security that had trading volume of at least 100,000,000 shares during the most recent six-month trading period; or (ii) on an underlying security that had trading volume of at least 75,000,000 shares during the most recent six-month trading period and has at least 300,000,000 shares currently outstanding. All fifty (50) underlying ETFs currently meet the requirements under Commentary .06(e).

¹⁷ These were based on position limits as of June 30, 2025. Position limits are available at OCC—

The Exchange understands that cash-settled FLEX ETF Options are currently traded in the OTC market by a variety of market participants, e.g., hedge funds, proprietary trading firms, and pension funds.¹⁸ These options are not fungible with the exchange listed options. The Exchange believes some of these market participants would prefer to trade these instruments on an exchange, where they would be cleared and settled through a regulated clearing agency. The Exchange expects that users of these OTC products would be among the primary users of exchange-traded cash-settled FLEX ETF Options. The Exchange also believes that the trading of cash-settled FLEX ETF Options would allow these same market participants to better manage the risk associated with the volatility of underlying equity positions given the enhanced liquidity that an exchange-traded product would bring.

In the Exchange’s view, cash-settled FLEX ETF Options traded on the Exchange would have three important advantages over the contracts that are traded in the OTC market. First, as a result of greater standardization of contract terms, exchange-traded contracts should develop more liquidity. Second, counter-party credit risk would be mitigated by the fact that the contracts are issued and guaranteed by OCC. Finally, the price discovery and dissemination provided by the Exchange and its members would lead to more transparent markets. The Exchange believes that its ability to offer cash-settled FLEX ETF Options would aid it in competing with the OTC market and at the same time expand the universe of products available to interested market participants. The Exchange believes that an exchange-traded alternative may provide a useful risk management and trading vehicle for market participants and their customers. Further, the Exchange believes listing cash-settled FLEX ETF Options would provide investors with competition on an exchange platform, as another exchange recently listed the same options.¹⁹

The Exchange notes that OCC has received approval from the SEC for rule changes that will accommodate the clearance and settlement of cash-settled ETF Options.²⁰ The Exchange has also

Position Limits (theocc.com). Position limits for ETFs are determined in accordance with the Exchange’s Rules regarding position limits.

¹⁸ As noted above, other options exchange currently list and trade certain cash-settled FLEX ETF Options. See *supra* notes 4 and 14.

¹⁹ *Id.*

²⁰ See Securities Exchange Act Release No. 94910 (May 13, 2022), 87 FR 30531 (May 19, 2022) (SR-OCC-2022-003).

analyzed its capacity and the capacity of The Options Price Reporting Authority (OPRA) and represents that it and OPRA have the necessary systems capacity to handle the additional traffic associated with the listing of cash-settled FLEX ETF Options. The Exchange believes any additional traffic that would be generated from the introduction of cash-settled FLEX ETF Options would be manageable. The Exchange represents that OTP Holders and OTP Firms will not have a capacity issue as a result of this proposed rule change. The Exchange also does not believe this proposed rule change will cause fragmentation of liquidity. The Exchange will monitor the trading volume associated with the additional options series listed as a result of this proposed rule change and the effect (if any) of these additional series on market fragmentation and on the capacity of the Exchange's automated systems.

The Exchange does not believe that allowing cash settlement as a contract term would render the marketplace for equity options more susceptible to manipulative practices. The Exchange believes that manipulating the settlement price of cash-settled FLEX ETF Options would be difficult based on the size of the market for the underlying ETFs that are the subject of this proposed rule change. The Exchange notes that each underlying ETF in the table above is sufficiently active to alleviate concerns about potential manipulative activity. Further, in the Exchange's view, the vast liquidity in the underlying ETFs that would currently be eligible to be traded as cash-settled FLEX options under the proposal ensures a multitude of market participants at any given time. Moreover, given the high level of participation among market participants that enter quotes and/or orders in physically settled options on these ETFs, the Exchange believes it would be very difficult for a single participant to alter the price of the underlying ETF or options overlying such ETF in any significant way without exposing the would-be manipulator to regulatory scrutiny. The Exchange further believes any attempt to manipulate the price of the underlying ETF or options overlying such ETF would also be cost prohibitive. As a result, the Exchange believes there is significant participation among market participants to prevent manipulation of cash-settled FLEX ETF Options.

Still, the Exchange believes it has an adequate surveillance program in place for cash-settled FLEX ETF Options and intends to apply the same program

procedures that it applies to the Exchange's other options products.

FLEX options products and their respective symbols are integrated into the Exchange's existing surveillance system architecture and are thus subject to the relevant surveillance processes. The Exchange believes that the existing surveillance procedures at the Exchange are capable of properly identifying unusual and/or illegal trading activity, which procedures the Exchange would utilize to surveil for aberrant trading in cash-settled FLEX ETF Options.

With respect to regulatory scrutiny, the Exchange believes its existing surveillance technologies and procedures adequately address potential concerns regarding possible manipulation of the settlement value at or near the close of the market. The Exchange notes that the regulatory program operated by and overseen by NYSE Regulation²¹ includes cross-market surveillance designed to identify manipulative and other improper trading, including spoofing, algorithm gaming, marking the close and open, as well as more general, abusive behavior related to front running, wash sales, quoting/routing, and Reg SHO violations, that may occur on the Exchange and other markets. These cross-market patterns incorporate relevant data from various markets beyond the Exchange and its affiliates and from markets not affiliated with the Exchange. The Exchange represents that its existing trading surveillances are adequate to monitor the trading in the underlying ETFs and subsequent trading of options on those securities on the Exchange, including cash-settled FLEX ETF Options.²²

Additionally, for options, the Exchange utilizes an array of patterns that monitor manipulation of options, or manipulation of equity securities (regardless of venue) for the purpose of impacting options prices on the Exchange (*i.e.*, mini-manipulation strategies). That surveillance coverage is initiated once options begin trading on the Exchange. Accordingly, the Exchange believes that the cross-market surveillance performed by the Exchange

²¹ The Exchange maintains regulatory services agreements with Financial Industry Regulatory Authority, Inc. ("FINRA") whereby FINRA provides certain regulatory services to the exchanges, including cross-market surveillance, investigation, and enforcement services.

²² Such surveillance procedures generally focus on detecting securities trading subject to opening price manipulation, closing price manipulation, layering, spoofing or other unlawful activity impacting an underlying security, the option, or both. The Exchange has price movement alerts, unusual market activity and order book alerts active for all trading symbols.

or FINRA, on behalf of the Exchange, coupled with NYSE Regulation's own monitoring for violative activity on the Exchange comprise a comprehensive surveillance program that is adequate to monitor for manipulation of the underlying ETF and overlying option. Furthermore, the Exchange believes that the existing surveillance procedures at the Exchange are capable of properly identifying unusual and/or illegal trading activity, which the Exchange would utilize to surveil for aberrant trading in cash-settled FLEX ETF Options.

In addition to the surveillance procedures and processes described above, improvements in audit trails (*i.e.*, the Consolidated Audit Trail), recordkeeping practices, and inter-exchange cooperation over the last two decades have greatly increased the Exchange's ability to detect and punish attempted manipulative activities. In addition, the Exchange is a member of the Intermarket Surveillance Group ("ISG").²³ The ISG members work together to coordinate surveillance and investigative information sharing in the stock and options markets. For surveillance purposes, the Exchange would therefore have access to information regarding trading activity in the pertinent underlying securities. The Exchange will monitor and adjust its surveillance procedures as needed for the cash settlement of FLEX ETF Options.

The proposed rule change is designed to allow investors seeking to effect cash-settled FLEX ETF Options with the opportunity for a different method of settling option contracts at expiration if they choose to do so. As noted above, market participants may choose cash settlement because physical settlement possesses certain risks with respect to volatility and movement of the underlying security at expiration that market participants may need to hedge against. The Exchange believes that offering innovative products flows to the benefit of the investing public. A robust and competitive market requires that exchanges respond to members' evolving needs by constantly improving their offerings. Such efforts would be stymied if exchanges were prohibited from offering innovative products for reasons that are generally debated in academic literature. The Exchange

²³ ISG is an industry organization formed in 1983 to coordinate intermarket surveillance among the SROs by cooperatively sharing regulatory information pursuant to a written agreement between the parties. The goal of the ISG's information sharing is to coordinate regulatory efforts to address potential intermarket trading abuses and manipulations.

believes that introducing cash-settled FLEX ETF Options would further broaden the base of investors that use FLEX Options to manage their trading and investment risk, including investors that currently trade in the OTC market for customized options, where settlement restrictions do not apply. The proposed rule change is also designed to encourage market makers to shift liquidity from the OTC market onto the Exchange, which, it believes, would enhance the process of price discovery conducted on the Exchange through increased order flow. The Exchange also believes that this may open up cash-settled FLEX ETF Options to more retail investors. The Exchange does not believe that this proposed rule change raises any unique regulatory concerns because existing safeguards—such as position limits (and the aggregation of cash-settled positions with physically-settled positions), exercise limits (and the aggregation of cash-settled positions with physically-settled positions), and reporting requirements—would continue to apply. The Exchange believes the proposed position and exercise limits may further help mitigate the concerns that the limits are designed to address about the potential for manipulation and market disruption in the options and the underlying securities.²⁴

Given the novel characteristics of cash-settled FLEX ETF Options, the Exchange will conduct a review of the trading in cash-settled FLEX ETF Options over an initial five-year period. The Exchange will furnish five reports to the SEC based on this review, the first of which would be provided within 60 days after the first anniversary of the initial listing date of the first cash-settled FLEX ETF Option under the proposed rule and each subsequent annual report to be provided within 60 days after the second, third, fourth and fifth anniversary of such initial listing. At a minimum, each report will provide a comparison between the trading volume of all cash-settled FLEX ETF Options listed under the proposed rule and physically-settled options on the same underlying security, the liquidity of the market for such options products and the underlying ETF, and any manipulation concerns arising in connection with the trading of cash-settled FLEX ETF Options under the proposed rule. The Exchange will also provide additional data as requested by the Commission during this five-year period. The reports will also discuss any recommendations the Exchange may have for enhancements to the listing

standards based on its review. The Exchange believes these reports will allow the Commission and the Exchange to evaluate, among other things, the impact such options have, and any potential adverse effects, on price volatility and the market for the underlying ETFs, the component securities underlying the ETFs, and the options on the same underlying ETFs and make appropriate recommendations, if any, in response to the reports.

The Exchange notes that it will issue a notice to OTP Holders via a Trader Update announcing the implementation date of the proposal.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the “Act”),²⁵ in general, and furthers the objectives of Section 6(b)(5) of the Act,²⁶ 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. Specifically, the Exchange believes that introducing cash-settled FLEX ETF Options will increase order flow to the Exchange, increase the variety of options products available for trading, and provide a valuable tool for investors to manage risk.

The Exchange believes that the proposal to permit cash settlement as a contract term for options on the specified group of equity securities would remove impediments to and perfect the mechanism of a free and open market as cash-settled FLEX ETF Options would enable market participants to receive cash in lieu of shares of the underlying security, which would, in turn provide greater opportunities for market participants to manage risk through the use of a cash-settled product to the benefit of investors and the public interest. The Exchange does not believe that allowing cash settlement as a contract term for options on the specified group of equity securities would render the marketplace for equity options more susceptible to manipulative practices. As illustrated in the table above, each of the qualifying underlying securities is actively traded and highly liquid and thus would not be susceptible to manipulation because, over a six-month period, each security

had an average daily notional value of at least \$500 million and an ADV of at least 4,680,000 shares, which indicates that there is substantial liquidity present in the trading of these securities, and that there is significant depth and breadth of market participants providing liquidity and of investor interest. The Exchange believes that the proposed bi-annual review to determine eligibility for an underlying ETF to have cash settlement as a contract term would remove impediments to and perfect the mechanism of a free and open market as it would permit the Exchange to select only those underlying ETFs that are actively traded and have robust liquidity as each qualifying ETF would be required to meet the average daily notional value and average daily volume requirements, as well as to select the same underlying ETFs on which other exchanges may list cash-settled FLEX ETF Options.²⁷

The Exchange believes that the data provided by the Exchange supports the supposition that permitting cash settlement as a FLEX term for the 50 underlying ETFs that would currently qualify to have cash settlement as a contract term would broaden the base of investors that use FLEX Options to manage their trading and investment risk, including investors that currently trade in the OTC market for customized options, where settlement restrictions do not apply.

The Exchange believes that the proposal to permit cash settlement would remove impediments to and perfect the mechanism of a free and open market because the proposed rule change would provide OTP Holders and OTP Firms with enhanced methods to manage risk by receiving cash if they choose to do so instead of the underlying security. In addition, this proposal would promote just and equitable principles of trade and protect investors and the general public because cash settlement would provide investors with an additional tool to manage their risk. Further, the Exchange notes that other exchanges have previously received approval that allow for the trading of cash-settled options²⁸ and, specifically, cash-settled FLEX ETF Options in an identical manner as the Exchange proposes to list them pursuant to this rule filing.²⁹ The proposed rule change therefore should not raise issues for the Commission that have not been previously addressed.

The proposed rule change to permit cash settlement as a contract term for

²⁴ See *supra* note 14.

²⁵ 15 U.S.C. 78f(b).

²⁶ 15 U.S.C. 78f(b)(5).

²⁷ See *supra*, note 14.

²⁸ See *supra*, note 13.

²⁹ See *supra*, notes 4 and 14.

options on the 50 underlying ETFs is designed to promote just and equitable principles of trade in that the availability of cash settlement as a contract term would give market participants an alternative to trading similar products in the OTC market. By trading a product in an exchange-traded environment (that is currently traded in the OTC market), the Exchange would be able to compete more effectively with the OTC market. The Exchange believes the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that it would lead to the migration of options currently trading in the OTC market to trading on the Exchange. Also, any migration to the Exchange from the OTC market would result in increased market transparency. Additionally, the Exchange believes the proposed rule change is designed to remove impediments to and to perfect the mechanism for a free and open market and a national market system, and, in general, to protect investors and the public interest in that it should create greater trading and hedging opportunities and flexibility. The proposed rule change should also result in enhanced efficiency in initiating and closing out positions and heightened contra-party creditworthiness due to the role of OCC as issuer and guarantor of the proposed cash-settled options. Further, the proposed rule change would result in increased competition by permitting the Exchange to offer products that are currently available for trading in the OTC market and are approved to trade on other options exchanges.

The Exchange believes that establishing position limits for cash-settled FLEX ETF Options to be the same as physically-settled options on the same underlying security, and aggregating positions in cash-settled FLEX ETF Options with physically-settled options on the same underlying security for purposes of calculating position limits is reasonable and consistent with the Act. By establishing the same position limits for cash-settled FLEX ETF Options as for physically-settled options on the same underlying security and, importantly, aggregating such positions, the Exchange believes that the position limit requirements for cash-settled FLEX ETF Options should help to ensure that the trading of cash-settled FLEX ETF Options would not increase the potential for manipulation or market disruption and could help to minimize such incentives. For the same reasons, the Exchange believes the proposed exercise limits are reasonable and consistent with the Act.

Finally, the Exchange represents that it has an adequate surveillance program in place to detect manipulative trading in cash-settled FLEX ETF Options and the underlying ETFs. Regarding the proposed cash settlement, the Exchange would use the same surveillance procedures currently utilized for the Exchange's other FLEX Options. For surveillance purposes, the Exchange would have access to information regarding trading activity in the pertinent underlying ETFs. The Exchange believes that limiting cash settlement to no more than 50 underlying ETFs that would currently be eligible to have cash-settlement as a contract term would minimize the possibility of manipulation due to the robust liquidity in both the equities and options markets.

As a self-regulatory organization, the Exchange recognizes the importance of surveillance, among other things, to detect and deter fraudulent and manipulative trading activity as well as other violations of Exchange rules and the federal securities laws. As discussed above, the Exchange has adequate surveillance procedures in place to monitor trading in cash-settled FLEX ETF Options and the underlying securities, including to detect manipulative trading activity in both the options and the underlying ETF.³⁰ The Exchange further notes the liquidity and active markets in the underlying ETFs, and the high number of market participants in both the underlying ETFs and existing options on the ETFs, helps to minimize the possibility of manipulation. The Exchange further notes that under Section 19(g) of the Act, the Exchange, as a self-regulatory organization, is required to enforce compliance by its members and persons associated with its members with the Act, the rules and regulations thereunder, and the rules of the Exchange.³¹ The Exchange believes its surveillance, along with the liquidity criteria and position and exercise limits requirements, are reasonably designed to mitigate manipulation and market disruption concerns and will permit it to enforce compliance with the proposed rules and other Exchange

rules in accordance with Section 19(g) of the Act. The Exchange performs ongoing evaluations of its surveillance program to ensure its continued effectiveness and will continue to review its surveillance procedures on an ongoing basis and make any necessary enhancements and/or modifications that may be needed for the cash settlement of FLEX ETF Options.

Additionally, the Exchange will monitor any effect additional options series listed under the proposed rule change will have on market fragmentation and the capacity of the Exchange's automated systems. The Exchange will take prompt action, including timely communication with the Commission and with other self-regulatory organizations responsible for oversight of trading in options, the underlying ETFs, and the ETFs' component securities, should any unanticipated adverse market effects develop.

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 does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, as all Floor Brokers and FLEX Market Makers that are authorized to trade FLEX Equity Options in accordance with the Exchange's Rules will be able to trade cash-settled FLEX ETF Options in the same manner. This includes that, for all FLEX Equity Options, including FLEX ETF Options, at least one of exercise style, expiration date, and exercise price must differ from options in the non-FLEX market. Additionally, positions in cash-settled FLEX ETF Options of all OTP Holders will be subject to the same position limits, and such positions will be aggregated with positions in physically settled options on the same underlying in the same manner.

The Exchange does not believe that the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, as the proposal is designed to increase competition for order flow on the Exchange in a manner that is beneficial to investors because it is designed to provide investors seeking to transact in FLEX ETF Options with the opportunity for an alternative method of settling their option contracts at expiration. The

³⁰ Among other things, the Exchange's regulatory program includes cross-market surveillance designed to identify manipulative and other improper trading, including spoofing, algorithm gaming, marking the close and open, as well as more general abusive behavior related to front running, wash sales, quoting/routing, and Reg SHO violations, that may occur on the Exchange and other markets. Furthermore, the Exchange stated that it has access to information regarding trading activity in the pertinent underlying securities as a member of ISG.

³¹ 15 U.S.C. 78s(g).

Exchange believes the proposed rule change will encourage competition, as it may broaden the base of investors that use FLEX Equity Options to manage their trading and investment risk, including investors that currently trade in the OTC market for customized options, where settlement restrictions do not apply. The proposed rule change would give market participants an alternative to trading similar products in the OTC market. By trading a product in an exchange-traded environment (that is currently traded in the OTC market), the Exchange would be able to compete more effectively with the OTC market. The Exchange believes the proposed rule change may increase competition as it may lead to the migration of options currently trading in the OTC market to trading on the Exchange. Also, any migration to the Exchange from the OTC market would result in increased market transparency and thus increased price competition.

The Exchange notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues who offer similar functionality. The Exchange believes the proposed rule change encourages competition amongst market participants to provide tailored cash-settled FLEX ETF Option contracts, as other exchanges have received approval to list these contracts (subject to the same position and exercise limits as proposed). Therefore, the Exchange believes the proposed rule change will enhance intermarket competition by providing investors with a choice of exchange venues on which to trade cash-settled FLEX ETF Options.

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 Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act³² and Rule 19b-4(f)(6) thereunder.³³ 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 prior to 30 days from the date on which it 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 Act³⁴ and Rule 19b-4(f)(6)³⁵ thereunder.

A proposed rule change filed under Rule 19b-4(f)(6)³⁶ normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b-4(f)(6)(iii),³⁷ 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 believes waiver of the operative delay will protect investors because another exchange was recently granted waiver of the operative delay to introduce cash-settled FLEX ETF Options in an identical manner and subject to the same position limit requirements as the Exchange proposes pursuant to this rule filing.³⁸ According to the Exchange, as other exchanges already allow such cash-settled FLEX ETF Option contracts, waiver of the operative delay will protect investors by providing them with an additional venue where they can trade cash-settled FLEX ETF Options, and will permit the Exchange to remain competitive with other exchanges. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because the proposal does not raise any novel regulatory issues and will allow the Exchange to offer, without delay, cash-settled FLEX ETF options that are already available on other exchanges. Accordingly, the Commission hereby waives the operative delay and designates the proposed rule change to be operative upon filing.³⁹

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 is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-NYSEARCA-2026-04 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-2026-04. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-NYSEARCA-2026-04 and should be submitted on or before February 20, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁴⁰

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026-01822 Filed 1-29-26; 8:45 am]

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³² 15 U.S.C. 78s(b)(3)(A)(iii).

³³ 17 CFR 240.19b-4(f)(6).

³⁴ 15 U.S.C. 240.19b-4(f)(6).

³⁵ 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 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.

³⁶ 17 CFR 240.19b-4(f)(6).

³⁷ 17 CFR 240.19b-4(f)(6)(iii).

³⁸ See *supra*, note 14.

³⁹ For the 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).

⁴⁰ 17 CFR 200.30-3(a)(12).

SECURITIES AND EXCHANGE COMMISSION**[OMB Control No. 3235–0609]****Agency Information Collection Activities; Submission for OMB Review; Comment Request; Extension: Regulation S–AM**

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (“SEC” or “Commission”) is submitting to the Office of Management and Budget (“OMB”) this request Extension of the proposed collection of information provided for in Regulation S–AM (17 CFR part 248, subpart B), under the Fair Credit Reporting Act (15 U.S.C. 1681 *et seq.*) (“FCRA”), the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*), the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*), and the Investment Advisers Act of 1940 (15 U.S.C. 80b–1 *et seq.*).

Regulation S–AM implements the requirements of Section 624 of the FCRA (15 U.S.C. 1681s–3) with respect to investment advisers and transfer agents registered with the Commission, as well as brokers, dealers and investment companies (collectively, “Covered Persons”). Section 624 and Regulation S–AM limit a Covered Person’s use of certain consumer financial information received from an affiliate to solicit a consumer for marketing purposes, unless the consumer was given notice and a reasonable opportunity and a reasonable and simple method to opt out of such solicitations. Regulation S–AM potentially applies to all of the approximately 22,824 Covered Persons registered with the Commission, although only approximately 12,781 of them have one or more corporate affiliates, and the regulation requires only approximately 2,282 to provide consumers with an affiliate marketing notice and an opt-out opportunity.

The Commission staff estimates that there are approximately 12,781 Covered Persons having one or more affiliates, and that they each spend an average of 0.20 hours per year to review affiliate marketing practices, for, collectively, an

estimated annual time burden of approximately 2,556 hours at an annual internal compliance cost of approximately \$1,686,960. The staff also estimates that approximately 2,282 Covered Persons provide notice and opt-out opportunities to consumers, and that they each spend an average of 7.6 hours per year creating notices, providing notices and opt-out opportunities, monitoring the opt-out notice process, making and updating records of opt-out elections, and addressing consumer questions and concerns about opt-out notices, for, collectively, an estimated annual time burden of approximately 17,343 hours at an annual internal compliance cost of approximately \$4,210,665. Thus, the staff estimates that the collection of information requires a total of approximately 12,781 respondents to incur an estimated total annual time burden of approximately 19,899 hours at a total annual internal cost of compliance of approximately \$5,897,625.

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 public may view and comment on this information collection request at: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202511-3235-006 or email comment to MBX.OMB.OIRA.SEC_desk_officer@omb.eop.gov within 30 days of the day after publication of this notice, by March 2, 2026.

Dated: January 28, 2026.

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2026–01888 Filed 1–29–26; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION**[License No. 04040348]****Wells Fargo Strategic Capital SBIC, L.P.; Surrender of License of Small Business Investment Company**

Pursuant to the authority granted to the United States Small Business Administration under Section 309 of the Small Business Investment Act of 1958, as amended, and 13 CFR 107.1900 of the Code of Federal Regulations to function as a small business investment company

under the Small Business Investment Company License No. 04040348 issued to Wells Fargo Strategic Capital SBIC, L.P. said license is hereby declared null and void.

Paul Salgado,

Director, Investment Monitoring Portfolio, Office of Investment and Innovation.

[FR Doc. 2026–01864 Filed 1–29–26; 8:45 am]

BILLING CODE P

DEPARTMENT OF STATE**[Public Notice: 12928]****Notice of Department of State Sanctions Action**

ACTION: Notice.

SUMMARY: The U.S. Department of State is publishing the names of persons who have been added to the Department of the Treasury’s List of Specially Designated Nationals and Blocked Persons (SDN List), administered by the Office of Foreign Assets Control (OFAC).

DATES: This action was issued on July 30, 2025. See **SUPPLEMENTARY INFORMATION** section for applicable dates.

FOR FURTHER INFORMATION CONTACT: Aaron P. Forsberg, Director, Office of Economic Sanctions Policy and Implementation, Bureau of Economic and Business Affairs, Department of State, Washington, DC 20520, tel.: (202) 647 7677, email: ForsbergAP@state.gov.

SUPPLEMENTARY INFORMATION:**Electronic Availability**

The SDN List and additional information concerning sanctions programs are available on OFAC’s website, <https://ofac.treasury.gov/sanctions-programs-and-country-information/iran-sanctions>.

Notice of Department of State Actions

On July 30, 2025, the Department of State, in consultation with other departments, as appropriate, determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below.

Entities

BILLING CODE 4700–09–P

1. ZHOUSHAN JINRUN PETROLEUM TRANSFER CO., LTD. (Chinese Simplified: 舟山市金润石油转运有限公司) (a.k.a. ZHOUSHAN JINRUN OIL STAGING CO., LTD.; a.k.a. ZHOUSHAN JINRUN OIL TRANSSHIPMENT CO., LTD.), F/17, No. 173, Construction Building, Qiandao Road, Lincheng, Zhoushan, Zhejiang 316021, China; Floor 5, Block B, Fuguo Mall, Shenjiamen Street, Putuo District, (Zhejiang) Pilot Free Trade Zone, Zhoushan, Zhejiang 316000, China; Executive Order 13846 information: BLOCKING PROPERTY AND INTERESTS IN PROPERTY. Sec. 5(a)(iv); Organization Established Date 26 Dec 2003; Unified Social Credit Code (USCC) 91330903757095304A (China) [IRAN-EO13846].

Designated pursuant to section 3(a)(ii) of Executive Order 13846 “Reimposing Certain Sanctions With Respect to Iran” (E.O. 13846), for knowingly engaging in a significant transaction for the purchase, acquisition, sale, transport, or marketing of petroleum or petroleum products from Iran.
2. ETIHAD ENGINEERING AND MARINE SERVICES FZC (Arabic: اتحاد الهندسة والخدمات البحرية ش م ح) (a.k.a. ETIHAD ENGG. & MARINE SERVICES; a.k.a. ETIHAD ENGINEERING & MARINE SERVICES FZC), Plot No. 1H03B, Ajman-Umm Al Quwaim Road E11, Hamriyah Free Zone, Sharjah, United Arab Emirates; Executive Order 13846 information: BLOCKING PROPERTY AND INTERESTS IN PROPERTY. Sec. 5(a)(iv); Organization Established Date 17 Jul

2004; Identification Number IMO 5700690; Economic Register Number (CBLS) 11578514 (United Arab Emirates) [IRAN-EO13846].

Designated pursuant to section 3(a)(ii) of E.O. 13846 for knowingly engaging in a significant transaction for the purchase, acquisition, sale, transport, or marketing of petroleum or petroleum products from Iran.

3. ARZO ALTEJARA FOR GOODS WHOLESALERS CO. L.L.C (Arabic: الارض

التجارة) Office No. 43-44 Bur Dubai

Municipality, Al Fahidi, Dubai, United Arab Emirates; Executive Order 13846

information: BLOCKING PROPERTY AND INTERESTS IN PROPERTY. Sec.

5(a)(iv); Organization Established Date 18 Jan 2024; License 1295204 (United

Arab Emirates); Economic Register Number (CBLS) 12278255 (United Arab

Emirates) [IRAN-EO13846].

Designated pursuant to section 3(a)(ii) of E.O. 13846 for knowingly engaging in a significant transaction for the purchase, acquisition, sale, transport, or marketing of petroleum or petroleum products from Iran.

4. ENSA SHIP MANAGEMENT PRIVATE LIMITED (a.k.a. ENSA SHIP MANAGEMENT PVT LTD), HD—441, 4th Floor, Wework Spectrum Tower, Malad, Malad West, Mumbai, Maharashtra 400064, India; Executive Order 13846 information: BLOCKING PROPERTY AND INTERESTS IN PROPERTY. Sec. 5(a)(iv); Organization Established Date 11 Nov 2024; C.I.N. U82990MH2024PTC434780 (India); Identification Number IMO 0108782;

Registration Number 434780 (India) [IRAN-EO13846].

Designated pursuant to section 3(a)(ii) of E.O. 13846 for knowingly engaging in a significant transaction for the purchase, acquisition, sale, transport, or marketing of petroleum or petroleum products from Iran.

5. AVANI LINES INC, Trust Company Complex, Ajeltake Road, Ajeltake Island, Majuro 96960, Marshall Islands; Executive Order 13846 information: BLOCKING PROPERTY AND

INTERESTS IN PROPERTY. Sec. 5(a)(iv); Organization Established Date 03 May 2024; Identification Number IMO 0113947; Registration Number 125736 (Marshall Islands) [IRAN-EO13846].

Designated pursuant to section 3(a)(iii) of E.O. 13846 for knowingly engaging in a significant transaction for the purchase, acquisition, sale, transport, or marketing of petrochemical products from Iran.

6. PEACE WORTH SHIPPING CO., LIMITED (Chinese Simplified: 譽睦船務有限公司),
Unit D, 16th Floor, One Capital Place, 18, Luard Road, Wan Chai, Hong Kong, China;
Executive Order 13846 information: BLOCKING PROPERTY AND INTERESTS IN
PROPERTY. Sec. 5(a)(iv); Organization Established Date 03 Apr 2019; Identification
Number IMO 6104171; Company Number 2811033 (Hong Kong); Business Registration
Number 70533079 (Hong Kong) [IRAN-EO13846].

Designated pursuant to section 3(a)(iii) of E.O. 13846 for knowingly engaging in
a significant transaction for the purchase, acquisition, sale, transport, or marketing
of petrochemical products from Iran.
7. FIVA PLASTIK ANONIM SIRKETI, Ali Enderer Is Merkezi D:104, No:1, Muratpasa
Mahallesi Buyuk Coskun Sokak, Bayrampasa, Istanbul 34040, Turkey; Executive Order
13846 information: BLOCKING PROPERTY AND INTERESTS IN PROPERTY. Sec.
5(a)(iv); Organization Established Date 1999; Registration Number 424303 (Turkey)
[IRAN-EO13846].

Designated pursuant to section 3(a)(iii) of E.O. 13846 for knowingly engaging in
a significant transaction for the purchase, acquisition, sale, transport, or marketing
of petrochemical products from Iran.
8. TRIOLIN TRADE FZCO (Arabic: تريولين ترید ش م ح) (a.k.a. KOIL TRADE FZCO),
Dubai, United Arab Emirates; Executive Order 13846 information: BLOCKING

PROPERTY AND INTERESTS IN PROPERTY. Sec. 5(a)(iv); Organization Established Date 2023; Economic Register Number (CBLS) 12084826 (United Arab Emirates) [IRAN-EO13846].

Designated pursuant to section 3(a)(iii) of E.O. 13846 for knowingly engaging in a significant transaction for the purchase, acquisition, sale, transport, or marketing of petrochemical products from Iran.

9. TANAIS WAY GENERAL TRADING L.L.C (Arabic: تنيس واي التجارة العامة ش.ذ.م.م) (a.k.a. TANAIS TRADING L.L.C), Office No. MF: 19, Hor Al Anz East, Deira, Dubai, United Arab Emirates; Executive Order 13846 information: BLOCKING PROPERTY AND INTERESTS IN PROPERTY. Sec. 5(a)(iv); Organization Established Date 24 Jan 2023; License 1142106 (United Arab Emirates); Economic Register Number (CBLS) 12006809 (United Arab Emirates) [IRAN-EO13846].

Designated pursuant to section 3(a)(iii) of E.O. 13846 for knowingly engaging in a significant transaction for the purchase, acquisition, sale, transport, or marketing of petrochemical products from Iran.

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10. KANCHAN POLYMERS, Room No. 204, Sowcarpet, 2nd Floor, No. 69, Wall Tax Road, Chennai, Tamil Nadu 600079, India; Executive Order 13846 information: BLOCKING PROPERTY AND INTERESTS IN PROPERTY. Sec. 5(a)(iv); Organization Established Date 10 Aug 2022; Legal Entity Number 9845004FD751Q7711C43 (India) [IRAN-EO13846].

Designated pursuant to section 3(a)(iii) of E.O. 13846 for knowingly engaging in a significant transaction for the purchase, acquisition, sale, transport, or marketing of petrochemical products from Iran.

11. ALCHEMICAL SOLUTIONS PRIVATE LIMITED (a.k.a. CHEMFORM TRADING PRIVATE LIMITED), Unit No.1406, 14th Floor, C Wing, One Bkc, Plot No. C66, G Block, Bandra Kurla Complex, Bandra East, Mumbai, Maharashtra 400051, India; Executive Order 13846 information: BLOCKING PROPERTY AND INTERESTS IN PROPERTY. Sec. 5(a)(iv); Organization Established Date 23 Mar 2021; C.I.N. U24299MH2021PTC357689 (India) [IRAN-EO13846].

Designated pursuant to section 3(a)(iii) of E.O. 13846 for knowingly engaging in a significant transaction for the purchase, acquisition, sale, transport, or marketing of petrochemical products from Iran.

12. ELM KIMYA ITHALAT IHRACAT SANAYI VE TICARET ANONIM SIRKETI, Efe Tower Sitesi B Blok, No:11B-6 Odunluk Mahallesi Liman Caddesi, Nilufer, Bursa 16110, Turkey; Executive Order 13846 information: BLOCKING PROPERTY AND INTERESTS IN PROPERTY. Sec. 5(a)(iv); Organization Established Date 2018; Registration Number 98100 (Turkey) [IRAN-EO13846].

Designated pursuant to section 3(a)(iii) of E.O. 13846 for knowingly engaging in a significant transaction for the purchase, acquisition, sale, transport, or marketing of petrochemical products from Iran.

13. LAVINYA PLAST KIMYEVI MADDELER VE PETROL URUNLERI NAKLIYE SANAYI IC VE DIS TICARET ANONIM SIRKETI, Nidapark K.Sehir D Blok, No:47Dj Kayabasi Mahallesi Kayasehir Bulvari, Basaksehir, Istanbul,

Turkey; Executive Order 13846 information: BLOCKING PROPERTY AND INTERESTS IN PROPERTY. Sec. 5(a)(iv); Organization Established Date 2015; Registration Number 967562 (Turkey) [IRAN-EO13846].

Designated pursuant to section 3(a)(iii) of E.O. 13846 for knowingly engaging in a significant transaction for the purchase, acquisition, sale, transport, or marketing of petrochemical products from Iran.

14. PT. ORIENTAL COMMERCE GARDEN, Sahid Sudirman Center 11st Floor Suite A Jl. Jend. Sudirman No. 86, Kota Administrasi Jakarta Pusat, Jakarta, Java 10220, Indonesia; Executive Order 13846 information: BLOCKING PROPERTY AND INTERESTS IN PROPERTY. Sec. 5(a)(iv); Business Registration Number 1232981 (Indonesia) [IRAN-EO13846].

Designated pursuant to section 3(a)(iii) of E.O. 13846 for knowingly engaging in a significant transaction for the purchase, acquisition, sale, transport, or marketing of petrochemical products from Iran.

15. FARADANESH TECHNICAL INSPECTION SERVICES COMPANY (a.k.a.

FARADANESH INSPECTION SERVICES (Arabic: Unit 201, شرکت بازرسی فرادانش), 202, 2nd Floor, No. 269, Ostad Nejatollahi St., Karim Khan Ave, Tehran 1598843391, Iran; Executive Order 13846 information: BLOCKING PROPERTY AND INTERESTS IN PROPERTY. Sec. 5(a)(iv); Organization Established Date 1995; National ID No. 10101602852 (Iran); Registration Number 116680 (Iran) [IRAN-EO13846].

Designated pursuant to section 3(a)(iii) of E.O. 13846 for knowingly engaging in a significant transaction for the purchase, acquisition, sale, transport, or marketing of petrochemical products from Iran.

16. RAMNIKLAL S GOSALIA AND COMPANY, 608, National House, B J Marg, Jacob Circle, Mahalaxmi, Mumbai, Maharashtra 400011, India; Executive Order 13846 information: BLOCKING PROPERTY AND INTERESTS IN PROPERTY. Sec. 5(a)(iv); Organization Established Date 1998; Tax ID No. 27AADFR2284G1Z6 (India) [IRAN-EO13846].

Designated pursuant to section 3(a)(iii) of E.O. 13846 for knowingly engaging in a significant transaction for the purchase, acquisition, sale, transport, or marketing of petrochemical products from Iran.

17. JUPITER DYE CHEM PRIVATE LIMITED, Office No. 92A/93A, Mittal Court, Nariman Point, Mumbai, Maharashtra 400021, India; Executive Order 13846 information: BLOCKING PROPERTY AND INTERESTS IN PROPERTY. Sec. 5(a)(iv); Organization Established Date 1977; C.I.N. U24230MH1977PTC019716 (India) [IRAN-EO13846].

Designated pursuant to section 3(a)(iii) of E.O. 13846 for knowingly engaging in a significant transaction for the purchase, acquisition, sale, transport, or marketing of petrochemical products from Iran.

18. GLOBAL INDUSTRIAL CHEMICALS LIMITED, 18th Flr, 1803, Lodha Codename No 1, One Lodha Place Senapati Bapat Marg, Upper Worli, Mumbai, Maharashtra 400013, India; Executive Order 13846 information: BLOCKING PROPERTY AND INTERESTS IN PROPERTY. Sec. 5(a)(iv); Organization Established Date 2023; C.I.N. U74999MH2023PLC397808 (India) [IRAN-EO13846].

Designated pursuant to section 3(a)(iii) of E.O. 13846 for knowingly engaging in a significant transaction for the purchase, acquisition, sale, transport, or marketing of petrochemical products from Iran.

19. BAB AL BARSHA TRADING L.L.C (Arabic: Office No. باب البرشاء للتجارة ش.ذ.م.م).

OF707-0185, Port Said, Deira, Dubai, United Arab Emirates; Executive Order 13846 information: BLOCKING PROPERTY AND INTERESTS IN PROPERTY. Sec. 5(a)(iv); Organization Established Date 16 Feb 2024; License 1312547 (United Arab Emirates); Economic Register Number (CBLS) 12302133 (United Arab Emirates) [IRAN-EO13846].

Designated pursuant to section 3(a)(iii) of E.O. 13846 for knowingly engaging in a significant transaction for the purchase, acquisition, sale, transport, or marketing of petrochemical products from Iran.

20. PERSISTENT PETROCHEM PRIVATE LIMITED, Unit 209, Plot No. C-5, E-Block, B K Complex, Keshava

Commercial Premises Cooperative Society, Bandra East, Mumbai, Maharashtra 400051, India; Executive

Order 13846 information: BLOCKING PROPERTY AND INTERESTS IN PROPERTY. Sec. 5(a)(iv); Organization

Established Date 28 Nov 2022; C.I.N. U24299MH2022PTC394244 (India); Legal Entity Number 9845003D4BF65E039M32 [IRAN–EO13846].

Designated pursuant to section 3(a)(iii) of E.O. 13846 for knowingly engaging in a significant transaction for the purchase, acquisition, sale, transport, or marketing of petrochemical products from Iran.

Vessels

21. SEATURBO (D6A2852) Crude Oil Tanker Comoros flag; Vessel Year of Build 2000; Vessel Registration Identification IMO 9204764; MMSI 620834000 (vessel) [IRAN–EO13846] (Linked To: ETIHAD ENGINEERING AND MARINE SERVICES FZC).

Identified as property in which ETIHAD ENGINEERING AND MARINE SERVICES FZC, a person whose property and interests in property are blocked pursuant to E.O. 13846, has an interest.

22. TRUGEN (D6IJ7) Oil Products Tanker Comoros flag; Vessel Year of Build 2000; Vessel Registration Identification IMO 9200861; MMSI 616999482 (vessel) [IRAN–EO13846] (Linked To: ETIHAD ENGINEERING AND MARINE SERVICES FZC).

Identified as property in which ETIHAD ENGINEERING AND MARINE SERVICES FZC, a person whose property and interests in property are blocked pursuant to E.O. 13846, has an interest.

23. SEABASS (D6A2856) Oil Products Tanker Comoros flag; Vessel Year of Build 2001; Vessel Registration Identification IMO 9251640; MMSI 620847000 (vessel) [IRAN–EO13846] (Linked To: ETIHAD ENGINEERING AND MARINE SERVICES FZC).

Identified as property in which ETIHAD ENGINEERING AND MARINE SERVICES FZC, a person whose property and interests in property are blocked pursuant to E.O. 13846, has an interest.

24. SEAHAKER (D6A3404) Oil Products Tanker Comoros flag; Vessel Year of Build 2003; Vessel Registration Identification IMO 9255488; MMSI 620999405 (vessel) [IRAN–EO13846] (Linked To: ETIHAD ENGINEERING AND MARINE SERVICES FZC).

Identified as property in which ETIHAD ENGINEERING AND MARINE SERVICES FZC, a person whose property and interests in property are blocked pursuant to E.O. 13846, has an interest.

25. ZEAL (TRAM4) Oil Products Tanker Gabon flag; Vessel Year of Build 2017; Vessel Registration Identification IMO 9486805; MMSI 626017000 (vessel)

[IRAN–EO13846] (Linked To: ETIHAD ENGINEERING AND MARINE SERVICES FZC).

Identified as property in which ETIHAD ENGINEERING AND MARINE SERVICES FZC, a person whose property and interests in property are blocked pursuant to E.O. 13846, has an interest.

26. MOLLY (D6A2707) Chemical/Oil Tanker Comoros flag; Vessel Year of Build 2013; Vessel Registration Identification IMO 9531375; MMSI 620693000 (vessel) [IRAN–EO13846] (Linked To: ETIHAD ENGINEERING AND MARINE SERVICES FZC).

Identified as property in which ETIHAD ENGINEERING AND MARINE SERVICES FZC, a person whose property and interests in property are blocked pursuant to E.O. 13846, has an interest.

27. SOFIA (D6A2525) Chemical/Oil Tanker Comoros flag; Vessel Year of Build 2013; Vessel Registration Identification IMO 9531387; MMSI 620525000 (vessel) [IRAN–EO13846] (Linked To: ETIHAD ENGINEERING AND MARINE SERVICES FZC).

Identified as property in which ETIHAD ENGINEERING AND MARINE SERVICES FZC, a person whose property and interests in property are blocked pursuant to E.O. 13846, has an interest.

28. COURAGE 7 (TRA050) Asphalt/Bitumen Tanker Gabon flag; Vessel Year of Build 2015; Vessel Registration Identification IMO 9553957; MMSI 626046000 (vessel) [IRAN–EO13846] (Linked To: ETIHAD ENGINEERING AND MARINE SERVICES FZC).

Identified as property in which ETIHAD ENGINEERING AND MARINE SERVICES FZC, a person whose property and interests in property are blocked pursuant to E.O. 13846, has an interest.

29. TIFANI (T8A5110) Crude Oil Tanker Palau flag; Vessel Year of Build 2003; Vessel Registration Identification IMO 9273337; MMSI 511101651 (vessel) [IRAN–EO13846] (Linked To: ENSA SHIP MANAGEMENT PRIVATE LIMITED).

Identified as property in which ENSA SHIP MANAGEMENT PRIVATE LIMITED, a person whose property and interests in property are blocked pursuant to E.O. 13846, has an interest.

30. TONDA SOURCE (HP7673) Chemical/Oil Tanker Panama flag; Vessel Year of Build 1997; Vessel Registration Identification IMO 9127667; MMSI 371997000 (vessel) [IRAN–EO13846] (Linked To: PEACE WORTH SHIPPING CO., LIMITED).

Identified as property in which PEACE WORTH SHIPPING CO.,

LIMITED, a person whose property and interests in property are blocked pursuant to E.O. 13846, has an interest.

Hugo Y. Yon,

Principal Deputy Assistant Secretary, Bureau of Economic and Business Affairs, U.S. Department of State.

[FR Doc. 2026–01819 Filed 1–29–26; 8:45 am]

BILLING CODE 4710–09–P

DEPARTMENT OF STATE

[Public Notice: 12927]

Notice of Department of State Sanctions Action

ACTION: Notice.

SUMMARY: The U.S. Department of State is publishing the names of persons who have been added to the Department of the Treasury's List of Specially Designated Nationals and Blocked Persons (SDN List), administered by the Office of Foreign Assets Control (OFAC).

DATES: This action was issued on July 3, 2025. See **SUPPLEMENTARY INFORMATION** section for applicable dates.

FOR FURTHER INFORMATION CONTACT:

Aaron P. Forsberg, Director, Office of Economic Sanctions Policy and Implementation, Bureau of Economic and Business Affairs, Department of State, Washington, DC 20520, tel.: (202) 647 7677, email: ForsbergAP@state.gov.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning sanctions programs are available on OFAC's website, <https://ofac.treasury.gov/sanctions-programs-and-country-information/iran-sanctions>.

Notice of Department of State Actions

On July 3, 2025, the Department of State, in consultation with other departments, as appropriate, determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below.

Entities

1. SAI SABURI CONSULTING SERVICES PRIVATE LIMITED (a.k.a. SAI SABURI CONSULTING SERVICES), Unit J101, The Green Valley CHGS, Plot 18, Sector 22, Dwaraka, New Delhi, Delhi 110077, India; Executive Order 13846 information: BLOCKING PROPERTY AND INTERESTS IN PROPERTY. Sec. 5(a)(iv); Organization Established Date 26 Nov 2013; C.I.N.

U70109DL2013PTC260922 (India); Identification Number IMO 6127236; Registration Number 260922 (India) [IRAN–EO13846].

Designated pursuant to section 3(a)(ii) of Executive Order 13846 “Reimposing Certain Sanctions With Respect to Iran” (E.O. 13846, for knowingly engaging in a significant transaction for the purchase, acquisition, sale, transport, or marketing of petroleum or petroleum products from Iran.

2. KAVEH METHANOL COMPANY (a.k.a. Kaveh Petrochemical Co.), Kaveh Building #4, Oshan Blvd., Sayad Shirazi Highway, Tehran, Iran; KM5 Dayyer to Bushehr Coasta Road, Bandar Dayyer,

Bushehr, Iran; Additional Sanctions Information—Subject to Secondary Sanctions; Executive Order 13846 information: BLOCKING PROPERTY AND INTERESTS IN PROPERTY. Sec. 5(a)(iv); Organization Established Date 17 Apr 2004; Registration Number 219476 (Iran) [IRAN–EO13846].

Designated pursuant to section 3(a)(iii) of E.O. 13846 for knowingly engaging in a significant transaction for the purchase, acquisition, sale, transport, or marketing of petrochemical products from Iran.

3. ARIA SINA CONTROL INTERNATIONAL TECHNICAL INSPECTION CO. (a.k.a. “ASCO

International”), 2nd Floor, No. 6, Gord West, Bidar, Fershteh St., Tehran, Iran; Additional Sanctions Information—Subject to Secondary Sanctions; Executive Order 13846 information: BLOCKING PROPERTY AND INTERESTS IN PROPERTY. Sec. 5(a)(iv); Organization Established Date 31 Jul 2011; Registration Number 409460 (Iran) [IRAN–EO13846].

Designated pursuant to section 3(a)(iii) of E.O. 13846 for knowingly engaging in a significant transaction for the purchase, acquisition, sale, transport, or marketing of petrochemical products from Iran.

BILLING CODE 4710–09–P

4. ASIAN SEA ANGEL SHIPPING CO (Arabic: شرکت فرشته دریای آسیا شرکت)

(a.k.a. Asian Sea Angel; a.k.a. Asian Sea Angel Shipping Agency; a.k.a.

“Angel Shipping”), No. 16 Molla Sadra St, District 3, Tehran, Tehran

Province, Iran; No. 31, Molla Sadra Street, Tehran, Tehran Province

1991916833, Iran; Additional Sanctions Information - Subject to Secondary

Sanctions; Executive Order 13846 information: BLOCKING PROPERTY

AND INTERESTS IN PROPERTY. Sec. 5(a)(iv); Organization Established

Date 03 Jun 2017; National ID No. 14006811644 (Iran); Commercial Registry

Number 2196 (Iran) [IRAN–EO13846].

Designated pursuant to section 3(a)(iii) of E.O. 13846 for knowingly engaging

in a significant transaction for the purchase, acquisition, sale, transport, or

marketing of petrochemical products from Iran.

BILLING CODE 4710–09–C

5. BREEZE MARINE ASSET MANAGEMENT INC, 24th Floor, Churchill Tower, Business Bay, Dubai, United Arab Emirates; Trust Company Complex, Ajeltake Road, Majuro, Ajeltake Island 96960, Marshall Islands; Executive Order 13846 information: BLOCKING PROPERTY AND INTERESTS IN PROPERTY. Sec. 5(a)(iv); Organization Established Date 24 Apr 2023; Identification Number IMO 6404952; Registration Number 119696 (Marshall Islands) [IRAN–EO13846].

Designated pursuant to section 3(a)(ii) of E.O. 13846 for knowingly engaging in a significant transaction for the purchase, acquisition, sale, transport, or marketing of petroleum or petroleum products from Iran.

6. ISLE INNOVATION INC, 20th Floor, Global Plaza Building, Calle 50, Panama City, Panama; Executive Order 13846 information: BLOCKING PROPERTY AND INTERESTS IN PROPERTY. Sec. 5(a)(iv); Organization Established Date 2024; Identification Number IMO 0108938; Folio Mercantil No. 155758327 (Panama) [IRAN–EO13846].

Designated pursuant to section 3(a)(ii) of E.O. 13846, for knowingly engaging in a significant transaction for the purchase, acquisition, sale, transport, or marketing of petroleum or petroleum products from Iran.

Vessels

7. BATELEUR (HOA5120) LPG Tanker Panama flag; Vessel Year of Build 1995; Vessel Registration Identification IMO 9045807; MMSI 352980786 (vessel) [IRAN–EO13846] (Linked To: SAI SABURI CONSULTING SERVICES PRIVATE LIMITED).

Identified as property in which SAI SABURI CONSULTING SERVICES PRIVATE LIMITED, a person whose property and interests in property are blocked pursuant to E.O. 13846, has an interest.

8. NEEL (3E2234) LPG Tanker Panama flag; Vessel Year of Build 1998; Vessel Registration Identification IMO 9157478; MMSI 352002246 (vessel) [IRAN–EO13846](Linked To: SAI SABURI CONSULTING SERVICES PRIVATE LIMITED).

Identified as property in which SAI SABURI CONSULTING SERVICES PRIVATE LIMITED, a person whose property and interests in property are blocked pursuant to E.O. 13846, has an interest.

9. ARTEMIS III (HQZY4) Crude Oil Tanker Honduras flag; Vessel Year of Build 1996; Vessel Registration Identification IMO 9102241; MMSI 334983000 (vessel) [IRAN–EO13846](Linked To: BREEZE MARINE ASSET MANAGEMENT INC).

Identified as property in which BREEZE MARINE ASSET MANAGEMENT INC, a person whose property and interests in property are blocked pursuant to E.O. 13846, has an interest.

10. RIEVERIA I (T7BC7) Crude Oil Tanker San Marino flag; Vessel Year of Build 2004; Vessel Registration Identification IMO 9286229; MMSI 268245201 (vessel) [IRAN–EO13846](Linked To: ISLE INNOVATION INC).

Identified as property in which ISLE INNOVATION INC, a person whose property and interests in property are blocked pursuant to E.O. 13846, has an interest.

Hugo Y. Yon,

Principal Deputy Assistant Secretary, Bureau of Economic and Business Affairs, U.S. Department of State.

[FR Doc. 2026–01818 Filed 1–29–26; 8:45 am]

BILLING CODE 4710–09–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36872]

Central of Georgia Railroad Company—Trackage Rights Exemption—Southern Electric Railroad Company

Central of Georgia Railroad Company (CGA), a Class III rail carrier,¹ has filed a verified notice of exemption under 49 CFR 1180.2(d)(7) to acquire approximately 2.64 miles of trackage

rights on a line of railroad of Southern Electric Railroad Company (SERC) between milepost SA18.2 at Blanford, Ga., and a connection with private industry track in the vicinity of SERC's track crossing of the CSX Transportation, Inc. (CSXT) main track in Rincon, Ga. CGA describes four segments on this line: Trackage Segment A, extending from the NSR main line to the centerline of State Highway 21; Trackage Segment B, extending from the centerline of State Highway 21 to P.S. Prop. Lead Track; Trackage Segment C, extending from P.S. Prop. Lead Track to Fort Howard T/O; and Trackage Segment D, extending from Fort Howard T/O to P.S. Plant McIntosh Loop Track. (Verified Notice, Ex. B.)

According to the verified notice, CGA and SERC will enter into a second amendment² to their existing trackage rights agreement.³ CGA states that the trackage rights will allow CGA to operate trains in line-haul service and/or switch and/or make or break up trains carrying traffic (i) originating from or destined to points on Trackage Segment A, (ii) destined to Plant McIntosh located on Trackage Segment D, (iii) destined to Georgia-Pacific's facility located on Trackage Segment C, and/or (iv) originating from or destined to the Georgia International Rail Park, located on Trackage Segment A, or for emergency use where provided.

The transaction may be consummated on or after February 14, 2026, the effective date of the exemption (30 days after the verified notice was filed).

As a condition to this exemption, any employees affected by the acquisition of the trackage rights will be protected by the conditions imposed in *Norfolk & Western Railway—Trackage Rights—Burlington Northern, Inc.*, 354 I.C.C. 605 (1978), as modified in *Mendocino Coast*

² CGA states that the agreement is being finalized and that CGA will submit an executed copy within 10 days of its execution pursuant to 49 CFR 1180.6(a)(7)(ii).

³ CGA states that it, SERC, and CSXT created a Memo for Operations on September 16, 1996, which was several months before the trackage rights agreement dated December 3, 1996, was entered into. According to CGA, based on available records, it appears operations commenced in 1997. CGA states that it searched extensively and could find no record that it ever sought authority for the trackage rights, which have been in place for nearly 28 years. CGA further states that there was an initial amendment of the original rights in June 2011, which was likewise inadvertently not submitted for approval. The June 2011 amendment primarily expanded the permissible purposes for which CGA could use the tracks. CGA explains that while negotiating the second amendment, CGA discovered its prior omissions, and CGA has filed its verified notice of exemption to correct the mistake going forward. Copies of the 1996 trackage rights agreement and June 2011 amendment were filed under seal with CGA's verified notice.

Railway—Lease & Operate—California Western Railroad, 360 I.C.C. 653 (1980).

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than February 6, 2026 (at least seven days before the exemption becomes effective).

All pleadings, referring to Docket No. FD 36872, must be filed with the Surface Transportation Board either via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on CGA's representative, William A. Mullins, Mullins Law Group PLLC, 2001 L Street NW, Suite 720, Washington, DC 20036.

According to CGA, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic preservation reporting requirements under 49 CFR 1105.8(b).

Board decisions and notices are available at www.stb.gov.

Decided: January 27, 2026.

By the Board, Anika S. Cooper, Chief Counsel, Office of Chief Counsel.

Regena Smith-Bernard,

Clearance Clerk.

[FR Doc. 2026–01834 Filed 1–29–26; 8:45 am]

BILLING CODE 4915–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36904]

Port of Moses Lake—Acquisition Exemption—Moses Lake, Wash

The Port of Moses Lake (Port), a Class III common carrier and municipality in the State of Washington, has filed a verified notice of exemption under 49 CFR 1150.41 to acquire from the Columbia Basin Railroad Company (CBRW) a 0.5-mile stub-ended rail segment extending between a point near Forbes Road and continuing north, terminating just south of Grant County International Airport at approximately milepost 18.3 (formerly milepost 19.97) in Moses Lake, Wash. (the Line).

The verified notice states that the Line is connected to a larger endeavor known as the Northern Columbia Basin Railroad Project (the Project). According to the verified notice, the Port acquired the Line as part of a transaction for another CBRW line, referred to as Segment 3, that connects with the Line.

¹ CGA states that it is a wholly owned subsidiary of Norfolk Southern Railway Company (NSR).

The Port's authority to acquire Segment 3 was previously approved in *Port of Moses Lake—Acquisition Exemption—Moses Lake, Wash. (Aug. 2009 Decision)*, FD 34936 (Sub-No. 1) (STB served Aug. 27, 2009). The *Aug. 2009 Decision* did not authorize the Port to acquire the Line. The Port states that it consummated its acquisition of Segment 3 and the Line on March 10, 2025. According to the Port, it is seeking authority to purchase the Line in accordance with the Board's September 12, 2025 decision in FD 34936 (Sub-No. 1). The Port states that CBRW will be the operator of the Line and that CBRW will seek an operation exemption before operations begin on the completed Project.

The Port certifies that the proposed transaction does not involve an interchange commitment. The Port also certifies that its projected annual revenues are not expected to exceed \$5 million and that the proposed transaction will not result in the Port becoming a Class I or Class II rail carrier.

The transaction may be consummated on or after February 20, 2026, the effective date of the exemption (30 days after the verified notice was filed).

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than February 13, 2026 (at least seven days before the exemption becomes effective).

All pleadings, referring to Docket No. FD 36904, must be filed with the Surface Transportation Board either via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423-0001. In addition, a copy of each pleading must be served on the Port's representative, Sandra L. Brown, Thompson Hine LLP, 1919 M Street NW, Suite 700, Washington, DC 20036.

According to the Port, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic preservation reporting requirements under 49 CFR 1105.8(b).

Board decisions and notices are available at www.stb.gov.

Decided: January 28, 2026.

By the Board, Anika S. Cooper, Chief Counsel, Office of Chief Counsel.

Stefan Rice,

Clearance Clerk.

[FR Doc. 2026-01887 Filed 1-29-26; 8:45 am]

BILLING CODE 4915-01-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2025-0622]

Agency Information Collection Activities; Approval of a New Information Collection Request: Restoring Integrity to the Issuance of Non-Domiciled Commercial Drivers Licenses (CDL)

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FMCSA announces its plan to submit the Information Collection Request (ICR) described below to the Office of Management and Budget (OMB) for review and approval. On September 29, 2025, FMCSA issued an interim final rule to restore the integrity of the commercial driver's license (CDL) issuance processes by significantly limiting the authority for SDLAs to issue and renew non-domiciled commercial learner's permits (CLPs) and CDLs to individuals domiciled in a foreign jurisdiction. That interim final rule included a new collection of information, OMB Control Number: 2126-0087, "Non-Domiciled Commercial Driver's License Records," which was approved by OIRA in September 2025 on an emergency basis. That emergency approval expires on February 28, 2026. FMCSA will submit this information collection request for a full three-year approval.

DATES: Comments on this notice must be received on or before March 2, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be submitted within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT:

Philip Thomas, Deputy Associate Administrator, Office of Safety, FMCSA,

1200 New Jersey Avenue SE, Washington, DC 20590-0001; (202) 366-9554; Philip.Thomas@dot.gov.

SUPPLEMENTARY INFORMATION:

Title: Non-Domiciled Commercial Driver's License Records.

OMB Control Number: 2125-0087.

Type of Request: Renewal.

Respondents: SDLAs issuing non-domiciled CDLs.

Estimated Number of Respondents:

51.

Estimated Time per Response: 15 minutes.

Expiration Date: February 28, 2026.

Frequency of Response: Ongoing.

Estimated Total Annual Burden: 1500 hours.

Background:

This information collection request (ICR) covers the collection and retention of the documentation provided to a SDLA during the application process for a non-domiciled CLP or CDL. The requirements found in this ICR were promulgated in an interim final rule (IFR), published on September 29, 2025 (90 FR 46509). FMCSA received approval for the ICR on September 28, 2025, and that approval is set to expire on February 28, 2026. On November 13, 2025, the U.S. Court of Appeals for the District of Columbia Circuit issued a stay pending review of the IFR. (*see Lujan v FMCSA*, 2025 WL 3182504). FMCSA is seeking a full three-year approval of the ICR, despite the stay, in order to ensure that the collection will be able to be enforced as soon as the stay is lifted or, alternately, as soon as FMCSA is able to issue a final rule.

The IFR and this ICR are based on the broad authority of the Commercial Motor Vehicle Safety Act of 1986 (CMVSA, 49 U.S.C. 31301, *et seq.*), as amended, which was also the basis on which FMCSA relied in establishing the CDL program and the performance standards with which State CDL programs must comply. The statute requires the Secretary of Transportation (Secretary), after consultation with the States, to prescribe uniform minimum standards "for testing and ensuring the fitness of an individual operating a commercial motor vehicle" (49 U.S.C. 31305(a)). In addition, the statute requires States that issue non-domiciled CDLs to do so in accordance with regulations established by the Secretary (49 U.S.C. 31311(a)(12)(B)(ii)). The Administrator of FMCSA is delegated authority under 49 U.S.C. 113(f) and 49 CFR 1.87 to carry out the functions vested in the Secretary by 49 U.S.C. chapters 311, 313, and 315 as they relate to CMV operators, programs, and safety.

The IFR and this ICR are also consistent with the concurrent

authorities of the Motor Carrier Safety Act of 1984 (49 U.S.C. 31131, *et seq.*), as amended, and the Motor Carrier Act of 1935 (49 U.S.C. 31502), as amended. The 1984 Act granted the Secretary broad authority to issue regulations “on commercial motor vehicle safety,” including regulations to ensure that “commercial motor vehicles are . . . operated safely” (49 U.S.C. 31136(a)(1)). The IFR and ICR are consistent with the safe operation of CMVs. In accordance with 49 U.S.C. 31136(a)(2), the information collection requirements will not impose any “responsibilities . . . on operators of commercial motor vehicles [that would] impair their ability to operate the vehicles safely.” Neither the IFR nor the ICR directly address medical standards for drivers (49 U.S.C. 31136(a)(3)) or possible physical effects caused by driving CMVs (49 U.S.C. 31136(a)(4)). FMCSA does not anticipate that the IFR or the ICR will result in the coercion of CMV drivers by motor carriers, shippers, receivers, or transportation intermediaries to operate a CMV in violation of the Federal Motor Carrier Safety Regulations (FMCSRs, 49 U.S.C. 31136(a)(5)).

Need for Information: The licensed drivers in the United States deserve reasonable assurances that their fellow motorists are properly qualified to drive the vehicles they operate. Under the Commercial Motor Vehicle Safety Act of 1986 (CMVSA, 49 U.S.C. 31301 *et seq.*), as amended, FMCSA established the CDL program and the performance standards with which State CDL programs must comply. The CDL regulations in 49 CFR part 383 prescribe uniform minimum standards for testing and ensuring the fitness of individuals who operating commercial motor vehicles (CMVs), and State compliance with the CDL program is addressed in Part 384. In particular, States that issue non-domiciled CDLs must do so in accordance with §§ 383.71, 383.73 and 384.212.

This collection is intended to ensure that States retain all documents involved in the licensing process for non-domiciled CLP and CDL holders for a period of no less than two years from the date of issuing (which includes amending, correcting, reprinting, or otherwise duplicating a previously issued CLP or CDL), transferring, renewing, or upgrading a non-domiciled CLP or CDL. If States do not retain this documentation, FMCSA is severely hindered in its efforts to ensure compliance with the regulatory requirements because States are unable to accurately determine the number of non-domiciled CLPs and CDLs they

have issued, or to prove to FMCSA officials that such CLPs and CDLs were properly issued.

Proposed Use of Information: State officials use the information collected from non-domiciled CDL applicants to determine whether an individual is eligible to receive a non-domiciled CDL and to prevent unqualified, and/or disqualified CLP and CDL holders and applicants from operating CMVs on the Nation’s highways. During State CDL compliance reviews, FMCSA officials review this information to ensure that the provisions of the regulations are being carried out. Without the aforementioned requirements, there would be no uniform control over driver licensing practices to prevent uncertified and/or disqualified foreign drivers from being issued a non-domiciled CLP or CDL. Failure to collect this information would render the regulations unenforceable.

Comments received on IFR: Pursuant to 5 CFR 1320.11, FMCSA notified the public of its intent to submit this collection to OMB for a full three-year approval period in the IFR (*see* 90 FR 46509, 46522) and sought public comment on the proposed ICR. FMCSA received the following comments:

In a joint submission, Massachusetts, California, and 17 Other Jurisdictions stated that FMCSA’s information collection is not “necessary for the proper performance of the functions of the agency” per the Paperwork Reduction Act (PRA) because the agency lacks statutory authority over immigration, as even FMCSA admits there is no evidence linking immigration status to CDL driver safety. The joint submission said requiring SDLAs to retain and produce immigration documents and SAVE query results duplicates DHS responsibilities and is unnecessary for the proper performance of FMCSA’s functions. In addition, the joint submission said the IFR does not “reduce[] to the extent practicable and appropriate the burden on persons who shall provide information to or for the agency” per the PRA. Rather, it places considerable burden on SDLAs, as it contains no limitation on documents and requires that SDLAs provide documents on a 48-hour turnaround. The joint submission said FMCSA provides no explanation for this new requirement, especially given existing regulations that already mandate APRs and information sharing. An individual asserted that the small entity impacts and PRA impacts are understated.

Massachusetts, California, and 17 Other Jurisdictions stated that, although FMCSA claims the rule does not involve

collecting PII, it requires SDLAs to retain and share immigration documents (*e.g.*, passports and I–94s) that contain PII. The joint submission said FMCSA’s failure to comply with the statutory requirement to assess the privacy impact of the PII collection was arbitrary and capricious. The joint submission and Asian Law Caucus said FMCSA provided no opportunity to review the supporting Privacy Impact Analysis despite stating that it would be available for review in the docket. The Small Business in Transportation Coalition stated that: (1) the proposed information collection is necessary; (2) they do not contest the accuracy of the estimated burden; (3) they have no suggestions on ways for FMCSA to enhance the quality, usefulness, or clarity of the collected information; and (4) they can offer no information on ways the burden could be minimized without reducing the quality of the collected information.

The information collection requirements in the IFR are necessary. FMCSA has extensive authority over the CDL issuance process and the review of State licensing programs. As discussed in the IFR, the APRs highlighted a lack of available information at the State-level regarding non-domiciled CLPs and CDLs that were issued and the documentation that was provided during the application process for those non-domiciled CLPs and CDLs. This led to difficulties for the Agency during the APR process. It became clear during the APR process that the prior information collection and retention requirements were not sufficient to ensure FMCSA has the ability to review non-domiciled CLP and CDL issuance by SDLAs in a reasonable timeframe. The requirement for SDLAs to retain copies of the information relied on during the non-domiciled application process is not only a minor burden, but it also ensures that FMCSA has access to the necessary information during the APR process and other audits in the future. The requirement for producing those copies within 48 hours of a request from FMCSA ensures that the Agency has adequate access to the records. The information collection is neither duplicative nor unlimited. It requires copies to be made of the two specific identification documents used in the application process for a non-domiciled CLP or CDL, both of which must already be inspected by the SDLA, and a copy of the required SAVE query. Commenters do not provide a citation to a specific, currently approved information collection containing a

duplicative requirement for retention of these documents.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) whether the proposed collection is necessary for the performance of FMCSA's functions; (2) the accuracy of the estimated burden; (3) ways for FMCSA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized without reducing the quality of the collected information.

Issued under the authority of 49 CFR 1.87.

Jonathan Mueller,

Acting Associate Administrator, Office of Research and Registration.

[FR Doc. 2026-01832 Filed 1-29-26; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA-2026-0034]

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of information collection; request for comment.

SUMMARY: Under the Paperwork Reduction Act of 1995 (PRA) and its implementing regulations, FRA seeks approval of the Information Collection Request (ICR) summarized below. Before submitting this ICR to the Office of Management and Budget (OMB) for approval, FRA is soliciting public comment on specific aspects of the activities identified in the ICR.

DATES: Interested persons are invited to submit comments on or before March 31, 2026.

ADDRESSES: Written comments and recommendations for the proposed ICR should be submitted on <https://>

www.regulations.gov to Docket No. FRA-2026-0034. All comments received will be posted without change to the docket, including any personal information provided. Please refer to the assigned OMB control number (2130-0516) in any correspondence submitted. FRA will summarize comments received in response to this notice in a subsequent notice, made available to the public, and include them in its information collection submission to OMB for approval.

FOR FURTHER INFORMATION CONTACT: Ms. Joanne Swafford, Information Collection Clearance Officer, at email: joanne.swafford@dot.gov or telephone: (757) 897-9908.

SUPPLEMENTARY INFORMATION: The PRA, 44 U.S.C. 3501-3520, and its implementing regulations, 5 CFR part 1320, require Federal agencies to provide 60 days' notice to the public to allow comment on information collection activities before seeking OMB approval of the activities. *See* 44 U.S.C. 3506, 3507; 5 CFR 1320.8 through 1320.12. Specifically, FRA invites interested parties to comment on the following ICR regarding: (1) whether the information collection activities are necessary for FRA to properly execute its functions, including whether the activities will have practical utility; (2) the accuracy of FRA's estimates of the burden of the information collection activities, including the validity of the methodology and assumptions used to determine the estimates; (3) ways for FRA to enhance the quality, utility, and clarity of the information being collected; and (4) ways for FRA to minimize the burden of information collection activities on the public, including the use of automated collection techniques or other forms of information technology. *See* 44 U.S.C. 3506(c)(2)(A); 5 CFR 1320.8(d)(1).

FRA believes that soliciting public comment may reduce the administrative and paperwork burdens associated with the collection of information that Federal regulations mandate. In summary, comments received will

advance three objectives: (1) reduce reporting burdens; (2) organize information collection requirements in a "user-friendly" format to improve the use of such information; and (3) accurately assess the resources expended to retrieve and produce information requested. *See* 44 U.S.C. 3501.

The summary below describes the ICR that FRA will submit for OMB clearance as the PRA requires:

Title: Remotely Controlled Switch Operations.

OMB Control Number: 2130-0516.

Abstract: 49 CFR 218.30 and 218.77 require that remotely controlled switches be properly lined to protect workers as they inspect or service rolling equipment or occupied camp cars on track. These sections require the operators of the remotely controlled switches to remove the locking device controlling the switches only once they have been informed by the person in charge of the workers that it is safe to do so. In addition, these operators are required to maintain a record of each protection request for 15 days. Operators of remotely controlled switches use the information in this record to document protection of workers or camp cars. This record also serves as a valuable resource for railroad supervisors as well as FRA and State inspectors monitoring regulatory compliance.

In this 60-day notice, FRA made an adjustment under § 218.77, which covers the protection of occupied camp cars. The number of notifications annually has been reduced to reflect the infrequent usage of these types of cars. All other information remains unchanged since the last submission.

Type of Request: Extension without change (with changes in estimates) of a currently approved collection.

Affected Public: Businesses.

Form(s): N/A.

Respondent Universe: 53 railroads.

Frequency of Submission: On occasion.

REPORTING BURDEN

Section	Respondent universe (railroads)	Total annual responses (A)	Average time per response (seconds) (B)	Total annual burden hours (C = A * B)	Wage rate ¹	Total cost equivalent in U.S.D. (D = C * wage rates)
218.30 Remotely Controlled Switches (Subpart B, Blue Signal Protection of Workers)						
—(c) Blue signal protection of workers.	53	1,837,775 notifications (53 × 95 responses per day × 365 days per year).	45	22,972	\$72.12	\$1,656,740.64

REPORTING BURDEN—Continued

Section	Respondent universe (railroads)	Total annual responses	Average time per response (seconds)	Total annual burden hours	Wage rate ¹	Total cost equivalent in U.S.D.
		(A)	(B)	(C = A * B)		(D = C * wage rates)
218.77 Remotely Controlled Switches (Subpart E, Protection of Occupied Camp Cars)						
—(c) Protection of occupied camp cars.	6	75 notifications	45	1	72.12	72.12
Total	53	1,837,850 responses		22,973		1,656,812.76

¹ Surface Transportation Board (STB), *Quarterly Wage Form A&B Data* (2024). Compiled from Class I railroad data reported on Wage Form A&B for year 2024. Calculated as: Wage (\$/hour) = sum of compensation for time worked and paid for straight time rates (\$) for Class I railroads ÷ sum of service hours for time worked and paid for straight time rates (hours) for Class I railroads. Available: <https://www.stb.gov/reports-data/economic-data/quarterly-wage-ab-data/>.

Total Estimated Annual Responses: 1,837,850.

Total Estimated Annual Burden: 22,973 hours.

Total Estimated Annual Burden Hour Dollar Cost Equivalent: \$1,656,812.76.

FRA informs all interested parties that it may not conduct or sponsor, and a respondent is not required to respond to, a collection of information that does not display a currently valid OMB control number.

Authority: 44 U.S.C. 3501–3520.

Christopher S. Van Nostrand,
Deputy Chief Counsel.

[FR Doc. 2026–01852 Filed 1–29–26; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2026–0035]

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of information collection; request for comment.

SUMMARY: Under the Paperwork Reduction Act of 1995 (PRA) and its implementing regulations, FRA seeks approval of the Information Collection Request (ICR) summarized below. Before submitting this ICR to the Office of Management and Budget (OMB) for approval, FRA is soliciting public comment on specific aspects of the activities identified in the ICR.

DATES: Interested persons are invited to submit comments on or before March 31, 2026.

ADDRESSES: Written comments and recommendations for the proposed ICR should be submitted on <https://www.regulations.gov> to Docket No. FRA–2026–0035. All comments

received will be posted without change to the docket, including any personal information provided. Please refer to the assigned OMB control number (2130–0519) in any correspondence submitted. FRA will summarize comments received in response to this notice in a subsequent notice, made available to the public, and include them in its information collection submission to OMB for approval.

FOR FURTHER INFORMATION CONTACT: Ms. Joanne Swafford, Information Collection Clearance Officer, at email: joanne.swafford@dot.gov or telephone: (757) 897–9908.

SUPPLEMENTARY INFORMATION: The PRA, 44 U.S.C. 3501–3520, and its implementing regulations, 5 CFR part 1320, require Federal agencies to provide 60 days’ notice to the public to allow comment on information collection activities before seeking OMB approval of the activities. *See* 44 U.S.C. 3506, 3507; 5 CFR 1320.8 through 1320.12. Specifically, FRA invites interested parties to comment on the following ICR regarding: (1) whether the information collection activities are necessary for FRA to properly execute its functions, including whether the activities will have practical utility; (2) the accuracy of FRA’s estimates of the burden of the information collection activities, including the validity of the methodology and assumptions used to determine the estimates; (3) ways for FRA to enhance the quality, utility, and clarity of the information being collected; and (4) ways for FRA to minimize the burden of information collection activities on the public, including the use of automated collection techniques or other forms of information technology. *See* 44 U.S.C. 3506(c)(2)(A); 5 CFR 1320.8(d)(1).

FRA believes that soliciting public comment may reduce the administrative and paperwork burdens associated with the collection of information that Federal regulations mandate. In summary, comments received will

advance three objectives: (1) reduce reporting burdens; (2) organize information collection requirements in a “user-friendly” format to improve the use of such information; and (3) accurately assess the resources expended to retrieve and produce information requested. *See* 44 U.S.C. 3501.

The summary below describes the ICR that FRA will submit for OMB clearance as the PRA requires:

Title: Bad Order and Home Shop Card and Stenciling Mark.

OMB Control Number: 2130–0519.

Abstract: Under 49 CFR part 215, railroads are required to inspect freight cars placed in service and take remedial action when defects are identified. A railroad freight car with a part 215 defect may be moved to another location for repair only after the railroad has complied with the process under 49 CFR 215.9. Section 215.9 requires railroads to affix a “bad order” tag (or card) describing each defect to each side of the freight car. It is imperative that a defective freight car be tagged “bad order” (or “home shop for repairs”) so it can be readily identified and moved to another location for repair purposes only, and so that the maximum speed and other restrictions necessary for safely conducting the movement are known. At the repair location, the “bad order” tag serves as a notification of the defective condition of the freight car. Railroads must retain each tag for 90 days to verify that proper repairs were made at the designated location. When inspecting freight cars, FRA and State inspectors review all pertinent records to determine railroads’ compliance with the movement restrictions of § 215.9.

In addition, § 215.301 requires railroads and private car owners to stencil or otherwise display identification marks on freight cars, including a car number and build date. FRA uses the identification marks to help obtain certain information related to a car’s compliance with Federal

safety requirements. The marks are used consistently across railroad records to identify the car and show: the type of car, what it is carrying, its movement history, and current maintenance schedule. Using the marks to identify the car helps FRA determine the application of Federal safety requirements to that car and who is responsible for compliance. FRA also

uses this information to determine if the freight car qualifies for dedicated service and is excluded from the requirements of part 215. Railroads use the required information to provide identification and control so that dedicated cars remain in the prescribed service.

In this 60-day notice, FRA made no changes to the previously approved burden or responses.

Type of Request: Extension without change of a currently approved collection.

Affected Public: Businesses.

Form(s): N/A.

Respondent Universe: 754 railroads.

Frequency of Submission: On occasion.

REPORTING BURDEN

CFR section	Respondent universe (railroads)	Total annual responses (A)	Average time per response (minutes) (B)	Total annual burden hours (C = A * B)	Wage rates ¹	Total cost equivalent U.S.D. (D = C * wage rates ²)
215.9 Movement of Defective Cars for Repair						
—(a)(2) Tagging of defective cars	754	150,000 Tags	5	12,500	\$73.41	\$917,625
—(b)(3) Notifications of removal of defective car tags.	754	75,000 notifications	2	2,500	73.41	183,525
215.11 Designated Inspectors						
—(c) Records of designated inspectors.	754	30,000 records	1	500	73.41	36,705
215.301 General (Subpart D, Stenciling)						
—Stenciling	754	30,000 stencils	45	22,500	73.41	1,651,725
Total	754	285,000 responses		38,000		2,789,580

¹ Surface Transportation Board (STB), *Quarterly Wage Form A&B Data* (2024). Compiled from Class I railroad data reported on Wage Form A&B for year 2024. Calculated as: Wage (\$/hour) = sum of compensation for time worked and paid for straight time rates (\$) for Class I railroads + sum of service hours for time worked and paid for straight time rates (hours) for Class I railroads. Available: <https://www.stb.gov/reports-data/economic-data/quarterly-wage-ab-data/>.

² The employee groups used to calculate hourly wage rates are Group 400 (Maintenance of Equipment & Stores): \$72.01 (41.15 × overhead of 1.75), and Group 600 (Transportation, Train, and Engine): \$79.02 (\$45.16 × overhead of 1.75). Time spent by these groups on the respective paperwork requirements are Group 400: 80%, and Group 600: 20%. This results in a combined wage rate of \$73.41 (\$72.01 × 0.8 + \$79.02 × 0.2 = \$57.61 + \$15.80 = \$73.41).

Total Estimated Annual Responses: 285,000.

Total Estimated Annual Burden: 38,000 hours.

Total Estimated Annual Burden Hour Dollar Cost Equivalent: \$2,789,580.

FRA informs all interested parties that it may not conduct or sponsor, and a respondent is not required to respond to, a collection of information that does not display a currently valid OMB control number.

Authority: 44 U.S.C. 3501–3520.

Christopher S. Van Nostrand,
Deputy Chief Counsel.
[FR Doc. 2026–01853 Filed 1–29–26; 8:45 am]
BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration
[Docket No. FRA–2026–0036]

Proposed Agency Information
Collection Activities; Comment
Request

AGENCY: Federal Railroad
Administration (FRA), Department of
Transportation (DOT).

ACTION: Notice of information collection; request for comment.

SUMMARY: Under the Paperwork Reduction Act of 1995 (PRA) and its implementing regulations, FRA seeks approval of the Information Collection Request (ICR) summarized below. Before submitting this ICR to the Office of Management and Budget (OMB) for approval, FRA is soliciting public comment on specific aspects of the activities identified in the ICR.

DATES: Interested persons are invited to submit comments on or before March 31, 2026.

ADDRESSES: Written comments and recommendations for the proposed ICR should be submitted on <https://www.regulations.gov> to Docket No. FRA–2026–0036. All comments received will be posted without change to the docket, including any personal information provided. Please refer to the assigned OMB control number (2130–0523) in any correspondence submitted. FRA will summarize comments received in response to this notice in a subsequent notice, made available to the public, and include them in its information collection submission to OMB for approval.

FOR FURTHER INFORMATION CONTACT: Ms. Joanne Swafford, Information Collection Clearance Officer, at email: joanne.swafford@dot.gov or telephone: (757) 897–9908.

SUPPLEMENTARY INFORMATION: The PRA, 44 U.S.C. 3501–3520, and its implementing regulations, 5 CFR part 1320, require Federal agencies to provide 60 days’ notice to the public to allow comment on information collection activities before seeking OMB approval of the activities. See 44 U.S.C. 3506, 3507; 5 CFR 1320.8 through 1320.12. Specifically, FRA invites interested parties to comment on the following ICR regarding: (1) whether the information collection activities are necessary for FRA to properly execute its functions, including whether the activities will have practical utility; (2) the accuracy of FRA’s estimates of the burden of the information collection activities, including the validity of the methodology and assumptions used to determine the estimates; (3) ways for FRA to enhance the quality, utility, and clarity of the information being

collected; and (4) ways for FRA to minimize the burden of information collection activities on the public, including the use of automated collection techniques or other forms of information technology. *See* 44 U.S.C. 3506(c)(2)(A); 5 CFR 1320.8(d)(1).

FRA believes that soliciting public comment may reduce the administrative and paperwork burdens associated with the collection of information that Federal regulations mandate. In summary, comments received will advance three objectives: (1) reduce reporting burdens; (2) organize information collection requirements in a “user-friendly” format to improve the use of such information; and (3) accurately assess the resources expended to retrieve and produce

information requested. *See* 44 U.S.C. 3501.

The summary below describes the ICR that FRA will submit for OMB clearance as the PRA requires:

Title: Rear End Marking Devices.

OMB Control Number: 2130–0523.

Abstract: 49 CFR part 221 contains requirements for rear end marking devices, which are subject to FRA approval. Railroads must provide FRA with a detailed description of the type of marking devices used for any locomotive operating singly or for cars or locomotives operating at the end of a train (trailing end) to ensure that they meet minimum standards for visibility and display. Specifically, part 221 requires railroads to furnish a certification that each device has been tested in accordance with current

“Guidelines for Testing of Rear End Marking Devices.” In addition, part 221 requires railroads to furnish detailed test records, which include the names of testing organizations, test descriptions, number of samples tested, and the test results, to demonstrate compliance with the performance requirements in this part.

In this 60-day notice, FRA made no changes to the previously approved burden hours or responses.

Type of Request: Extension without change of a currently approved collection.

Affected Public: Businesses.

Form(s): N/A.

Respondent Universe: 754 railroads and 30 manufacturers.

Frequency of Submission: On occasion.

REPORTING BURDEN

CFR	Respondent universe	Total annual responses	Average time per response (hours)	Total annual burden hours	Wage rate ¹	Total cost equivalent U.S.D
		(A)	(B)	(A * B = C)		(D = C * wage rate)
Appendix A to Part 221—Procedures for Approval of Rear End Marking Devices						
—Approval of marking devices in accordance with appendix procedures.	754 railroads 30 manufacturers.	2 submissions & records.	1	2	\$90.19	\$180.38
Total	754 railroads 30 manufacturers.	2 responses		2		180.38

¹ Surface Transportation Board (STB), *Quarterly Wage Form A&B Data* (2024). Compiled from Class I railroad data reported on Wage Form A&B for year 2024. Calculated as: Wage (\$/hour) = sum of compensation for time worked and paid for straight time rates (\$) for Class I railroads + sum of service hours for time worked and paid for straight time rates (hours) for Class I railroads. Available: <https://www.stb.gov/reports-data/economic-data/quarterly-wage-ab-data/>. Using employee group 200 (Professional and Administrative) hourly wage rate of \$51.54 multiplied by 1.75 gives a total burdened wage rate of \$90.19.

Total Estimated Annual Responses: 2.

Total Estimated Annual Burden: 2

hours.

Total Estimated Annual Burden Hour Dollar Cost Equivalent: \$180.38.

FRA informs all interested parties that it may not conduct or sponsor, and a respondent is not required to respond to, a collection of information that does not display a currently valid OMB control number.

Authority: 44 U.S.C. 3501–3520.

Christopher S. Van Nostrand,

Deputy Chief Counsel.

[FR Doc. 2026–01854 Filed 1–29–26; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[Docket FTA–2026–0001]

Notice of Establishment of Emergency Relief Docket for Calendar Year 2026

AGENCY: Federal Transit Administration (FTA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: By this notice, the Federal Transit Administration (FTA) is establishing an Emergency Relief Docket for calendar year 2026, so grantees and subgrantees affected by a national or regional emergency or disaster may request temporary relief from FTA administrative and statutory requirements.

FOR FURTHER INFORMATION CONTACT:

Diane Alexander, Attorney-Advisor, Office of Chief Counsel, Federal Transit Administration, phone: (202) 366–4043, or email, Diane.Alexander@dot.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 49 CFR 601.42, FTA is establishing the Emergency Relief Docket for calendar year 2026. In the case of a national or regional emergency or disaster, or in anticipation of such an event, when FTA requirements impede a grantee or subgrantee’s ability to respond to the emergency or disaster, a grantee or subgrantee may submit a request for relief from specific FTA requirements.

If FTA determines that a national or regional emergency or disaster has occurred, or in anticipation of such an event, FTA will place a message on its web page (<https://www.transit.dot.gov>) indicating the Emergency Relief Docket has been opened and including the docket number.

All petitions for relief from FTA administrative or statutory requirements must be posted in the docket to receive consideration by FTA. The docket is publicly available and can be accessed 24 hours a day, seven days a week, via the internet at <https://www.regulations.gov/>. Any grantee or subgrantee submitting petitions for relief or comments to the docket must include the agency name (Federal Transit Administration) and docket number FTA–2026–0001.

Interested parties may consult 49 CFR part 601, subpart D for information on FTA’s emergency procedures for public transportation systems. FTA strongly encourages grantees and subgrantees to contact their FTA regional office and notify FTA of the intent to submit a petition to the docket.

A grantee or subgrantee seeking relief has three avenues for submitting a petition. First, a grantee or subgrantee may submit a petition for waiver of FTA requirements to <https://www.regulations.gov/> for posting in the docket (FTA–2026–0001). Alternatively, a grantee or subgrantee may submit a petition in duplicate (two copies) to the FTA Administrator, via U.S. mail or hand delivery to Federal Transit Administration, 1200 New Jersey Ave. SE, Washington, DC 20590; via fax to (202) 366–3472; or via email to Diane.Alexander@dot.gov; or via U.S. mail or hand delivery to the DOT Docket Management Facility, 1200 New Jersey Ave. SE, Room W58–213, Washington, DC 20590. Finally, if a grantee or subgrantee needs to request immediate relief and does not have access to electronic means to request that relief, the grantee or subgrantee may contact any FTA regional office or FTA headquarters and request that FTA staff submit the petition on its behalf.

Federal public transportation law at 49 U.S.C. 5324(d) provides that a grant awarded under Section 5324, or under 49 U.S.C. 5307 or 49 U.S.C. 5311, that is made to address an emergency shall be subject to the terms and conditions the Secretary determines are necessary. This language allows FTA to waive certain statutory and administrative requirements.

An FTA grantee or subgrantee receiving financial assistance under 49 U.S.C. 5324, 5307, or 5311 that is affected by a national or regional emergency or disaster may request a waiver of provisions of Chapter 53 of Title 49 of the United States Code in connection with such financial assistance, when a grantee or subgrantee demonstrates that the requirement(s) will limit a grantee's or subgrantee's ability to respond to a national or regional emergency or disaster.

Pursuant to 49 CFR 601.42, a grantee or subgrantee must include certain information when requesting a waiver of statutory or administrative requirements. A petition for relief shall:

- (a) Include the agency name (Federal Transit Administration) and docket number FTA–2026–0001;
- (b) Identify the grantee or subgrantee and its geographic location;
- (c) Identify the section of Chapter 53 of Title 49 of the United States Code, or the portion of an FTA policy statement, circular, guidance document or rule, from which the grantee or subgrantee seeks relief;
- (d) Specifically address how a requirement in Chapter 53 of Title 49 of the United States Code or an FTA requirement in a policy statement,

circular, guidance, or rule will limit a grantee's or subgrantee's ability to respond to a national or regional emergency or disaster; and

(e) Specify if the petition for relief is one-time or ongoing and, if ongoing, identify the period for which the relief is requested. The period may not exceed three months; however, additional time may be requested through a second petition for relief.

Pursuant to 49 CFR 601.46, a petition for relief from administrative requirements will be conditionally granted for a period of three (3) business days from the date it is submitted to the Emergency Relief Docket. FTA will review the petition after the expiration of the three business days and review any comments submitted regarding the petition. FTA may contact the grantee or subgrantee that submitted the request for relief, or any party that submits comments to the docket, to obtain more information prior to making a decision. FTA will then post a decision to the Emergency Relief Docket. FTA's decision will be based on whether the petition meets the criteria for use of these emergency procedures, the substance of the request, and any comments submitted regarding the petition. If FTA does not respond to the request for relief to the docket within three business days, the grantee or subgrantee may assume its petition is granted for a period not to exceed three months until and unless FTA states otherwise.

A petition for relief from statutory requirements will not be conditionally granted and requires a written decision from the FTA Administrator. Further, grantees seeking a waiver from Buy America requirements must follow the procedures in 49 CFR 661.7 and 661.9. Buy America waivers will not be granted through the Emergency Relief Docket.

An FTA decision either granting or denying a petition will be posted in the Emergency Relief Docket and will reference the document number of the petition to which it relates. FTA reserves the right to reconsider any decision made pursuant to these emergency procedures based upon its own initiative, based upon information or comments received subsequent to the three-business-day comment period, or at the request of a grantee or subgrantee upon denial of a request for relief. FTA shall notify the grantee or subgrantee if FTA plans to reconsider a decision.

Pursuant to FTA's Charter Rule at 49 CFR 604.2(f), grantees and subgrantees may assist with evacuations or other movements of people that might otherwise be considered charter

transportation when that transportation is in response to an emergency declared by the President, governor or mayor, or in an emergency requiring immediate action prior to a formal declaration, even if a formal declaration of an emergency is not eventually made by the President, governor or mayor. Therefore, a request for relief is not necessary to provide this service. However, if the emergency lasts more than 45 calendar days and the grantee will continue to provide service that would otherwise be considered charter service, the grantee or subgrantee must follow the procedures set out in this notice.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies. Grantees and subgrantees should refer to FTA's regulations, including 49 CFR part 601, for requirements for submitting a request for emergency relief.

Marcus J. Molinaro,

Administrator.

[FR Doc. 2026–01891 Filed 1–29–26; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2026–0034]

Request Notice: Use of Foreign-Built Small Passenger Vessel in United States Coastwise Trade, M/V FLIPSIDE

AGENCY: Maritime Administration (MARAD), U.S. Department of Transportation (DOT).

ACTION: Notice and request for comments.

SUMMARY: The Secretary of Transportation, as represented by MARAD, is authorized to make determinations regarding the coastwise use of foreign built; certain U.S. built; and U.S. and foreign rebuilt vessels that solely carry no more than twelve passengers for hire. MARAD has received such a determination request and is publishing this notice to solicit comments to assist with determining whether the proposed use of the vessel set forth in the request would have an adverse effect on U.S. vessel builders or U.S. coastwise trade businesses that use U.S.-built vessels in those businesses. Information about the requestor's vessel, including a description of the proposed

service, is in the **SUPPLEMENTARY INFORMATION** section below.

DATES: Submit comments on or before March 2, 2026.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD-2026-0034 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to <https://www.regulations.gov>. Search the above DOT Docket Number and follow the instructions for submitting comments.

- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12-140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include the DOT Docket Number, your name and a mailing address, an email address or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific DOT Docket Number. All comments received will be posted without change to the docket at www.regulations.gov, including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Mail Stop 2, MAR-620, Washington, DC 20590. Telephone: (202) 366-5400. Email: smallvessels@dot.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 46 U.S.C. 12121(b), the U.S. Coast Guard may issue a certificate of documentation with a coastwise trade endorsement for eligible, small passenger vessels authorized to carry no more than 12 passengers for hire if MARAD, after notice and an opportunity for public comment, determines the use of the small passenger vessel in the coastwise trade will not adversely affect United States vessel builders or the coastwise trade business of any person that employs

vessels built in the United States in that business.¹

MARAD has received an eligibility determination request. Further details about the requester's vessel and its proposed operations may be found in the determination request posted in the DOT Docket Number listed in the **ADDRESSES** section above at <https://www.regulations.gov>. Interested parties may comment on the undue adverse effect this action may have on U.S. vessel builders or coastwise trade businesses in the U.S. that employ U.S.-built vessels in those businesses.

Comments should refer to the vessel name, state the commenter's interest in the request, and demonstrate, with supporting documentation, the undue adverse effect on U.S. vessel builders and coastwise trade businesses.

Public Participation

How do I submit comments?

Please submit comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. It may take a few hours or even days for comments to be reflected on the docket. Comments must be written in English. Provide concise comments and attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

The docket online is located at <https://www.regulations.gov>, keyword search the DOT Docket Number list in the **ADDRESSES** section above or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). Please periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

You may request that MARAD treat your comments as commercially confidential by submitting them to SmallVessels@dot.gov. Include in the email subject heading "Contains Confidential Commercial Information" or "Contains CCI" and state in your submission, with specificity, the basis for any such confidential treatment

¹ The U.S. Coast Guard and MARAD have authority under 46 U.S.C. 12121(b) through the Secretary of the Department of Homeland Security and the Secretary of the Department of Transportation, respectively.

highlighting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

If MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit <https://www.transportation.gov/privacy>.

(Authority: 46 U.S.C. 12121, 49 CFR 1.93(a))

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2026-01860 Filed 1-29-26; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2026-0037]

Request Notice: Use of Foreign-Built Small Passenger Vessel in United States Coastwise Trade, M/V CHANGE ORDER

AGENCY: Maritime Administration (MARAD), U.S. Department of Transportation (DOT).

ACTION: Notice and request for comments.

SUMMARY: The Secretary of Transportation, as represented by MARAD, is authorized to make determinations regarding the coastwise use of foreign built; certain U.S. built; and U.S. and foreign rebuilt vessels that solely carry no more than twelve passengers for hire. MARAD has received such a determination request and is publishing this notice to solicit comments to assist with determining whether the proposed use of the vessel set forth in the request would have an adverse effect on U.S. vessel builders or U.S. coastwise trade businesses that use U.S.-built vessels in those businesses. Information about the requestor's vessel, including a description of the proposed

service, is in the **SUPPLEMENTARY INFORMATION** section below.

DATES: Submit comments on or before March 2, 2026.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2026–0037 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to <https://www.regulations.gov>. Search the above DOT Docket Number and follow the instructions for submitting comments.

- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include the DOT Docket Number, your name and a mailing address, an email address or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific DOT Docket Number. All comments received will be posted without change to the docket at www.regulations.gov, including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Mail Stop 2, MAR–620, Washington, DC 20590. Telephone: (202) 366–5400. Email: smallvessels@dot.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 46 U.S.C. 12121(b), the U.S. Coast Guard may issue a certificate of documentation with a coastwise trade endorsement for eligible, small passenger vessels authorized to carry no more than 12 passengers for hire if MARAD, after notice and an opportunity for public comment, determines the use of the small passenger vessel in the coastwise trade will not adversely affect United States vessel builders or the coastwise trade business of any person that employs

vessels built in the United States in that business.¹

MARAD has received an eligibility determination request. Further details about the requester's vessel and its proposed operations may be found in the determination request posted in the DOT Docket Number listed in the **ADDRESSES** section above at <https://www.regulations.gov>. Interested parties may comment on the undue adverse effect this action may have on U.S. vessel builders or coastwise trade businesses in the U.S. that employ U.S.-built vessels in those businesses.

Comments should refer to the vessel name, state the commenter's interest in the request, and demonstrate, with supporting documentation, the undue adverse effect on U.S. vessel builders and coastwise trade businesses.

Public Participation

How do I submit comments?

Please submit comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. It may take a few hours or even days for comments to be reflected on the docket. Comments must be written in English. Provide concise comments and attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

The docket online is located at <https://www.regulations.gov>, keyword search the DOT Docket Number list in the **ADDRESSES** section above or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). Please periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

You may request that MARAD treat your comments as commercially confidential by submitting them to SmallVessels@dot.gov. Include in the email subject heading “Contains Confidential Commercial Information” or “Contains CCI” and state in your submission, with specificity, the basis for any such confidential treatment

¹ The U.S. Coast Guard and MARAD have authority under 46 U.S.C. 12121(b) through the Secretary of the Department of Homeland Security and the Secretary of the Department of Transportation, respectively.

highlighting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

If MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit <https://www.transportation.gov/privacy>.

(Authority: 46 U.S.C. 12121, 49 CFR 1.93(a))

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2026–01859 Filed 1–29–26; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2026–0035]

Request Notice: Use of Foreign-Built Small Passenger Vessel in United States Coastwise Trade, M/V SERENDIPITY

AGENCY: Maritime Administration (MARAD), U.S. Department of Transportation (DOT).

ACTION: Notice and request for comments.

SUMMARY: The Secretary of Transportation, as represented by MARAD, is authorized to make determinations regarding the coastwise use of foreign built; certain U.S. built; and U.S. and foreign rebuilt vessels that solely carry no more than twelve passengers for hire. MARAD has received such a determination request and is publishing this notice to solicit comments to assist with determining whether the proposed use of the vessel set forth in the request would have an adverse effect on U.S. vessel builders or U.S. coastwise trade businesses that use U.S.-built vessels in those businesses. Information about the requestor's vessel, including a description of the proposed

service, is in the **SUPPLEMENTARY INFORMATION** section below.

DATES: Submit comments on or before March 2, 2026.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD-2026-0035 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to <https://www.regulations.gov>. Search the above DOT Docket Number and follow the instructions for submitting comments.

- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12-140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include the DOT Docket Number, your name and a mailing address, an email address or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific DOT Docket Number. All comments received will be posted without change to the docket at www.regulations.gov, including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Mail Stop 2, MAR-620, Washington, DC 20590. Telephone: (202) 366-5400. Email: smallvessels@dot.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 46 U.S.C. 12121(b), the U.S. Coast Guard may issue a certificate of documentation with a coastwise trade endorsement for eligible, small passenger vessels authorized to carry no more than 12 passengers for hire if MARAD, after notice and an opportunity for public comment, determines the use of the small passenger vessel in the coastwise trade will not adversely affect United States vessel builders or the coastwise trade business of any person that employs

vessels built in the United States in that business.¹

MARAD has received an eligibility determination request. Further details about the requester's vessel and its proposed operations may be found in the determination request posted in the DOT Docket Number listed in the **ADDRESSES** section above at <https://www.regulations.gov>. Interested parties may comment on the undue adverse effect this action may have on U.S. vessel builders or coastwise trade businesses in the U.S. that employ U.S.-built vessels in those businesses.

Comments should refer to the vessel name, state the commenter's interest in the request, and demonstrate, with supporting documentation, the undue adverse effect on U.S. vessel builders and coastwise trade businesses.

Public Participation

How do I submit comments?

Please submit comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. It may take a few hours or even days for comments to be reflected on the docket. Comments must be written in English. Provide concise comments and attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

The docket online is located at <https://www.regulations.gov>, keyword search the DOT Docket Number list in the **ADDRESSES** section above or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). Please periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

You may request that MARAD treat your comments as commercially confidential by submitting them to SmallVessels@dot.gov. Include in the email subject heading "Contains Confidential Commercial Information" or "Contains CCI" and state in your submission, with specificity, the basis for any such confidential treatment

¹ The U.S. Coast Guard and MARAD have authority under 46 U.S.C. 12121(b) through the Secretary of the Department of Homeland Security and the Secretary of the Department of Transportation, respectively.

highlighting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

If MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

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Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit <https://www.transportation.gov/privacy>.

(Authority: 46 U.S.C. 12121, 49 CFR 1.93(a))

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2026-01862 Filed 1-29-26; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2026-0036]

Request Notice: Use of Foreign-Built Small Passenger Vessel in United States Coastwise Trade, S/V LUNA CAT

AGENCY: Maritime Administration (MARAD), U.S. Department of Transportation (DOT).

ACTION: Notice and request for comments.

SUMMARY: The Secretary of Transportation, as represented by MARAD, is authorized to make determinations regarding the coastwise use of foreign built; certain U.S. built; and U.S. and foreign rebuilt vessels that solely carry no more than twelve passengers for hire. MARAD has received such a determination request and is publishing this notice to solicit comments to assist with determining whether the proposed use of the vessel set forth in the request would have an adverse effect on U.S. vessel builders or U.S. coastwise trade businesses that use U.S.-built vessels in those businesses. Information about the requestor's vessel, including a description of the proposed

service, is in the **SUPPLEMENTARY INFORMATION** section below.

DATES: Submit comments on or before March 2, 2026.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2026–0036 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to <https://www.regulations.gov>. Search the above DOT Docket Number and follow the instructions for submitting comments.

- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include the DOT Docket Number, your name and a mailing address, an email address or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific DOT Docket Number. All comments received will be posted without change to the docket at www.regulations.gov, including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Mail Stop 2, MAR–620, Washington, DC 20590. Telephone: (202) 366–5400. Email: smallvessels@dot.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 46 U.S.C. 12121(b), the U.S. Coast Guard may issue a certificate of documentation with a coastwise trade endorsement for eligible, small passenger vessels authorized to carry no more than 12 passengers for hire if MARAD, after notice and an opportunity for public comment, determines the use of the small passenger vessel in the coastwise trade will not adversely affect United States vessel builders or the coastwise trade business of any person that employs

vessels built in the United States in that business.¹

MARAD has received an eligibility determination request. Further details about the requester's vessel and its proposed operations may be found in the determination request posted in the DOT Docket Number listed in the **ADDRESSES** section above at <https://www.regulations.gov>. Interested parties may comment on the undue adverse effect this action may have on U.S. vessel builders or coastwise trade businesses in the U.S. that employ U.S.-built vessels in those businesses.

Comments should refer to the vessel name, state the commenter's interest in the request, and demonstrate, with supporting documentation, the undue adverse effect on U.S. vessel builders and coastwise trade businesses.

Public Participation

How do I submit comments?

Please submit comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. It may take a few hours or even days for comments to be reflected on the docket. Comments must be written in English. Provide concise comments and attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

The docket online is located at <https://www.regulations.gov>, keyword search the DOT Docket Number list in the **ADDRESSES** section above or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). Please periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

You may request that MARAD treat your comments as commercially confidential by submitting them to SmallVessels@dot.gov. Include in the email subject heading "Contains Confidential Commercial Information" or "Contains CCI" and state in your submission, with specificity, the basis for any such confidential treatment

¹ The U.S. Coast Guard and MARAD have authority under 46 U.S.C. 12121(b) through the Secretary of the Department of Homeland Security and the Secretary of the Department of Transportation, respectively.

highlighting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

If MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit <https://www.transportation.gov/privacy>.

(Authority: 46 U.S.C. 12121, 49 CFR 1.93(a))

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,
Secretary, Maritime Administration.

[FR Doc. 2026–01861 Filed 1–29–26; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA–2026–0199 (Notice No. 2026–01)]

Hazardous Materials: Information Collection Activities

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, PHMSA invites comments on seven Office of Management and Budget (OMB) control numbers pertaining to hazardous materials transportation. PHMSA intends to request renewal and extension for these seven control numbers from OMB.

DATES: Interested persons are invited to submit comments on or before March 31, 2026.

ADDRESSES: You may submit comments identified by the Docket Number PHMSA–2026–0199 (Notice No. 2026–01) by any of the following methods:

• *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

• *Fax:* 1–202–493–2251.

• *Mail:* Docket Management System; U.S. Department of Transportation, West Building, Ground Floor, Room W12–140, Routing Symbol M–30, 1200 New Jersey Avenue SE, Washington, DC 20590.

• *Hand Delivery:* To the Docket Management System; Room W12–140 on the ground floor of the West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Instructions: All submissions must include the agency name and Docket Number (PHMSA–2026–0199) for this notice at the beginning of the comment. To avoid duplication, please use only one of these four methods. All comments received will be posted without change to the Federal Docket Management System (FDMS) and will include any personal information you provide.

Requests for a copy of an information collection should be directed to Ryan Larson or Steven Andrews, Standards and Rulemaking Division, (202) 366–8553, ohmspra@dot.gov, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

Docket: For access to the dockets to read background documents or comments received, go to <http://www.regulations.gov> or DOT's Docket Operations Office (see **ADDRESSES**).

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at www.dot.gov/privacy.

Confidential Business Information: Confidential Business Information (CBI) is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments in response to this notice contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this notice, it is important that you clearly designate the submitted comments as CBI. Pursuant to 49 CFR 105.30, you

may ask PHMSA to provide confidential treatment to the information you give to the agency by taking the following steps: (1) mark each page of the original document submission containing CBI as “Confidential;” (2) send PHMSA a copy of the original document with the CBI deleted along with the original, unaltered document; and (3) explain why the information you are submitting is CBI. Submissions containing CBI should be sent to Ryan Larson or Steven Andrews, Standards and Rulemaking Division, and addressed to the Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590–0001 or ohmspra@dot.gov. Comments received by PHMSA which are not specifically designated as “CBI” will be placed in the public docket for this notice.

FOR FURTHER INFORMATION CONTACT:

Ryan Larson or Steven Andrews, Standards and Rulemaking Division, (202) 366–8553, ohmspra@dot.gov, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

SUPPLEMENTARY INFORMATION: Section 1320.8(d), title 5, Code of Federal Regulations (CFR) requires the Pipeline and Hazardous Materials Safety Administration (PHMSA) to provide interested members of the public and affected agencies an opportunity to comment on information collection and recordkeeping requests. This notice identifies information collection requests PHMSA will be submitting to OMB for renewal and extension. These information collections are contained in 49 CFR 171.6 of the Hazardous Materials Regulations (HMR; 49 CFR parts 171–180). PHMSA has revised burden estimates, where appropriate, to reflect current reporting levels or adjustments based on changes in proposed or final rules published since the information collections were last approved. The following information is provided for each information collection: (1) title of the information collection, including former title if a change is being made; (2) OMB control number; (3) summary of the information collection activity; (4) description of affected public; (5) estimate of total annual reporting and recordkeeping burden; and (6) frequency of collection. PHMSA will request a 3-year term of approval for each information collection activity and will publish a notice in the **Federal Register** upon OMB's approval.

PHMSA requests comments on the following information collections:

Title: Inspection and Testing of Portable Tanks and Intermediate Bulk Containers.

OMB Control Number: 2137–0018.

Summary: This OMB control number describes the information collections in parts 173, 178, and 180 of the HMR pertaining to the documenting qualifications, inspections, tests, and approvals pertaining to the manufacture and use of portable tanks and intermediate bulk containers (IBCs) under various provisions of the HMR. Information collections under this OMB control number include:

(1) *Design Qualification Testing for IBCs:* This information collection consists of the minimum requirements for testing procedures to ensure that IBCs containing hazardous materials can withstand normal conditions of transportation. Each packaging must pass the prescribed tests and conform to § 173.24 while in transportation. The testing requirements in § 178.801(d) ensure that the packaging manufacturer achieves successful test results for the design qualification testing at the start of production of each new or different IBC design type.

(2) *Periodic Design Requalification Testing of IBCs:* This information collection consists of the requirements for periodic design re-qualification of each qualified IBC design type to maintain authorization for continued production. IBC manufacturers must conduct successful tests at sufficient frequency to ensure each packaging produced is capable of passing the design qualification tests, which must be conducted at least once every 12 months.

(3) *Applications for Approval of Equivalent Packaging:* This information collection consists of the requirements for approval of equivalent packaging applications submitted by the regulated community to PHMSA, which allows the use of an IBC differing from the standards outlined in the HMR if it is shown to be equally effective and if the testing methods used are equivalent.

(4) *Reporting Requirements for Retest and Inspection of IBCs:* This information collection consists of the requirements for the continuing qualification, maintenance, or periodic retesting of an IBC by any person responsible for it. Each IBC constructed in accordance with a United Nations (UN) standard for which a test or inspection is required may not be filled and offered for transportation or transported until the testing and inspection have been successfully completed. The information collection

also reflects the creation of a report that identifies the testing and inspection of IBCs.

(5) *Recordkeeping for IBC Testing:* This information collection consists of the recordkeeping requirements associated with IBC testing in §§ 178.801 and 180.352. The IBC owner or lessee must keep records of periodic retests, initial and periodic inspections, and test performance on the IBC if it has been repaired. Records must be kept for each packaging at each location where periodic tests are conducted and must be available for inspection by a DOT representative upon request.

(6) *Manufacturers Data Report (ASME) for Portable Tanks:* This information collection consists of the requirements for tanks designed and constructed in accordance with, and that fulfill all the requirements of, the American Society of Mechanical Engineers (ASME) Code. In addition to the markings required by the ASME Code, every tank must bear permanent marks that include the information specified in § 178.255–14, which must

be stamped into the metal near the center of one of the tank heads or stamped into a plate permanently attached to the tank by means of brazing or welding or other suitable means.

(7) *Approval Applications for Specification UN Portable Tank Design:* This information collection requires an owner or manufacturer of a portable tank to apply for an approval to a designated approval agency authorized to approve new portable tanks designs.

(8) *Applications for Modifications to Portable Tank Designs:* This information collection requires an owner or manufacturer of a portable tank to apply for an approval to a designated approval agency authorized to approve the modifications to portable tanks designs.

(9) *Portable Tanks—Approval Agency Retention of Documents:* This information collection consists of the requirement for approval agencies to review all drawings and calculations to ensure that the design is compliant with the relevant specification. The approval agency must maintain the drawings and approval records for as long as the

portable tank remains in service and provide this information to the DOT upon request.

(10) *Portable Tanks—Manufacturers Retention of Documents:* This information collection requires that qualification records for specification portable tanks be retained for at least 5 years by the tank manufacturer and made available to duly identified representatives of the DOT or the owner of the tank.

(11) *Recordkeeping for the Testing of Portable Tank:* This information collection requires that the owner of the portable tank or his/her authorized agent will retain a written record indicating the date and results of all required tests, as well as the name and address of the tester, until the next retest has been satisfactorily completed and recorded. This information must be provided to the DOT upon request.

The following is a list of the information collections and burden estimates associated with this OMB Control Number:

Information collection	Respondents	Total annual responses	Hours per response	Total annual burden hours
Design Qualification Testing for IBCs—Applications for the Certification Mark	13	494	3	1,482
Periodic Design Requalification Testing of IBCs—Submission of Changes to Test Frequency to the Associate Administrator	13	494	3	1,482
Applications for Approval of Equivalent Packaging—IBCs	5	5	3	15
Reporting Requirements for Retest and Inspection of IBCs	1,000	100,000	0.25	25,000
Recordkeeping for IBC Testing	150	150	0.25	38
Manufacturers Data Report (ASME) for Portable Tanks	50	50,000	0.25	12,500
Approval Applications for Specification UN Portable Tank Design	13	494	3	1,482
Applications for Modifications to Portable Tank Designs	13	494	3	1,482
Portable Tanks—Approval Agency Retention of Documents	13	494	0.25	124
Portable Tanks—Manufacturers Retention of Documents	50	50,000	0.25	12,500
Recordkeeping for the Testing of Portable Tanks	150	150	0.25	38

Affected Public: Manufacturers and owners of portable tanks and intermediate bulk containers.

Annual Reporting and Recordkeeping Burden:

Number of Respondents: 1,470.

Total Annual Responses: 202,775.

Total Annual Burden Hours: 56,143.

Frequency of Collection: On occasion.

Title: Hazardous Materials Incident Reports.

OMB Control Number: 2137–0039.

Summary: This information collection is applicable upon occurrence of an

incident as prescribed in 49 CFR 171.15 and 171.16. A Hazardous Materials Incident Report, DOT Form F 5800.1, must be completed by a person in physical possession of a hazardous material at the time a hazardous material incident occurs in transportation, such as a release of materials, serious accident, evacuation, or closure of a main artery. Incidents meeting criteria in 49 CFR 171.15 also require a telephonic report. This information collection enhances the

Agency's ability to evaluate the effectiveness of its regulatory program, determine the need for regulatory changes, and address emerging hazardous materials transportation safety issues. The requirements apply to all interstate and intrastate carriers engaged in the transportation of hazardous materials by rail, air, water, and highway. The following information collections and their burdens are associated with this OMB Control Number:

Information collection	Respondents	Total annual responses	Hours per response	Total annual burden hours
Telephone Notifications	180	720	0.08	58
Incident Reports Paper—Written	172	2,888	1.6	4,621
Incident Reports—Electronic	166	19,720	0.8	15,776

Affected Public: Shippers and carriers of hazardous materials.

Annual Reporting and Recordkeeping Burden:

Number of Respondents: 518.

Total Annual Responses: 23,328.

Total Annual Burden Hours: 20,455.

Frequency of Collection: On occasion.

Title: Rail Carrier and Tank Car Tanks Requirements, Rail Tank Car Tanks—Transportation of Hazardous Materials by Rail.

OMB Control Number: 2137–0559.

Summary: This information collection consolidates and describes the information provisions in parts 172, 173, 174, 179, and 180 of the HMR pertaining to the transportation of hazardous materials by rail and the manufacture, qualification, maintenance, and use of tank cars. The types of information collected include:

(1) *Tank Car Approvals:* This information collection consists of special provisions that mandate the approval of the Associate Administrator or the Association of American Railroads (AAR) Committee on Tank Cars before certain hazardous material packaging or packaging components can be used for transportation of hazardous materials by rail.

(2) *AAR approval required when a tank car is proposed for commodity service other than specified on a certificate of construction:* This information collection consists of requirements for obtaining AAR Tank Car Committee approval for the use of a tank car for commodities other than those specified in part 173 and the certificate of construction. It also includes requirements for AAR approval of tank car design, materials, construction, conversion, alteration, or construction to a new specification. This information is used to ensure that tank cars are suitable for transporting specific commodities and that tank car

design, construction, and modification comply with the relevant regulations.

(3) *Annual tank car owner progress report to FRA:* This information collection consists of the requirement for tank car owners to submit progress reports to the Federal Railroad Administration (FRA) if their tank cars need to be modified to meet the requirements specified in § 173.31. The FRA uses this information to track progress and ensure that all affected tank cars are modified before the regulatory compliance date.

(4) *Compressed Gases and Cryogenic Liquids in Tank Cars and Multi Unit Tank Cars Reporting:* This information collection requires the shipper to notify the FRA whenever a tank car transporting hydrogen chloride, refrigerated liquids, or vinyl fluoride, stabilized is not received by the consignee within 20 days from the date of shipment.

(5) *Reporting to the Bureau of Explosives regarding any restrictions over any portion of its lines:* This information collection requires each rail carrier to report to the Bureau of Explosives (BOE), for publication, all information as to any restrictions which it imposes against the acceptance, delivery, or transportation of any hazardous materials, over any portion of its lines.

(6) *Nonconforming bulk packages must be repaired or approved from movement by the FRA:* This information collection requires that a bulk packaging, such as a tank car tank, that no longer conforms to applicable HMR requirements may not be forwarded by rail unless repaired or approved for movement by the Associate Administrator for Safety, FRA. Notification and approval must be furnished in writing or through telephonic or electronic means, with

subsequent written confirmation provided within two weeks.

(7) *FRA Approval for transportation of bulk packages containing a hazardous material in COFC or TOFC service:* This information collection requires that the Associate Administrator for Safety, FRA approve the transportation of bulk packages, such as portable tanks and cargo tanks, containing a hazardous material in container-on-flatcar (COFC) or trailer-on-flatcar (TOFC) service if not otherwise authorized for transportation.

(8) *Division 1.1 or 1.2 explosive material inspection and Car Certificate requirements:* This information collection requires that before a Division 1.1 or 1.2 explosive materials may be loaded into a rail car, the car must have been inspected and certified to be in compliance with the requirements of § 174.104(b) by a qualified person designated under 49 CFR 215.11.

(9) *Initial marking, requalification marking, and requalification reporting requirements:* This information collection consist of the requirements for the detail marking of a newly manufactured tank car, requalification tank car marking requirements, and reporting of details for a requalified tank car.

(10) *Quality Assurance Program:* This information collection requires facilities that build, repair, and ensure the structural integrity of tank cars are required to develop and implement a quality assurance program. This information is used by the facility and DOT compliance personnel to ensure that each tank car is constructed or repaired in accordance with the applicable requirements.

The following is a list of the information collections and burden estimates associated with this OMB Control Number:

Information collection	Respondents	Total annual responses	Hours per response	Total annual burden hours
Tank Car Approvals	2	2	6.5	13
AAR approval required when a tank car is proposed for commodity service other than specified on a certificate of construction	25	1,200	0.167	200
Annual tank car owner progress report to FRA	100	100	1	100
Compressed Gases and Cryogenic Liquids in Tank Cars and Multi Unit Tank Cars Reporting	6	141	0.25	35
Reporting to the Bureau of Explosives regarding any restrictions over any portion of its lines	34	51	0.333	17
Nonconforming bulk packages must be repaired or approved from movement by the FRA	388	4,308	0.4	1,695
FRA Approval for transportation of bulk packages containing a hazardous material in COFC or TOFC service	6	6	0.5	3
Division 1.1 or 1.2 explosive material inspection and Car Certificate requirements	25	600	0.333	200
Record when a car seal is changed when the car is placarded with Division 1.1 or 1.2 explosive materials	34	170	0.166	28
Initial marking, requalification marking, and requalification reporting requirements	100	15,000	0.116	1,768

Information collection	Respondents	Total annual responses	Hours per response	Total annual burden hours
Quality assurance program	75	75	5.5	413

Affected Public: Manufacturers, owners, and rail carriers of tank.

Annual Reporting and Recordkeeping Burden:

Total Number of Respondents: 795.

Total Annual Responses: 21,653.

Total Annual Burden Hours: 4,472.

Frequency of Collection: Annually.

Title: Testing Requirements for Non-Bulk Packaging.

OMB Control Number: 2137-0572.

Summary: These OMB control number describes the information collections in parts 173 and 180 of the HMR pertaining to the testing requirements for non-bulk packagings. This OMB control number covers performance-oriented packaging standards and allows packaging manufacturers and shippers more flexibility in selecting more economical packagings for their products. These information collections also allow customizing the design of packagings to better suit the transportation environment that they will encounter and encourages technological innovations, decreases packaging costs, and significantly reduces the need for special permits. These information collections specifically include:

(1) *Testing Requirements for Non-Bulk Packaging (Reporting):* This information collection consists of

various testing requirements that must be met by non-bulk packaging, depending on the type of material it will contain. These include thermal resistance tests for packaging transporting oxygen cylinders, leakproofness tests for liquid hazardous materials, hydrostatic pressure tests for metal, plastic, and composite containers, cooperage tests for bung-type wooden barrels, and additional testing for packaging intended to contain infectious substances. The specific tests required may vary based on the outer and inner packaging material used.

(2) *Additional Test Reports (Reporting):* This information collection consists of the requirement to prepare and maintain a test report after each design qualification test or periodic retest of a packaging. The test report must be available to the user of the packaging or a representative of the DOT upon request and includes details such as the date, name, and address of the testing facility, packaging design type, maximum capacity, characteristics of test contents, and test descriptions and results.

(3) *Test Reports (Recordkeeping):* This information collection requires that test report must be made available to a user of a packaging or a representative of the

DOT, upon request. The test report includes information such as: the date, name, and address of the testing facility; a description of the packaging design type; the maximum capacity; characteristics of test contents; and test descriptions and results.

(4) *Closure Instructions (Reporting):* This information collection consists of the requirement for the manufacturer or certifier of non-bulk packaging to create closure instructions, in accordance with § 178.2(c). These instructions indicate the means of closure with which the package was tested and ensure that any subsequent shipper maintains the same level of safety when the package is closed for transportation of hazardous materials.

(5) *Closure Instructions (Recordkeeping):* This information collection requires that the manufacturer or other person certifying compliance, along each subsequent distributor of the packaging, provide closure instructions to each person to whom the packaging is transferred, as well as any representative of the DOT, for inspection.

The following is a list of the information collections and burden estimates associated with this OMB Control Number:

Information collection	Respondents	Total annual responses	Hours per response	Total annual burden hours
Testing Requirements for Non-Bulk Packaging—Reporting	5,000	15,000	2.016	30,250
Additional Test Reports—Reporting	10	30	2	60
Test Reports—Recordkeeping	100	1,000	0.1	100
Closure Instructions—Reporting	500	500	2	1,000
Closure Instructions—Recordkeeping	16,080	16,080	0.083	1,340

Affected Public: Each non-bulk packaging manufacturer that tests packagings to ensure compliance with the HMR.

Annual Reporting and Recordkeeping Burden:

Total Number of Respondents: 21,690.

Total Annual Responses: 32,610.

Total Annual Burden Hours: 32,750.

Frequency of Collection: On occasion.

Title: Hazardous Materials Public Sector Training and Planning Grants.

OMB Control Number: 2137-0586.

Summary: This OMB control number describes the information collections in parts 110 of the HMR pertaining to the procedures for reimbursable grants for public sector planning and training in support of the emergency planning and training efforts of States, Indian tribes, and local communities to manage

hazardous materials emergencies, particularly those involving transportation. Sections in this part address information collection and recordkeeping with regard to applying for grants, monitoring expenditures, and reporting and requesting modifications.

The following is a list of the information collections and burden estimates associated with this OMB Control Number:

Information collection	Respondents	Total annual responses	Hours per response	Total annual burden hours
Hazardous Materials Grants Applications	68	68	83.23	5,661

Affected Public: State and local governments, Indian tribes.

Annual Reporting and Recordkeeping Burden:

Total Annual Respondents: 68.

Annual Responses: 68.

Annual Burden Hours: 5,661.

Frequency of collection: On occasion.

Title: Cargo Tank Motor Vehicles in Liquefied Compressed Gas Service.

OMB Control Number: 2137–0595.

Summary: This information collection and recordkeeping burden pertains to the requirements applicable to the manufacture, certification, inspection,

repair, maintenance, and operation of certain DOT specification and non-specification cargo tank motor vehicles used to transport liquefied compressed gases. These requirements are intended to ensure cargo tank motor vehicles used to transport liquefied compressed gases are operated safely, and to minimize the potential for catastrophic releases during unloading and loading operations. They include: (1) requirements for operators of cargo tank motor vehicles in liquefied compressed gas service to develop operating procedures applicable to unloading

operations and carry the operating procedures on each vehicle; (2) inspection, maintenance, marking, and testing requirements for the cargo tank discharge system, including delivery hose assemblies; and (3) requirements for emergency discharge control equipment on certain cargo tank motor vehicles transporting liquefied compressed gases that must be installed and certified by a Registered Inspector.

The following information collections and their burdens are associated with this OMB Control Number:

Information collection	Respondents	Total annual responses	Hours per response	Total annual burden hours
Marking New/Repaired Hoses with Unique Identifier	6,800	12,172	0.083	1,010
Monthly Hose Inspections Record	6,800	439,960	0.1	43,996
Record of Monthly Piping Tests Record	6,800	400,112	0.2	80,022
Hose Pressure Test Marking Record	6,800	12,172	0.083	1,010
Annual Hose Test Record	6,800	36,652	0.42	15,394
Cargo Tanks in Other Than Metered Delivery Service—Design Certification for Automatic Shutoff	150	900	8	7,200
Cargo Tanks in Other Than Metered Delivery Service—Instillation of Shutoff System by a Registered Inspector	150	900	8	7,200
Cargo Tank Motor Vehicles in Metered Delivery Service—Certification of Remote-Control Equipment by a Registered Inspector	150	3,300	8	26,400

Affected Public: Carriers in liquefied compressed gas service, manufacturers and repairers.

Annual Reporting and Recordkeeping Burden:

Number of Respondents: 34,450.

Total Annual Responses: 906,168.

Total Annual Burden Hours: 182,232.

Frequency of Collection: On occasion.

Title: Inspection and Testing of Meter Provers.

OMB Control Number: 2137–0620.

Summary: This information collection and recordkeeping burden results from the requirements pertaining to the use, inspection, and maintenance of mechanical displacement meter provers (meter provers) used to check the accurate flow of liquid hazardous materials into bulk packagings, such as portable tanks and cargo tank motor vehicles, under the HMR. These meter provers are used to ensure that the proper amount of liquid hazardous

materials is being loaded and unloaded. These meter provers consist of a gauge and several pipes that always contain small amounts of the liquid hazardous material in the pipes as residual material and, therefore, must be inspected and maintained in accordance with the HMR to ensure they are in proper calibration and working order. These meter provers are not subject to the specification testing and inspection requirements in 49 CFR part 178.

However, these meter provers must be visually annually inspected and hydrostatic pressure tested every five years in order to ensure they are properly working as specified in 49 CFR 173.5a of the HMR. Therefore, this information collection requires that:

(1) Each meter prover must undergo and pass an annual external visual inspection to ensure that the meter provers used in the flow of liquid hazardous materials into bulk

packagings are accurate and in conformance with the performance standards in the HMR.

(2) Each meter prover must undergo and pass a hydrostatic pressure test at least every 5 years to ensure that the meter provers used in the flow of liquid hazardous materials into bulk packagings are accurate and in conformance with the performance standards in the HMR.

(3) Each meter prover must successfully complete the test and inspection and must be marked in accordance with 49 CFR 180.415(b) and 173.5a.

(4) Each owner must retain a record of the most recent visual inspection and pressure test until the meter prover is requalified.

The following information collections and their burdens are associated with this OMB Control Number:

Information collection	Respondents	Total annual responses	Hours per response	Total annual burden hours
Annual Visual Inspection	250	250	0.5	125
Hydrostatic Pressure Test (Every 5 Years)	250	250	0.2	50

Affected Public: Owners of meter provers used to measure liquid hazardous materials flow into bulk packagings such as cargo tanks and portable tanks.

Annual Reporting and Recordkeeping Burden:

Number of Respondents: 500.

Total Annual Responses: 500.

Total Annual Burden Hours: 175.

Frequency of Collection: On occasion.

Issued in Washington, DC, on January 27, 2026 under authority delegated in 49 CFR 1.97.

Matthew Nickels,

Acting Director, Standards and Rulemaking Division, Office of Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration.

[FR Doc. 2026–01856 Filed 1–29–26; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket ID Number: DOT–OST–2010–0054]

Notice of Submission of Proposed Information Collection to OMB; Agency Request for Renewal of Previously Approved Collections: Nondiscrimination on the Basis of Disability in Air Travel: Reporting Requirements for Disability-Related Complaints

AGENCY: Office of the Secretary (OST), Department of Transportation (Department or DOT).

ACTION: Notice of submission to the Office of Management and Budget (OMB) and request for comments.

SUMMARY: In accordance with the *Paperwork Reduction Act of 1995* (44 U.S.C. Chapter 35, as amended), the Department is forwarding the Information Collection Request (ICR) described below to OMB for review. DOT published a **Federal Register** notice with a 60-day comment period soliciting comments on the following collections of information on November 28, 2025 (90 FR 54,880). DOT received four comments on the 60-day notice which are addressed below. DOT considered the comments and concluded that it will not make any changes to the information collections before it submits the ICR to OMB for review. This notice is to allow the public an additional 30 days from the date of this notice to submit comments to the recently published application to renew OMB Control Number: 2105–0551, “Reporting Requirements for Disability-Related Complaints.”

DATES: Interested persons are invited to submit comments regarding this proposal. Written comments should be submitted by March 2, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice via www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT: John Wood, Office of Aviation Consumer Protection, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, Telephone Number (202) 366–9342, C70notice@dot.gov (email).

Arrangements to receive this document in an alternative format may be made by contacting the above-named individual.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2105–0551.

Title: Reporting Requirements for Disability-Related Complaints.

Type of Request: Renewal of information collections.

Background: The Department’s regulation 14 CFR 382.157 requires U.S. and foreign air carriers operating to, from and within the United States that conduct passenger-carrying service with at least one aircraft with a designed seating capacity of more than 60 passengers (large aircraft) to record disability-related complaints. The carriers must also categorize these complaints according to the type of disability and nature of complaint, prepare a summary report annually of the complaints received during the preceding calendar year, submit the report to the Department’s Office of Aviation Consumer Protection, and retain copies of correspondence and records of action taken on the reported complaints for three years. Carriers are required to submit their annual report to the Department by the last Monday in January of each year for the complaints received during the priority calendar year. Carriers must submit their annual report through the World Wide Web except if the carrier can demonstrate an undue burden by doing so and receives permission from the Department to submit it in an alternative manner.

The Department relies on the disability-related complaint information collections primarily to comply with 49 U.S.C. 41705(c)(3), which requires the Secretary of Transportation to “regularly review all complaints received by carriers alleging discrimination on the basis of disability” and “report annually

to Congress on the results of such review.” The Department may also rely on this information to inform policy and in enforcement matters. The Department publishes the data collected from airlines each year, and the corresponding reports to Congress, on its website at: <https://www.transportation.gov/airconsumer/annual-report-disability-related-air-travel-complaints>.

The Paperwork Reduction Act of 1995 (PRA) and its implementing regulations, 5 Code of Federal Regulations (CFR) Part 1320, require Federal agencies to issue two notices seeking public comment on information collection activities before OMB may approve paperwork packages. On November 28, 2025, DOT published a 60-day notice in the **Federal Register** soliciting comment on the ICRs for which the agency seeks OMB approval. *See* 90 FR 54,880.

DOT received four comments on the notice. The commenters include the Muscular Dystrophy Association (MDA), Paralyzed Veterans of America (PVA)—writing on behalf of 23 disability rights organizations or chapters—a representative of North Central Independent Living Services, and an anonymous member of the public.

In general, the commenters agreed that the requirements for carriers to collect and report disability-related complaints received by carriers are necessary. The commenters urged the Department to enhance the collection of information so that it is more useful to individuals with disabilities and better reflects what may be violations of the Air Carrier Access Act (ACAA). In support of this, PVA and MDA referenced the new reporting requirement of section 545 of the FAA Reauthorization Act of 2024 that requires the Department to submit a report to Congress on consumer complaints related to passengers with disabilities filed with DOT. PVA stated that the information required for this new report is more specific than information that the Department currently collects from airlines, and that some of the required information goes beyond the current data collection.

With regard to the Department’s burden estimates, PVA and MDA highlighted the reporting efficiencies and capabilities of the Department’s Aviation Complaint, Enforcement, and Reporting System (ACERS), which the Department recently rolled out for air carriers to use to submit their reports. PVA asserted that DOT’s estimate of .5 hours per year for airlines to submit reports to DOT may be overestimated due to the efficiencies ACERS provides.

To minimize burden associated with the collections, PVA suggested that carriers utilize check boxes for established complaint categories on their complaint forms and make complaint forms easier to find on the carriers' websites, so passengers do not have to call the carrier about their complaint, which could increase the burden.

The anonymous commenter suggested that the Air Carrier Access Act Advisory Committee participate in any discussions on changes to the reporting requirement and provide recommendations for improvement. That commenter also urged the Department to ensure that the report and its web page are accessible with ACAA and Americans with Disabilities Act (ADA) requirements.

After reviewing all the comments, DOT has determined that no changes are necessary to the ICR prior to submission to OMB for review. DOT's annual reports are comprised of data that airlines are currently required to report under 14 CFR part 382. As such, any enhancements to these reporting requirements, including those suggested by the commenters, would be more appropriately addressed through rulemaking.

The Department agrees with PVA and MDA that ACERS offers carriers enhanced reporting efficiencies. However, for the purposes of seeking renewal of these ICRs, DOT will retain its burden estimate of .5 hours. This estimate accounts for all reporting carriers and includes a reasonable estimate of time carriers will need to conduct the due diligence required to prepare and submit an accurate report. With respect to publishing accessible content on its web pages, DOT remains committed to ensuring that content posted on its website, including reports, is accessible to individuals with disabilities to federal accessibility standards.

The Department announces that these information collection activities have been re-evaluated and certified under 5 CFR 1320.5(a) and is forwarding to OMB for review and approval pursuant to 5 CFR 1320.12(c). Before OMB decides whether to approve these proposed collections of information, it must provide 30 days for public comment. 44 U.S.C. 3507(b); 5 CFR 1320.12(d). Federal law requires OMB to approve or disapprove paperwork packages between 30 and 60 days after the 30-day notice is published. 44 U.S.C. 3507(b)–(c); 5 CFR 1320.12(d); *see also* 60 FR 44,983 (Aug. 29, 1995). Therefore, respondents should submit their respective comments to OMB within 30 days of publication to best ensure their

full consideration. 5 CFR 1320.12(c); *see also* 60 FR 44,983 (Aug. 29, 1995).

For each information collection, the title, a description of the respondents, and an estimate of the annual recordkeeping and periodic reporting burden are set forth below.

(1) Requirement to record and categorize complaints received.

Respondents: U.S. air carriers and foreign air carriers operating to and from the United States that conduct passenger-carrying service with at least one large aircraft.

Number of Respondents: 170 (the total number of respondents that reported for Calendar Year (CY) 2023).¹

Frequency: 49,082 complaints per year total for all respondents, which represents the number of complaints received by all respondents combined during CY 2023 (0–9,717 complaints is the range of the lowest number of complaints and the highest number of complaints received by any respondent during CY 2023).

Estimated Burden on Respondents: .25 hours on each respondent to categorize and record each complaint.

Estimated Total Annual Burden: 12,270.5 hours for all respondents (time to record and categorize each complaint (.25 hours) multiplied by the total number of complaints received during CY 2023 (49,082)). On average, the estimated annual burden per respondent is a range of 0–2,429.25 hours per carrier.

(2) Requirement to prepare and submit annual report.

Carriers will generally submit their reports electronically through ACERS or another means approved by the Department.

Respondents: U.S. air carriers and foreign air carriers operating to and from the United States that conduct passenger-carrying service with at least one large aircraft.

Number of Respondents: 170 (the total number of respondents that reported for CY 2023).

Frequency: 1 report to DOT per year for each respondent.

Estimated Burden on Respondents: 0.5 hours a year for each respondent to report to DOT.

Estimated Total Annual Burden: 85 hours for all respondents (time to report (0.5 hours) multiplied by 170, the total number of respondents).

(3) Requirement to retain correspondences and records of action taken on all disability-related complaints.

Respondents: U.S. air carriers and foreign air carriers operating to and from the United States that conduct passenger-carrying service with at least one large aircraft.

Number of Respondents: 170 (the total number of respondents that reported for CY2023).

Frequency: 49,082 complaints per year total for all respondents, which represents the number of complaints received by all respondents combined during CY 2023 (0–9,717 complaints is the range of the lowest number of complaints and the highest number of complaints received by any respondent during CY 2023).

Estimated Burden on Respondents: 0.083 (repeating) hours per complaint (the time it takes for a respondent to retain or save the correspondences and records of action taken on a single disability-related complaint).

Estimated Total Annual Burden: 4,090.17 hours (time it takes for a respondent to retain or save the correspondences and records of action taken on a single disability-related complaints (0.083 (repeating) hours) multiplied by the total number of complaints received during CY 2023 (49,082)).

Comments Invited

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (b) the accuracy of the Department's estimate of the burden of the proposed information collection; (c) 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 respondents.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended; and 49 CFR 1.26, 1.27, 1.48; DOT Order 1351.29A.

Issued in Washington, DC, on January 28, 2026.

Liv Vaughn Chapman, Jr.,

Deputy Assistant General Counsel.

[FR Doc. 2026–01914 Filed 1–29–26; 8:45 am]

BILLING CODE 4910–9X–P

¹ Disability-related complaints data for CY 2023 were the most recent data available to the Department as of the time of the Department's estimates to support this request for renewal.

DEPARTMENT OF THE TREASURY**Alcohol and Tobacco Tax and Trade Bureau**

[Docket No. TTB–2026–0001]

**Proposed Information Collections;
Comment Request (No. 97)****AGENCY:** Alcohol and Tobacco Tax and Trade Bureau (TTB); Treasury.**ACTION:** Notice and request for comments.**SUMMARY:** As part of our continuing effort to reduce paperwork and respondent burden, and as required by the Paperwork Reduction Act of 1995, we invite comments on the continuing or proposed information collections listed below in this document.**DATES:** We must receive your written comments on or before March 31, 2026.**ADDRESSES:** You may send comments on the information collections described in this document using one of these two methods:

- *Internet*—To submit comments electronically, use the comment form for this document posted on the “Regulations.gov” e-rulemaking website at <https://www.regulations.gov> within Docket No. TTB–2026–0001.

- *Mail*—Send comments to the Paperwork Reduction Act Officer, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW, Box 12, Washington, DC 20005.

Please submit separate comments for each specific information collection described in this document. You must reference the information collection’s title, form number or recordkeeping requirement number (if any), and OMB control number in your comment.

You may view copies of this document, the relevant TTB forms, and any comments received at <https://www.regulations.gov> within Docket No. TTB–2026–0001. TTB has posted a link to that docket on its website at <https://www.ttb.gov/rrd/information-collection-notice>. You also may obtain paper copies of this document, the listed forms, and any comments received by contacting TTB’s Paperwork Reduction Act Officer at the addresses or telephone number shown below.

FOR FURTHER INFORMATION CONTACT: Michael Hoover, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW, Box 12, Washington, DC 20005; 202–453–1039, ext. 135; or complete the Regulations and Rulings Division contact form at <https://www.ttb.gov/contact-rrd>.

SUPPLEMENTARY INFORMATION:**Request for Comments**

The Department of the Treasury and its Alcohol and Tobacco Tax and Trade Bureau (TTB), as part of a continuing effort to reduce paperwork and respondent burden, invite the general public and other Federal agencies to comment on the proposed or continuing information collections described below, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Comments submitted in response to this document will be included or summarized in our request for Office of Management and Budget (OMB) approval of the relevant information collection. All comments are part of the public record and subject to disclosure. Please do not include any confidential or inappropriate material in your comments.

We invite comments on: (a) Whether an information collection is necessary for the proper performance of the agency’s functions, including whether the information has practical utility; (b) the accuracy of the agency’s estimate of the information collection’s burden; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) ways to minimize the information collection’s burden 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 the requested 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 has a valid OMB control number.

**Information Collections Open for
Comment**

Currently, we are seeking comments on the following forms, letterhead applications or notices, recordkeeping requirements, questionnaires, or surveys:

OMB Control No. 1513–0011

Title: Formula and/or Process for Articles Made with Specially Denatured Spirits.

TTB Form Number: TTB F 5150.19.

Abstract: In general, under the Internal Revenue Code (IRC) at 26 U.S.C. 5214, distilled spirits used in the manufacture of nonbeverage articles are not subject to Federal excise tax, and, under the IRC at 26 U.S.C. 5273, persons who intend to produce such articles using specially denatured distilled

spirits (SDS) must obtain prior approval of their formulas and manufacturing processes. For medicinal preparations and flavoring extracts intended for internal human use, that section also prohibits SDS from remaining in the finished articles. Therefore, the Alcohol and Tobacco Tax and Trade Bureau (TTB) regulations in 27 CFR part 20 require persons to file formula and process approval requests for articles made with SDS using form TTB F 5150.19. TTB personnel examine the collected information to verify that the described articles are nonbeverage products made in compliance with 26 U.S.C. 5273. TTB field personnel also may compare manufacturing records to approved formulas to verify that such articles are being made in accordance with their approved formulas and processes.

Current Actions: There are no program changes to this information collection at this time, and TTB is submitting it for extension purposes only. As for adjustments, due to changes in agency estimates, TTB is decreasing the number of annual respondents, responses, and total burden hours associated with this collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profits.

Estimated Annual Burden

- *Number of Respondents:* 60.
- *Average Responses per Respondent:* 1 (one).
- *Number of Responses:* 60.
- *Average Per-Response Burden:* 0.66 hour.
- *Total Burden:* 40 hours.

OMB Control No. 1513–0024

Title: Report—Export Warehouse Proprietor.

TTB Form Number: TTB F 5220.4.

Abstract: In general, under chapter 52 of the IRC, tobacco products and cigarette papers and tubes manufactured in, or imported into, the United States are subject to Federal excise tax while tobacco products and cigarette papers and tubes removed for export, and all processed tobacco, are not subject to that tax. Additionally, the IRC at 26 U.S.C. 5722 requires export warehouse proprietors to provide reports regarding such articles as the Secretary of the Treasury (the Secretary) prescribes by regulation. Under the authority that section, the TTB regulations in 27 CFR part 44 require export warehouse proprietors to file a monthly operations report using TTB F 5220.4, Report—Proprietor of Export Warehouse, listing the amount of tobacco products,

cigarette papers and tubes, and processed tobacco received, removed, lost, or unaccounted for during a given month. The collected information is necessary to support the detection of unlawful diversion, and to verify compliance with Federal laws and regulations related to the removal and export of such articles.

Current Actions: There are no program changes to this information collection at this time, and TTB is submitting it for extension purposes only. As for adjustments, due to changes in agency estimates, TTB is decreasing the number of annual respondents, responses, and total burden hours associated with this collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profits.

Estimated Annual Burden

- *Number of Respondents:* 65.
- *Average Responses per Respondent:* 12 (once per month).
- *Number of Responses:* 780.
- *Average Per-Response Burden:* 1 hour.
- *Total Burden:* 780 hours.

OMB Control No. 1513-0035

Title: Inventory—Export Warehouse Proprietor.

TTB Form Number: TTB F 5220.3.

Abstract: In general, chapter 52 of the IRC imposes a Federal excise tax on all tobacco products and cigarette papers and tubes manufactured in, or imported into, the United States, while exempting such articles removed for export, as well as all processed tobacco, from that tax. Export warehouses receive and store such non-taxpaid articles until they are removed without payment of tax for export to a foreign country, Puerto Rico, or the U.S. Virgin Islands, or for consumption beyond the internal revenue laws of the United States. In addition, section 5721 of the IRC requires export warehouse proprietors to take an inventory of all tobacco products, cigarette papers and tubes, and processed tobacco on hand at the commencement of business, the conclusion of business, and at other times as the Secretary prescribes by regulation.

Under that IRC authority, the TTB regulations in 27 CFR part 44 require all export warehouse proprietors to take and report an inventory on TTB F 5220.3 at the opening and closing of their business, when certain changes in control of the business occur, and if required by TTB. As authorized by section 5741 of the IRC, the TTB regulations in part 44 also require

export warehouse proprietors to retain record copies of their inventory reports for 3 years following the close of the calendar year in which the inventory was taken, available for TTB inspection upon request. Because export warehouse proprietors hold untaxed tobacco products and cigarette papers and tubes until such articles are exported without payment of tax, transferred in bond to another export warehouse, or returned to the manufacturer, TTB uses these inventories to establish a contingent Federal excise tax liability on such articles. These inventories also aid TTB in detecting diversion of untaxed articles into the taxable domestic market. In addition, inventories of processed tobacco, which is not subject to tax, help TTB detect and prevent diversion of materials used for making tobacco products to unauthorized manufacturers.

Current Actions: There are no program changes to this information collection at this time, and TTB is submitting it for extension purposes only. As for adjustments, due to changes in agency estimates, TTB is decreasing the number of annual respondents, responses, and total burden hours associated with this collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profits.

Estimated Annual Burden

- *Number of Respondents:* 65.
- *Average Responses per Respondent:* 1 (one).
- *Number of Responses:* 65.
- *Average Per-Response Burden:* 5 hours.
- *Total Burden:* 325 hours.

OMB Control No. 1513-0039

Title: Distilled Spirits Plants Warehousing Records (TTB REC 5110/02), and Monthly Report of Storage Operations.

TTB Form Number: TTB F 5110.11.

Abstract: The IRC at 26 U.S.C. 5207 requires distilled spirits plant (DSP) proprietors to maintain records and submit reports of their production, storage, denaturation, and processing activities as required under regulations prescribed by the Secretary. Under that IRC authority, the TTB regulations in 27 CFR part 19 require DSP proprietors to keep certain records regarding their storage and warehousing operations. Those regulations also require DSP proprietors to report a summary of those operations, based on the required records, to TTB on a monthly basis using form TTB F 5110.11. Also, under

the IRC at 26 U.S.C. 5005(c), a DSP proprietor is liable for the Federal excise tax on all distilled spirits stored on their plant's premises. As such, the required storage records and reports are necessary to protect the revenue and ensure compliance with the relevant Federal laws and regulations.

Current Actions: There are no program changes to this information collection at this time, and TTB is submitting it for extension purposes only. As for adjustments, due to changes in agency estimates resulting from continued growth in the number of DSPs in the United States, TTB is increasing the number of annual respondents, responses, and total burden hours associated with this collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profits.

Estimated Annual Burden

- *Number of Respondents:* 5,700.
- *Average Responses per Respondent:* 12 (once per month).
- *Number of Responses:* 68,400.
- *Average Per-Response Burden:* 2 hours.
- *Total Burden:* 136,800 hours.

OMB Control No. 1513-0046

Title: Formula for Distilled Spirits Under the Federal Alcohol Administration Act.

TTB Form Number: TTB F 5110.38.

Abstract: The Federal Alcohol Administration Act (FAA Act) at 27 U.S.C. 205(e) authorizes the Secretary to issue regulations regarding the labeling of alcohol beverage products to prevent consumer deception, to provide the consumer with adequate information as to the identity and quality of such products, and to require a statement of composition in certain cases of distilled spirits produced by blending or rectification or if neutral spirits were used in the product's production. In addition, the IRC at 26 U.S.C. 5222(c), 5223, and 5232, authorizes the Secretary to issue regulations regarding the removal and addition of extraneous substances to distilling materials or the redistillation of domestic and imported spirits. Under those authorities, the TTB regulations in 27 CFR parts 5, 19, and 26 require proprietors to obtain TTB approval of formulas for distilled spirits products when operations such as blending, mixing, purifying, refining, compounding, or treating change the character, composition, class, or type of the spirits. Most respondents now use TTB's Formulas Online (FONL) online system, or its paper equivalent, TTB F

5100.51, to file such formulas, but TTB continues to allow respondents to file distilled spirits formulas using the legacy form, TTB F 5110.38, which is approved under this control number. Respondents use this form to list ingredients, and, in some cases, the process used to produce the product. TTB uses the collected information to determine if a distilled spirits product meets the applicable statutory and regulatory requirements.

Current Actions: There are no program changes to this information collection at this time, and TTB is submitting it for extension purposes only. As for adjustments, due to changes in agency estimates, TTB is decreasing the number of annual respondents, responses, and total burden hours associated with this collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profits.

Estimated Annual Burden

- *Number of Respondents:* 12.
- *Average Responses per Respondent:* 3.
- *Number of Responses:* 36.
- *Average Per-Response Burden:* 1 hour.
- *Total Burden:* 36 hours.

OMB Control No. 1513-0063

Title: Stills: Notices, Registration, and Records (TTB REC 5150/8).

Abstract: The IRC at 26 U.S.C. 5101 and 5179 authorizes the Secretary to issue regulations requiring manufacturers of stills to submit notices regarding the manufacture and set up of stills, and it requires all persons to register any stills in their possession with the Secretary and provide information as to the location, type, capacity, ownership, and the purpose for which the stills will be used. Under those authorities, the TTB regulations in 27 CFR part 29 require manufacturers and vendors of stills and distilling apparatus to provide certain notices and keep certain records regarding the manufacture and setup of such equipment. In addition, those regulations require owners of stills and distilling apparatus to register such equipment with TTB and provide certain notices regarding changes in the ownership, location, or disposal of such registered equipment. TTB uses the collected information to ensure that the relevant provisions of the IRC are appropriately applied and to protect the revenue as distilled spirits are generally subject to Federal excise tax under the IRC.

Current Actions: There are no program changes to this information collection at this time, and TTB is submitting it for extension purposes only. As for adjustments, due to changes in agency estimates, TTB is increasing the number of annual respondents, responses, and total burden hours associated with this collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profits.

Estimated Annual Burden

- *Number of Respondents:* 40.
- *Average Responses per Respondent:* 4.
- *Number of Responses:* 160.
- *Average Per-Response Burden:* 1 hour.
- *Total Burden:* 160 hours.

OMB Control No. 1513-0072

Title: Applications and Notices—Manufacturers of Nonbeverage Products (TTB REC 5530/1).

Abstract: In general, the IRC at 26 U.S.C. 5001 imposes Federal excise tax on each proof gallon of distilled spirits produced in or imported into the United States. However, under the IRC at 26 U.S.C. 5111–5114, persons using distilled spirits to produce certain nonbeverage products (medicines, medicinal preparations, food products, flavors, flavoring extracts, or perfume) may claim drawback (refund) of all but \$1.00 per proof gallon of the excise tax paid on the distilled spirits used to make such products, subject to regulations issued by the Secretary “to secure the Treasury against frauds.” Under those IRC authorities, the TTB regulations in 27 CFR part 17 require manufacturers to submit certain applications and notices to TTB regarding their use of distilled spirits in the production of nonbeverage products eligible for drawback. The applications, which require TTB approval, cover nonbeverage activities that present significant jeopardy to the revenue, while the notices, which do not require TTB approval, cover activities that present less jeopardy to the revenue. The collected information provides a basis for TTB to verify that nonbeverage product drawback claimants are in fact eligible for such refunds under the IRC, and it ensures that such respondents are in compliance with the IRC statutory and TTB regulatory provisions governing nonbeverage product activities.

Current Actions: There are no program changes to this information collection at this time, and TTB is submitting it for extension purposes

only. As for adjustments, due to changes in agency estimates, TTB is decreasing the number of annual respondents, responses, and total burden hours associated with this collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profits.

Estimated Annual Burden

- *Number of Respondents:* 30.
- *Average Responses per Respondent:* 1 (one).
- *Number of Responses:* 30.
- *Average Per-Response Burden:* 0.5 hour.
- *Total Burden:* 15 hours.

OMB Control No. 1513-0077

Title: Records of Things of Value to Retailers, and Occasional Letter Reports from Industry Members Regarding Information on Sponsorships, Advertisements, Promotions, etc., under the FAA Act.

Abstract: The FFA Act at 27 U.S.C. 205 generally prohibits alcohol beverage producers, importers, or wholesalers from offering inducements to alcohol retailers—giving things of value or conducting certain types of advertisements, promotions, or sponsorships—unless such an action is specifically exempted by regulation. Under that authority, TTB regulations in 27 CFR part 6, “Tied-House,” describe exceptions to the general FAA Act prohibition on offering inducements to retailers and also describe things that are considered to be “things of value” for purposes of determining whether an inducement has been offered. Among other provisions, those regulations require alcohol beverage industry members to keep records concerning things of value furnished to retailers, identifying the item and the retailer receiving it, along with the industry member’s cost and any charges to the retailer for the item. Industry members may use usual and customary business records to satisfy that recordkeeping requirement, and such records must be retained for 3 years, available for TTB inspection. In addition, TTB regulations in 27 CFR parts 6, 8, and 10 provide that TTB may require, as part of a trade practice investigation, a letterhead report from an alcohol industry member regarding any advertisements, promotions, sponsorships, or other activities conducted by, on behalf of, or benefiting the industry member. TTB uses the collected information to detect and prevent unfair trade practices as defined by the FAA Act and ensure compliance with that Act’s trade practice exceptions and limitations.

Current Actions: There are no program changes to this information collection at this time, and TTB is submitting it for extension purposes only. As for adjustments, due to changes in agency estimates, TTB is increasing the number of annual respondents required to keep records under this information collection. However, there is no change to the number of annual respondents required to make reports under this collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profits.

Estimated Annual Burden

- **Number of Respondents:** 97,000.
- **Average Responses per Respondent:**

One (one annual response for all respondents for recordkeeping, and annual 1 response for 10 respondents required to submit reports).

- **Number of Responses:** 97,010.
- **Average Per-Response Burden:** For recordkeeping, under the OMB regulations at 5 CFR 1320.3(b)(2), there is no per-respondent burden for the keeping of the usual of customary business records required under this collection. For the 10 respondents required by TTB to submit letterhead reports, the estimated burden is 8 hours per response.
- **Total Burden:** 80 hours.

OMB Control No. 1513–0078

Title: Application for Permit to Manufacture or Import Tobacco Products or Processed Tobacco or to Operate an Export Warehouse and Applications to Amend Such Permits.

TTB Form Numbers: TTB F 5200.3, 5230.4, 5230.5, and 5200.16.

Abstract: The IRC at 26 U.S.C. 5712 and 5713 requires that importers and manufacturers of tobacco products or processed tobacco and export warehouse proprietors apply for and obtain a permit before engaging in such operations, or at such other times, as the Secretary prescribes by regulation. In addition, 26 U.S.C. 5712 sets forth circumstances under which a permit application may be denied, such as if the applicant is ineligible to obtain a permit by reason of business experience, financial standing, or certain criminal convictions. Under those IRC authorities, the TTB regulations in 27 CFR parts 40, 41, and 44 require tobacco industry members to submit applications using the prescribed TTB forms for new permits or, under certain circumstances, amended permits. Respondents use the prescribed forms and any required supporting documents to identify themselves and their

business, along with its location, organization, financing, and major investors. Once TTB issues a permit, the permittee must retain a copy of their application package for as long as they continue in business and make it available for TTB inspection upon request. This information is necessary to protect the revenue by ensure that only persons eligible under the relevant provisions of the IRC are approved to engage in tobacco-related businesses.

Current Actions: There are no program changes to this information collection at this time, and TTB is submitting it for extension purposes only. As for adjustments, due to changes in agency estimates, TTB is decreasing the number of annual respondents, responses, and total burden hours associated with this collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profits.

Estimated Annual Burden

- **Number of Respondents:** 300.
- **Average Responses per Respondent:** 1 annually.
- **Number of Responses:** 300.
- **Average Per-Response Burden:** 1.65 hours.
- **Total Burden:** 495 hours.

OMB Control No. 1513–0080

Title: Distilled Spirits Plant Equipment and Structures (TTB REC 5110/12).

Abstract: The IRC at 26 U.S.C. 5178 and 5180 authorizes the Secretary to issue regulations regarding the location, construction, and arrangement of distilled spirits plants (DSPs), the identification of DSP structures, equipment, pipes, and tanks, and the posting of an exterior sign at their place of business. The IRC at 26 U.S.C. 5206 also requires DSP proprietors to mark containers of distilled spirits, subject to regulations prescribed by the Secretary. The TTB regulations concerning the identification of DSP plants, equipment, structures, and bulk containers are contained in 27 CFR part 19. Those regulations describe the exterior identification sign required at DSPs and the identification signs or marks on DSP structures, cookers, fermenters, stills, tanks, and other major equipment. The regulations also require tank cars and tank trucks used by DSPs as bulk conveyances for distilled spirits to be permanently and legibly marked with identifying information and capacity. The information set forth under this information collection is necessary to protect the revenue and facilitate inspections, as TTB uses the required

signs and marks to identify the location, use, and capacity of a DSP's structures, equipment, and conveyances to prevent illegal operations and diversion.

Current Actions: There are no program changes to this information collection at this time, and TTB is submitting it for extension purposes only. As for adjustments, due to changes in agency estimates resulting from continued growth in the number of DSPs in the United States, TTB is increasing the number of annual respondents and responses associated with this collection. However, because the marking of DSP equipment and structures is a usual and customary business practice, there is no increase in the estimated annual per-response or total burden hours associated with this collection as the OMB regulations at 5 CFR 1320.3(b)(2) provide that regulatory requirements to display usual and customary markings impose no additional burden on respondents.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profits.

Estimated Annual Burden

- **Number of Respondents:** 5,800.
- **Average Responses per Respondent:** 1 per year.
- **Number of Responses:** 5,800.
- **Average Per-Response and Total Burden:** None. Per the OMB regulations at 5 CFR 1320.3(b)(2), regulatory requirements to make usual and customary markings impose no additional hour burden on respondents.

OMB Control No. 1513–0084

Title: Labeling of Sulfites in Alcohol Beverages.

Abstract: The U.S. Food and Drug Administration (FDA) has determined that sulfating agents are human allergens that can have serious health implications for persons who are allergic to sulfites, particularly asthmatics, and, as a result, FDA regulations require food labels to declare the presence of sulfites if there are 10 parts per million (ppm) or more of a sulfating agent in a finished food product. Under the FAA Act at 27 U.S.C. 205(e), the Secretary is authorized to issue regulations requiring alcohol beverage labels to provide “adequate information” to consumers regarding the identity and quality of such products. Under that FAA Act authority and consistent with FDA's food labeling requirements, the TTB alcohol beverage labeling regulations in 27 CFR part 4 (wine), part 5 (distilled spirits), and part 7 (beer) require a declaration of sulfites on the labels of

alcohol beverages released from domestic bottling premises or customs custody when sulfites are present in such products at levels of 10 or more ppm. This label disclosure is necessary to protect sulfite-sensitive consumers from products that potentially could be harmful to them.

Current Actions: There are no program changes to this information collection at this time, and TTB is submitting it for extension purposes only. As for adjustments, due to a change in agency estimates, TTB is increasing the estimated number of annual respondents, responses, and total burden hours associated with this collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profits.

Estimated Annual Burden

- **Number of Respondents:** 35,210.
- **Average Responses per Respondent:** 1 (one).
- **Number of Responses:** 35,210.
- **Average Per-Response Burden:** 40 minutes.
- **Total Burden:** 23,473 hours).

OMB Control No. 1513-0098

Title: Supporting Data for Nonbeverage Drawback Claims.

TTB Form Number: TTB F 5154.2.

Abstract: Under the IRC at 26 U.S.C. 5111-5114 and 7652(g), persons using distilled spirits to produce medicines, medicinal preparations, food products, flavors, flavoring extracts, or perfume may claim drawback (refund) of all but \$1.00 per proof gallon of the Federal excise tax paid on the distilled spirits used to make such nonbeverage products, subject to regulations prescribed by the Secretary. As required by the TTB regulations in 27 CFR parts 17 and 26, when submitting nonbeverage product drawback claims to TTB, respondents are required to report certain supporting data regarding the distilled spirits used and the products produced, using form TTB F 5154.2. TTB uses the collected information to ensure that drawback of Federal excise tax is provided only to eligible entities.

Current Actions: There are no program changes associated with this information collection, and TTB is submitting it for extension purposes only. As for adjustments, due to changes in agency estimates, TTB is decreasing the number of annual respondents, responses, and total burden hours associated with this collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profits.

Estimated Annual Burden

- **Number of Respondents:** 280.
- **Average Responses per Respondent:** 6.2.
- **Number of Responses:** 1,736.
- **Average Per-Response Burden:** 58 minutes.
- **Total Burden:** 1,678 hours.

OMB Control No. 1513-0110

Title: Recordkeeping for Tobacco Products Removed in Bond from a Manufacturer's Premises for Experimental Purposes—27 CFR 40.232(e).

Abstract: The IRC at 26 U.S.C. 5704(a) provides that manufacturers of tobacco products (cigars, cigarettes, smokeless tobacco, pipe tobacco, and roll-your-own tobacco) may remove such products for experimental purposes without payment of Federal excise tax, as prescribed by regulation. Under that IRC authority, the TTB regulations at 27 CFR 40.232(e) require tobacco product manufacturers to keep certain usual and customary business records documenting the amount, kind, recipient, use, and disposition of tobacco products removed for experimental purposes outside of a factory. These records, which are subject to TTB inspection, are necessary to protect the revenue as they allow TTB to account for the lawful use and disposition of nontaxpaid tobacco products removed from a factory and detect diversion of such products into the domestic market.

Current Actions: There are no program changes or adjustments associated with this information collection, and TTB is submitting it for extension purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profits.

Estimated Annual Burden

- **Number of Respondents:** 235.
- **Average Responses per Respondent:** 1 per year.
- **Number of Responses:** 235.
- **Average Per-Response and Total Burden:** None. This information collection consists of usual and customary consignment and shipping records kept by respondents during the normal course of business, regardless of any regulatory requirement to do so. As such, this collection requirement imposes no additional hour burden on respondents per the OMB regulations at 5 CFR 1320.3(b)(2).

Dated: January 27, 2026.

Amy R. Greenberg,

Acting Assistant Administrator, Headquarters Operations.

[FR Doc. 2026-01828 Filed 1-29-26; 8:45 am]

BILLING CODE 4810-31-P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Renewal; Submission for OMB Review; Stress Testing Rules for National Banks and Federal Savings Associations

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995 (PRA). In accordance with the requirements of the PRA, the OCC 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 OCC is soliciting comment concerning the renewal of its information collection titled, "Stress Testing Rules for National Banks and Federal Savings Associations." The OCC also is giving notice that it has sent the collection to OMB for review.

DATES: Comments must be received by March 2, 2026.

ADDRESSES: Commenters are encouraged to submit comments by email, if possible. You may submit comments by any of the following methods:

- **Email:** prainfo@occ.treas.gov.
- **Mail:** Chief Counsel's Office, Attention: Comment Processing, Office of the Comptroller of the Currency, Attention: 1557-0343, 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) 293-4835.

Instructions: You must include "OCC" as the agency name and "1557-0343" 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.

Written comments and recommendations for the proposed information collection should also be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. You can find this information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

You may review comments and other related materials that pertain to this information collection following the close of the 30-day comment period for this notice by the method set forth in the next bullet.

- **Viewing Comments Electronically:** Go to www.reginfo.gov. Hover over the “Information Collection Review” tab and click on “Information Collection Review” from the drop-down menu. From the “Currently under Review” drop-down menu, select “Department of Treasury” and then click “submit.” This information collection can be located by searching OMB control number “1557–0343” or “Stress Testing Rules for National Banks and Federal Savings Associations.” 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.

FOR FURTHER INFORMATION CONTACT:

Shaquita Merritt, Clearance Officer, (202) 649–5490, Chief Counsel’s Office, Office of the Comptroller of the Currency, 400 7th Street SW, Washington, DC 20219. If you are deaf, hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501 *et seq.*), Federal agencies must obtain approval from the OMB for each collection of information that they conduct or sponsor.

“Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests or requirements that members of the public

submit reports, keep records, or provide information to a third party. The OCC asks the OMB to extend its approval of the collection in this notice.

Title: Stress Testing Rules for National Banks and Federal Savings Associations.

OMB Control No.: 1557–0343.

Type of Review: Regular.

Affected Public: Businesses or other for-profit.

Description: The Annual Stress Test rule¹ implemented Section 165(i) of the Dodd-Frank Wall Street Reform and Consumer Protection Act² (“Dodd-Frank Act”) which requires certain companies to conduct stress tests. As enacted by the Dodd-Frank Act, national banks and Federal savings associations with total consolidated assets of more than \$10 billion were required to conduct annual stress tests and comply with reporting and disclosure requirements under the rule. The reporting templates for institutions with total consolidated assets of over \$50 billion were finalized in 2012.³

Section 165(i)(2) of the Dodd-Frank Act requires certain financial companies, including national banks and Federal savings associations, to conduct annual stress tests⁴ and requires the primary financial regulatory agency⁵ of those financial companies to issue regulations implementing the stress test requirements.⁶

Under section 165(i)(2), a covered institution was required to submit to the Board of Governors of the Federal Reserve System (Board) and to its primary financial regulatory agency a report at such time, in such form, and containing such information as the primary financial regulatory agency may require.⁷

The Economic Growth, Regulatory Relief, and Consumer Protection Act (EGRRCPA), enacted on May 24, 2018, amended certain aspects of the company-run stress testing requirement in section 165(i)(2) of the Dodd-Frank Act.⁸ Specifically, section 401 of EGRRCPA raises the minimum asset threshold for financial companies covered by the company-run stress testing requirement from \$10 billion to

\$250 billion in total consolidated assets; revises the requirement for banks to conduct stress tests “annually” and instead requires them to conduct stress tests “periodically”; and no longer requires the OCC to provide an “adverse” stress-testing scenario, thus reducing the number of required stress test scenarios from three to two.

Estimated Burden

Estimated Frequency of Response: On occasion.

Estimated Number of Respondents: 9 (biennial testing: 5; annual testing: 4).

Estimated Total Annual Responses: 27 responses.

Estimated Total Annual Burden: 6,760 hours.

Comments: On November 24, 2025, the OCC published a 60-day notice for this information collection, 90 FR 53059. No comments were received.

Comments continue to be invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC’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 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.

Carl Kaminski,

Assistant Director, Office of the Comptroller of the Currency.

[FR Doc. 2026–01896 Filed 1–29–26; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Agency Information Collection Activities; Comment Request on Annual Return/Report of Employee Benefit Plan

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of information collection; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the IRS is inviting comments on the information collection request outlined in this notice.

¹ 77 FR 61238 (October 9, 2012) (codified at 12 CFR part 46).

² Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, 124 Stat. 1376 (2010).

³ 77 FR 49485 (August 16, 2012); 77 FR 66663 (November 6, 2012).

⁴ 12 U.S.C. 5365(i)(2)(A).

⁵ 12 U.S.C. 5301 (12).

⁶ 12 U.S.C. 5365(i)(2)(C).

⁷ 12 U.S.C. 5365(i)(2)(B).

⁸ Public Law 115–174, 132 Stat. 1296–1368 (2018).

DATES: Written comments should be received on or before March 31, 2026 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to pra.comments@irs.gov. Include "OMB Control No. 1545-1610" in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: View the latest drafts of the tax forms related to the information collection listed in this notice at <https://www.irs.gov/draft-tax-forms>. Requests for additional information or copies of this collection should be directed to Jason Schoonmaker, (801) 620-6008.

SUPPLEMENTARY INFORMATION: The IRS, 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 IRS assess the impact and minimize the burden of its information collection requirements. 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, and viewable on relevant websites. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information. 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.

Title: Annual Return/Report of Employee Benefit Plan.

OMB Control Number: 1545-1610.

Form Number: 5500 and associated Schedules, 5500-SF, 5500-EZ and 5558.

Abstract: The Annual Return/Report of Employee Benefit Plan is an annual information return filed by employee benefit plans. The IRS uses this information for a variety of matters, including ascertainment whether a qualified retirement plan appears to

conform to requirements under the Internal Revenue Code or whether the plan should be audited for compliance. Form 5500 including all required schedules and attachments is an annual return filed to report information concerning employee benefit plans and Direct Filing Entities. Form 5500-SF is a simplified annual reporting form for use by certain small pension and welfare benefit plans. Form 5500-EZ is an annual return filed by a one participant plans and foreign plans that are not subject to the requirements of section 104 (a) of the Employee Retirement Income Security Act of 1974 (ERISA). Form 5558 is used to apply for a one-time extension of time to file the Form 5500 series and the Form 8955-SSA.

Current Actions: There is no change to the previously approved information collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, and individuals or households.

Estimated Number of Responses: 1,706,419.

Estimated Time per Response: 1 hour, 34 minutes.

Estimated Total Annual Burden Hours: 2,674,140.

Dated: January 27, 2026.

Jason M. Schoonmaker,
Tax Analyst.

[FR Doc. 2026-01814 Filed 1-29-26; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Agency Information Collection

Activities: Comment on IRS Taxpayer Burden Surveys

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of information collection; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the IRS is inviting comments on the information collection request outlined in this notice.

DATES: Written comments should be received on or before March 31, 2026 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue, Washington, DC 20224, or by email to pra.comments@irs.gov. Include "OMB Number: 1545-2212" in the subject line of the message.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of this collection should be directed to LaNita Van Dyke, at (202) 317-6009.

SUPPLEMENTARY INFORMATION: The IRS, 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 IRS assess the impact and minimize the burden of its information collection requirements. 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, and viewable on relevant websites. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information. 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.

Title: IRS Taxpayer Burden Surveys.

OMB Control Number: 1545-2212.

Abstract: The IRS Taxpayer Burden Surveys are designed to gather statistically representative data that allows the IRS to provide accurate estimates of taxpayer compliance burden. These surveys also help the IRS understand how and why taxpayer burden changes over time. An ongoing survey effort is necessary to inform the IRS of the impact of ever-changing tax law that leads to regularly-issued and updated IRS regulations as well as improvements and changes in tax-filing technology.

Changes in tax regulations, tax administration, tax preparation methods, and taxpayer behavior continue to alter the amount and distribution of taxpayer burden. Data from updated surveys will better reflect the current tax rules and regulations, the increased usage of tax preparation software, increased efficiency of such

software, changes in tax preparation regulations, the increased use of electronic filing, the behavioral response of taxpayers to the tax system, the changing use of services, both IRS

and external, and related information collection needs.

Current Actions: The Taxpayer Burden Surveys allow RAAS to update and validate the IRS Taxpayer Burden Model which is used to provide

estimates for consolidated taxpayer segments, such as OMB numbers 1545–0074, 1545–0123, and 1545–0047. These surveys are being submitted for revision purposes.

Data collection	Responses	Average annual burden hours	Total hours	Total monetized cost (\$) *
Individual Taxpayers	30,000	3,300	9,900	323,334
ITB-A (Individual Taxpayers—Amended Returns)	3,500	356	1,075	35,110
ITB-L (Individual Taxpayers—Late Filers)	7,000	717	1,505	70,219
Business Taxpayer Burden (BTBS & BTBL)	12,500	1,375	4,125	134,723
Tax-Exempt Organization (TEB)	12,000	1,200	3,600	117,576
TEB 990-N	900	88	265	8,655
Information Returns (IRBS)	10,000	1,100	3,300	107,778
Employer Reporting Burden (ERB)	3,750	413	1,238	40,417
Trust/Estate Income (TEIT-T & TEIT-E)	13,500	1,325	3,975	129,824
Excise Tax (EXT)	3,000	317	950	31,027
Estate Transfer Tax (ETT)	3,150	333	998	32,578
Gift Transfer Tax (GTT)	7,500	792	2,375	77,568
Retirement Plan Burden (RPB)	6,150	649	1,948	63,605
Individual Taxpayers, Enforcement (ITB-E)	5,000	550	1,650	53,889
Business Compliance (BCBS & BCBL)	8,875	976	2,929	95,653
Special Studies—Individual Taxpayers	37,500	4,125	12,375	404,168
Special Studies—Entities	37,500	4,125	12,375	404,168
Total		21,742	65,226	*2,130,289

*Based on May 2024 average wage rate from the Bureau of Labor and Statistics Occupational Employment Survey. Monetized value at 32.66 per hour.

Type of Review: Revision of a currently approved collection.

Affected Public: Individual, Business or other for-profit organizations.

Estimated Total Number of Responses: 201,825.

Estimated Time per Respondent: 19 min.

Estimated Total Burden Hours: 65,226.

Approved: January 28, 2026.

LaNita Van Dyke,

IRS Tax Analyst.

[FR Doc. 2026–01863 Filed 1–29–26; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Quarterly Federal Excise Tax Return

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Notice of information collection; request for comment.

SUMMARY: The Department of the Treasury will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. The

public is invited to submit comments on this request.

DATES: Comments should be received on or before March 2, 2026 to be assured of consideration.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT:

Copies of the submissions may be obtained from Spencer W. Clark by emailing PRA@treasury.gov, calling (202) 927–5331, or viewing the entire information collection request at www.reginfo.gov.

SUPPLEMENTARY INFORMATION:

Internal Revenue Service (IRS)

1. *Title:* Quarterly Federal Excise Tax Return.

OMB Control Number: 1545–0023.

Type of Request: Revision of a currently approved collection.

Description: Excise taxes are taxes paid when purchases are made on a specific good, such as gasoline. 26 U.S.C. 4081 imposes tax for miscellaneous excise taxes, manufacturers excise taxes, automotive

and related items, petroleum products and motor and aviation fuel. Form 720, Quarterly Federal Excise Tax Return, is used to report liability by IRS number and to pay the excise taxes listed on the form. Form 720–X is used to make adjustments to liability reported on Form 720 filed in previous quarters. Form 6627 is used to figure the environmental tax on petroleum, ODCs, imported products that used ODCs as materials in the manufacture or production of the product, and the floor stocks tax on ODCs. Form 6627 is filed with Form 720.

Forms: 720, 720–X, and 6627.

Affected Public: Business and other for-profit organizations.

Estimated Number of Respondents: 206,700.

Frequency of Response: On Occasion.

Estimated Total Number of Annual Responses: 206,700.

Estimated Time per Response: Varies from 6 hours, 54 minutes to 16 hours, 10 minutes.

Estimated Total Annual Burden Hours: 3,105,408.

(Authority: 44 U.S.C. 3501 *et seq.*)

Spencer W. Clark,

Treasury PRA Clearance Officer.

[FR Doc. 2026–01820 Filed 1–29–26; 8:45 am]

BILLING CODE 4810–25–P

U.S.-CHINA ECONOMIC AND SECURITY REVIEW COMMISSION**Notice of Open Public Hearing**

AGENCY: U.S.-China Economic and Security Review Commission.

ACTION: Notice of open public hearing.

SUMMARY: Notice is hereby given of the following hearing 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 hearing in Washington, DC on February 17, 2026 on “India, China, and the Balance of Power in the Indo-Pacific.”

DATES: The hearing is scheduled for Tuesday, February 17, 2026 at 9:30 a.m.

ADDRESSES: Members of the public will be able to attend in person at or near the U.S. Capitol and adjacent Congressional office buildings (specific building and room number to be announced) or view a live webcast via the Commission’s website at www.uscc.gov. Visit the Commission’s website for updates to the hearing location or possible changes to the hearing schedule. Reservations are

not required to view the hearing online or in person.

FOR FURTHER INFORMATION CONTACT: Any member of the public seeking further information concerning the hearing should contact Jameson Cunningham, 444 North Capitol Street NW, Suite 602, Washington, DC 20001; telephone: 202–624–1496, or via email at jcunningham@uscc.gov. Reservations are not required to attend the hearing.

ADA Accessibility: For questions about the accessibility of the event or to request an accommodation, please contact Jameson Cunningham via email at jcunningham@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:

Background: This is the first public hearing the Commission will hold during its 2026 reporting cycle. The hearing will examine geopolitical and military issues pertaining to India’s relations with both China and the United States, including tensions over disputed territory, maritime access in the Indian Ocean, and India’s role as an Indo-Pacific power. Next, the hearing will explore the economic and technology dimensions of India-China relations, including trade and investment ties and India’s efforts to build self-reliance in critical and

emerging technology sectors like artificial intelligence, semiconductors, and pharmaceutical supply chains. The hearing will review U.S. policy efforts to enhance the strategic partnership with India, and implications of India’s relations with China on vital U.S. economic and national security interests going forward.

The hearing will be co-chaired by Commissioner Hal Brands and Commissioner Jonathan N. Stivers. Any interested party may file a written statement by February 17, 2026 by transmitting it to the contact above. A portion of the hearing will include a question and answer period between the Commissioners and the witnesses.

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: January 27, 2026.

Christopher P. Fioravante,

Deputy Executive Director, U.S.-China Economic and Security Review Commission.

[FR Doc. 2026–01847 Filed 1–29–26; 8:45 am]

BILLING CODE 1137–00–P



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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 486

Medicare and Medicaid Programs; Organ Procurement Organizations
Conditions for Coverage: Revisions to the Conditions for Coverage;
Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 486

[CMS-3409-P]

RIN 0938-AU54

Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Conditions for Coverage

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Conditions for Coverage for Organ Procurement Organizations (OPOs) to clarify outstanding procedural questions and enable OPOs to make better informed decisions to achieve high performance resulting in the successful procurement, distribution, and transplantation of more life-saving organs. This rule would revise definitions, add new Quality Assessment Performance Improvement (QAPI) requirements related to medically complex organs and donors, revise the designation requirements for OPOs, clarify when an OPO's service area is open for competition, and update the process for appeals. It also includes a discussion of factors we would consider when selecting a successor OPO during a competition under the tiered approach to re-certification. We are committed to holding all OPOs accountable for their performance and this proposed rule does not revise the focus on improving the volume of donors and transplants assessed in the outcome measures or the tier structure used for re-certification and de-certification of OPOs.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by March 31, 2026.

ADDRESSES: In commenting, please refer to file code CMS-3409-P. Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of

Health and Human Services, Attention: CMS-3409-P, P.O. Box 8010, Baltimore, MD 21244-8010.

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-3409-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Diane Corning, (410) 786-8486; James Cowher, (410) 786-1948; Claudia Molinar, (410) 786-8445; Danielle Shearer, (410) 786-6617; or Jasmine Alexis, (410) 786-0861.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this rule may be found at <https://www.regulations.gov/>.

I. Executive Summary and Severability

A. Executive Summary

1. Purpose

At any given time, at least 100,000 people are on the waiting list for a lifesaving transplant and every 8 minutes, another person is added to the transplant waiting list.¹ Many individuals on the organ transplant

waiting list will wait several years for a suitable donor, while others will die before an organ becomes available. A variety of factors affect wait times, including how well a waitlisted individual matches with available donors, how sick the person is, and the availability of organs in the local area. Despite continued growth in organ donation, procurement, and transplantation, the need for transplantable organs continues to grow. Optimal performance of organ procurement organizations (OPOs) is critical to ensure that the maximum possible number of transplantable human organs are available to the yearly average of 100,000+ seriously ill people on waiting lists for a lifesaving organ transplant.

In 2019, President Trump issued Executive Order 13879 "Advancing American Kidney Health," directing the Secretary to enhance the procurement and utilization of organs available through deceased donation and to establish more transparent, reliable, and enforceable metrics for evaluating an OPO's performance. In response, CMS published the final rule, "Medicare and Medicaid Programs; Organ Procurement Organization Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations" in 2020 (85 FR 77898, referred to hereafter as the December 2020 final rule), which, among other changes, revised the previous outcome measures to drive performance improvement and increase the number of transplantable organs. OPOs are evaluated on their performance on both the donor and transplantation measures. Since publishing the December 2020 final rule, CMS has received many inquiries from OPOs and others seeking clarification on operational and administrative elements. These inquiries have increased in frequency and volume as the system moves closer to the 2026 re-certification period. This proposed rule contains operational and administrative provisions which would govern the competition process, to provide programmatic clarity and address interested party requests for additional guidance. Additionally, this proposed rule contains provisions aimed at driving further improvement in OPO operations, reflecting our continued commitment to enhancing the organ procurement and transplant system, and better serving prospective organ donors, their families, and patients on the transplant waitlist.

¹ Organ Donation Statistics. <https://www.organdonor.gov/learn/organ-donation-statistics>. Accessed on April 29, 2025.

2. Summary of Major Provisions

a. Definition Changes (§ 486.302)

Adverse Event. The current definition of “adverse event” is “an untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk thereof. As applied to OPOs, adverse events include but are not limited to transmission of disease from a donor to a beneficiary, avoidable loss of a medically suitable potential donor for whom consent for donation has been obtained, or delivery to a transplant center of the wrong organ or an organ whose blood type does not match the blood type of the intended beneficiary.” We propose to remove the examples in this definition and add a revised list of examples to the QAPI requirements at § 486.348(c).

Donor. We propose to revise the definition of the term “donor” to clarify that an individual from whom only the pancreas is procured and used for islet cell research is included in the definition of “donor” for purposes of the donation rate outcome measure, consistent with the Public Health Service (PHS) Act’s requirement that pancreata used for islet cell transplantation or research be counted for purposes of certification and re-certification.

Organ. The current definition of the term “organ” includes the pancreas when it is used for research or islet cell transplantation. This definition applies to the organ transplantation outcome measure, counting a pancreas used for research in the same way that a transplanted organ is counted. We propose to remove pancreata used for research from the definition of “organ” and thus, such pancreata would also be removed from the organ transplantation rate outcome measure. Research activity would no longer count as a transplant for purposes of certification and re-certification.

Medically Complex Organs and Donors. Organs from donors that fall outside the generally accepted standards for transplantation due to donor age or health status are underutilized. However, research has indicated that many of these organs can be successfully transplanted when appropriately placed with a transplant candidate.^{2 3} We propose to define the

term “medically complex donor” as a donor whose medical history requires special or additional considerations to identify the best recipient for the organs. These donors include, but are not limited to, all Donation after Cardiac Death (DCD) donors and donors with elevated Kidney Donor Profile Index (KDPI) scores. We also propose that OPOs track procurement and placement of these organs as part of their QAPI program. Additionally, we propose to define the term “medically complex organ” as an organ procured from a “medically complex donor”.

Unsound Medical Practices. We are also proposing a new definition for “unsound medical practices.” Unsound medical practices are referenced in § 486.312(b) as an example of circumstances in which CMS may de-certify an OPO based on “urgent need.” However, there is no definition of “unsound medical practices” in the regulations. We propose to define unsound medical practices as failures by OPOs that create an imminent threat to patient health and safety or pose a risk to patients or the public. These practices include, but are not limited to, failures in governance; patient or potential donor evaluation and management; and procurement, allocation and transport practices and procedures.

b. Requirements for Certification (§ 486.303)

We have historically interpreted the OPO Certification Act of 2000 (the Certification Act), which added section 371(b)(1)(D) of the Public Health Service Act (PHS Act), to mean the Secretary lacks the authority to certify new OPOs after January 1, 2000. However, we have reassessed this view and determined that the statute was not intended to strip the Secretary of his authority to certify new OPOs. Therefore, to align with our reinterpretation of the Certification Act, we are proposing to remove § 486.303(e), which conditions OPO certification on an entity having been re-certified as an OPO from January 1, 2002, through December 31, 2005.

c. OPO Designation to Donation Service Areas (DSAs) (§§ 486.308 and 486.309)

Designation is the process CMS utilizes to assign an OPO to a specific geographic area, or donation service area (DSA), for a specific period of time, called an agreement cycle. Currently,

there are 55 OPOs designated to 55 DSAs with the same 4-year agreement cycle. We propose changes to the OPO designation process to facilitate implementation of the tiered system for OPO re-certification and competition that was finalized in the December 2020 final rule. Specifically, we propose to add provisions to address the possibility of one OPO being designated to more than one DSA. The current regulatory structure does not address this situation and the potential impacts it may have for competition and OPO re-certification. We will address these impacts throughout the respective provisions in this proposed rule. Finally, the tiered system for re-certification seeks to incentivize continued performance improvement through increased competition. Therefore, we propose to address all situations when an OPO’s DSA may be opened for competition from other OPOs.

d. OPO Agreements, Non-Renewal (§ 486.311) and De-Certification (§ 486.312)

OPO agreements with CMS may be impacted by actions initiated by an OPO or adverse determinations by CMS. Currently, there are three categories of actions that impact an OPO’s agreement, including voluntary termination of the agreement by the OPO; involuntary termination during the re-certification cycle as a result of enforcement action for non-compliance with certification requirements; and non-renewal of the agreement for non-compliance with the outcome measures and other certification requirements. Generally, these actions result in de-certification of the OPO. In our December 2020 final rule, we implemented a tiered system for OPO re-certification that seeks to drive OPO performance through increased competition. The current requirements for de-certification do not address the possibility of an OPO being unsuccessful in a competition for its own or another DSA and no longer being designated to any DSA. We propose to address this potential scenario as well as better categorize and clarify situations that could lead to non-renewal of an agreement or de-certification of an OPO. We also propose that a voluntary termination or a scenario in which an OPO is no longer designated to any DSA after competition would result in non-renewal of the OPO’s agreement with CMS, while an OPO’s non-compliance with the outcome measures, non-compliance with the process performance measures, and situations involving urgent need to protect patient health and safety would

² Walls, DO, Lee-Riddle, Gs, Manderski, MB, Sawinski, DL, and Abt, PL. *Kidney transplant outcomes from donation after circulatory death donors of advanced age*. Clinical Transplantation. 2020;34:e13881. <http://doi.org/10.1111/ctr.13881>. Accessed at <https://onlinelibrary.wiley.com/doi/pdf/10.1111%2Fctr.13881>. Accessed on September 23, 2025.

³ Haque, O, Yuan, Q, Uygun, K, and Markmann, JF. Evolving utilization of donation after circulatory

death livers in liver transplantation: the day of DCD has come. Clinical Transplantation. 2021;35:e14211. <https://doi.org/10.1111/ctr.14211>. Accessed at <https://onlinelibrary.wiley.com/doi/pdf/10.1111%2Fctr.14211>. Accessed on September 21, 2015.

result in de-certification (see Section II.B. of this proposed rule, “Regulatory History” for more information on compliance determinations). We also propose to address appeal rights based on CMS determinations and which determinations may be appealable.

e. Appeals of Adverse Actions (§ 486.314)

As a result of significant changes made since the 2006 OPO final rule, we reviewed the OPO appeals process set forth at § 486.314 and are proposing the following changes. The current introductory statement in the regulation states that OPOs can appeal a de-certification on substantive and procedural grounds if the de-certification is due to involuntary termination or non-renewal of its agreement with CMS. We propose to revise the introductory text at § 486.314 to state that OPOs may appeal a de-certification as described at proposed § 486.312(a) or the removal of designation to a tier 3 DSA without de-certification as specified at proposed § 486.316(b)(2)(iii)(B), to comply with changes to that section. We also propose to add references to the removal of designation for a DSA assigned as tier 3 without de-certification alongside references to de-certification in § 486.314, as applicable, to reflect that an appeal would be available in either scenario.

Throughout § 486.314 we propose to modify the time periods in this section for current requirements from “business days” to “calendar days”. We also propose to use “calendar days” for all proposed requirements. This is both for consistency and to avoid confusion.

Throughout the current process, we are proposing changes to the various time frames to reduce inefficiencies while preserving OPOs’ right to appeal.

We are also proposing a new paragraph at § 486.314(*l*), CMS Administrator discretionary review. We are proposing to codify a process for the CMS Administrator to elect to review or decline to review the hearing officer’s decision. We are proposing specific time periods for the review, if the Administrator elects to review, and providing that the Administrator may remand the appeal to CMS for review and redetermination of the certification decision. We are also proposing to clarify the appeals process for OPOs that are de-certified due to urgent need.

f. Re-Certification and Competition (§ 486.316)

Our December 2020 final rule included changes to our requirements for OPO re-certification and competition

processes to clarify how the tiered system associated with the outcome measures would impact these activities. We are proposing additional revisions to § 486.316 to include situations when an OPO is designated to more than one DSA. We are proposing to evaluate each DSA for which an OPO is designated separately on the outcome measures. This would address the potential situation of an OPO having DSAs with different tier designations and how this would impact re-certification and competition. Additionally, it would enable CMS to selectively remove a DSA where an OPO is underperforming and does not meet the outcome measures, while allowing the OPO to retain its designation to another DSA if it meets the performance requirements in that DSA. We also propose that we would evaluate an OPO as a single entity across all DSAs for the process performance requirements. The process performance measures are the broad operational requirements for OPOs and include items such as administration and governance, prospective donor and donor management, organ preparation and transport, and quality assessment and performance improvement, among other requirements. While an OPO may have varied performance on the outcome measures at different times and in different DSAs, if applicable, we expect OPOs to be in compliance with the process performance measures at all times and in all DSAs.

g. Outcome Measures (§ 486.318)

The 2020 final rule revised the outcome measures for OPOs. We propose to remove the previous and now obsolete outcome measures and redesignate the current outcome measures within § 486.318. We also propose to revise the requirement for when CMS will hold an OPO accountable on the outcome measures when it takes over another OPO’s DSA. We describe the different scenarios when this may occur and factors we considered in proposing when we would hold the OPO accountable on its outcome measure performance in the new DSA.

h. Human Resources (§ 486.326)

The current human resources requirement addresses the need for a sufficient number of qualified staff to obtain all usable organs from potential donors, and to ensure that required services are provided to families of potential donors, hospitals, tissue banks, and individuals and facilities that use organs for research. All OPOs are required to ensure that all individuals who provide services and/or

supervise services are qualified to provide or supervise the services. We propose to further specify that all OPOs are required to assure the current State or local licensure, certification, or registration of OPO staff that furnish clinical services. We also propose to add a requirement that personnel performing clinical duties must act within the scope of the State licensure, certification, or registration requirements.

i. Information Management (§ 486.330)

The current information management requirements at § 486.330 focus on maintaining both donor records and records showing the disposition of each organ recovered for the purpose of transplantation, including information identifying transplant beneficiaries. We propose to amend § 486.330 by adding a requirement that OPOs maintain records for organs that are procured for research, including pancreata used for islet cell research.

j. Quality Assessment and Performance Improvement (QAPI) (§ 486.348)

The current QAPI requirements focus on OPOs developing, implementing, and maintaining a comprehensive, data driven QAPI program designed to monitor and evaluate performance of all donation services. Section 486.348(c) requires OPOs to establish written policies to address, at a minimum, the process for identification, reporting, analysis, and prevention of adverse events and conduct a thorough analysis of any adverse event to identify and implement effective changes to prevent those types of incidences from recurring again. We propose to include a revised list of examples of adverse events in this section that is currently located in the “adverse event” definition in § 486.302.

To further the goal of improving procurement and transplantation of medically complex organs, we propose to require each OPO as part of its QAPI program in new § 486.348(e) to: (1) assess its policies and procedures regarding medically complex donors and medically complex organs and ensure they are optimizing opportunities to recover and place these organs for transplant; (2) assess its performance regarding the number of medically complex donors by determining the number of medically complex donors from whom the OPO has obtained consent for donation, the number of organs recovered from those donors, and the number of medically complex organs transplanted at least annually; and (3) implement actions to improve its performance with medically complex donors or medically complex

organs when the OPO identifies opportunities for such improvement.

3. Summary of Costs and Benefits

The December 2020 final rule, among establishing other requirements, revised previous outcome measures to drive performance improvement and increase the number of transplantable organs. The December 2020 final rule's estimated costs were primarily driven by increased expenses related to organ procurement. Secondary costs were driven by the additional expense for OPOs to implement performance improvement policies. Additional costs accounted for the potential of OPO mergers.

The estimated benefits quantified were due to the number of lives saved and lives extended and, in addition, reduced costs to CMS payments for dialysis treatments for patients waiting on the transplant waitlist.

This proposed rule is important due to its functional proximity to the December 2020 final rule. Its purpose is to address and prevent administrative and operational concerns related to the competition process. This proposed rule would impose an estimated \$19.1 million in Year 1 and \$6.3 million in subsequent years. Year 1 costs including collection of information costs are approximately \$17.9 million for OPOs and \$1.2 million for CMS. Recurring annual costs include approximately \$6.2 million for OPOs and \$331,000 for CMS. Quantified benefits are estimated at \$884,000 annually with an additional one-time benefit of \$300,000.

These costs reflect clarifications and refinements to operational and administrative requirements rather than fundamental system restructuring.

B. Severability

To the extent a court may enjoin any part of the rule, the Department intends that other provisions or parts of provisions should remain in effect. Any provision of this rule held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provisions permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this rule and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

II. Organ Procurement Organizations (OPOs)

A. Background

OPOs are vital partners in the procurement, distribution, and transplantation of human organs in a safe and effective manner for all potential transplant recipients. The role of OPOs is critical to ensuring that the maximum possible number of transplantable human organs are available to individuals with organ failure who are on a waiting list for an organ transplant. Section 371(b) of the PHS Act sets out certain requirements for OPO certification. There are currently 55 OPOs that are responsible for identifying patients who may become prospective donors and recovering organs from deceased donors in the United States (U.S.), and currently each OPO serves a single DSA (55 in total). The Centers for Medicare & Medicaid Services (CMS) views OPO performance as a critical element of the organ transplantation system in the U.S. We established conditions for coverage (CfCs) for OPOs at 42 CFR part 486, subpart G, and OPOs must meet these requirements to receive payments from transplant hospitals participating in the Medicare and Medicaid programs. The CfCs include reliable, data-based outcome measures related to donor and transplant volume that are used to assess OPO performance for Medicare certification purposes and a three-tier certification structure that incentivizes high OPO performance on these outcome measures. In general, we are committed to using objective data to assess OPO performance and continuously incentivize OPO performance improvement.

In 2024, there were a total of 48,150 organ transplants, compared to 46,634 and 42,889 transplants in years 2023 and 2022, respectively.⁴ Although the volume of transplants has increased over time, there continues to be an ongoing shortage of transplantable organs. At any given time, at least 100,000 people are on the waiting list for a lifesaving organ transplant.⁵ Many people face tremendous quality of life burdens, illness progression, or death while on the waiting list. An OPO that is efficient in procuring organs and delivering them to recipients will help more people on the waiting list receive lifesaving organ transplants and reduce

the waiting time, which could ultimately save more lives and improve health outcomes.

B. Regulatory History

The December 2020 final rule (85 FR 77898) revised the OPO CfCs with the policy goal of increasing organ donation and transplantation to better serve patients on the organ transplant waiting list. The December 2020 final rule revised the outcome measures that are used to assess OPO compliance for purposes of certification, shifting from heavily risk-adjusted metrics that were not capable of demonstrating changes in OPO performance to metrics that measure OPO volume and drive OPO performance in areas most important to patients on the transplant waiting list. It also revised the assessment criteria to move from a bifurcated pass/fail system to a three tier system with dynamic performance thresholds and incentives for achieving the highest level of performance. Finally, the December 2020 final rule utilizes increasing competition to drive performance improvement. An OPO's performance in a DSA is ranked in comparison to the performance of all other OPOs in their assigned DSAs relative to a numerical threshold, using competition for higher ranking as a tier 1 as an incentive for performance improvement. We believe that the absence of meaningful competition contributed to the very slow pace of system improvement prior to CMS initiating its OPO regulatory reform efforts in 2019, culminating with publication of the December 2020 final rule.

Specifically, the December 2020 final rule measures OPO performance on two outcome measures described in § 486.318—the donation rate and the transplantation rate. Both rates assess OPO performance within the OPO's DSA, which is a geographical area that each OPO is assigned to, meaning that the OPO is responsible for all organ procurement activities that occur in that area, with certain exceptions. The denominator for each measure is the donor potential of each DSA, based on inpatient deaths within the DSA from patients 75 or younger with a primary cause of death that is consistent with organ donation, consistent with the OPO Certification Act of 2000.⁶ We estimate the donor potential of each DSA using death certificate information obtained from the Center for Disease Control and Preventions' (CDC), National Center for Health Statistics' (NCHS's) Detailed Multiple Cause of

⁴ Organ Procurement and Transplantation Network (OPTN) Data. <https://hrsa.unos.org/data/view-data-reports/national-data/>. Accessed January 6, 2026.

⁵ Organ Donation Statistics. <https://www.organdonor.gov/learn/organ-donation-statistics>. Accessed April 24, 2025.

⁶ Public Law 106–505, section 701, codified at 42 U.S.C. 273(b)(1)(D)(ii)(II).

Death (MCOD) file. The MCODE is published annually, reflecting data collected from the previous full calendar year, and is publicly available upon request. As such, there is an approximate 11 to 12 month data lag to allow for all activities related to the collection and compilation of the data. The MCODE comprises county-level national mortality data that include a record for every death of a U.S. resident recorded in the U.S. The MCODE files contain an extensive set of variables derived from the death certificates which are standardized across the 57 jurisdictions that provide CDC with the data.⁷ The jurisdictions use the U.S. Standard Certificate of Death as a template for their forms. We use the death certificate data to adjust the denominator to better reflect the population in the DSA that will more closely resemble individuals likely to have died in a manner consistent with organ donation. As we described in the December 2020 final rule, death that is consistent with organ donation means all deaths of individuals 75 or younger from the State death certificates with the primary cause of death listed as the ICD-10-CM codes I20-I25 (ischemic heart disease); I60-I69 (cerebrovascular disease); V-1-Y89 (external causes of death), which includes causes such as blunt trauma, gunshot wounds, drug overdose, suicide, drowning, and asphyxiation. Our methodology is designed to estimate the likely donor referral population to normalize the inpatient deaths across the different DSAs. While each DSA may face its own unique challenges, the method for estimating donor potential is designed to be standardized and equally applied to all OPOs, allowing for variances in performance when facing challenges to be measured and for high performance to be incentivized. Since the donor potential is part of a rate calculation, identifying the exact, donor potential of those candidates that are universally considered by all OPOs to be ideal is less relevant than providing standardized, reasonable, and impartial criteria to estimate it and applying those criteria consistently to all OPO DSAs.

The donation rate is calculated as the number of donors in the DSA as a percentage of the donor potential. The donation rate assesses the ability of the OPO to obtain consent for donation, successfully manage the donor, procure and place at least one organ for

transplantation (or pancreas for islet cell transplantation or research), and ensure the safe and timely transport of that organ for transplantation. By including the donation rate, we incentivize OPOs to pursue all donors, including the single organ donors. An OPO is more likely to meet the donation rate measure if it procures organs from DCD or medically complex donors where relatively fewer organs may be transplantable. Incentivizing OPOs to pursue all potential donors means introducing more opportunities for individual transplant waitlist candidates to receive a good organ match, which is impacted by factors such as blood type, body size, and immune system antibody compatibility. A wider variety of donors means a better chance of good matches for more patients.^{8,9}

The transplantation rate is calculated as the number of organs transplanted from donors in the DSA as a percentage of the donor potential. Organs, including pancreatic islet cells, transplanted into patients on the Organ Procurement and Transplantation Network (OPTN) waiting list as part of research are included in the organ transplantation rate. Pancreata that are used in islet cell research are also included. The organ transplantation rate is an important measure as it measures the benefit for patients from OPO performance. The unique geographical challenges associated with servicing the Hawaii DSA necessitated using a different outcome measure to evaluate the OPO's transplantation performance in that DSA. Instead of using the organ transplantation rate, we use the kidney transplantation rate. Although we do not use the organ transplantation rate for the Hawaii DSA, we continue to monitor the development and Food and Drug Administration (FDA) clearance of organ transport devices and expect the OPO serving the Hawaii DSA to adopt these new technologies when they are available.

Our outcome measures and process measures, taken as a whole, represent a reasonable effort to estimate the donor potential and other related factors in the DSA. The outcome measures denominator, as previously described in this section, is an estimate of donor potential in each DSA. The outcome

measure numerators measure OPO performance (through the number of donors and organs transplanted) and are somewhat related because if there are more donors, there are likely to be more organs transplanted. However, these numerators are not the same, and each is necessary to measure different OPO outcomes and to properly incentivize OPOs to pursue all potential donors, succeed in obtaining consent, successfully manage their care, and successfully deliver viable organs for transplant. For example, OPOs that focus primarily on medically complex donors that may yield fewer organs per donor may need to seek more donations to have sufficient organs transplanted to mathematically meet the threshold organ transplantation rates. On the other hand, OPOs that are very effective at placing all possible organs from younger, healthier donors with larger yields may achieve the targeted organ transplantation rate, but not the donation rate, if they choose not to pursue the medically complex and DCD donors with only one or two transplantable organs. In measuring both donation and transplantation rates, we seek to achieve both more donors and more transplants. By focusing on the outcomes of OPO processes in the form of donation and transplant rates, we have created a system in which a wide variety of changeable factors, such as levels of public awareness and understanding about organ donation, relationships with donor hospitals, and the quality and timeliness of OPO interactions with potential donors and their families all coalesce in an end result of successful organ donation and transplantation.

Both outcome measures, and their threshold rates, are calculated using a full single calendar year of data. There is typically an 11- to 12-month long data lag for the MCODE file following the close of the calendar year. For example, the MCODE file containing data for deaths that occurred in 2025 is not expected to be available until December 2026 or as late as early spring 2027. To account for this and assure that CMS uses data from the same calendar year for both the numerators and denominators to calculate the donation and transplantation rates and threshold rates, there is a 1.5-year difference between the time when OPOs submit data for the performance period and the time when that data is fully analyzed by CMS and used to calculate OPO performance on the outcome measures. CMS provides each OPO with a preview of its calendar year data report and has a process established for OPOs to

⁸ Madbouly A and Bolon Y-T (2024) Race, ethnicity, ancestry, and aspects that impact HLA data and matching for transplant. *Front. Genet.* 15:1375352. doi: 10.3389/fgene.2024.1375352.

⁹ Tiercy JM, Claas F. Impact of HLA diversity on donor selection in organ and stem cell transplantation. *Hum Hered.* 2013;76(3-4):178-86. doi: 10.1159/000358798. Epub 2014 May 21. PMID: 24861862.

⁷ The 57 jurisdictions that provide data to the CDC are the 50 States, New York City, the District of Columbia, and the 5 territories. Data for New York City is reported separately from the State of New York.

provide feedback on their preview reports to assure accuracy before the reports are made publicly available. For example, in 2025, CMS used OPTN (numerator) and MCOD (denominator) data from calendar year 2023 to develop an annual interim data report for each OPO. The MCOD file for 2023 became available early in 2025. CMS calculated each OPO's performance on each outcome measure, provided each OPO with its own preview reports and correction opportunities, and then made the 2023 performance data for all OPOs publicly available in late spring 2025.¹⁰ CMS repeats this process on an annual basis such that OPOs and the public are aware of individual OPO performance and nationwide performance trends.

OPO performance on the outcome measures is assessed on an annual basis. For each assessment period, threshold rates are established based on the observed donation and transplantation rates during the 12-month period immediately prior to the period being evaluated. In the 2025 annual interim data report described above, OPO performance using 2023 data is compared to the OPO performance data of 2022. The median observed rate for each outcome measure in 2022 was used as the standard to measure OPO performance in 2023. To establish the threshold rates CMS calculates both the lowest observed rate among the top 25 percent in the DSAs, and the median observed rate among the DSAs. To measure OPO performance in a DSA, CMS uses a 95 percent confidence interval for each DSA's donation and organ transplantation rates using a one-sided test. A confidence interval is a statistical measure of precision. In the context of OPO evaluations, it provides the range of outcome measure values (donation rates or transplant rates) that are expected to most reasonably describe the OPO's true performance based on the available data. The confidence interval accounts for uncertainty to describe a broader range of OPO performance levels that could plausibly explain the observed donation and transplant outcomes. Confidence intervals tend to be wider when there are fewer potential donors because there is less information available to precisely measure the OPO's influence on the observed outcomes, and it becomes more difficult to confidently describe the OPO's performance with a very specific range of quality measure values. For example, consider a hypothetical situation where an OPO has just one potential donor. In this extreme case, it

would only be possible to observe a donation rate of $1/1 = 100$ percent or $0/1 = 0$ percent. However, it would be misleading to claim that this OPO is always or never successful at recovering donor organs. In fact, there is almost no information available about this OPO's general performance because only one potential donor's outcome was observed. The confidence interval would be very wide under this scenario to appropriately reflect the low degree of certainty in the OPO's true donation performance. Likewise, OPOs with DSAs that have a larger donor potential, and thus a larger data set for performance measurement, tend to have smaller confidence intervals. Confidence intervals tend to be narrower for large data sets because it is easier to confidently describe performance due to the large amount of available data. Each OPO's confidence intervals for the donation and transplant rate are compared to benchmark levels of performance based on the prior year's observed rates. If the upper end of the OPO's confidence interval does not meet or surpass the threshold value established using the prior year's observed performance data, then there is statistical evidence that the OPO is not performing at that threshold level for donation or transplantation. For example, in the 2025 data report that is based on performance data from 2023, one OPO had an observed donation rate of 15.17 and the upper limit of its confidence interval was 16.64. The threshold rate for the outcome measure using the observed performance of all OPOs in the previous data year, 2022, was 12.49 for the median and 14.11 for the top 25 percent. In comparing the upper end of this OPO's confidence interval, 16.64, to the median performance threshold of 12.49 established using the previous year's observed performance, we determine that this OPO has met the median threshold rate for the donation outcome measure and complies with the minimum standard to be eligible for designation to tier 2 for that outcome measure. Likewise, in comparing the upper end of this OPO's confidence interval, 16.64, to the top 25 percent threshold of 14.11 as established using the previous year's observed performance data, we determine that this OPO has met and exceeded the top 25 percent threshold for the donation rate outcome measure. Indeed, this OPO's observed performance of 15.17 exceeded the top 25 percent threshold, meaning that even in the absence of a confidence interval it would still have performed in the top 25 percent on the

donation rate outcome measure. In examining the 2025 public report, we note that 27 of the 42 OPOs that performed well enough to be in tier 1 on the donation rate outcome measure qualified by their observed performance, rather than by the upper limit of their calculated confidence interval. The performance thresholds for OPO evaluation are determined from the prior year's data, meaning that every OPO has the opportunity to improve its donation and transplantation performance such that its confidence intervals meet or surpass these threshold values. Even OPOs with donation or transplant rates below the performance thresholds can have confidence intervals that surpass these thresholds, depending on the size of 95 percent confidence interval and proximity to the benchmark. For example, in the 2025 public OPO data report, five OPOs that performed in tier 2 for the transplantation outcome were classified as tier 2 based on their confidence interval with an observed age-adjusted rate below the median of 38.56. Therefore, ten OPOs that performed in tier 2 on the transplantation outcome measure had an observed performance level that met or exceeded the median threshold and would be in tier 2 in the absence of a confidence interval. As such, it is possible for more than half of OPOs to be at or above the 25 percent and median thresholds. Indeed, in the 2025 public OPO report, 30 of the 55 OPOs (roughly 55 percent) performed well enough on both measures to be in tier 1 and the majority of these OPOs did so through their observed performance. This OPO performance evaluation system is designed to create incentives for OPOs to rapidly improve their performance in serving donor families and people on the transplant waitlist and exceed the performance thresholds established using the previous year's performance data.

Section 371(b)(1)(D)(ii)(II) of the PHS Act¹¹ provides that a qualified OPO must meet performance standards defined through regulations promulgated by the Secretary that rely on outcome and process performance measures that are based on empirical evidence, obtained through reasonable efforts, of donor potential and other related factors in each DSA. CMS established process measures (§ 486.320 through § 486.360) related to DSA-specific factors like relationships with donor hospitals in the DSA and OPO-specific processes such as QAPI, and uses empirical evidence gathered upon

¹⁰ Quality, Certification, and Oversight Reports. <https://qcor.cms.gov/main.jsp>.

¹¹ 42 U.S.C. 273(b)(1)(D)(ii)(II).

survey to assess compliance with these requirements. The process measures complement the outcome measures, focusing on essential OPO-level and DSA-level processes and factors to facilitate high performance. While the December 2020 final rule added two new outcome measures that use empirical data from the MCOD file and the procurement and transplant data submitted by OPOs (§ 486.328) and transplant centers (§ 482.45(b)(3)) to replace the self-reported, unverified outcome measures that were implemented by the 2006 final rule,¹² it in no way replaced the essential process measure focus on other DSA-specific factors. Indeed, the December 2020 final rule also established a 3-tier system whereby OPOs are stratified into different tiers based on their performance on both outcome measures and compliance with the process performance measures. A successful OPO must meet the measures for both processes and outcomes to be considered compliant with the CfCs and eligible for re-certification. The consequences of being in each tier based on outcome measure performance differ based on whether the performance occurs as part of the annual assessment or if it occurs during the final assessment period.¹³ Tier 1 DSAs have an upper limit of the one-sided 95 percent confidence interval for the donation and organ transplantation rate outcome measures that are at or above the top 25 percent threshold rate. Tier 2 DSAs have an upper limit of the one-sided 95 percent confidence interval for the donation and organ transplantation rates that are at or above the median threshold rate established for their DSA but are not tier 1 for both outcome measures Tier 2 performance, meaning that an OPO DSA has met the median threshold for both outcome measures but has not met the tier 1 top 25 percent threshold for both measures, is the minimum compliance standard established in the OPO regulations. OPO DSAs that fall into tier 2 will be opened for competition from other interested OPOs, to allow for the replacement of an OPO performing at the minimum compliance standard where there is a clearly better OPO prepared and capable of taking over the DSA. As such, OPOs are incentivized to assure that each of their DSAs are high performing such that they meet the top 25 percent performance thresholds and are not open for competition. Instead of using a 50 percent rate or a mean rate, we chose the median rate because both the top 25

percent threshold rate and the median rate represent the actual rates performed by one or two OPOs (when there is an even number, the median is calculated by averaging the two rates in the median). The mean rate, on the other hand, is a mathematical rate that may not reflect the performance of an actual OPO and may be dragged down by a small number of very low performing OPOs. A median, however, is less affected by extremes in performance as compared to a mean. By identifying the specific rate of an OPO, OPOs can directly compare their performance with that of other OPOs. Likewise, we did not choose to assess performance and thus compliance with the CfCs using a standard deviation from the mean methodology for several reasons. Under our methodology, all OPOs have the opportunity to cluster at the top because the threshold rate is based on the previous year's rate, meaning that all OPOs begin each year with a new opportunity to meet or exceed the median from the previous year. As a contrast, the standard deviation from the mean methodology generates a contemporaneous list of OPOs that are a certain distance from the mean. As discussed previously, the mean is problematic because several lower performing OPOs could skew the calculated mean. Beyond this, the mean and the standard deviations are generated contemporaneously with the ranking of the OPOs, giving OPOs no notice of their targeted performance. And, by nature of the statistical method of standard deviation, there will always be an OPO below the targeted standard deviation from the mean, meaning that not all OPOs would have the opportunity to be a top performing OPO unless they all had identical rates. As the outcome measures are used for certification and re-certification, consistent with the requirements set forth in the PHS Act, we do not believe that establishing a system in which at least one OPO must be determined to be out of compliance and therefore de-certified during each re-certification cycle is appropriate. Rather, we sought and continue to seek a system where all OPOs perform at a high level, exceed the previous year's median, and cluster at the top. As we stated in the December 2020 final rule, "Our goal in creating these tiers is to reward the top performing OPOs (Tier 1), while giving OPOs in Tiers 2 and 3 sufficient incentives to improve their performance and achieve ranking in the next level up" ¹⁴ We note that tier 3 DSAs, which have an upper limit of the one-

sided 95 percent confidence interval for their donation or organ transplantation rates that are below the median threshold rate established using the previous year's data, are considered to be DSAs that fail to meet the outcome measures and are non-compliant with the CfCs.

Our goal is for all OPOs to be compliant with the process measure CfCs and the outcome measure CfCs, meeting or exceeding the prior year's median performance threshold, such that no OPOs are ranked in tier 3 and de-certified. As such, we have established a system of incentives to reward high performance on the outcome measures. CMS calculates the outcome measures and tier rankings annually and makes that information publicly available in interim reports, and OPOs with DSAs that rank in tier 2 or tier 3 must use their QAPI program to identify opportunities for improvement and implement changes that lead to improvement in these measures. Since publication of the December 2020 final rule the donation and transplantation system has entered a period of accelerated improvement. Based on data provided in the 2025 OPO Public Performance Report ¹⁵ the median donation rate increased 11 percent from 2021 to 2023, while historical records show that it only increased 2.6 percent in the 3 years preceding CMS rulemaking (2017 through 2019). Likewise, the median transplantation rate increased 7.3 percent from 2021 to 2023, while it only increased 1 percent in the 3 years preceding CMS rulemaking (2017 through 2019). Taken together, these data suggest that the sustained regulatory pressure of our system of tiered incentives, coupled with reliable and transparent performance metrics that drive continuous improvement and improve accountability, is working as we intended to accelerate OPO performance improvement in serving donors, their families, and patients on the transplant waiting list. As we stated in the December 2019 OPO proposed rule, "Our ultimate definition of success, however, is to encourage the performance of all OPOs to cluster around the highest performers." ¹⁶ In the 2023 data report (based on data collected in 2021) there were 15 OPOs with tier 1 DSAs, increasing to 25 in 2024 (data from 2022), and 30 in 2025 (data from 2023). While top performing OPOs continue to improve on the

¹² 71 FR 31046.

¹³ 85 FR 77911.

¹⁴ 85 FR 77911–12.

¹⁵ Quality, Certification, and Oversight Reports. <https://qcor.cms.gov/main.jsp>. Accessed on June 12, 2025

¹⁶ 84 FR 70634.

outcome measures, mid-performing OPOs are further accelerating their own improvements to catch up to their peers. Finally, in the December 2019 OPO proposed rule, we predicted that OPOs achieving the standard of the top 25 percent or a 20 percent increase, whichever is greater, would lead to an improvement in donors from 10,000 in 2017 to over 12,000 in 2026 and in transplants from 32,000 in 2017 to almost 42,000 in 2026. In 2023, there were 14,571 deceased organ donors and 45,407 transplants, surpassing CMS' original predictions 3 years sooner than predicted. These initial data suggest that the 3-tier methodology we finalized in the December 2020 final rule has led to a sustained improvement in organ procurement and transplant as intended.

We have reason to believe, and research suggests,¹⁷ that this acceleration in better service of patients on the transplant waiting list is connected to the sustained regulatory pressures exerted by use of the tier structure in the re-certification process to bring about accountability. An OPO with a DSA that qualifies for tier 1 designation will be re-certified, retaining its tier 1 DSA, provided that the OPO is also found to be in compliance with all other OPO process performance measure CfCs via the re-certification survey. An OPO with a DSA that qualifies for tier 1 designation also qualifies to enter any competitions that are conducted to fill DSAs that are open for competition. An OPO with a DSA that qualifies for tier 2 designation and is also found in compliance with all other OPO process measure CfCs via the re-certification survey is also in compliance with the regulations, but its tier 2 DSA will be open to competition from other OPOs with tier 1 and tier 2 DSAs, should any eligible OPO choose to compete for it. An OPO with a tier 2 DSA may compete for any DSAs that are open for competition and must retain its DSA or obtain a new DSA in competition to be designated to the DSA and have an agreement with CMS. An OPO that only has DSAs designated to tier 3 will receive an initial notice of de-certification determination due to non-compliance with the OPO CfCs and has the appeal rights set forth at § 486.314. Once de-certified, an OPO cannot compete for either its own or any other open DSA. CMS utilizes competition to drive performance to achieve a higher

tier ranking and to decide which OPOs should be awarded the opportunity to compete for additional DSAs if and when they are open. The conclusion of the 2022–2026 certification cycle will mark the first use of the outcome measures and tiers system for re-certification purposes. CMS publishes interim annual reports each year to provide transparency in OPO performance and the opportunity for OPOs to implement performance improvement plans. These reports are posted on the Quality, Certification and Oversight Reports (QCOR) website.¹⁸

In addition to the outcome measures and their implications with respect to tier status and re-certification, OPOs must also comply with the process performance measures set forth at §§ 486.320 through 486.360 to be considered in compliance with the CfCs. While tier assignment recognizes different levels of performance with respect to the outcome measures, it does not guarantee compliance with other requirements. Therefore, OPOs that are high performing on the outcome measures could be found non-compliant with one or more of the process performance measures during a survey, which could lead to de-certification if the OPO is unable to remedy the non-compliance. The process performance measures span a range of operational requirements. Specifically, at § 486.320 we require that an OPO must become a member of, participate in, and abide by the rules and requirements of the OPTN. At § 486.322 we address relationships with donor hospitals in the OPO's DSA, providing training to donor hospital staff, and cooperating with tissue banks. At § 486.324 we specify the required members of the OPO advisory board, its authorities and restrictions, limitations on the members of the board, and having bylaws for board member conflicts of interest and other key concerns. This condition also addresses the OPO's governing body and requires each OPO to declare in policy whether it recovers organs from donors after cardiac death. At § 486.326 we include specific human resources requirements that are further discussed in section III.I. of this proposed rule. At § 486.328 we include data reporting requirements for reporting to the OPTN, Scientific Registry of Transplant Recipients (SRTR), Department of Health and Human Services (HHS), and to transplant hospitals. At § 486.330 we address maintaining records for all donors and the disposition of each organ recovered for transplantation.

This requirement is further discussed in section III.J. of this proposed rule. At § 486.342 we address requesting consent from prospective donor families with discretion and sensitivity, and at § 486.344 we address written protocols for donor evaluation, donor management, and organ placement and recovery to maximize organ quality and optimize the number of donors and the number of organs recovered and transplanted per donor. At § 486.346 we address organ preparation and transportation, covering topics including organ testing for infectious diseases and tissue typing, documentation provided to a transplant center and its verification for accuracy, and the protocols for packaging, labeling, handling, and shipping organs. The issue of organ transportation is further discussed in section III.K. of this proposed rule. At § 486.348 we include specific QAPI requirements, addressing the components of the program, death record reviews, adverse events, and the connection between performance on the CMS outcome measures and QAPI activities. The requirements for QAPI are further discussed in section III.K. of this proposed rule. Finally, at § 486.360 we address emergency preparedness standards for OPOs.

On February 2, 2021, we published a notice in the **Federal Register** (86 FR 7814) temporarily delaying the effective date of the December 2020 final rule by 60 days and providing an additional 30-day public comment period, during which we received over 150 timely public comments. The comments received included both support for immediate implementation of the December 2020 final rule and requests for additional time before implementation. We considered the additional public comments and the rule subsequently became effective on March 30, 2021.

On December 3, 2021, we published a "Request for Information (RFI); Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease (ESRD) Facilities" (86 FR 68594) ("December 2021 RFI"), which solicited comments that would help to inform potential changes that would create system-wide improvements, including improvements in organ donation, organ transplantation, quality of care in dialysis facilities, and access to dialysis services.

We received almost 400 timely comments in response to the December 2021 RFI. Commenters included transplant recipients, those awaiting transplants, donor families, and donor representatives. A range of health care

¹⁷ Doby BL, Ross-Driscoll K, Shuck M, Wadsworth M, Durand CM, Lynch RJ. Public discourse and policy change: Absence of harm from increased oversight and transparency in OPO performance. *Am J Transplant*. 2021;00:1–7. <https://doi.org/10.1111/ajt.16527>.

¹⁸ Quality, Certification and Oversight Reports. <https://qcor.cms.gov/main.jsp>.

providers, including donor hospitals, transplant programs, ESRD suppliers, hospital systems, OPOs, and tissue banks; researchers and academic institutions; professional organizations; trade groups such as technology and pharmaceutical companies as well as insurers; and advocacy and philanthropic organizations also provided comments. These comments informed this proposed rule and may be used in future rulemaking for system-wide changes to advance organ transplant system performance.

Recent peer reviewed research using the same method for estimating donor potential from our December 2020 final rule highlights the ability to detect variable performance both across OPOs and across areas of practice within OPOs as well as how this information can be leveraged for performance improvement to increase organ donation.^{19 20} One group of researchers found that 74 percent of differences in overall donor procurement rates could be explained using model variables that represent different domains of OPO practice activities, such as DCD procurement, and procurement of older and minority patient populations.²¹ Having this type of in depth performance data analysis available to OPOs for use in their QAPI programs, based on impartial and reliable data and outcome measures, is vital for OPOs to utilize in designing and implementing QAPI activities to drive improvements. The ability of OPOs to use this type of information to potentially implement appropriate practice changes will be critical to their success in the future. It is our role, with a continued focus on better patient outcomes, to maintain and enforce a regulatory structure that capitalizes on recent developments in data analysis and insights to enhance system-level and OPO-level performance.

To assist OPOs in improving performance, we developed two initiatives that OPOs could participate in to facilitate organ procurement and placement. The ESRD Treatment

Choices Learning Collaborative brought transplant centers, OPOs, donor hospitals, patients, and donor families together to spread the use of highly effective practices to increase kidney procurement, recovery, and utilization.²² The program provided technical assistance to several interested parties, including OPOs, with three aims: increasing the number of deceased donor kidneys transplanted, decreasing the current national discard rate of all procured kidneys, and increasing the percentage of kidneys recovered for transplant in the greater than or equal to 60 KDPI score group. Fifty-three OPOs participated in this collaborative, which ended in August 2025. CMS, through its quality improvement organizations, also initiated an OPO Special Innovation Project (SIP) to provide technical assistance to OPOs for improvement on the OPO performance outcome measures. In this program, OPOs had the opportunity to actively participate in a variety of technical assistance activities such as completing Root Cause Analyses (RCAs) and Plan-Do-Study-Act (PDSA) cycles, implementing evidenced-based strategies, and developing process and decision pathways. The objective was for OPOs to permanently integrate effective processes to improve and sustain improvements in their donation rate and transplant rate. Forty OPOs participated in this program, which concluded in March 2025.

C. Statutory and Regulatory Provisions

To be an OPO, an entity must meet the applicable requirements of both the Social Security Act (the Act) and the PHS Act. Section 1138(b) of the Act provides the statutory qualifications and requirements that an OPO must meet in order for its organ procurement costs to be paid under the Medicare program or the Medicaid program. Section 1138(b)(1)(A) of the Act specifies that payment may be made for organ procurement costs only if the agency is a qualified OPO operating under a grant made under section 371(a) of the PHS Act or has been certified or re-certified by the Secretary of the Department of Health and Human Services (the Secretary) as meeting the standards to be a qualified OPO within a certain time period. Section 1138(b)(1)(C) of the Act provides that payment may be made for organ procurement costs only if the OPO meets the performance-related standards prescribed by the Secretary. Section 1138(b)(1)(F) of the Act requires that to receive payment under the

Medicare or Medicaid programs for organ procurement costs, the entity must be designated by the Secretary. The requirements for such designation are set forth in § 486.304 and include being certified as a qualified OPO by CMS. Regulations at § 486.303 address the requirements to be certified as a qualified OPO.

Pursuant to section 371(b)(1)(D)(ii)(II) of the PHS Act, the Secretary is required to establish outcome and process performance measures for OPOs to meet based on empirical evidence, obtained through reasonable efforts, of organ donor potential and other related factors in each service area of the qualified OPO. Section 1138(b)(1)(D) of the Act requires an OPO to be a member of, and abide by the rules and requirements of, the Organ Procurement and Transplantation Network (OPTN). OPOs must also comply with the regulations governing the operation of the OPTN (42 CFR part 121). The Department of Health and Human Services (HHS) has explained that only those OPTN policies approved by the Secretary will be considered “rules and requirements” of the OPTN for purposes of section 1138 of the Act.²³ The OPTN is a membership organization that oversees the U.S. organ transplant system, links all professionals in the U.S. organ procurement and transplantation system, and maintains a national registry for matching donated organs with recipients in need of transplantation. OPOs are required under OPTN regulations (42 CFR 121.11(b)(2)) and § 486.328 of our OPO CfCs to report information specified by the Secretary to the OPTN, including the data used to calculate the outcome measures for OPOs.

In addition, OPOs are required to comply with existing Federal civil rights laws, including the Americans with Disabilities Act of 1990 (ADA), 42 U.S.C. 12101 *et seq.*, Title VI of the Civil Rights Act of 1964 (Title VI), 42 U.S.C. 2000d, Section 504 of the Rehabilitation Act of 1973 (Section 504), 29 U.S.C. 794, and Section 1557 of the Patient Protection and Affordable Care Act, 42 U.S.C. 18116.²⁴ Title VI protects individuals on the basis of race, color, and national origin. Section 1557 protects individuals on the basis of race, color, national origin, age, disability, or sex. Among other things, these laws require OPOs to take reasonable steps to

²³ 63 FR 16296.

²⁴ Recipients of Federal financial assistance must comply with Federal civil rights laws, including but not limited to Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, the Americans with Disabilities Act, and Section 1557 of the Affordable Care Act.

¹⁹ Doby BL, Hanner K, Johnson S, Purnell TS, Shah MB, Lynch RJ. Results of a data-driven performance improvement initiative in organ donation. *Am J Transplant.* 2020;00:1–8. <https://doi.org/10.1111/ajt.16442>.

²⁰ Lynch RJ, Doby BL, Goldberg DS, Lee KJ, Cimen A, Karp SJ. Procurement characteristics of high- and low-performing OPOs as seen in OPTN/SRTR data. *Am J Transplant.* 2022 Feb;22(2):455–463. doi: 10.1111/ajt.16832. Epub 2021 Sep 29. PMID: 34510735.

²¹ Doby BL, Casey K, Ross-Driscoll K, Rahman Ovi M, Hossain Bhuiyee MS, Isty IA, Lynch RJ. What is visible is fixable: visual dashboards for multi-domain assessment of OPO performance. *American Journal of Transplantation.* <https://doi.org/10.1016/j.ajt.2023.08.020>.

²² <https://innovation.cms.gov/innovation-models/esrd-treatment-choices-model>.

ensure meaningful access to their programs by individuals with limited English proficiency. Reasonable steps may include providing language assistance services at no cost to the individual, such as providing interpreters or translated material. Also, the ADA, Section 504 and Section 1557 protect otherwise qualified individuals with a disability, including prospective organ recipients with a disability and prospective organ donors with a disability, from discrimination in the administration of organ transplant programs that receive Federal financial assistance. Under these laws, OPOs must ensure that qualified individuals with disabilities are afforded opportunities to participate in or benefit from the organ donation programs that are equal to opportunities afforded to others. Furthermore, OPOs and transplant teams risk violating these Federal civil rights laws through discriminatory actions during the organ donation process. Such violations include providing substandard care to a prospective donor with a disability based solely on that disability.

Qualified individuals with disabilities are also entitled to reasonable modifications needed to participate in and benefit from a program, as well as appropriate auxiliary aids and services needed for effective communication. These rights extend in some circumstances to companions of a prospective organ donor or recipient. For example, health care providers and organ donation programs are required to provide auxiliary aids and services (including sign language interpreters) when necessary for effective communication between a relative involved in a prospective donor or recipient's care and a health care provider or procurement program.

Section 1102 of the Act gives the Secretary the authority to make and publish such rules and regulations as may be necessary to the efficient administration of the functions with which the Secretary is charged under the Act. Moreover, section 1871 of the Act gives the Secretary broad authority to establish regulations that are necessary to carry out the administration of the Medicare program.

We established CfCs for OPOs at 42 CFR part 486, subpart G, and OPOs must meet these requirements in order to be designated and therefore able to receive payments from the Medicare and Medicaid programs. These regulations set forth the certification and re-certification processes, outcome requirements, and process performance measures for OPOs. The outcome measures, found under § 486.318, are

used to assess OPO performance for re-certification and competition purposes (see § 486.316(a) and (d)).

III. Provisions of the Proposed Regulations

In response to the December 2020 final rule, which revised the regulations that establish the framework for OPO re-certification, we have received questions on technical implementation of the rule from OPOs and other interested parties. In this proposed rule, we seek to clarify outstanding procedural and technical questions on the implementation of the rule so that OPOs can better understand the procedures for re-certification and de-certification that will be used in 2026. We remain committed to holding OPOs accountable for their performance and are proposing additional revisions to the OPO regulations that will assist in driving improvements.

A. Definitions (§ 486.302)

We are proposing to revise our current regulations defining the terms “adverse event,” “donor,” “medically complex donors,” “medically complex organs,” “organ,” and “unsound medical practices” at § 486.302 to provide greater clarity.

1. Adverse Event

Section 486.302 currently defines “adverse event” as “an untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk thereof. As applied to OPOs, adverse events include, but are not limited to, transmission of disease from a donor to a beneficiary, avoidable loss of a medically suitable potential donor for whom consent for donation has been obtained, or delivery to a transplant center of the wrong organ or an organ whose blood type does not match the blood type of the intended beneficiary.” Adverse events trigger QAPI requirements so that for each adverse event, the OPO is required to “conduct a thorough analysis of any adverse event and must use the analysis to affect changes in the OPO’s policies and practices to prevent repeat incidents” (§ 486.348(c)(2)).

Through feedback we have received, we are concerned that the examples set forth in this definition are not being viewed as examples but rather as an exhaustive list of the adverse events that apply to OPOs. We do not believe an exhaustive list of adverse events is possible, given the broad range of potential occurrences that might qualify as “an untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk

thereof.” Thus, to avoid any confusion, we are proposing to remove the second sentence of the current definition and move a revised list of examples to § 486.348(c) in the QAPI requirements. If this change is finalized as proposed, OPOs should continue to identify “adverse events” according to the definition in § 486.302, regardless of whether the incident is covered in the examples that we are proposing to insert into § 486.348(c). We solicit public comment on the proposed changes to the definition of adverse events.

2. Donor

The Pancreatic Islet Cell Transplantation Act of 2004²⁵ (hereafter referred to as “PICTA 2004”) amended the PHS Act to add section 371(c), which requires that “[p]ancreata procured by an organ procurement organization and used for islet cell transplantation or research shall be counted for purposes of certification or re-certification[.]” In the December 2020 final rule we implemented the requirements of PICTA 2004 in the definition of “donor” in the OPO regulations at § 486.302, stating that a donor is “. . . a deceased individual from whom at least one vascularized organ (heart, liver, lung, kidney, pancreas, or intestine) is transplanted. An individual also would be considered a donor if only the pancreas is procured and is used for research or islet cell transplantation.”

OPOs are required by the OPTN to report data related to pancreata procured and used for research, and this data is incorporated into calculations used to assess compliance with the donor and transplant outcome measures used for re-certification purposes. In finalizing the definition of “donor” in 2020 we noted that, “[w]e think that the impact of pancreata for research on the overall rankings of OPOs will continue to be minimal.”²⁶ This prediction was based upon a clear downward trend in OPO-reported procurement of pancreata procured and used for research, and our expectation of a leveling off or further downward trend was further substantiated by a 2021 article titled, “The Demise of Islet Allograft Transplantation in the US: A Call for an Urgent Regulatory Update,”²⁷ which noted changes over time in the pancreata islet cell research and transplantation

²⁵ October 25, 2004, Public Law 108–362.

²⁶ 85 FR 77902.

²⁷ Witkowski et al. The Demise of Islet Allograft Transplantation in the US: A Call for an Urgent Regulatory Update The “ISLETS FOR US” Collaborative. *Am J Transplant*. 2021 Apr;21(4):1365–1375. <https://doi.org/10.1111/ajt.16397>.

landscape, from its peak in the years 2000–2015 with numerous phase 1 and 2 clinical trials declining to only 11 patients receiving a pancreatic islet cell transplant between 2018 and 2021. Upon review of ongoing clinical trials for pancreatic islet cells as described on the National Institute of Health's (NIH) website *clinicaltrials.gov*,²⁸ we identified 16 active clinical trials in October 2023 with a total possible enrollment of 325 persons, which was consistent with the procurement rates for research pancreata that existed prior to publication of the December 2020 final rule, coinciding with the period of decline noted in the 2021 article. We note that the number of active clinical trials appears to have declined since October 2023, with a total of 4 active clinical trials and a total possible enrollment of 108 persons identified in November 2025.

However, since the publication of the December 2020 final rule and the updated definition of the term “donor”, OPOs’ reported procurement of pancreata for research purposes has increased dramatically, rising from 562 in 2020 to 573 in 2021, 1,448 in 2022, 1,819 in 2023, and 2,004 in 2024, based on internal CMS review of data submitted by OPOs to the SRTR. The roughly 250 percent increase in procurement between 2020 and 2024 has not been matched by a corresponding increase in the number of clinical trials for pancreatic islet cells reported to the NIH and made public on the *clinicaltrials.gov* site. On January 18, 2024, we issued a memorandum²⁹ clarifying that for purposes of the definition of “donor”, the pancreata must be used for islet cell research or islet cell transplantation, consistent with PICTA 2004, to be counted. On October 9, 2024, the OPTN and SRTR updated the disposition reason codes that OPOs use when entering data regarding pancreata procured for any research purpose. The updated disposition reason codes differentiate pancreata procured and used for islet cell research activities from pancreata used for all other research purposes to enhance the specificity of data reported by OPOs. We propose to revise the definition of the term “donor” to further reiterate the clarification made in the January 2024 memorandum. The revised definition would state that an individual from whom only the pancreas is procured and is used for islet cell transplantation or for islet cell research is included in the definition of

“donor.” Procurement for other research uses does not count for purposes of certification and re-certification. These proposed revisions are intended to clarify the rule to improve regulatory consistency with the requirements set forth in PICTA 2004, which specifies that pancreata procured for “islet cell transplantation or research” are required to be counted for certification and re-certification of OPOs.

Per the National Diabetes Statistics Report³⁰ issued by the Centers for Disease Control there were approximately 1.7 million Americans living with diagnosed type 1 diabetes in 2021. Experts estimate that 375,000 suffer from impaired hypoglycemic awareness and 66 percent suffer from recurrent severe hypoglycemic episodes (SHE).³¹ Nearly 70,000 patients with type 1 diabetes fail to improve for hypoglycemia avoidance despite patient education efforts and advanced technologies, such as insulin pumps and continuous glucose monitoring sensors.³² In 2020, hypoglycemia led to 202,000 emergency department visits.³³

Although pancreas transplantation remains a therapeutic option that effectively treats type 1 diabetes, it requires major surgery with a significant risk of complications. Pancreatic islet allotransplantation offers a minimally-invasive alternative that lowers morbidity and mortality, improves glycemic control and prevents SHE, conferring complete protection from SHE in more than 90 percent of patients.³⁴ Federally funded clinical trials involving several U.S. academic centers have been conducted for pancreatic islet allotransplantation following results of a study conducted in 2000 where a series of seven patients with type 1 diabetes remained insulin-free for a full year following allotransplantation.³⁵ “Research,” as the

term is used in the OPO regulations, for pancreatic islet allotransplantation involves all stages of *bona fide* bench research conducted by a qualified researcher that uses donor pancreatic islet cells to advance scientific and healthcare knowledge, but occurs without transplanting pancreatic islet cells into a patient. This may include safety studies, studies of innovative routes of administration, and studies of modified allogenic islet cell products.³⁶ Islet cell research includes donor pancreata used for research related to islet isolation as well as pancreata used for islet cell research when the islets remain in the organ, such as may be used in organ slice studies or in situ islet histology. In the Congressional Record associated with passage of PICTA 2004, a member of the U.S. House of Representatives described “research that can result in being able to replicate the islet cells so that every diabetic in the country that wants one of these transplants can get that”³⁷ (emphasis added). Another Representative described the purpose of PICTA 2004 as follows, “Pancreatic islet transplantation has been hailed as the most important advance in diabetes research since the discovery of insulin in 1921. The procedure, which involves transplanting insulin-producing cells into an individual with juvenile diabetes, has been performed on over 300 individuals, and the majority of them no longer need to take insulin to stay alive. While significant research remains to be done to expand this procedure to all who suffer with juvenile diabetes, its promise is incredibly exciting . . .”³⁸ (emphasis added). We believe that there continues to be a role for using donor pancreata to advance islet cell research, fulfilling this stated vision of widespread treatment for type 1 diabetes. Pancreatic islet cells used for *bona fide* bench research conducted by a qualified researcher would continue to be included in the definition of “donor” and OPOs that procure pancreata that are used in *bona fide* pancreatic islet cell research would continue to receive credit for these donors in the donation outcome measure. As described in section III.J. of this proposed rule, we would require OPOs to document information regarding the islet cell

³⁰ National Diabetes Statistics Report. <https://www.cdc.gov/diabetes/php/data-research/index.html>. Accessed on March 25, 2025.

³¹ Byrne M, Hopkins D, Littlejohn W, et al. Outcomes for Adults with Type 1 Diabetes Referred with Severe Hypoglycaemia and/or Referred for Islet Transplantation to a Specialist Hypoglycaemia Service. *Horm Metab Res*. 2014;47(01):9–15.

³² Rickels MR. Hypoglycemia-associated autonomic failure, counterregulatory responses, and therapeutic options in type 1 diabetes. *Ann N Y Acad Sci*. 2019;1454(1):68–79.

³³ National Diabetes Statistics Report. <https://www.cdc.gov/diabetes/php/data-research/index.html>. Accessed on March 25, 2025.

³⁴ Witkowski et al. The Demise of Islet Allotransplantation in the US: A Call for an Urgent Regulatory Update The “ISLETS FOR US” Collaborative. *Am J Transplant*. 2021 Apr;21(4):1365–1375. doi: 10.1111/ajt.16397.

³⁵ Witkowski et al. The Demise of Islet Allotransplantation in the US: A Call for an Urgent Regulatory Update The “ISLETS FOR US”

Collaborative. *Am J Transplant*. 2021 Apr;21(4):1365–1375. doi: 10.1111/ajt.16397.

³⁶ Shapiro AMJ, Ricordi C, Hering BJ, et al. International Trial of the Edmonton Protocol for Islet Transplantation. *N Engl J Med*. 2006;355(13):1318–1330.

³⁷ Congressional Record- House, H8074, October 5, 2004.

³⁸ Congressional Record- House, H8074, October 5, 2004.

²⁸ Accessed October 17, 2023.

²⁹ QSO–24–04–[OPO], <https://www.cms.gov/files/document/qso-24-04-opo.pdf>.

research to which donor pancreata are supplied. This documentation, including information regarding approval from an institutional review board or other similar entity, as appropriate, would allow CMS to verify the existence of *bona fide* research activities conducted by a qualified researcher to advance scientific and healthcare knowledge and confirm that the research uses donor islet cells.

We continue to believe that pancreata used for islet cell research will have little effect on the rankings of OPOs when calculating the donation outcome measure because the volume of *bona fide* pancreatic islet cell research conducted by a qualified researcher, that is bench only research with no transplants, is limited nationwide. By nature of the status of the research field and the requirements needed to move this treatment from research to standard clinical practice, the overall impact of including these pancreata used for islet cell research to implement the requirements of PICTA 2004 is limited. As described in section III.J. of this proposed rule, we propose to require that OPOs maintain specific documentation regarding pancreata used for islet cell research. We intend to verify both the existence and accuracy of this documentation to assure that OPOs accurately code reported pancreata used for islet cell research when submitting data to the OPTN, thereby upholding the integrity of the donor outcome measure.

As set forth in the PICTA 2004, a pancreas must be “used for islet cell transplantation or research” to be subject to the requirement that it be counted for certification or re-certification purposes. We propose to continue to include the criterion that the pancreas be “used” for islet cell transplantation or research in the definition of “donor” at § 486.302. At the time PICTA 2004 was enacted, it was not possible to cryopreserve pancreatic islet cells for future use. However, such cryopreservation of pancreatic islet cells is now possible and must be considered when deciding what activities constitute “use” for purposes of implementing the statute. To ensure that OPOs can accurately code data when entering it into the OPTN system within five days of organ procurement, per the data standards set forth by the OPTN, we consider “use” for purposes of islet cell research to be the acceptance and either immediate use or cryopreservation of the pancreatic islet cells by a *bona fide* pancreatic islet cell research program to advance scientific and healthcare knowledge. We have partnered with

HRSA to implement enhanced OPO data reporting that more accurately conveys the disposition and use of pancreata, either for use in research that does not involve transplantation or in transplants of the pancreata or its islet cells to a patient on the OPTN waiting list. CMS uses data entered by OPOs into the OPTN data system in calculating the outcome measures.

Requiring research pancreata to be “used” for islet cell research to be included in the donation rate is consistent with how we treat other organs in the donation rate outcome measure. We only consider donors to be those for whom an organ was used for transplant. Procurement for transplant without an actual transplant is insufficient for inclusion in the donor outcome measure (see 84 FR 70631 and 85 FR 77903 for discussion of including only those organs that are used rather than procured with intent to use). Likewise, procurement of pancreata for islet cell research without actual use in that research is insufficient for inclusion in the donation rate outcome measure.

3. Organ

In the December 2020 final rule, we implemented the requirements of PICTA 2004 in the definition of “organ” in the OPO regulations at § 486.302, stating that an organ is “. . . a human kidney, liver, heart, lung, pancreas, or intestine (or multivisceral organs when transplanted at the same time as an intestine). The pancreas counts as an organ even if it is used for research or islet cell transplantation.” Although the term “organ” is used frequently throughout the regulations, it has a specific relationship to the “organ transplantation rate,” which is defined as the number of organs transplanted from donors in the DSA as a percentage of the donor potential. Organs that are transplanted into patients on the OPTN waiting list as part of research are explicitly included in the organ transplantation rate. The definition of the organ transplantation rate focuses entirely on transplant activities and the inclusion of bench research activities in this rate has created significant concern in the OPO and transplant communities. We agree with interested parties that including bench research within the definition of “organ” and by extension the “organ transplantation rate” has created a performance incentive that is not serving patients on transplant waitlists because the transplantation rate counts the use of a pancreas in islet cell bench research as being equivalent to a pancreas or pancreatic islet cell transplant. As such, the inclusion of pancreatic islet cell bench research in

the definition of “organ” has proven to be inconsistent with the goals of the 2020 rulemaking to increase the number of transplants in that OPOs may have used the placement of pancreata for islet cell research to mask their performance in successfully facilitating actual organ and pancreatic islet cell transplants. Therefore, we propose to revise the definition of the term “organ” in a way that would no longer include pancreata used for islet cell research, unless the research is islet cell transplantation that occurs under a research protocol.

While PICTA 2004 requires that pancreata used in islet cell research be counted for purposes of certification and re-certification, it does not require that these organs be included in all established OPO outcome measures. In the 2006 OPO final rule (71 FR 30982) that established the formerly used set of OPO outcome measures, one of the three yield measures counted pancreata used for islet cell research while a separate yield measure counted pancreata used for islet cell transplantation. Previous CMS policy differentiated the treatment of pancreatic islet cells based on their use for either transplantation or research, and we propose to reinstate that differentiation as it relates to current policy. Under our proposal, a pancreas that is used for islet cell research without a transplant to a patient on the OPTN waiting list would count towards the donation rate outcome measure, but would not be included in the transplantation rate outcome measure. A pancreatic islet allotransplant to a patient on the OPTN waiting list, on the other hand, would be included in both the transplantation rate outcome measure and the donation rate outcome measure, whether it is conducted under standard or research protocols.³⁹ This policy of only including pancreatic islet cell transplants in the transplant outcome measure advances the CMS goal of increasing the number of transplants in service of those patients on the OPTN transplant waiting list.

We are specifically soliciting comments on modifications to the proposed definitions of donor and organ, including any additional considerations that should be addressed in these definitions and alternative approaches to meeting the statutory

³⁹ In accordance with the regulations set forth at 42 CFR 413.406, Medicare only covers and pays for reasonable costs of acquisition of pancreata for islet cell transplants into Medicare beneficiaries participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial of islet cell transplantation in accordance with section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

requirements set forth by PICTA 2004. We are interested in information regarding data sources to verify data submitted regarding pancreatic islet cell research organs, alternative data sources for research organs that are independently verified and nationally available for the development of new outcome measures, and additional information that focuses on pancreata used for islet cell research and the statutory requirements for their counting in OPO certification and recertification.

4. Medically Complex Donors and Medically Complex Organs

Traditionally, some donors and their organs have been preferred over others, based on the age and health status of the donor, by transplant programs and surgeons. Organs from donors with less-preferred characteristics may be perceived as less valuable for organ transplantation or not appropriate for transplantation at all. To address these misconceptions, we are proposing to both define and utilize the terms “medically complex donors” and “medically complex organs.” Moreover, in the QAPI CfC set out at section § 486.348, we propose to require that OPOs must track procurement and placement of these organs, assess their policies and procedures regarding medically complex donors and organs, and ensure they are optimizing the recovery and placement of those organs for transplant.

Although we have not previously defined these less-preferred organs, the OPO CfCs have differentiated between organs from different types of donors. In the 2006 OPO final rule (71 FR 30982), we defined “eligible organs” as organs recovered from a donor that met the “eligible death” definition. Those donors had to be (1) 70 years old or younger, (2) declared dead by the hospital’s brain death criteria, and (3) patients who did not meet certain exclusionary criteria, which included, among other things, tuberculosis, human immunodeficiency virus (HIV), multiple-system organ failure, and certain cancers. These eligible deaths constituted the denominator for the donation rate outcome measure. Other organs, such as those recovered from donors over 70 years old or from donors who were declared dead by cardiac death criteria, were not “eligible organs.” Those donors and organs would however be counted and added to the outcome measures when the OPO obtained consent, and the organs were transplanted. In 2016, we modified the definition of “eligible death” to, among other things, include specific

exclusionary criteria for kidneys, livers, hearts, and lungs.⁴⁰ Effective in 2022, we removed the “eligible death” definition and now the donor potential that is the denominator for the outcome measures is based on the number of inpatient deaths of persons 75 and younger within the DSA with a primary cause of death that is consistent with organ donation (currently 42 CFR 486.318(d)(1)(iv)).⁴¹

As a result of these policies, some people in the organ transplant community may have considered those organs that did not meet the definition of “eligible organ” to be less valuable organs or did not consider transplanting them into their patients despite many individuals being on the waiting lists. These organs may have included organs from DCD donors, from donors older than 70 or 75, or from younger individuals with deteriorating health conditions.

Current research demonstrates that “medically complex organs” can produce positive and similar outcomes to other organs, and better outcomes than no transplant for patients. For example, recent research has demonstrated that kidneys recovered from DCD donors have similar long-term outcomes to organs from donors declared dead by brain death or neurological criteria (brain death donors), although some increases in complications related to graft function have been noted.⁴² Another example is donors who have a KDPI over 50 percent. Recent research has also demonstrated that transplant recipients who received these organs had a lower mortality rate, and an improved quality of life compared to patients who are on chronic renal dialysis.⁴³

In addition, we are concerned that OPOs are not actively pursuing “medically complex” donors and their organs because of a perception that such

organs may not be accepted by others in the transplant community, despite many individuals waiting on the transplant lists. Declining to use these organs, however, contributes to the chronic undersupply of transplantable organs, as well as potentially increasing mortality and decreasing quality of life for ESRD patients.

We believe that encouraging the pursuit of medically complex donors and organs when there is medical evidence that these organs can improve the quality of life or save the lives of more patients on the waiting list, by increasing the overall number of transplantable organs. The National Academies of Sciences, Engineering, and Medicine (NASEM) issued a report regarding the transplant ecosystem, “Realizing the Promise of Equity in the Organ Transplantation System” (NASEM 2022 organ transplant report).⁴⁴ The NASEM 2022 organ transplant report used the term “medically complex” to describe organs that were recovered from donors who had medical histories that deserved special considerations to identify the best recipient for that organ. The proposed definitions for “medically complex donor” and “medically complex organ” are primarily based upon the NASEM 2022 organ transplant report’s description of medically complex donors and organs. Medically complex donors would include DCD donors and those with elevated KDPI scores over 50 that require greater consideration in choosing a potential recipient due to the DCD donation process and possible kidney damage. Since DCD donors have not been declared dead by brain death criteria, OPOs need protocols that address at a minimum: how these potential donors should be evaluated; how life support would be withdrawn, and the relationship between the time of consent to donation and withdrawal of life support; the use of medications and interventions not related to withdrawal of support; family members’ involvement prior to organ recovery; and the criteria for declaration of death and the time period that must elapse prior to organ recovery (§ 486.344(f)). We also believe DCD donors need to be identified specifically because the number of recovered DCD organs has steadily increased over the last decade. In 2024, there were 7,280 DCD donors, which is an increase of 23.5 percent

⁴⁰ 81 FR 79562.

⁴¹ Organ Procurement Organizations Conditions for Coverage; Revisions to Outcome Measures Requirements for Organ Procurement Organizations (85 FR 77898).

⁴² Rijkse E, Ceuppens S, Qi H, IJzermans JNM, Hesselink DA, Minnee RC. Implementation of donation after circulatory death kidney transplantation can safely enlarge the donor pool: A systematic review and meta-analysis *Int J Surg*. 2021 August;92:106021. doi: 10.1016/j.ijsu.2021.106021. Epub 2021 Jul 10. Accessed at <https://pubmed.ncbi.nlm.nih.gov/34256169/>. Accessed on September 29, 2022. See also FN#2, Wall, et al.

⁴³ Tonelli M, Wiebe N, Knoll G, Bello A, Browne S, Jadhav D, Klarenbach S, and Gill J. Systematic Review: Kidney Transplantation Compared With Dialysis in Clinically Relevant Outcomes. <https://doi.org/10.1111/j.1600-6143.2011.03686.x>. Accessed at <https://onlinelibrary.wiley.com/doi/full/10.1111/j.1600-6143.2011.03686.x>. Accessed on September 29, 2022. See also FN#2, Wall, et al.

⁴⁴ NASEM. (2022). Accessed at <https://nap.nationalacademies.org/catalog/26364/realizing-the-promise-of-equity-in-the-organ-transplantation-system>. Accessed on May 10, 2022.

over 2023.⁴⁵ We also believe donors with elevated KDPI scores should be considered medically complex. We are proposing that the term medically complex donors include those with a KDPI score of 50 or greater. However, we are specifically soliciting comments on at what score should the KDPI be considered elevated so that the potential donor would be considered “medically complex” and may revise the proposed KDPI score threshold in the final rule in response to comments received.

Medically complex donors and organs also include donors that are HIV+ or have Hepatitis C. While HIV+ infection remains a serious illness, fewer individuals are dying from it and it is now considered a chronic disease.⁴⁶ In addition, transplants from an HIV+ donor to an HIV+ recipient must comply with the requirements set forth in the HIV Organ Policy Equity Act (HOPE Act), which includes complying with designated research protocols.⁴⁷ Hepatitis C can be an acute or chronic infection and, with treatment, most individuals can be cured.⁴⁸ While organs from donors that are HIV+ or have Hepatitis B or C can be successfully transplanted, these transplants require special or additional considerations in identifying the best potential recipient for these organs. For example, one study found that with appropriate consideration of both the DCD donor and the potential recipient, DCD liver transplants could have outcomes that were both acceptable and comparable to outcomes for non-DCD liver transplants. The considerations included but were not limited to cold and warm ischemic times, and comorbidities of the donor and the potential recipient, such as age, obesity, and “Model for End-Stage Liver

Disease” (MELD) scores, which estimates the severity of the donor’s liver disease.⁴⁹

Hence, medically complex organs can be successfully transplanted and enhance and even prolong patients’ lives; however, they have not been fully utilized. To encourage the use of these organs, we are proposing to define the term “medically complex donor” in § 486.302 as a donor whose medical history requires special or additional considerations to identify the best recipient for the organs. These donors would include all DCD donors and donors with elevated KDPI scores of 50 or more. We also propose to define the term “medically complex organ” as an organ procured from a “medically complex donor”.

We believe that defining “medically complex organs” and “medically complex donors” and including these organs and donors in OPOs’ QAPI programs could result in more of these organs being procured and increase the number of transplantable organs for patients on the various waiting lists. However, we are also concerned that there could be unintended consequences resulting from this proposal. For example, could this requirement put unreasonable pressure on OPOs to procure medically complex organs? Thus, we are specifically soliciting comments on modifications to the proposed definitions of “medically complex donor” and “medically complex organ”, including any specific criteria that should be added. We are also specifically soliciting comments on how to define an “elevated KDPI”. Is 50 or more appropriate? If not, what KDPI score should be used? Also, are there any unforeseen consequences to this proposal?

5. Unsound Medical Practices

In the 2006 final rule, CMS finalized § 486.312(b), which states CMS may terminate an OPO’s agreement immediately in cases of urgent need, such as the discovery of unsound medical practices. In addition, we finalized a definition for “urgent need” in § 486.302. Urgent need occurs when an OPO’s noncompliance with one or more conditions for coverage has caused, or is likely to cause, serious injury, harm, impairment, or death to a potential or actual organ donor or an

organ recipient. While we referenced “unsound medical practices” as grounds for immediate termination, the OPO CfCs do not currently include a definition for “unsound medical practices”.

Through feedback we have received, we recognize the need to clearly define what constitutes “unsound medical practices”. Therefore, we propose at § 486.302, to add a definition for “unsound medical practices”. We propose that the term “unsound medical practices” would refer to failures by OPOs that create an imminent threat to patient health and safety or pose a risk to patients or the public. These practices include, but are not limited to, failures in governance; patient or potential donor evaluation and management; and procurement, allocation, and transport practices and procedures. Some examples of unsound medical practices include, but are not limited to, failure to ensure the potential donor is declared dead according to applicable State law and hospital policies; negligent or deliberate failure to perform necessary and customary tests to determine whether a potential donor meets exclusionary criteria, such as certain malignancies or active infections; and pursuing patients with inappropriately high neurologic function as potential donors. Our intent is to ensure that instances of actions that constitute unsound medical practices are addressed appropriately and that OPOs continue to provide high quality care to patients, potential donors and potential transplant recipients. We solicit public comment on the proposed definition of “unsound medical practices”.

B. Requirements for Certification (§ 486.303)

Section 486.303(e) requires that to be “certified as a qualified organ procurement organization,” an organization must have “been re-certified as an OPO under the Medicare program from January 1, 2002 through December 31, 2005.” The Certification Act amended the PHS Act to add subparagraph (D) to section 371(b)(1), which defines a qualified OPO as an organization that “has met the other requirements of this section and has been certified or recertified by the Secretary within the previous 4-year period as meeting the performance standards to be a qualified organ procurement organization through a process” defined in regulations.⁵⁰ Section 371(b) of the PHS Act sets forth requirements that an OPO must meet to be certified. These requirements are also

⁴⁵ Organ transplants exceeded 48,000 in 2024; a 33 percent increase for the transplants performed in 2023. OPTN. Jan 14, 2025. Accessed at <https://www.hrsa.gov/optn/news-events/news/organ-transplants-exceeded-48000-2024-33-percent-increase-transplants-performed-2023>. Accessed on August 25, 2025.

⁴⁶ Deeks SG, Lewin SR, Havlir DV. The end of AIDS: HIV infection as a chronic disease. *Lancet*. 2013 Nov 2;382(9903):1525–33. doi: 10.1016/S0140-6736(13)61809-7. Epub 2013 Oct 23. PMID: 24152939; PMCID: PMC4058441. Accessed on January 24, 2024.

⁴⁷ Public Law 113–51 (2013); Final Human Immunodeficiency Virus (HIV) Organ Policy Equity (HOPE) Act Safeguards and Research Criteria for Transplantation of Organs Infected With HIV. A Notice by the National Institutes of Health on November 25, 2015 *Federal Register*/Vol. 80, No. 227/Wednesday, November 25, 2015/Notices 73785 <https://www.federalregister.gov/documents/2015/11/25>.

⁴⁸ CDC. Hepatitis C. Accessed at <https://www.cdc.gov/hepatitis-c/about/index.html> <https://www.cdc.gov/hepatitis/hcv/index.htm>. Reviewed October 31, 2023. Accessed on January 24, 2024.

⁴⁹ Haque, O, Yuan, Q, Uygun, K, and Markmann, JF. Evolving utilization of donation after circulatory death livers in liver transplantation: the day of DCD has come. *Clinical Transplantation*. 2021;35:e14211. <https://doi.org/10.1111/ctr.14211>. Accessed at <https://onlinelibrary.wiley.com/doi/pdf/10.1111%2Fctr.14211>. Accessed on September 21, 2015.

⁵⁰ 42 U.S.C. 273(b)(1)(D).

set forth in our regulations at § 486.303. Once certified, section 371(b)(1)(D)(ii)(I) of the PHS Act requires that OPOs must be re-certified not more frequently than once every 4 years.

After the Certification Act was passed, CMS proposed to remove language from our regulations that referred to new entities or organizations becoming OPOs.⁵¹ We explained that “given the provision in (b)(1)(D) added by the OPO Certification Act . . . it appears impossible for the Secretary to give a grant to an organization that was not one of the 59 OPOs that was certified by the Secretary as meeting the performance standards in the 4-year period before January 1, 2000.”⁵² We also proposed adding § 486.303(e), requiring that OPOs have been re-certified as an OPO under the Medicare program from January 1, 2002 through December 31, 2005.⁵³ When finalizing the proposal, we reiterated that “we currently do not have the authority to permit new entities to take over part or all of an OPO’s service area,” which “would be possible only if the Congress enacts legislation to change the requirement in the PHS Act because currently to be re-certified, an OPO must have been certified as of January 1, 2000.”⁵⁴ We have since repeated this interpretation.⁵⁵

However, upon further review, we no longer believe that the Certification Act is best read to require all qualified OPOs to have been previously certified as of January 1, 2000. Instead, it is better read to mean that whenever the agency initially certifies or recertifies that an OPO meets the Secretary’s performance standards within a 4-year period, OPOs must demonstrate at the end of that period that they still meet the agency’s performance standards. Section 371(b)(1)(D)(ii) of the PHS Act specifically provides that a qualified OPO may be “certified or recertified” through “a process” that is “defined through regulations . . . promulgated by the Secretary.” There is no language in that provision requiring that an OPO show it was certified as of January 1, 2000 as part of those standards. In fact, the statute requires the Secretary to “use multiple outcome measures as part of the certification process.”⁵⁶ That the statute contemplates creation of a *certification* process indicates that the Secretary is not limited to *recertifying* OPOs. Thus, nothing in the text of the

statute supports reading it to strip the Secretary of his authority to certify either an entirely new OPO or one that was previously decertified.

This interpretation of the Certification Act is reinforced by the statutory history. The prefatory language in section 371(b)(1)(D) of the PHS Act is drawn from section 1138(b)(1)(A) of the Social Security Act. The main change Congress made was to swap out a reference to a qualified OPO needing to have been certified or recertified “within the previous 2 years” to a reference to a qualified OPO needing to have been certified or recertified “within the previous 4-year period.” Congress made legislative findings explaining that this change requires the agency “to extend the period for recertifications of an organ procurement organization from 2 years to 4 years.”⁵⁷ This use of familiar statutory language with a single targeted change that Congress explained does not indicate that Congress meant also to silently restructure the OPO market by prohibiting all new entrants.

We acknowledge that this is a change in our understanding of the Certification Act. Executive Order 14219 directs Federal agencies to review existing regulations for potential candidates for rescission, prioritizing those that can no longer be justified under several recent decisions of the U.S. Supreme Court, including *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024). In *Loper Bright*, the Court explained that statutes have a “single, best meaning” that agencies must follow. Because we believe this is the best reading of the statute, it is consistent with the rationale of *Loper Bright* to adopt it. Additionally, OPOs were able to operate even with new entrants before 2000, and we have confidence they will be able to do so in the future. We have not previously cited independent policy reasons that would justify exercising our express authority to promulgate performance standards to include a requirement that OPOs have been re-certified as an OPO under the Medicare program from January 1, 2002 through December 31, 2005. By contrast, we believe that removing this requirement would address concerns about market consolidation by creating a more diverse and robust market that enhances competition among OPOs. This proposal could also introduce innovation from new entities and increase the number of organs available for transplant.

Therefore, to align with our reinterpretation of the Certification Act

and the directive in Executive Order 14219 to remove regulatory requirements that can no longer be justified in light of *Loper Bright*, we are proposing to remove § 486.303(e). We acknowledge that our prior rule removed references to newly certified OPOs and we are not, at this time, proposing to reinstate those references or to otherwise provide for the certification of new OPOs. However, we anticipate addressing the certification of new OPOs in the near term and are soliciting public comments on factors CMS should consider when certifying new OPOs. We specifically request public comments related to:

- The specific elements of the existing OPO regulations that an entity should be required to meet in order to become a newly certified OPO;
- The outcome and process performance measures organizations seeking certification should meet. What empirical evidence of organ donor potential and other related factors should be considered?
- Other criteria for evaluating the suitability of a potential new OPO to serve an open DSA;
- The process by which a newly certified OPO might obtain designation to a DSA.

++ Should newly certified OPOs be given priority for designation to open DSAs, compete against existing OPOs in open competition, or only compete in competitions against other newly certified OPOs?

++ If newly certified OPOs compete against currently certified OPOs, should the competition selection criteria be revised? If so, what factors should be considered for selection criteria given the lack of historical outcome and process performance data for new OPOs?

We would particularly appreciate comments that identify which specific provisions commenters would recommend we consider changing, and what specific changes commenters would recommend.

C. Designation of One OPO for Each Service Area (§ 486.308)

We propose to revise requirements at § 486.308 to further address changes made in the December 2020 final rule related to when a DSA is open for competition. Additionally, we intend to clarify how an OPO is assigned to a DSA and how we determine the OPO designation period. As described in section II.A. of this proposed rule, a DSA is a donation service area, and each OPO is currently designated to a DSA for organ procurement activities.

⁵¹ 70 FR 6091.

⁵² 70 FR 6091.

⁵³ 70 FR 6090.

⁵⁴ 71 FR 30998.

⁵⁵ 85 FR 77898.

⁵⁶ 42 U.S.C. 273(b)(1)(D)(ii)(III) (emphasis added).

⁵⁷ Public Law 106–505 § 701(b)(5), 144 Stat. at 2347.

There are OPO-specific qualifications, processes, and timeframes found in the requirements at section 371(b) of the PHS Act and section 1138 of the Act. Section 371(b) of the PHS Act and § 486.303 list the requirements that an OPO must meet to be certified. Once certified, section 371(b)(1)(D)(ii)(I) of the PHS Act requires that OPOs must be re-certified not more frequently than once every 4 years. The re-certification cycle, defined at § 486.302, is the 4-year cycle during which an OPO is certified.

Only a certified OPO may be designated to a DSA. Once an OPO is designated for a DSA, certain organ procurement costs are eligible for Medicare and Medicaid payment under section 1138(b)(1)(F) of the Act. OPOs sign an agreement with CMS called a Health Insurance Benefits Agreement, Form CMS-576A, to provide services for the duration of an “agreement cycle”, defined at § 486.302 as “the time period of at least 4 years when an agreement is in effect between CMS and an OPO”. OPOs must periodically submit a Request for Designation as an OPO under section 1138 of the Act, Form CMS-576, and supporting documentation for a specific DSA. This is normally conducted during the re-certification process.

CMS evaluates OPOs periodically to ensure that the organizations continue to meet the requirements for certification. As referenced previously, under section 371(b)(1)(D)(ii)(I) of the PHS Act, re-certifications of qualified OPOs must not be more frequent than once every 4 years. In most cases, near the end of the agreement cycle there is a re-certification survey to ensure that the OPO continues to comply with statutory and regulatory requirements for certification. Surveys may also be conducted at other times to investigate complaints and allegations of non-compliance with the CfCs. Surveys are conducted by CMS staff from the various CMS locations and Federal contract surveyors. Currently, the agreement cycle for the designation period is 4 years and 6 months in duration and is reflected on the Form CMS-576A (CMS-R-13; OMB No. 0938-0512) that the OPO signs. The additional 6 months between the end of the re-certification cycle and the end of the agreement cycle provides time for an OPO to appeal a de-certification determination to the agency on substantive or procedural grounds and to enable the agency to select a successor OPO if necessary. The current re-certification cycle began on August 1, 2022, and will end on July 31, 2026. However, the current OPO agreement

cycle began on August 1, 2022, and is scheduled to end on January 31, 2027.

To implement changes for OPO DSA designation and competition, we propose to revise § 486.308(a) and (b). Currently, § 486.308(a) states that, “CMS designates only one OPO per service area. A service area is open for competition when the OPO for the service area is de-certified and all administrative appeals under § 486.314 are exhausted.” We propose to relocate and revise the information pertaining to designation and relocate requirements for competition. Specifically, we propose to add introductory text (referred to as condition statement of the CfC) at § 486.308 to clarify that CMS designates only one OPO to a DSA. We will not designate multiple OPOs for one DSA, consistent with section 1138(b)(2) of the Act, but we may designate a single OPO for more than one DSA as discussed in sections III.D. of this proposed rule. We also propose to relocate the requirement that re-certification must occur not more frequently than once every 4 years from § 486.308(b)(2) to the introductory text at § 486.308 without change as part of the reorganization of these requirements.

We propose to revise the current requirements at § 486.308(b)(1) to address designation periods and relocate the requirements to proposed § 486.308(a). The current requirements indicate that “[a]n OPO is normally designated for a 4-year agreement cycle. The period may be shorter, for example, if an OPO has voluntarily terminated its agreement with CMS and CMS selects a successor OPO for the balance of the 4-year agreement cycle. In rare situations, a designation period may be longer, for example, a designation may be extended if additional time is needed to select a successor OPO to replace an OPO that has been de-certified.” We propose to redesignate and revise the requirements related to the length of designation periods from § 486.308(b)(1) to proposed § 486.308(a) to clarify that the planned duration of the designation period is at least 4 years for renewal of an OPO agreement.

We propose, at revised § 486.308(a)(1), to retain the flexibility to shorten or extend the agreement cycle in certain limited circumstances. However, we are proposing to clarify this provision by identifying involuntary termination, in addition to voluntary termination of an OPO’s contract with CMS as the two circumstances under which an OPO’s designation period may be shortened. A voluntary termination occurs when an OPO requests to voluntarily terminate

its agreement with CMS. An involuntary termination that would shorten a designation period occurs when an OPO is de-certified due to non-compliance with CMS requirements, as specified at proposed § 486.312(a)(1) or (a)(4). In the event of non-compliance with the process performance measures (§§ 486.320 through 486.360), an OPO would normally be afforded the opportunity to submit a plan of correction to remedy non-compliance within a specific period of time. If the plan of correction is acceptable, involuntary termination would be averted provided the plan was successfully implemented by the OPO resulting in correction of noncompliance and verified by CMS. (See 42 CFR 488, subpart A). We propose at new § 486.308(a)(1) that CMS may adjust the length of a designation period when (i) there is a voluntary termination of an OPO’s agreement with CMS, (ii) there is an involuntary termination of an OPO’s agreement with CMS, (iii) additional time is needed to complete an appeal, conduct a competition, select a successor OPO, or transition the DSA to a successor OPO, or (iv) there is an extension of the agreement cycle for extraordinary circumstances as specified at § 486.316(f). At paragraph (a)(2) we propose that CMS would conduct a competition for all vacated DSAs.

We also propose at new § 486.308(a)(3) that the designation period for any newly acquired DSA following a competition, or as the result of being assigned a DSA as specified at § 486.316(e), will be the remaining portion of the agreement for the OPO’s current re-certification cycle. For instance, if an OPO is designated to a new DSA following a competition in 2027, it would be designated for the remainder of the original OPO’s re-certification cycle that would be anticipated to end in 2030. The successor OPO would fulfill the remaining portion of this re-certification cycle. We propose at § 486.308(a)(4) that if an OPO does not fulfill the term of its agreement, whether voluntarily or involuntarily, and there is insufficient time to conduct a competition to select a successor OPO for its DSA, we may designate another OPO, without a competition. We would exercise this option only if there were concern for continuity of organ donation in the DSA in situations such as a termination for urgent need, a cessation of business, or because the incumbent OPO was unable to sustain services to provide an orderly transition to a successor OPO. In selecting an OPO under these

circumstances, we would consider the following factors: contiguity to the DSA, performance on outcome measures at § 486.318, history of compliance with the process performance measures at §§ 486.320 through 486.360, and willingness of the OPO to perform the responsibilities.. We solicit public comment on these factors, how these factors should be weighed in making a decision, and whether other factors should be considered in this situation.

The December 2020 final rule was limited in scope and focused on revisions to the outcome measures at § 486.318, leaving certain operational aspects to be revised through additional rulemaking. Given the tiered system for re-certification that was implemented in that rule, we are now clarifying when a DSA is open for competition and how competition affects designation. Currently, § 486.308(a) states that a service area is open for competition when the OPO for the DSA is de-certified and all administrative appeals at § 486.314 are exhausted. We propose to relocate this language to § 486.308(b) and amend it to conform with requirements for competition at § 486.316 and outcome measures at § 486.318.

We propose to address all instances when a DSA is open for competition.

- We propose to amend § 486.308(b)(1) to reflect that a DSA becomes open for competition when an OPO's DSA is assigned tier 3 status in the final assessment period and all administrative appeals are exhausted. An OPO's DSA is assigned tier 3 status if it has outcome measures currently described at § 486.318(e)(6) (tier 3), redesignated as proposed § 486.318(b)(6), and § 486.316(a)(3).

- We also propose conforming changes at § 486.308(b)(2) to clarify that an OPO's DSA is open for competition when the DSA is assigned to tier 2 for the outcome measures in the final assessment period, as currently described at § 486.318(e)(5), proposed to be redesignated to § 486.318(b)(5), and § 486.316(a)(2).

- We propose to add § 486.308(b)(3), stating that an OPO's DSAs are open for competition when the OPO is not in compliance with the process performance measures at §§ 486.320 through 486.360, as specified at § 486.312(a)(1) and § 486.316(b)(1), all administrative appeals are exhausted, and the OPO is pending de-certification.

- Finally, we propose at new § 486.308(b)(4) that a DSA would be open for competition when an OPO requests to voluntarily terminate its agreement to participate as specified in § 486.312(a), redesignated as proposed

§ 486.311(a)(2). However, this provision would not apply to a voluntary termination associated with an OPO's change in control or ownership or service area as specified at § 486.310, in which case the OPO is voluntarily terminating its agreement to participate in a merger with another OPO.

We solicit public comment on these proposed changes and ways to provide clarity to the designation and competition process.

D. Designation of an OPO to More Than One Service Area (§ 486.309)

We propose to remove obsolete requirements at § 486.309 and add new requirements to address situations if an OPO is responsible for more than one DSA. The current requirements at § 486.309 addressed the re-certification from August 1, 2006, through July 31, 2010 indicating that an OPO would be considered to be re-certified for the period of August 1, 2006 through July 31, 2010 if an OPO met the standards to be a qualified OPO within a 4-year period ending December 31, 2001 and has an agreement with the Secretary that is scheduled to terminate on July 31, 2006. Since this time period has passed, these requirements are now obsolete.

Since the December 2020 final rule was issued, some OPOs have requested guidance on how an OPO could manage more than one DSA. Section 1138(b)(2) of the Act provides that the Secretary may not designate more than one OPO for each service area and the current OPO CfCs only address one OPO being designated to only one DSA. Given that OPOs have expressed interest in this area and the statute does not explicitly restrict this situation, we are proposing requirements to address one OPO being designated to more than one DSA. Currently, there is a limited market in regard to the number of OPOs and DSAs, with 55 OPOs in total, each serving a single DSA (55 in total). Therefore, permitting an OPO to separately maintain multiple DSAs could maintain some level of market diversity to support future competition. This proposal would also mitigate risk of geographic consolidation when OPOs maintain separate DSAs rather than merging DSAs into one service area. Finally, some OPOs have expressed concern for assuming responsibility for DSAs where other OPOs have historically underperformed and merging those areas with their existing DSA. These OPOs have indicated they would prefer to manage DSAs separately to ensure they could improve performance without risk to their existing DSA.

We are proposing that an OPO may be responsible for more than one DSA when a new DSA is added following a change in control, ownership, or service area as specified at § 486.310, as result of a competition as specified at § 486.316, or following a voluntary or involuntary termination of an OPO's agreement as specified at § 486.311(a)(2) or § 486.312(a) respectively, or there is insufficient time to conduct a competition as specified at proposed § 486.308(a)(4). In these instances described previously, the OPO would need to determine how best to manage its organization for the respective areas. Some OPOs may find it beneficial to merge all assigned DSAs into a single DSA; however, other OPOs may not want to merge a new DSA into an existing DSA and may find it beneficial to maintain a separate designation for each DSA. We propose to revise § 486.309 to give OPOs more flexibility to address this situation. We are considering alternative policies on how an OPO could manage more than one DSA, which are discussed in detail in section VII.C. of this proposed rule.

Section 1138(b)(1)(C) of the Act permits the Secretary to provide payment with respect to organ procurement costs attributed to an organ procurement agency only if the agency meets performance-related standards prescribed by the Secretary. Additionally, section 371(b) of the PHS Act requires the Secretary to utilize outcome and process performance measures for the process of certification and re-certification of OPOs based on empirical evidence of organ donor potential and other related factors in each service area of qualified OPOs. Since OPOs have historically only been designated to one DSA, these requirements have not yet been applied to an OPO that is designated to more than one DSA. We propose to clarify application of both the outcome and process performance measures when an OPO may be designated to multiple DSAs. Our existing regulations require that OPOs must meet the minimum standards for both outcome measures at § 486.318 and the process performance measures at §§ 486.320 through 486.360 (see § 486.303(h)). The process measures are the broad operational requirements for OPOs and include items such as administration and governance, donor management, organ preparation and transport, and QAPI. An OPO found out of compliance with a process performance measure is subject to being de-certified at any time (§ 486.312(b)) but may be able to resolve the non-compliance within prescribed

timeframes (see generally § 488.28 and State Operations Manual (SOM), CMS Pub. 100–07, Chapter 2, Section 2728).⁵⁸

OPOs must meet outcome measures for re-certification and payment purposes. To meet the outcome measures, an OPO is evaluated by measuring the donation rate and the transplantation rate in their DSA. In general, the outcome measures are assessed annually based on calendar year data and the final assessment period is used for re-certification (§ 486.302 (definition of “Assessment Period”).

We are proposing that when an OPO consolidates multiple DSAs, regardless of contiguity, into a single DSA we would assess the OPO’s performance on the outcome measures as a single DSA. The outcome measures for that merged DSA, however, would be used for any future assessment periods, including the final assessment, and potential disparate performance between the former two separate DSAs would not be reflected in the outcome measure data for the consolidated DSA. At the final assessment period, if the OPO could not satisfy the outcome measures for the merged DSA, the OPO would be de-certified (subject to the available appeal rights).

An OPO with one DSA faces de-certification if it is non-compliant with any of the CfCs, including the process performance measures (§§ 486.320 through 486.360) or the outcome measures (§ 486.318) at the time of re-certification. However, our proposed approach would permit an OPO that obtains a new additional DSA to choose to maintain separate DSAs, rather than consolidating its new DSA with its existing DSA. While the OPO would still be required to meet the process performance measures in the conditions for coverage for all of its DSAs to avoid de-certification, we propose that we would consider the OPO’s performance on the outcome measures separately for each DSA when the OPO chooses to maintain separate DSAs. This would enable the OPO to meet the outcome measures in one DSA, even if the OPO did not satisfy the outcome measures in a separate DSA at the time of re-certification. If at the time of re-certification an OPO met the outcome measures at § 486.318 for one of its DSAs (tier 1 as specified at § 486.318(e)(4), proposed to be redesignated as § 486.318(b)(4) or tier 2 as specified at § 486.318(e)(5), proposed to be redesignated as § 486.318(b)(5))

and did not meet the outcome measures for another of its DSAs (tier 3 as specified at § 486.318(e)(6), proposed to be redesignated as § 486.318(b)(6)), CMS would remove designation for the DSA in which the OPO has tier 3 performance, and the DSA would be opened for competition. The OPO would be able to appeal the decision to remove the designation prior to the competition due to its failure to meet the outcome measures in that DSA. In this instance, the OPO would not be given a notice of de-certification as specified in proposed § 486.312(b) and would instead receive a notice of removal of designation to a DSA without de-certification (proposed § 486.314(a)(2)). If all of an OPO’s DSAs have tier 3 performance, the OPO fails to meet the performance standards to be a qualified OPO and would be sent a notice of an initial de-certification determination as specified at proposed §§ 486.312(b), 486.314(a)(1), and 486.316(b)(2)(iii)(A). The OPO would have the opportunity to appeal the de-certification determination. If the CMS determination is upheld on appeal, the OPO would be de-certified and all of its DSAs opened for competition. De-certification is discussed in detail in section III.E. and appeals are discussed in section III.F. of this proposed rule.

To give OPOs this additional flexibility to maintain separate DSAs, we propose to add a new requirement for OPO designation of more than one DSA at § 486.309 to replace the current requirements. First, we propose a new section heading at § 486.309 for OPO designation to more than one service area. Second, at § 486.309(a), we propose three circumstances for which an OPO may be designated to more than one DSA. Such circumstances include a change in control, ownership or service area as specified at § 486.310 (proposed paragraph (a)(1)); following a competition as specified at § 486.316 (proposed paragraph (a)(2)); or following a voluntary or involuntary termination of an OPO’s agreement with CMS, when a new OPO was assigned to the DSA and there was insufficient time to conduct a competition as specified at § 486.308(a)(4) (proposed paragraph (a)(3)). Third, we propose at § 486.309(b), that when requirements of paragraphs (a)(1) or (a)(2) of proposed § 486.309 are met after a change in ownership, control or service area or competition, the OPO may choose to consolidate the DSAs, maintain separate DSAs, or a combination thereof if more than two DSAs are involved. If we were to assign an OPO to a DSA after a voluntary or involuntary termination, as

proposed at § 486.309(a)(3), we would not permit the DSA to be consolidated to facilitate future competition for that DSA and would open that DSA for competition at the end of the designation period. Designation of an OPO to a DSA in this situation would be a temporary measure intended to maintain organ procurement services to provide time to facilitate an orderly transition of the DSA to a successor OPO following a competition.

We propose, at § 486.309(c), that when an OPO is designated to more than one DSA, CMS would remove designation to a tier 3 DSA in the event of non-compliance with the outcome measures for that DSA at the end of the re-certification cycle (that is, donation or organ transplantation rates are below the median threshold rates established), as specified at proposed § 486.316(a)(3) and § 486.318(e)(6), proposed to be redesignated as § 486.318(b)(6). At paragraph (c)(1), we propose that removal of designation will not result in de-certification until an OPO is no longer designated to any DSA due to tier 3 outcome measure performance in all of its DSAs, as specified at § 486.316(b)(2)(iii)(A). We also propose at paragraph (c)(2) that an OPO may appeal the decision to remove its designation to a tier 3 DSA as specified at § 486.314 and that the DSA will be opened to competition after all appeals are exhausted for that DSA. We request public comment on these proposed changes in § 486.309, including additional factors that OPOs may want to consider related to consolidating DSAs versus keeping them separate as well as alternative policy approaches to address a single OPO being designated to more than one DSA.

We note that the OPO Life Alliance Organ Recovery Agency (LAORA)’s DSA was opened for competition with the application deadline closing on December 8, 2025, as a result of the OPO’s pending de-certification. In the competition announcement, CMS indicated that the successor OPO to this DSA would be required to maintain the DSA separately from their existing DSA. We note this agency decision was based on both the long history of underperformance in this DSA and CMS’ desire to carefully monitor the changes after the successor OPO assumes responsibility for the DSA. This has prompted the consideration of alternative policies regarding the process for when an OPO manages more than one DSA, which are discussed in detail in section VII.C. of this proposed rule.

We seek to provide sufficient flexibility to OPOs so that they can

⁵⁸ <https://www.cms.gov/regulations-and-guidance/manuals/downloads/som107c02.pdf>.

determine how to best tailor their operations for maximum benefit to improve organ procurement within existing statutory and regulatory requirements. As previously stated, some OPOs may determine it to be beneficial to consolidate DSAs while others may determine that maintaining separate DSAs is advantageous. We believe the factors considered in this decision can be wide ranging and include items such as contiguity of DSAs, existing size of DSAs, geographic characteristics, population factors, DSA healthcare infrastructure and networks, leadership preferences, and financial considerations, among others. We seek public comment on the factors OPOs believe to be most important in making decisions related to DSA management and the benefits of DSA consolidation versus DSAs being managed separately. Additionally, we seek public comment on alternatives being considered as discussed in Section VII.C. of this proposed rule.

E. Non-Renewal of Agreement (§ 486.311) and De-Certification (§ 486.312)

To address the implementation of the tier system for re-certification of OPOs, we propose to establish a new CfC at § 486.311 for non-renewal of an OPO agreement. Additionally, we propose to revise § 486.312 to address enforcement actions that may result in de-certification of an OPO.

In the December 2020 final rule, we finalized a new tier designation process for re-certification of OPOs. OPOs are designated to DSAs that are assigned as either tier 1, tier 2, or tier 3 based upon their performance on the outcome measures set forth in § 486.318 and their re-certification survey. This tiered system for re-certification and competition became effective on March 30, 2021, and is currently being implemented during the 2022 through 2026 re-certification cycle that began on August 1, 2022, and is scheduled to end on July 31, 2026. OPOs with DSAs that are in tier 3 during the final assessment period in the re-certification cycle will be decertified, pending appeals. OPOs with DSAs that are in tier 2 during the final assessment period in the re-certification cycle will be required to compete to retain their DSA, but they may also compete for any other DSA that is open for competition. An important distinction between tier 3 DSAs and tier 2 DSAs is that only tier 3 DSAs reflect that the OPO is out of compliance with the outcome measures for that DSA. Therefore, an OPO with all of its DSAs in tier 3 may be de-certified. Alternatively, an OPO with a tier 2 DSA

is in compliance with the outcome measures for that DSA, and provided it is also in compliance the process performance measures, is re-certified as meeting the performance standards to be a qualified OPO and will have its agreement renewed provided it is successful in a competition for that or another open DSA.

The competition process means there is a possibility that an OPO with a tier 2 DSA would not be successful in the competition to retain its DSA. If the OPO is not designated for its DSA (and it did not win a competition for any other open DSA), the OPO would no longer be designated as an OPO at the end of the current agreement.

The current requirements for non-renewal of an agreement are located at § 486.312(c) and state that “CMS will not voluntarily renew its agreement with an OPO if the OPO fails to meet the requirements for certification at § 486.318, based on findings from the most recent re-certification cycle, or the other requirements for certification at § 486.303. CMS will de-certify the OPO as of the ending date of the agreement.” This requirement does not address the differences between tier 2 and tier 3, which is that an OPO with one or more tier 2 DSAs, while in compliance with the outcome measures in those DSAs, is not de-certified but will not be offered a new agreement if it does not retain any of its DSAs or successfully compete for an open DSA; whereas OPOs with tier 3 DSAs are out of compliance with the outcome measures in those DSAs, potentially resulting in de-certification. To address this issue, we propose a new CfC at § 486.311, non-renewal of agreement.

We propose, at § 486.311(a)(1), to address non-renewal for OPOs with tier 2 DSAs that are unsuccessful in competition. We propose that CMS will not renew an agreement with an OPO if the OPO is subject to a competition (as set forth at § 486.316(a)(2)), the OPO is unsuccessful in the competition, and the OPO is no longer designated to any DSA. The OPO would not be afforded appeal rights for loss of a competition, consistent with our long-standing policy, as described in the 2006 final rule. (see 71 FR 30998). In the 2006 final rule, we stated, “The statute requires only that we provide the opportunity to appeal a de-certification. An appeals process following a competition would be both expensive and unwieldy. We believe it would increase uncertainty for the OPO that prevailed in the competition and that this may disrupt the new OPO’s ability to increase organ donation in the service area”. We also stated that “our competition decision is

final” (71 FR 30998). This position is based on our intent to be able to choose the OPO most likely to increase organ donation and best serve the interests of all impacted by the actions and outcomes of the OPO. OPOs do not have an intrinsic right to be awarded a DSA following a competition and CMS may select the OPO most appropriate for that DSA.

In our proposed approach, an OPO with tier 2 DSAs that fails to retain any of its DSAs in competition would not be de-certified and could secure another agreement if it were successful in a concurrent or subsequent competition for another DSA, assigned a DSA by CMS (see § 486.316(e)), or selected for an open DSA under proposed § 486.308(a)(4). Since the OPO is compliant with the CfCs, it would be re-certified without being designated to a DSA. This would permit the OPO to compete in any additional open competitions during the following 4-year re-certification period. If the OPO is successful in a competition, assigned a DSA by CMS under § 486.316(e), or selected for an open DSA under § 486.308(a)(4), it could then be designated to a DSA during this period. If the OPO does not obtain a new DSA through competition, assignment under § 486.316(e), or selection under proposed § 486.308(a)(4) by the end of the re-certification cycle following the non-renewal of the OPO’s agreement, it would not meet outcome measure standards for that cycle.

Consequently, the OPO would be de-certified at that time in accordance with the requirements at proposed § 486.312(a)(3). The OPO would be afforded appeal rights for the de-certification in accordance with the requirements at § 486.314. For instance, during the anticipated 2026 re-certification cycle, an OPO with a single tier 2 DSA that did not win any competition would be re-certified for the duration of the next recertification cycle that would extend to 2030. However, the OPO would not be designated to a DSA unless it was successful in subsequent competition or assigned a new DSA by CMS prior to the end of the re-certification cycle in 2030. Therefore, if the OPO was not designated to any DSA at the end of the re-certification cycle in 2030, it would be de-certified at that time.

We propose at § 486.311(b) that we would provide notification to the OPO at least 90 days before the effective date of the non-renewal and that the notice would state the reasons for non-renewal and include the end date of the agreement.

We also propose, at § 486.311(a)(2), that non-renewal of an agreement (currently at § 486.312(c)) would include a voluntary termination of an agreement by an OPO. The current requirement for voluntary termination of an agreement is located at § 486.312(a). If an OPO wishes to terminate its agreement with CMS, it must send written notice of its intention to terminate and the proposed effective date. Currently, we may approve the proposed date, set a different date no later than 6 months after the proposed effective date, or set a date less than 6 months after the proposed effective date if we determine that a different date would not disrupt services to the service area. Additionally, if we determine that a designated OPO has ceased to furnish organ procurement services to its service area, the cessation of services is deemed to constitute a voluntary termination by the OPO. The current rule states that we will de-certify the OPO as of the effective date of the voluntary termination. We propose to relocate and revise the voluntary termination of agreement provision from § 486.312(a) to § 486.311(a)(2) and remove the requirement that we would de-certify the OPO. An OPO voluntarily withdrawing from its agreement or ceasing to furnish organ procurement services has taken an affirmative step to end its duties under the OPO agreement, but that action does not entitle the OPO to appeal a de-certification on substantive or procedural grounds. As such, the voluntarily withdrawing OPO would not be afforded appeal rights. The OPO would no longer have an agreement, and would no longer be designated to any DSAs, as of the effective date determined by CMS. We note that in Section III.C. of this proposed rule, we provide an alternative considered related to voluntary withdrawal. In this section, we consider an alternative approach of permitting an OPO with more than one DSA to withdraw from a specific DSA without effectively ending its agreement with CMS. We seek public comment on this alternative approach as well as the benefits and risks of establishing such a policy.

We also propose a public notice requirement at § 486.311(c) consistent with the current public notice requirements at § 486.312(e) to inform the public of the change. We would provide public notice in the service area of the date that a new OPO will be designated for the DSA. We also propose new § 486.311(d) to provide that no payment under titles XVIII or XIX of the Act will be made with

respect to organ procurement costs attributable to an OPO that no longer has an agreement with CMS.

We propose to reorganize and revise the requirements at § 486.312 to clarify the actions we may take related to de-certification of an OPO. The current requirements pertain to (a) voluntary termination of agreement, (b) involuntary termination of agreement, (c) non-renewal of agreement, (d) notice to OPO, and (e) public notice. As mentioned earlier in this proposed rule, requirements for non-renewal of agreement (currently § 486.312(c)) and voluntary termination (currently § 486.312(a)) would be relocated to proposed § 486.311(a).

We propose to relocate and revise the requirements for involuntary termination of agreement at § 486.312(b) to proposed § 486.312(a). Involuntary termination would result in de-certification of the OPO. Specifically, we propose at paragraph (a)(1) that we may involuntarily terminate an OPO during the re-certification cycle if the OPO no longer meets the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360, as specified at proposed § 486.316(b)(1). The conditions for coverage at §§ 486.320 through 486.360 are generally referred to as process performance measures. Non-compliance means the OPO has one or more condition-level deficiencies that it is unable to resolve within a specified timeframe. We propose at paragraph (a)(2) that we may involuntarily terminate an OPO if the OPO is only designated to tier 3 DSAs in the final assessment period, as described at proposed § 486.316(b)(2)(iii)(A), at the end of the agreement. At paragraph (a)(3) we propose that we would de-certify an OPO if it is no longer designated to any DSA and does not have data available from the final assessment period to demonstrate compliance with the outcome measures at the end of the re-certification cycle. This would address the potential outcome of a tier 2 OPO that was re-certified but did not have an agreement renewed because it did not win a competition as specified at proposed § 486.311(a)(1) and was not otherwise assigned a DSA by CMS. Finally, we propose to relocate and revise the requirements for immediate termination in cases of urgent need, such as the discovery of unsound medical practices, currently located at § 486.312(b) to proposed new paragraph at § 486.312(a)(4). We also propose to revise and relocate the requirements regarding notice of de-certification to the OPO by redesignating and revising

§ 486.312(d) as paragraph § 486.312(b). We propose that except in cases of urgent need, the initial notice of de-certification would be provided to the OPO at least 90 calendar days before the effective date of the de-certification. In cases of urgent need, the notice would be provided at least 3 calendar days prior to the effective date of the de-certification. The notice would state the reasons for de-certification, explain the available appeal rights, and include the effective date of the de-certification.

We also propose to revise and redesignate the requirements pertaining to public notice of de-certification currently at § 486.312(e) to § 486.312(c). The current requirements indicate that “[o]nce CMS approves the date for a voluntary termination, the OPO must provide prompt public notice in the service area of the date of de-certification and such other information as CMS may require. In the case of involuntary termination or nonrenewal of an agreement, CMS also provides notice to the public in the service area of the date of de-certification. No payment under titles XVIII or XIX of the Act will be made with respect to organ procurement costs attributable to the OPO on or after the effective date of de-certification.” We are proposing to remove the requirement that the OPO provide public notice in these situations. We have proposed to revise this requirement to indicate that CMS will provide public notice in the service area of the date of de-certification and the date that a new OPO will be designated for the DSA.

We believe that this proposed reorganization will provide greater clarity into the actions that may occur as a result of the tiered system and competition under the outcome measures. Grouping items based on potential outcomes and impact to the OPO agreement and certification status better aligns with the program requirements, including any appeals process that may follow an adverse action. We solicit public comment on these proposed changes and additional factors to consider or changes to assist in refining the requirements of this section.

F. Appeals (§ 486.314)

The Organ Procurement Organization Certification Act of 2000⁵⁹ required the Secretary to issue regulations that allow an OPO to appeal a de-certification on substantive and procedural grounds. To

⁵⁹ Section 701(c)(3) of the Organ Procurement Organization Certification Act of 2000, 114 STAT. 2346, Public Law 106–305. Published November 13, 2000.

fulfill this statutory requirement, § 486.314 Appeals, was finalized in the 2006 OPO final rule (71 FR 30982). The introductory text at § 486.314 states that “[i]f an OPO’s de-certification is due to involuntary termination or non-renewal of its agreement with CMS, the OPO may appeal the de-certification on substantive and procedural grounds.” In the December 2020 final rule (85 FR 77898), we finalized new outcome measures and made some changes to the re-certification and competition processes. As a result of significant changes made since the 2006 final rule, we reviewed the OPO appeals process to consider what, if any, changes should be proposed. Based upon that review, we are proposing the following changes to § 486.314 as described below.

We propose to revise the introductory text at § 486.314 to allow an OPO to appeal a de-certification as described at § 486.312(a) or the removal of a designation to a tier 3 DSA without de-certification as described at § 486.316(b)(2)(iii)(B). As a result of the competition process as set forth at revised § 486.316, some OPOs might eventually be designated for more than one DSA. Thus, an OPO may not be de-certified because at least one of their DSAs is assigned to tier 1 or tier 2 in the final assessment period of the re-certification cycle. However, if one of the OPO’s DSAs is assigned to tier 3 in the final assessment period, the OPO could lose its designation for that DSA. Although the removal of a designation for a DSA is not a de-certification if the OPO retains at least one DSA that is not assigned to tier 3, the OPO has been found to be non-compliant with the outcome measures in the tier 3 DSA. Thus, we believe that an OPO should also have appeal rights for the removal of designation to a DSA without de-certification. Consequently, we propose to add references to the removal of designation for a DSA assigned as tier 3 without de-certification alongside references to de-certification in § 486.314, as applicable, to reflect that an appeal would be available in either scenario. We propose to revise paragraph (a) for the notice of initial determination and add new paragraphs (a)(1) and (a)(2) to address de-certification and removal of a DSA without de-certification respectively.

We propose to modify the time periods in this section for existing requirements from “business days” to “calendar days”. We also propose to use “calendar days” for all proposed requirements. CMS will compute time periods based on “calendar days” according to the process described in Federal Rules of Civil Procedure (FRCP),

Rule 6(a)(1).⁶⁰ This is for both consistency and to avoid confusion in the appeals process.

Currently, the OPO has 15 business days from receipt of the notice to request reconsideration from CMS. If the OPO does not request a reconsideration within those 15 business days, the OPO has no right to further administrative review. We propose to change this to 20 calendar days as set forth in proposed § 486.314(b)(1). CMS currently has 10 business days from receipt of the reconsideration request to make a written reconsidered determination that would affirm, reverse, or modify the initial de-certification determination. We propose to modify this to 15 calendar days to make a written reconsidered determination that would affirm or reverse the initial de-certification determination, as set forth in proposed § 486.314(b)(3). We are also proposing that CMS has the right to extend this time based on a determination that additional time is necessary to thoroughly review, make a decision and the extension does not prejudice either party. We also propose to remove the option for the reconsideration official to “modify” the initial de-certification determination. We do not believe it is appropriate for the reconsideration official to modify the determination. Not only does he or she usually only have 15 calendar days to review the initial de-certification determination, but also we believe there will be insufficient time and information for the official to develop a modification to that determination.

Currently, if the de-certification decision is upheld, the OPO then has 40 business days from receipt of CMS’ reconsideration decision to request a hearing before a CMS hearing officer. If an OPO does not request a hearing or its request is not received timely, the OPO has no right to further administrative review. The hearing officer must set a date for the hearing that is no more than 60 calendar days after receiving that request for a hearing and must render his or her decision within 20 business days of the hearing.

We propose at § 486.314(c) to reduce the number of days within which an OPO must request a hearing before a CMS hearing officer from 40 business days to 15 calendar days. We did not

previously explain the 40-business day timeline beyond stating that the appeals process generally “will protect a de-certified OPO’s rights, provide it with sufficient time to pursue its appeal, and ensure that it receives a fair hearing”.⁶¹ However, a full 40 business days could contribute to disruptions in organ procurement activities in the DSA and unduly extend the appeals process. This proposed change is limited to the request for a hearing before a CMS hearing officer. The shorter timeline to request a hearing would continue to sufficiently protect an OPO’s rights, including time to pursue an appeal and receive a fair hearing. The only decision the OPO needs to make before filing its request for a hearing is whether it wants to challenge the de-certification or the removal of a designation to a DSA without de-certification. However, we also believe that in making the decision to appeal, the OPO would have also begun gathering relevant documents and other evidence, as well as formulating the arguments it would need for the hearing. If the OPO requests a hearing, the hearing officer must set a hearing date that is not more than 60 calendar days following the receipt of the request for a hearing (§ 486.314(f)). The OPO and CMS would have additional time from the date the hearing is requested until the hearing date to more fully prepare their legal arguments and factual support for the hearing. Both the OPO and CMS could submit briefs, have witnesses testify, and submit additional evidence during the hearing as currently allowed under § 486.314(g). During the conduct of the hearing, the hearing officer would inquire fully into all relevant and material document and witness testimonies (§ 486.314(g)). Requiring OPOs to file a request for a hearing before a CMS hearing officer within 15 calendar days of receiving the notice of the reconsideration determination balances the OPO’s interest in providing ample time to file an appeal with the interests of patients’ access to organ transplants by shortening the time required for the appeals process. During the appeals process, some resources will by necessity be devoted to the appeal, which means that not all the OPO’s resources will be devoted to organ procurement activities. Hence, an efficient appeals process is necessary to resolve the appeal and either have the OPO devote all its resources to the procurement activities in the DSA or proceed with identifying and transitioning to a successor OPO.

⁶⁰ FRCP, Rule 6(a)(1) (providing that when a time period is stated in days or a longer unit of time, “(A) exclude the day of the event that triggers the period; (B) count every day, including intermediate Saturdays, Sundays, and legal holidays; and (C) include the last day of the period, but if the last day is a Saturday, Sunday, or legal holiday, the period continues to run until the end of the next day that is not a Saturday, Sunday, or legal holiday.”).

⁶¹ 71 FR 30994.

Also, § 486.314(d) currently states that the hearing officer sends the administrative record to both parties within 10 business days of receipt of the request for a hearing. Because the Office of Hearings now uses an electronic case management system in which both parties have access to each other's filings, the reconsideration official does not need to forward their administrative record to the hearing officer unless and until there has been a request for a hearing. We propose to revise § 486.314(d) to state that upon receipt of a request for a hearing, the hearing officer will promptly request the administrative record from the reconsideration official. We also propose that the hearing officer, within 15 calendar days of receipt of the request for a hearing, would send the administrative record to both parties, or make it available through their electronic filing system, rather than the current 10 business days. Now that there is an electronic filing system available, we believe this would be a timely and efficient way to share the administrative record and we want to encourage its use.

Additionally, we propose to revise and redesignate paragraph § 486.314(i) and redesignate paragraphs (j) and (k) to incorporate new paragraphs for requirements to update the appeals process. Specifically, we propose redesignating the current paragraph (i) to paragraph (k) to address the hearing officer's decision and to extend the time for the hearing officer to render their decision to 90 calendar days. Under current § 486.314(i), the CMS hearing officer has 20 business days to render their decision. We are concerned that 20 business days may not be enough for the hearing officer to complete their tasks. In addition to conducting the hearing and rendering a decision, the hearing officer must develop an administrative record of the hearing that is sufficient for any subsequent review. This could include post-hearing activities, such as the hearing officer, at their discretion, permitting the filing of post-hearing briefs on issues raised at the hearing. Thus, we propose to revise and redesignate the current requirements at § 486.314(i) to paragraph (k), extend the time for the hearing officer to issue their decision to 90 calendar days, and provide that the hearing officer has the right to extend that time upon notifying both the OPO and CMS, if the extension does not unduly prejudice either of the parties and is necessary for the hearing officer to issue a legally sufficient decision. We also propose that the hearing officer can affirm or reverse the

notice of de-certification or removal of designation to a DSA without de-certification. The hearing officer would then promptly forward his or her decision and the administrative record to the CMS Administrator to decide whether or not to exercise discretionary review of the hearing officer's decision.

We propose a new (i) that will set forth requirements related to scope of review. In the appeals process, we believe OPOs should have the burden to demonstrate that they are entitled to relief. This is not explicitly stated in the current version of § 486.314. Since it is the OPO that is challenging the notice of de-certification or the removal of designation for a DSA without de-certification, we believe the burden of proof on the OPO is implicit. Thus, we propose in new paragraph (i) to clarify that OPOs have the burden of proof by a preponderance of the evidence.

We also propose to revise and redesignate the current paragraph (j) to paragraph (n). This subsection already provides CMS the authority to extend its agreement with an OPO to allow for competition and, if necessary, transition of the service area to a successor OPO. However, we are concerned that the effective date of de-certification or removal of designation for a DSA may be significantly delayed by the appeal process. Hence, we propose adding the appeals process to the reasons an extension of the agreement past the expiration date might be necessary. We are also soliciting comments regarding whether there should be any limitations on CMS' authority to extend the OPO's agreement with CMS. In particular, we are considering what, if any, conditions we should place on the extension, and what, if any, maximum amount of time CMS could extend the agreement.

We also propose establishing an additional provision in the administrative appeals process. The CMS Administrator has the right to review CMS hearing officers' decisions, regardless of whether the hearing officer reversed or affirmed the de-certification or the removal of designation for a tier 3 DSA without de-certification. However, the Administrator's review is not currently addressed in the appeals section. Without requirements addressing the Administrator's review, OPOs and the public would not be aware of the procedures that would be followed after the hearing officer renders their decision. The CMS Administrator's discretionary review is a crucial phase of the appeals process, and we want to provide clarity to ensure that all parties and the public have a clear understanding of the process. The proposed requirements will also clarify

when the appeals process is exhausted and, if the OPO is de-certified, when CMS will move forward with competition for the open DSA. Therefore, we propose new § 486.314(l) to codify the process for discretionary review by the CMS Administrator of the hearing officer's decision. Specifically, we propose that the CMS Administrator has 30 calendar days from receipt of the hearing officer's decision to elect to review or decline to review the hearing officer's decision. If the CMS Administrator elects to review the hearing officer's decision within the 30-day period, the CMS Administrator will promptly notify the OPO and CMS of his or her election to review and the parties' right to submit written arguments within 15 calendar days of the notification. If the Administrator does not elect to review the decision within 30 calendar days of its receipt, the hearing officer's decision is final.

We propose that within 45 calendar days of notification of the CMS Administrator electing to review the hearing officer's decision, the CMS Administrator must render a final decision, in writing, to the parties. The CMS Administrator can affirm, reverse, or remand the hearing officer's decision to CMS as discussed below. We are also proposing that the CMS Administrator has the right to extend this time if he or she determines they need more time to thoroughly review and make a decision and the extension does not prejudice either party. We propose that the CMS Administrator's review be limited to the hearing's administrative record developed by the hearing officer and written arguments submitted by the OPO or CMS. The CMS Administrator's administrative record would be composed of all documents submitted to the hearing officer or developed in the course of the hearing, including the hearing officer's decision, as well as written arguments from the OPO or CMS explaining why either or both parties believe the hearing officer's determination was correct or incorrect, and the CMS Administrator's written decision explaining his or her decision and the reason for that decision.

We propose that our decision whether to de-certify an OPO or remove its designation to a particular DSA would become final if the OPO does not request review by a hearing officer in the time allowed under these regulations, or after the CMS Administrator declines to review the hearing officer's decision, renders a final decision in writing to the parties, or does not render a final decision or a remand in writing to the parties within 45 calendar days of electing to review

the hearing officer's decision or by the extended deadline if the Administrator extends the 45-day period. As noted below, a decision would not take effect until (among other things) all administrative appeals are exhausted to avoid any undue prejudice to the OPO.

We also propose to revise and redesignate current (k) to new paragraph (o) at § 486.314 to clarify when the OPO's DSA is opened for competition. Consistent with our current rule, an OPO will not be de-certified or lose its designation to a DSA until all administrative appeals are exhausted. If at the end of the appeals process the notice of de-certification or removal of designation for a DSA without de-certification has not been reversed or remanded, the decision is final. At that time, the OPO's DSA would be competed and a successor OPO would be chosen. CMS would then determine a transition period that is sufficient for the new OPO to take full responsibility for the DSA. After the transition period is determined by CMS, CMS would forward to the de-certified OPO a written communication indicating the effective date of de-certification, at which time Medicare and Medicaid payments may no longer be made for organ procurement costs attributable to the OPO. For an OPO that loses its designation to a tier 3 DSA without being de-certified, CMS would forward a written communication indicating the effective date of the decision, at which time Medicare and Medicaid payments may no longer be made for organ procurement costs attributable to the affected OPO for that particular DSA. We would not begin the competition process before the appeals process is exhausted.

We believe that there might be circumstances in which the CMS Administrator could want CMS to conduct further review or have other instructions for CMS regarding the appeal. For example, the CMS Administrator might want further analysis of data. Hence, we propose that the CMS Administrator may remand the appeal to CMS for any appropriate reason in proposed (m). Remanding the appeal means that the appeal is sent back to CMS for re-evaluation and a new initial determination regarding de-certification or removal of designation for a DSA without de-certification. Also, if the appeal is remanded to CMS, the agency will comply with any instructions in the remand. We are not proposing remand authority for the hearing officer.

We propose a new subsection (p) to address de-certification due to urgent need. We have received feedback that

there is some confusion about how the appeals process would proceed for an OPO de-certified due to urgent need. The appeals process is the same regardless of the reason for the OPO's de-certification. However, if an OPO is de-certified due to urgent need, it may be de-certified immediately (proposed 42 CFR 486.312(a)(4)). In such circumstances, the affected OPO's service area would be reassigned to one or more other OPOs as set forth at proposed § 486.308(a)(4) by the effective date specified in the notice of de-certification provided under proposed § 486.312(b). Hence, if the de-certified OPO pursues an appeal, it would not be operating its DSA while proceeding through the appeals process.

Notwithstanding the reason for the de-certification, if the initial notice of de-certification is reversed in the appeals process, the OPO will be recertified for the next re-certification cycle. However, its tier status does not change. If the CMS Administrator chooses to modify the hearing officer's decision, CMS will comply with his or her determination.

We are soliciting public comments on these proposed changes to the appeals process. We are especially interested in comments on the proposed time frames for the different stages of the appeals process.

G. Re-Certification and Competition (§ 486.316)

In section III.D. of this proposed rule, we discussed the proposal regarding OPO designation to more than one DSA. In that section, we proposed that we would evaluate each DSA separately on the outcome measures at § 486.318. However, we also proposed that an OPO would be evaluated across all DSAs on the process performance measures at §§ 486.320 through 486.360. The current requirements at § 486.316 address OPO re-certification and competition. These requirements do not currently address the potential situation of one OPO being designated to more than one DSA and the impact this may have on the re-certification and competition processes. We propose to make conforming changes to this section to clarify the requirements related to OPO designation, re-certification, and competition to also include situations when an OPO is designated to more than one DSA.

We propose to revise § 486.316(a) to address the impact of the OPO outcome measures at § 486.318 on OPO designation at the time of re-certification. We propose that an OPO's performance on the outcome measures and tier assignment in each DSA at the

final assessment period of the agreement cycle would determine OPO designation to the DSA. Depending on its performance on the outcome measures, an OPO's performance in each DSA would be assigned to tier 1, tier 2, or tier 3 as specified at § 486.318(e)(4), (5), and (6) respectively, redesignated as proposed § 486.318(b)(4), (5), and (6). We propose, at § 486.316(a)(1), that an OPO with a DSA that is assigned to tier 1, as specified at § 486.318(e)(4), redesignated as proposed § 486.318(b)(4), would retain designation to the DSA for another agreement period. An OPO with a tier 1 DSA would be eligible to compete for any open DSAs, provided that CMS determined it to be in compliance with the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360 during the most recent survey.

At § 486.316(a)(2), we propose that an OPO with a DSA that was assigned to tier 2, as specified at § 486.318(e)(5), redesignated as proposed § 486.318(b)(5), would have to successfully compete and be awarded a DSA in a competition to retain designation to a DSA for another agreement period. An OPO with tier 2 DSAs would be eligible to compete for any open DSAs provided that CMS determined the OPO to be in compliance with the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360 during the most recent survey. We also propose, at § 486.316(a)(3), that an OPO with a DSA that is assigned to tier 3, as specified at § 486.318(e)(6), redesignated as proposed § 486.318(b)(6), would have the designation removed at the end of the agreement period. Additionally, an OPO with all of its DSAs assigned to tier 3 would not be eligible to compete in competitions for any open DSAs.

In paragraph (b) of proposed § 486.316, we propose how performance on the process performance measures (§§ 486.320 through 486.360) and outcome measures (§ 486.318) will impact OPO re-certification and competition.

At proposed § 486.316(b)(1), we address compliance with the process performance measures. We propose an OPO must maintain compliance with the process performance measures at all times and that non-compliance with the requirements at §§ 486.320 through 486.360 in any DSA would result in the OPO receiving an initial de-certification determination. We propose that the OPO has the right to appeal the de-certification. If the OPO does not appeal the determination, or the OPO appeals

and the determination is upheld after the appeal process is completed, the OPO's service areas are opened for competition from other OPOs that qualify to compete for open service areas.

At proposed § 486.316(b)(2), we describe the proposed impact of tier assignment during the final assessment period to OPO designation at the time of re-certification. At paragraph (i), we propose that an OPO designated to at least one DSA that is assigned to tier 1 in the final assessment period would be re-certified for another re-certification cycle, as long as it is compliant with conditions for coverage at §§ 486.320 through 486.360 during the most recent survey. At paragraph (ii), we propose that an OPO that is designated to at least one DSA that is assigned to tier 2 in the final assessment period and is not designated to any DSA assigned to tier 1, will be re-certified for another recertification cycle, as long as it is compliant with conditions for coverage at §§ 486.320 through 486.360 during the most recent survey. The OPO will be eligible to compete in competitions for any open DSA. However, their agreement will not be renewed if they are not successful in at least one competition in accordance with § 486.311(a)(1). We propose that if the OPO is successful in a competition, it will then be designated to a DSA and receive a new agreement. We also propose that if the OPO is not successful in at least one competition, it will receive a notice of non-renewal as specified in § 486.311(b). Because the OPO is re-certified, it will remain eligible to compete in future competitions, be assigned a DSA under § 486.316(e), or be selected for an open DSA under § 486.308(a)(4) during the next re-certification cycle.

At paragraph (b)(2)(iii), we propose that an OPO that is designated to a DSA that is assigned to tier 3 in the final assessment period will receive one of two notices. At sub-paragraph (A) the OPO will receive notice of its initial de-certification determination for an OPO that has no other designated DSA that is assigned to tier 1 or tier 2, or no other designated DSA that is pending evaluation of its outcome measures as specified at proposed § 486.318(c)(3) or (4) at the end of the re-certification cycle. At sub-paragraph (B), the OPO will receive a notice of removal of designation to the DSA assigned as tier 3 for an OPO that has another designated DSA assigned as tier 1 or tier 2, or another designated DSA that is pending evaluation of its outcome measures as specified at proposed

§ 486.318(c)(3) or (4) at the end of the re-certification cycle.

We are proposing changes at § 486.318(f), proposed to be redesignated as § 486.318(c), to address when we would hold an OPO accountable on the outcome measures when it acquires a new area, such as after a change of control or ownership or service area, a competition, or assignment of a DSA by CMS. We refer readers to section III.H of this proposed rule for additional information on this topic. At paragraph 486.316(b)(2)(iv), we propose that an OPO would have the right to appeal a de-certification or removal of designation to the DSA assigned as tier 3 as established in § 486.314. If an OPO does not appeal the determination, or the OPO appeals and the determination is upheld after the appeal process is completed, the OPO's tier 3 DSA is opened for competition from other OPOs that qualify to compete for open service areas.

We address the competition requirements at proposed § 486.316(b)(3). We propose that DSAs assigned as tier 2 or tier 3 in the final assessment period would be opened for competition. The OPO's tier 2 or tier 3 service area is opened for competition from other OPOs that qualify to compete for open service areas as set forth in proposed § 486.316(c). Competition for DSAs assigned to tier 3 will not begin until after any applicable appeal under § 486.314 has been exhausted.

In proposed § 486.316(c), we list existing criteria to compete for an open DSA and proposed to redesignate these as paragraphs (1) and (2). To compete for an open DSA, an OPO would have to be designated to at least one DSA that meets the performance requirements for the outcome measures for tier 1 at § 486.318(e)(4), or tier 2 at § 486.318(e)(5), redesignated as proposed § 486.318(b)(4) and (b)(5) respectively. The OPO would also have to meet the requirements for certification at § 486.303 and would have to meet the process performance measures at §§ 486.320 through 486.360 during the most recent routine survey. Additionally, the OPO must compete for the entire DSA. At proposed paragraph (2), we propose to amend these criteria to address competition eligibility for any OPO subject to non-renewal of their agreement for failure to be designated to a DSA after competition. We propose that an OPO in this situation would be eligible to compete in additional competitions after its agreement expired and could enter into a new agreement with CMS, provided it had not been de-certified and met the criteria to compete at that time it entered the competition

process that resulted in non-renewal. This would enable the OPO to participate in subsequent competitions and enter into a new agreement with CMS if it was successful in a competition. If the OPO did not obtain a new DSA before the end of the next re-certification cycle, it would not be able to demonstrate compliance with the outcome measures at § 486.318 for that re-certification cycle and would be de-certified at that time.

We propose to revise text at § 486.316(d) to describe the selection and designation of an OPO following a competition more accurately. The current text states that "CMS will designate an OPO for an open service area based on the following criteria." We propose to revise this to state, "CMS will select an OPO for designation to an open DSA based on the following criteria". We also propose to make a conforming change at § 486.316(d)(2) to include relative success in meeting the process performance measures and other conditions at §§ 486.320 through 486.360.

Discussion of OPO Criteria for Selection at § 486.316(d)

In the December 2021 RFI (86 FR 68594), we solicited public comments on potential changes to the requirements that transplant programs, OPOs, and ESRD facilities must meet to participate in the Medicare and Medicaid programs. One topic from the December 2021 RFI that received considerable comments and that we are addressing in this proposed rule is the competition process for OPOs that may occur at the end of the 2022 through 2026 OPO certification cycle. Our goals in developing the tiered re-certification system were to ensure that OPOs are held to a high level of performance expectations and that all OPOs are pushed to perform better to better serve patients awaiting a transplant. In creating the tiered approach, we sought to reward the top performing OPOs (tier 1 DSAs), while giving OPOs with DSAs in tiers 2 and 3 sufficient incentives to improve their performance and achieve ranking in the next level. Additionally, we sought to give OPOs with tier 2 DSAs the opportunity to demonstrate that the OPO could perform better than other OPOs in a particular service area. While we previously expressed this intent in rulemaking, many commenters in the recent RFI expressed concern for how OPOs with tier 2 DSAs would be evaluated in future competitions and requested clarification of the competitive process. These commenters recommended that CMS provide special consideration when evaluating OPOs

with tier 2 DSAs. Specifically, they stated that CMS should give particular attention in cases where an OPO with a tier 2 DSA has one of its two outcome measures for that DSA in tier 1. In these instances, commenters recommended that CMS recognize and give significant weight to sustained improvement in the incumbent OPO's existing DSA when evaluating the OPO in a competitive process against an OPO with tier 1 performance in both outcome measures.

We seek to clarify the existing selection criteria for evaluating OPOs in a competition and how this will be utilized in future competitions under the tier system for re-certification; however, we are not proposing any new regulatory changes. Currently, we consider the following four criteria when designating an OPO for an open service area, as stated in § 486.316(d):

- Performance on the outcome measures at § 486.318.
- Relative success in meeting the process performance measures and other conditions at §§ 486.320 through 486.348, proposed to be amended to §§ 486.320 through 486.360.
- Success in identifying and overcoming barriers to donation within its own service area and the relevance of those barriers to barriers in the DSA that is open for competition. An OPO competing for an open service area must submit information and data that describe the barriers in its service area, how they affected organ donation, what steps the OPO took to overcome them, and the results.

- Contiguity to the open service area.

In our 2006 final rule (71 FR 30999), we stated that we would evaluate the first three criteria equally and use the fourth criterion, contiguity, as a deciding factor if we determine that two competing OPOs were equally competent to take over an open area. Additionally, in the 2006 final rule where we described the competition requirements (71 FR 30998), we stated, "The competition process is designed to enable CMS to choose the OPO that is most likely to increase organ donation in the service area and thereby serve the best interests of organ donation, potential organ donors and recipients in the service area, and the organ donation and transplantation system in the United States."⁶² We believe the existing selection criteria would continue to provide sufficient objective measures in designating the most appropriate OPO to be awarded a DSA in a competition. The criteria also provide a sufficient level of discretion in rating OPOs that would address the

concerns raised by commenters in the RFI. For instance, when considering performance on the outcome measures, we may consider the degree to which the top performing OPO's performance on the outcome measures exceeds the performance of other competitors and may judge small differences in performance among competitors to be relatively insignificant (see § 486.316(d)(1). Additionally, continuous improvement in outcome measures over successive years would be considered and we would expect an OPO to address any such improvement in describing how it identified and overcame barriers in its DSA (see § 486.316(d)(4). We would also consider each OPO's relative success in meeting the process performance measures, the conditions for coverage, during the most recent re-certification period (see § 486.316(d)(2). By "relative success," we mean that we will judge whether the OPO satisfied the requirements necessary to meet the process performance measures. Noncompliance deficiencies cited on surveys, including complaint surveys since the last re-certification, are other aspects we would consider when ranking OPOs in competition. Finally, the degree to which an OPO had identified and overcome barriers to donation identified in its own DSA would be considered (see § 486.316(d)(4). This would provide the OPO the opportunity to describe the barriers it has faced and document its performance gains over time.⁶³ An OPO competing for an open service area must submit information and data that describe the barriers in its service area, how they affected organ donation, what steps the OPO took to overcome the barriers, and the results. CMS will evaluate the OPOs based on the information and data provided in describing the barriers in its service area, the impact to organ donation, the steps (or plan) the OPO implemented to overcome the barriers, and the results. CMS will also consider the extent to which the OPO identified and addressed the relevance of barriers to donation within its own service area to barriers in the open DSA. This information is important for competing OPOs in demonstrating a record of performance gains and a trajectory of improvement that could enable CMS to make the determination that the OPO is likely to continue improving, is likely to achieve tier 1 status in the near term and should be designated to the DSA. Our goal in the competitive selection process is to ensure that we designate OPOs to DSAs that will continue to

accelerate system improvement and better serve patients awaiting transplants.

We received comments on the issue of contiguity in response to the December 2021 RFI. While some commenters highlighted the use of technology to aid in operating non-contiguous DSAs or indicated their opinion that contiguity no longer mattered, other commenters provided information to validate retaining this criterion as a means to selecting an OPO when they were otherwise ranked equally. Some of the rationales included observations about efficiencies related to resource utilization and distribution; agreements and networks with regional partners covering geographic areas that overlap both DSAs; and potentially familiarity with the geographic area, demographics, high volume transplant centers, and local courier relationships. While we believe that OPOs could operate non-contiguous DSAs successfully, we also believe there is benefit to geographic proximity. Consistent with § 486.316(d)(3) and the policy described in the 2006 final rule, we will continue to utilize contiguity in situations when OPOs are ranked equally and will give positive consideration to a competing OPO that is contiguous to the open DSA.

We anticipate this preamble discussion will alleviate the concerns of commenters that may have been under the impression that we would rigidly apply the selection criteria based on tier standing alone. We also believe this information will assist OPOs in determining both a strategy for competition and the information that may be most beneficial when participating in a competition for an open DSA. However, we solicit public comment on alternative factors that we may not have considered regarding the implementation of the tiered approach to re-certification and competition.

Finally, we propose to remove the current text in § 486.316(g) and replace it with a new paragraph (g). Currently, paragraph (g) addresses an exception to the outcome measures for the 2022 re-certification cycle. This period has passed; therefore the current requirements are now obsolete. We propose to revise paragraph (g) to address DSA transition from an incumbent OPO to a successor OPO. This information is currently included in sub regulatory guidance for OPOs (CMS Pub 100-07, State Operations Manual (SOM), Chapter 2, Section

⁶² 71 FR 30998.

⁶³ 42 CFR 486.316(d).

2812).⁶⁴ We propose to codify the requirement for OPOs to cooperate during transitions following a competition to facilitate a smooth transition and continuity of organ donation activities in the DSA. We propose at paragraph (1) that an incumbent OPO must cooperate with a successor OPO that is newly designated to facilitate an orderly transition of the DSA and submit a transition plan, as specified by CMS, that provides details on how all aspects of the OPO operation will be transmitted, including timeframes, to a new OPO. At paragraph (2), we propose that the successor OPO must submit a transition plan and periodic reports, as specified by CMS, related to progress on its transition activities until the process is completed. Current sub-regulatory guidance at SOM Section 2812.4 describes elements to be included in the transition plan an applicant submits when applying to compete for an open DSA. The CMS location office will specify the frequency of reporting at the time of the transition. We propose that the successor OPO must provide a final notice to CMS no later than 30 calendar days after completion of the transition and prior to the end of the incumbent OPO's agreement.

H. Outcome Measures (§ 486.318)

The requirements for the previous outcome measures that were superseded by the December 2020 final rule are located at § 486.318(a) through (c). These requirements are no longer in effect and have been superseded by new requirements at § 486.318(d) through (f). We propose to remove the obsolete requirements at paragraphs (a) through (c) and to redesignate paragraphs (d) through (f) as paragraphs (a) through (c). We propose a conforming change at the proposed redesignated paragraph (a)(1) (currently paragraph (d)(1)) by removing the reference to paragraph (d)(2) and replacing it with paragraph (a)(2). We propose a conforming change at the proposed redesignated paragraph (b)(5) (currently paragraph (e)(5)) by removing the reference to paragraph (e)(4) and replacing it with paragraph (b)(4). We propose a conforming change at the proposed redesignated paragraph (b)(7) (currently paragraph (e)(7)) by removing the reference to paragraphs (e)(4), (5), and (6) and replacing it with paragraphs (b)(4), (5), and (6).

The current language of § 486.318(d)–(e) refers to the outcome measures as applied to each OPO. However, this

does not account for the possibility of an OPO being designated to more than one DSA where outcome measures would be reported separately for each DSA. We propose to revise § 486.318(d)–(e), redesignated as paragraphs (a)–(b), to replace “OPO” with “DSA” when referencing the outcome measures as applied to each DSA. We also propose a technical correction to the introductory statement that is currently at § 486.318(d)(1), proposed as redesignated § 486.318(a)(1), that reads, “For all OPOs, except as set forth in paragraph (d)(2) of this section, for all OPOs:”. The proposed text would remove the second “for all OPOs”, revise “OPOs” to “DSAs”, and also revise the reference to paragraph (d)(2) as paragraph (a)(2). We also propose adding introductory text to the proposed redesignated paragraph (c) (currently paragraph (f)) to read as follows: “CMS will evaluate OPO performance on the outcome measures at each assessment period.” We propose to add this provision to the regulations to reinforce the fact that CMS oversight is not a one-time event that occurs at the conclusion of each recertification cycle. Rather, CMS evaluates OPO performance on the outcome measures on an annual schedule as the newest year of data becomes available for that assessment period as part of its oversight duties.

The current requirements at § 486.318(f)(3) state, “If an OPO takes over another OPO's DSA on a date later than January 1 of the first year of the agreement cycle so that 12 months of data are not available to evaluate the OPO's performance in its new DSA, we will hold the OPO accountable for its performance on the outcome measures in the new area once 12 months of data are available.” This requirement specifically addresses the availability of data for the outcome measures and when we would hold an OPO accountable for its performance in a new area. OPOs may acquire new areas (DSAs) through a change of control, or ownership or service area (§ 486.310); competition (§ 486.316(c)); assignment by CMS if no one competes for the DSA (§ 486.316(e)); or be selected for an open DSA if there is insufficient time to conduct a competition (proposed § 486.308(a)(4)).

However, when an OPO assumes responsibility for a new DSA, there is an inherent delay in the availability of the CMS-calculated outcome measures. This delay impacts the time frame for an OPO to assess the outcome measures, identify areas for improvement, and implement changes to improve performance. Additionally, other

information that would assist an OPO in assuming responsibility for a new area will vary depending on the nature of how an OPO assumes responsibility for a new DSA. We believe these are important factors that should be considered when holding an OPO responsible for its performance in a new DSA.

The primary, publicly available sources of information on a DSA are the OPO Specific Reports (OSRs) published by the SRTR and the CMS outcome measures that are published annually on the CMS QCOR website. However, other types of information an incumbent OPO possesses regarding its operations would likely be proprietary and would not be available in most instances unless OPOs are working collaboratively as part of a merger associated with a change of control or ownership or service area (§ 486.310). Vital data and information such as internal OPO quality improvement and other proprietary data sets would not be available to an OPO that is new to the DSA following a competition or assignment by CMS. This greatly impacts an OPO's preplanning activities and readiness to assume responsibility for a new DSA. An OPO that has won a competition or has been assigned to an open DSA when no OPO competes for it must begin with significantly limited information and resources. OPOs in these situations would have large information gaps coupled with potentially significant expansion demands. While these are not insurmountable, they are unique challenges to be worked through, nonetheless, and require additional consideration when assessing outcomes data for re-certification purposes. Alternatively, a voluntary merger would provide a new OPO with the sharing of critical insights into the existing operations; access to proprietary data sets and internal analyses; enable pre-formed relationships and contacts; leverage established financial, personnel, and physical resources; and include other intangible elements that smooth a transition. Therefore, we believe that an OPO that assumes responsibility for a new DSA after a competition or has been assigned to a DSA should have an additional amount of time to demonstrate improvement before being held accountable on its performance for re-recertification purposes.

To address these concerns, we propose to revise § 486.318(f)(3), proposed to be redesignated as § 486.318(c)(3), to state that if an OPO takes over another OPO's DSA as a result of a change of control or

⁶⁴ <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/som107c02.pdf>.

ownership or service area, on a date later than January 1 of the first year of the agreement cycle so that 12 months of data are not available to evaluate the OPO's performance in its new DSA, the OPO will be held accountable for its performance on the outcome measures in the new area once 12 months of data are available. In this situation, the OPO may or may not be held accountable for the outcome measures in the new DSA for re-certification in the current cycle and this would be dependent on the timing of the change within the current agreement cycle. Regardless, the OPO would still be subject to an onsite re-certification survey to determine compliance with the process performance measures at the end of the re-certification cycle. The OPO would be recertified at that time if CMS determined that the OPO was in compliance with the process performance measures. For instance, if the change occurred prior to the start of the final assessment period, there would be 12 months of data available reflecting the OPOs performance in the DSA at the end of the re-certification cycle to determine compliance with the outcome measures. If the change occurred after the start of the final assessment period, the availability of outcome measure data would depend on whether the OPO merged DSAs or retained separate DSAs. If the OPO merged DSAs, there would not be 12 months of data reflecting the OPO's performance in the merged DSAs to determine compliance with the outcome measures in the new area so re-certification would be determined based on the process performance measures. Alternatively, if the OPO maintained the DSAs separately, its original DSA would have outcome measure data available that could be considered for purposes of re-certification at the end of the re-certification cycle.

We also propose a new paragraph at § 486.318(c)(4) to address the assessment of outcome measures when a new DSA is acquired after a competition, or an OPO is assigned a DSA by CMS. If either of these events occur on a date later than January 1 of the first year of the agreement cycle, we propose that we would hold the OPO accountable for its performance on the outcome measures in the new DSA (1) for QAPI, once 12 months of outcome measure performance data are available, and (2) for re-certification purposes, in the final assessment period of the following agreement cycle. This would provide OPOs in these circumstances with additional time necessary to improve performance in a new DSA before being held accountable for re-

certification purposes. We note that the "new DSA" would be either a newly formed DSA if the OPO merged its DSAs or only the newly acquired DSA if the OPO decided to retain separate DSAs. However, the OPO would still be assessed on the process performance measures via an onsite re-certification survey at the end of the current agreement cycle and be recertified based on the outcome of that survey.

These proposed requirements will work in tandem with the proposed requirements at § 486.316(a) and (b) to enable assessing an OPO's DSAs separately on the outcome measures when an OPO has more than one DSA, and in some instances, delay assessment of outcome measures until an appropriate time when the OPO should be held accountable for its performance in a new DSA. We seek public comment on this approach and other considerations that may impact the timeframes for holding OPOs accountable on their performance with the outcome measures.

I. Human Resources (§ 486.326)

We propose to revise § 486.326(d), "Medical director," to specify that an OPO's medical director would be a physician licensed in at least one of the States or territories within one of the OPO's service areas or as required by State or territory law or by the jurisdiction in which the OPO is located. We propose this change from "service area" to "service areas" to conform to a potential scenario of one OPO serving more than one DSA at a time. We note that many OPO DSAs already cross State lines, meaning that the OPO community is already familiar with navigating the operational complexities of functioning across State lines and that operating across State lines due to designation to more than 1 DSA does not represent a new challenge for OPOs. While the new policy of allowing OPOs to serve multiple DSAs at once may increase the frequency of these occurrences, the policy would not introduce a new level of operational complexity in relationship to the licensure requirements for OPO medical directors.

In addition to proposing this conforming change, we propose revising personnel qualifications for other OPO staff that engage in clinical practices, whether they are in explicitly clinical positions or other positions in which clinical decision making or actions are expected. In accordance with current requirements at § 486.342, as part of its responsibilities, an OPO must encourage discretion and sensitivity with respect to the circumstances, views, and beliefs

of potential donor families. This requirement reflects the crucial role that OPO staff fill in interacting with potential donor families in an emotionally charged environment to obtain consent for donation and effectively manage care of the potential donor. Beyond obtaining consent to donate, OPOs perform essential clinical functions such as implementing established donor evaluation and management protocols under the oversight of the OPO's medical director, determining whether there are conditions that may influence organ acceptance, obtaining the potential donor's medical and social history, reviewing the potential donor's medical chart, performing a physical examination of the donor, obtaining the potential donor's vital signs, and performing all pertinent tests (see § 486.344). Each OPO is already required by § 486.326 to ensure that all individuals who provide services and/or supervise services, including services furnished under contract or arrangement, are qualified to provide or supervise these services, and provide its staff with the education, training, and supervision necessary to furnish required services. The training must include performance expectations for staff, applicable organizational policies and procedures, and QAPI activities. Additionally, OPOs must evaluate the performance of their staff and provide training, as needed, to improve individual and overall staff performance and effectiveness.

The expertise required to fulfill the broad responsibilities and functions of OPOs, spanning from educating donor hospitals to conducting internal QAPI activities to implementing donor management protocols, requires varied training, education, and experience specific to each role. As such, the OPO CfCs do not currently include minimum personnel requirements for OPO staff roles beyond the medical director. We seek to establish such minimum qualifications as are necessary to assure organ quality to facilitate more transplants and propose to add a new standard § 486.326(e), Licensure, to require that personnel performing clinical duties are legally authorized (licensed, certified, or registered) in accordance with applicable Federal, State and local laws. Furthermore, we propose that these staff would be required to act only within the scope of the individual's State license or certification, or registration. Finally, we propose that the individual's licensure, certification, or registration must be kept current at all times. State licensure,

certification, or registration would ensure that individuals meet the minimum training, education, and professional experience requirements set forth by each State to assure the quality and safety of organs provided to patients on the transplant waitlist, thus furthering our policy goal of more transplants and more lives saved. Similar requirements for personnel licensure apply to many other provider and supplier types that deliver patient care to the same patient population served by OPOs, such as hospitals, transplant centers, and dialysis facilities, to assure the health and safety of patients when they receive care from these entities. We believe that it is necessary to assure that OPOs utilize qualified, licensed staff for the performance of clinical functions for potential donors and donors to assure safe, effective donor care management and thus improve the likelihood of a donated organ resulting in a successful transplant.^{65 66 67 68}

While we believe that these proposals are an appropriate step towards establishing more robust personnel requirements to assure the quality of procured and transplanted organs, we also request public comments regarding additional minimum personnel qualification standards in furtherance of this goal. Specifically, we request comment regarding which staff roles should have minimum personnel requirements and what requirements should be included for those specific staff roles for purposes of improving OPO processes in ways that advance the policy goals of more donors and more transplants. We request that commenters provide available evidence,

such as research and existing professional standards or guidelines, to support their recommendations, if possible.

J. Information Management (§ 486.330)

The current requirements for information management at § 486.330 focus on maintaining donor records and records regarding the disposition of each organ recovered for the purpose of transplantation, including information identifying transplant beneficiaries. To assure the accuracy of data reported to the OPTN and the integrity of the CMS donation rate outcome measure that uses data reported by OPOs regarding pancreata procured for islet cell research, we propose to establish a new documentation requirement specific to organs procured by OPOs for research, including pancreata procured for islet cell research. We propose that OPOs would maintain records regarding the disposition of organs recovered and sent for *bona fide* research studies, including information identifying approval by an institutional review board (IRB) or other formal authorizing body, as appropriate, research institution, principal investigator, and contact information. This recordkeeping would foster OPO accountability in the responsible disposition of any organ sent for research, including pancreata that are used for islet cell research, and be consistent with existing OPO practices for maintaining records regarding the disposition of transplanted organs. CMS would use the survey process to review OPO organ disposition records and may conduct validation efforts to confirm their accuracy. We request public comment regarding this proposed documentation requirement for all organs procured for research and alternative ways that CMS could assure the reliability of OPO self-reported data regarding pancreata that are used for islet cell research.

K. Quality Assessment and Performance Improvement (QAPI) (§ 486.348)

We propose to make a conforming change at § 486.348(d)(3) by removing the reference to “§ 486.318(e)(5) and (6)” and replacing it with “§ 486.318(b)(5) and (6)”.

Section 486.348 requires OPOs to develop, implement, and maintain a comprehensive, data driven QAPI program designed to monitor and evaluate performance of all donation services. Section 486.348(c), governing adverse events, requires that OPOs establish written policies to address, at a minimum, the process to identify, report, analyze, and prevent adverse events that occur during the organ

donation process. It also requires that OPOs conduct a thorough analysis of any identified adverse event and use that analysis to effect changes in their policies and practices to prevent repeat incidents. We propose to insert a new paragraph (3) that would set forth the examples that are currently in, but proposed for removal from, the “adverse event” definition in § 486.302 with some revisions.

We propose to insert the example of “transmission of disease from donor to a beneficiary” with revisions at paragraph (c)(3)(i). We propose to insert “infectious or communicable” before “disease”. Also, in organ transplantation the transmission of infectious or communicable diseases or other diseases, such as malignancies, is a critical concern. OPOs are responsible for evaluating potential donors, which includes obtaining comprehensive medical histories, if available, and performing screening and testing for infectious diseases according to current standards of practice (§ 486.344(a) through (c) and § 486.346(a)). By adding “infectious or communicable” before “disease”, we are clarifying the types of diseases of which transmission to a transplant recipient constitutes an “adverse event.” Since we are also concerned about the transmission, dissemination, and seeding of malignancies, we are proposing to also add “or other disease that may be transmissible from a donor to an organ recipient, such as the transmission, dissemination, and seeding of malignancies”.

We propose to insert “[a]voidable loss of a medically suitable potential donor for whom consent for donation has been obtained” without revision into paragraph (c)(3)(ii).

We propose to add a new example at paragraph (c)(3)(iii) that addresses the evaluation and management of patients or potential donors. Section 486.344 sets forth the requirements for potential donor evaluation and management, as well as organ placement and recovery. Potential donor evaluation and management are critical for maximizing the number of transplantable organs an OPO can procure. OPOs are required to have written protocols for donor evaluation and management that meet current standards of practice and are designed to maximize organ quality, as well as the number of donors and the number of organs recovered and transplanted. Both potential donors that have been declared dead by brain death (DBD) criteria and those being evaluated and managed as donors declared dead by cardiac or circulatory death (DCD) criteria must be evaluated. OPOs must

⁶⁵ Malinoski DJ, Daly MC, Patel MS, Oley-Graybill C, Foster CE 3rd, Salim A. Achieving donor management goals before deceased donor procurement is associated with more organs transplanted per donor. *J Trauma*. 2011 Oct;71(4):990–5; discussion 996. doi: 10.1097/TA.0b013e31822779e5. PMID: 21808207.

⁶⁶ Malinoski DJ, Patel MS, Ahmed O, Daly MC, Mooney S, Graybill CO, Foster CE, Salim A; United Network for Organ Sharing (UNOS) Region 5 Donor Management Goals (DMG) Workgroup. The impact of meeting donor management goals on the development of delayed graft function in kidney transplant recipients. *Am J Transplant*. 2013 Apr;13(4):993–1000. doi: 10.1111/ajt.12090. Epub 2013 Feb 13. PMID: 23406284.

⁶⁷ Malinoski DJ, Patel MS, Daly MC, Oley-Graybill C, Salim A; UNOS Region 5 DMG workgroup. The impact of meeting donor management goals on the number of organs transplanted per donor: results from the United Network for Organ Sharing Region 5 prospective donor management goals study. *Crit Care Med*. 2012 Oct;40(10):2773–80. doi: 10.1097/CCM.0b013e31825b252a. PMID: 22846779.

⁶⁸ Clarke C. Management of the brain-dead organ donor. *Indian J Thorac Cardiovasc Surg*. 2021 Sep;37(Suppl 3):395–400. doi: 10.1007/s12055-021-01224-y. Epub 2021 Sep 17. PMID: 34548770; PMCID: PMC8445737.

evaluate each patient or potential donor to verify that death has been declared according to applicable local, State, and Federal laws; determine whether there are conditions that may influence donor acceptance; if possible, obtain the potential donor's medical and social history; review the potential donor's medical chart and perform a physical examination of the potential donor; and obtain the potential donor's vital signs and perform all pertinent tests (42 CFR 486.344(b)). We also want to emphasize that this evaluation of potential donors includes active collaboration with primary medical teams in the care of those patients. Medical management of the potential donor is critical to ensure they are kept stable, and if proper consent is obtained, their organs recovered, which could be several hours or longer.

We have concerns that there have been some instances where deviations from the current standards of practice or the OPO's policies and procedures have resulted in loss of transplantable organs or have otherwise constituted an adverse event. For example, failure to ensure that death has been verified according to all applicable laws could contribute to mistrust in the organ donation process. In addition, failure to determine if there are conditions that may influence donor acceptance; obtain the potential donor's medical and social history, when possible; perform a physical examination and review the potential donor's medical chart; or perform all pertinent tests could result in the OPO expending unnecessary resources on a potential donor whose organs could be unsuitable for transplant or increase the chances of transmission of an infection or communicable disease or malignancy. We are also concerned about the number of organs that are recovered but not transplanted. OPTN data indicates that in 2024 nearly 12,000 potentially transplantable organs were recovered but were discarded. About 9,200 of those organs were kidneys.^{69 70} Also, there has been an increase in potential donors who have one or more organs recovered but have no recovered organs transplanted, also known as zero organ donors. Our internal analysis indicates the number of zero organ donors increased over 130 percent between 2019 and 2023. Since OPOs determine medical suitability and transplant

surgeons determine if a particular organ will be transplanted into a specific recipient, there will always be some organs that are discarded. However, we are concerned that the increase in zero organ donors and the number of discarded organs could, at least partially, be a result of issues in potential donor evaluation and management. By requiring OPOs to include adverse events related to potential donor evaluation and management in their QAPI program, this should assist the OPOs in identifying and addressing any problems in their policies and procedures that could be resulting in the loss of transplantable organs. Hence, due to the critical nature of the patient or potential donor's evaluation and management, we are proposing to add an example at paragraph (c)(3)(iii) to clarify that OPOs should be including in their QAPI program adverse events resulting from deviations from the current standards of practice or their own policies and procedures regarding the evaluation and management of patients or potential donors that result in loss of a patient, potential donor, or transplantable organ(s). Hence, OPOs would need to comply with § 486.348(c) if they identify any instances that meet this example.

OPOs must “develop and follow a written protocol for packaging, labeling, handling, and shipping organs in a manner that ensures their arrival [at the transplant center] without compromise to the quality of the organ” (§ 486.346(c)). We have received feedback about numerous incidents involving organs transported to transplant programs that did not arrive, were delayed such that it was too late for the organ to be transplanted, or arrived in conditions incompatible with transplantation. Although we believe this happens only to a small percentage of organs, usually kidneys (which are lost or delayed more often due to their frequency of being transported commercially), this still amounts to potentially hundreds of organs that are recovered but not transplanted. At a Senate hearing in 2022, it was stated that it has been estimated that it is 15 times more likely for an organ to be lost or damaged in transit as it is for an airline to lose or damage passenger luggage.⁷¹ Also, there have been reports

of organs arriving at a transplant center frozen solid or otherwise physically damaged.⁷² We are concerned about cases of organs that are lost in transit, delayed and arrive too late to be transplanted, or arrive in a condition that is incompatible with transplantation. All types of donated organs have specific ischemic timeframes in which the organ is suitable for their transplantation. If the organ(s) arrives at the transplant center without sufficient time to transplant that organ(s) within that timeframe, it cannot be transplanted. In addition, the organ must be in a condition suitable for transplantation, which is ultimately up to the transplant surgeon. If the organ is damaged in some way, it will not be acceptable. These are organs that could have been transplanted but are in some way rendered incompatible for transplant, causing potential transplant recipients to be denied a transplant or extending their time on the transplant waiting list. These missed opportunities may also result in the potential donor recipient potentially becoming too sick for a transplant or even dying before another organ is available. We are especially concerned about the reports we have received that these types of incidents have not been followed up with an adverse event investigation as required. To address these concerns, we propose to add examples of adverse events at § 486.348(c)(3)(v) and (vi) to include organs that are either lost or delayed and arrive too late to be transplanted or arrive in a condition incompatible with transplantation.

The current examples of adverse events in § 486.302 also include delivery of “the wrong organ”. For greater specificity and to avoid confusion, we propose to replace “the wrong organ” with “an organ that was not for the intended organ recipient”. We also propose to remove the two references to “beneficiary” that currently appear in the examples in the “adverse event” definition. All OPOs must comply with the OPO CfCs, which apply to all patients regardless of payor source. Hence, the term “beneficiary” in the OPO CfCs is not appropriate. We propose to remove the two references to “beneficiary” and instead use “organ recipient”.

uss-organ-procurement-and-transplantation-network.

⁷² Farmer, B. Transplant agency is criticized for donor organs arriving late, damaged or diseased. NPR. Accessed at <https://www.npr.org/sections/health-shots/2022/08/17/1118009567/damaged-and-diseased-organs-the-agency-overseeing-transplants-faces-intense-scrutiny>. Published August 17, 2022. Accessed on February 9, 2023.

⁶⁹ OPTN National Data. <https://hrrsa.unos.org/data/view-data-reports/national-data/>.

⁷⁰ Hanson, T, Zalani, A, Gold, R, and Herman, J. Discarded: Why donated organs are left unused. CBS News Investigations. Accessed at <https://www.cbsnews.com/organdonors/>. Accessed on July 14, 2025.

⁷¹ A System in Need of Repair: Addressing Organizational Failures of the U.S.'s Organ Procurement and Transplantation Network. United States Senate Committee on Finance. Full Committee Hearing August 3, 2022. <https://www.finance.senate.gov/hearings/a-system-in-need-of-repair-addressing-organizational-failures-of-the->

Paragraph (d), “Standard: Review of outcome measures,” requires OPOs to review their performance on the outcome measures and incorporate that data into their QAPI program. This process must be a continuous activity to improve their performance and OPOs should endeavor to use more frequent, interim monitoring of process and outcomes measures to identify areas for performance improvement. If the annual assessment of the OPOs’ performance on the outcome measures indicates an OPO has a DSA that is assigned as either in tier 2 or tier 3, the OPO is required to identify opportunities for improvement and implement changes that lead to improvement in the measures.

OPOs should leverage their QAPI programs as they look to increase the number of medically complex organs recovered and transplanted. Some members of the OPO and transplant communities have expressed their opinion that increasing the acceptance of medically complex organs would likely result in a considerable increase in the total number of organs transplanted. Recent efforts by the OPTN to increase the number of medically complex organs recovered and transplanted have yielded results that support this position. In response to the growth in the use of DCD organs over the last several years, the OPTN conducted a collaborative improvement project with OPOs to identify and share effective practices related to procurement of DCD organs.⁷³ DCD donations increased from 2,718 in 2019 to 5,894 in 2023.⁷⁴ OPOs vary substantially in their performance with DCD donation with some OPOs having over 50 percent of donors coming from DCD donation while other OPOs have very few DCD donors.

The OPTN also conducted other collaborative improvement projects, including the Collaborative Improvement and Innovation Network.⁷⁵ The objective of that improvement project was to increase the number of deceased donor kidneys with a high KDPI, which is a score derived from a variety of donor factors to

estimate how long a donated kidney is expected to function compared to other kidneys recovered in the U.S.⁷⁶

Generally, the waiting time for a kidney with a low KDPI is longer. The decision on whether a particular kidney will result in a successful transplant for a specific recipient depends on the transplant surgeon’s judgment and the risk the potential recipient is willing to take. The higher the KDPI, the fewer years the kidney is expected to function. As a result of this collaborative activity, one transplant center was able to increase the percentage of its patients listed for high KDPI kidneys from 9.2 percent to 16.03 percent over a 9-month period.

In researching KDPI levels, we discovered that there does not appear to be any universally accepted measure. In the OPTN Collaborative discussed in the previous paragraph, they addressed donors with a KDPI over 50. However, a review of OPTN’s website revealed an “Accelerated placement of hard-to-place kidneys” protocol that addressed donors with KDPI of 75 to 100.⁷⁷ That protocol also noted the kidney from donor with KDPI score of 70 percent or greater are used much less frequently than those with lesser scores. In this rule, we propose to use 50 percent. However, we are specifically soliciting comments on what the percentage score for KDPI should be in our definition of “medically complex organs”, such as 50, 70, or another percentage.

We believe there is significant interest in increasing the number of organs recovered from DCD donors, as well as other medically complex donors. We discussed our proposal for including definitions for medically complex organs and medically complex donors in section II.A. of this proposed rule. We will not consider these organs separately in the outcome measures; however, we do believe it is important that OPOs pursue medically complex donors from whom they could potentially recover transplantable organs. To further the goal of improving procurement and transplantation of medically complex organs, we propose to add a new paragraph (e) at § 486.348, Review of performance on the recovery and transplantation of medically complex organs, so that each OPO in its QAPI program must: (1) assess its

policies and procedures regarding medically complex donors and medically complex organs and ensure they are optimizing opportunities to recover and place these organs for transplant; (2) assess its performance regarding the number of medically complex donors by determining the number of medically complex donors from whom the OPO has obtained consent for donation, the number of organs recovered from those donors, and the number of medically complex organs transplanted at least annually; and (3) implement actions to improve its performance (from an initial assessment) with medically complex donors or medically complex organs when the OPO identifies opportunities for such improvement.

We solicit comments on this proposed addition, including but not limited to, comments on how often each OPO should review their performance on medically complex donors and organs as part of their QAPI program.

L. Proposed Conforming Changes to § 486.322 Relationships With Hospitals, Critical Access Hospitals, and Tissue Banks; § 486.324 Administration and Governing Body; and § 486.360 Emergency Preparedness

The previous OPO CfCs were developed based on the assumption that each OPO would only be responsible for a single DSA at any time. While the statute requires that only one OPO may operate within a DSA, it does not prohibit one OPO from operating multiple DSAs at one time. OPOs have expressed interest in operating multiple DSAs under the control of a single OPO, and we propose to include conforming changes to address several areas within the CfCs that specifically relate to the number of DSAs an OPO may be responsible for. Specifically, we propose at § 486.322(a) to align the requirement to have a written agreement with 95 percent of the Medicare and Medicaid participating hospitals and critical access hospitals (CAHs) with both a ventilator and an operating room to specify that the written agreements must be with hospitals and CAHs in each of its designated DSAs. We also propose conforming changes at § 486.324(a)(1), (a)(2), (a)(5), (b)(2), and (b)(8) to replace the word “area” with “area(s)”. Additionally, we propose a conforming change at § 486.328(c) to require that data used for OPO re-certification must include data for all deaths in all hospitals and CAHs in the OPO’s donation service area(s), unless a waiver has been granted. Finally, we propose two conforming changes to the emergency preparedness requirements

⁷³ OPTN DCD Procurement Collaborative Project. https://hrsa.unos.org/media/mcsl2ebu/optn-dcd-procurement-collaborative_2022-executive-summary.pdf.

⁷⁴ OPTN/SRTR Annual Data Report 2020. <https://onlinelibrary.wiley.com/doi/epdf/10.1111/ajt.16976>.

⁷⁵ Wey A, Foutz J, Gustafson SK, Carrico RJ, Sisaithong K, Tosoc-Haskell H, McBride M, Klassen D, Salkowski N, Kasiske BL, Israni AK, Snyder JJ. The Collaborative Innovation and Improvement Network (COIN): Effect on donor yield, waitlist mortality, transplant rates, and offer acceptance. *Am J Transplant*. 2020 Apr;20(4):1076–1086. doi: 10.1111/ajt.15657.

⁷⁶ Kidney Donor Profile Index (KDPI) Guide for Clinicians. HRSA/OPTN. Accessed at <https://www.hrsa.gov/optn/professionals/resources/guidance/kidney-donor-profile-index-kdpi-guide-for-clinicians>. Accessed on May 11, 2022.

⁷⁷ OPTN.org. Accessed at https://hrsa.unos.org/media/jppbstey/optn_accelerated-placement-of-hard-to-place-kidneys.pdf. Accessed on July 15, 2025.

for OPOs. In § 486.360 we propose to revise paragraph (c)(1)(v) to require that OPOs have an emergency communication plan with the names and contact information for transplant and donor hospitals in each of the OPO's DSAs. We also propose to revise paragraph (e)(2)(i) by replacing "DSA" with "DSA(s)".

IV. Comment Solicitation and Discussion on Emerging Issues

A. Conflicts of Interest

CMS has been aware for some time that some OPO staff at various levels of organization leadership and employment are also engaged in outside activities that may present a conflict of interest with their official OPO duties and with their position of public trust as a crucial point in the organ donation, procurement, and transplantation system. While these activities are not prohibited by law or regulation, interested parties have raised transparency concerns regarding the matter, as well as CMS' ability to exercise its oversight responsibilities in light of this lack of transparency. Conflicts of interest can be actual or potential, meaning that they may exist or there may be a reasonable perception of their existence that necessitates equal treatment. Conflicts arise when a covered person, and by extension the individuals with whom they are closely associated, such as immediate family members, has a financial (ownership, investment, employment, or other compensation) interest in another business with which the covered person's OPO is doing, or will do, business. Compensation includes both direct and indirect forms, as well as gifts or favors.⁷⁸ Conflicts of interest may also be ethical or political in nature,⁷⁹ involving issues that reflect misaligned or competing interests among various parties with whom the individual has personal or professional relationships or interactions that juxtapose personal or professional interests with larger public interests.

The relationship and potential for conflicting incentives between organ and tissue procurement was described in a November 2020 report from The Bridgespan Group, "Transforming Organ Donation in America" Appendix A.⁸⁰ The report notes that non-profit OPOs, with their status as DSA-specific

monopolies for organ recovery, are compensated by tissue-processing partners (which may be for-profit corporations) for procurement of tissue, cornea, bone, and skin, and that prices for tissue and non-organ body parts are subject to market forces, meaning increased demand can increase prices and bring additional revenue for every incremental tissue recovery. The report surmises thusly that, "OPOs have greater financial incentives to focus more on tissue recovery compared to their incentives to recover lifesaving organs." The report goes on to note that there is no demonstrable connection between increased revenues related to tissue procurement and increased OPO performance, citing a specific OPO that reported spending \$392,472,519 on "tissue processing" compared with only \$22,397,590 on "organ procurement" in its most recent tax filings (2018) while simultaneously being a tier 3 OPO. The report concluded, "that a large pool of tissue-related profits do not guarantee improvements in organ recovery."

While the OPO CfCs at § 486.322(c) require that OPOs must have arrangements to cooperate with willing tissue banks that work with the same hospitals as the OPO does, and that they must cooperate in specified activities to ensure that all usable tissues are obtained from potential donors, this requirement is in no way meant to replace organ procurement efforts with tissue procurement efforts. Organ transplants save and prolong lives, such that a focus on improving organ procurement and transplantation must remain upmost for all OPOs. An L.A. Times news article summarized that, "There's no denying that organs can extend lives, and tissue is sometimes life-enhancing. Corneas can save sight in those going blind. Tendons are used to repair sports injuries. But, in convincing people to become donors, companies rarely mention that a growing part of the multibillion-dollar body parts industry is cosmetic surgery—or that unlike organs, tissues are rarely of immediate need."⁸¹ The article cited that while the number of organ donors grew from 8,085 to 9,079 from 2007 to 2015, the number of tissue donors grew from 29,799 to 39,121 in that same time, with companies harvesting so much tissue from Americans that they are increasingly exporting it overseas. Tissue recovery and sale is an area that is particularly vulnerable to financial conflicts of interest that may negatively impact the

health and safety of patients on the transplant waitlist.

The issue of conflicts of interest in the organ procurement industry has gained considerable interest from members of the United States Senate Committee on Finance. In a February 2020 letter⁸² addressed to the United Network for Organ Sharing from the Committee, signed by Senators Grassley, Wyden, Young, and Cardin, the Committee questioned, "Given that multiple OPOs recover tissue and some operate tissue banks, on what mechanisms does UNOS rely to minimize conflicts of interest, and what measures does UNOS take to protect against OPOs prioritizing tissue recovery over organ recovery due to financial incentives?" The Committee continued to pursue the subject in an April 2022 letter⁸³ to the HHS Secretary and CMS Administrator, signed by Senators Wyden, Grassley, Young, Cardin and Moran, which suggested that CMS should, "require robust, independent oversight by each OPO governing board and medical advisory boards consistent with best practices for non-profit governance. Members of these boards should follow professional guidelines that require them to attest to serve the public interest and oversee OPO leadership, policies, and procedures. Members should also disclose any conflicts of interest, including any direct or indirect financial arrangements relating to organ donation or transplantation, and make these attestations available to CMS."

In July 2024, as part of the OPTN Modernization Initiative and with new flexibilities authorized by the Securing the U.S. Organ Procurement and Transplantation Network Act signed in September 2023, HRSA announced a critical step in reducing conflicts of interest in OPO oversight by separating the OPTN Board of Directors from the OPTN contractor.⁸⁴ This effort led to a June 2025 HRSA announcement⁸⁵ of the launch of a new 34-member OPTN Board of Directors, each of whom has completed a comprehensive Conflict of Interest Disclosure Questionnaire that encompasses both existing and potential relationships. HRSA describes a conflict

⁸² [https://www.finance.senate.gov/imo/media/doc/2020-02-10%20Grassley,%20Wyden,%20Young,%20Cardin%20to%20UNOS%20\(Information%20Request%20on%20Organ%20Transplant%20System\).pdf](https://www.finance.senate.gov/imo/media/doc/2020-02-10%20Grassley,%20Wyden,%20Young,%20Cardin%20to%20UNOS%20(Information%20Request%20on%20Organ%20Transplant%20System).pdf).

⁸³ <https://www.finance.senate.gov/imo/media/doc/040722%20Wyden%20Grassley%20Young%20Transplant%20System%20RFT%20letter.pdf>.

⁸⁴ <https://www.hrsa.gov/optn-modernization/july-2024>.

⁸⁵ <https://www.hrsa.gov/optn/news-events/news/new-optn-board-members-associate-regional-councillors-elected-2025>.

⁷⁸ https://www.grassley.senate.gov/imo/media/doc/operation_transplant_staff_report.pdf.

⁷⁹ https://www.grassley.senate.gov/imo/media/doc/operation_transplant_staff_report.pdf.

⁸⁰ <https://www.bridgespan.org/insights/transforming-organ-donation-in-america>. Accessed on June 13, 2025.

⁸¹ <https://www.latimes.com/business/la-fi-how-body-brokers-took-over-county-morgue-20190408-story.html>. Accessed on June 13, 2025.

of interest as specific matters that come, “into direct or indirect conflict (or appears to come into direct or indirect conflict) with a financial, personal, business, professional, positional, programmatic or organizational interest or oversight responsibility of a covered person, including affiliates and family members thereof (a “Covered Person”), or otherwise whenever a Covered Person’s financial, personal, business, professional, positional, programmatic or organizational interest or oversight responsibility could be reasonably perceived as having the potential to affect his or her independent, objective, disinterested or good faith decision-making or judgment in fulfilling his or her duties and/or responsibilities.”⁸⁶

In continuation of these ongoing efforts, in June 2025 the United States Senate Committee on Finance issued a staff report, “Operation Transplant: Examining the Need for Oversight in the Organ Donation System”⁸⁷ with new analysis of current OPO conflict of interest practices and additional recommendations for CMS. The report described transparency and oversight efforts for conflicts of interest among OPO leaders and governing board members as “inadequate” and described the issue as a “foundational” concern “that, if not adequately addressed, undermine public trust in this vital, lifesaving activity.” The report concluded that, “additional transparency is needed to ensure these financial and business relationships do not place Americans in need of a lifesaving organ transplant at risk.”

One example of OPO leadership having a conflict of interest that went unidentified within the OPO and resulted in illegal practices comes from a 2012 case from the U.S. Attorney’s Office Northern District of Alabama. A release from the U.S. Attorney’s Office,⁸⁸ based on court documents, described that from about March 2007 until June 2011, leadership of the OPO at the center of the case solicited and received kickbacks from a local funeral home that did business with the organ center. In exchange for the kickbacks, OPO leadership would promote the funeral home and recommended the hiring of the funeral home for its services. Neither person in a leadership position disclosed that they were

receiving payments from the funeral home. These individuals falsely represented that neither of them had any financial conflicts of interest from customers, suppliers, contractors or competitors. This case of undisclosed, improper financial relationships between OPO staff and businesses with which the OPO conducts business risks directly undermining public confidence in the integrity of organ donation. The perception that OPOs could profit from activities adjacent to organ procurement may erode public trust in an OPO’s role within the organ procurement and transplantation system, thereby risking the willingness of individuals to sign up for organ donation and the willingness of families to authorize donation. Without organ donors, waitlist patients wait longer, jeopardizing their health and safety.

CMS also has concerns related to the relationships between OPOs with tissue banks and officials from local morgues and medical examiner offices, which are the original source of data that populates the CDC MCOD file that CMS uses for establishing the eligible death denominator for its outcome measures. The 2019 LA Times news article, “How organ and tissue donation companies worked their way into the county morgue,”⁸⁹ described overlapping employment relationships with procurement staff serving both the procurement entity and as pathologists performing autopsies to determine cause of death in local morgues within the OPO’s DSA. The article also described a specific situation in which a city’s chief medical examiner also sat as a paid member of the board of the OPO that serves the city in question. Furthermore, the article stated, “The procurement companies have become so influential at the medical examiners’ association that their executives now sit on the group’s board of directors.” One State’s chief medical examiner’s office reported that it has taken action to prevent conflicts of interest by revising its policy to prohibit procurement company employees who serve as part-time medical examiners from authorizing the retrieval of organs or tissues.

The OPO CfCs at § 486.324, Administration and governing body, permit each OPO to have more than one board, while specifying that an OPO must have an advisory board, which is not the OPO’s governing body, comprised of certain specified members, including transplant surgeons that

represent each transplant center in the DSA with which the OPO has agreements and tissue bank representatives. This advisory board is charged by the CfCs with authority to recommend policies for a wide variety of essential OPO activities, including organ procurement, organ allocation, and organ transportation (including the purchase and use of private air transportation). Members of the advisory board are prohibited from serving on any other OPO board. The influential role of the advisory board, coupled with the required membership types, may create opportunities for conflicts of interest. As such, the CfCs at § 486.324(d) require that an OPO must have bylaws for each of its board(s) that address potential conflicts of interest, length of terms, and criteria for selecting and removing members.

In addition to the advisory board, in accordance with § 486.324(e), an OPO must have a governing body with full legal authority and responsibility for the management and provision of all OPO services. The governing body is responsible for developing and overseeing implementation of policies and procedures considered necessary for the effective administration of the OPO, including the OPO’s fiscal operations, its QAPI program, and the services furnished under contract or arrangement, including agreements for those services. The governing body is further responsible for appointing an individual to be responsible for the day-to-day operation of the OPO. Given the wide breadth of the authorities vested in the governing body, § 486.324(f) requires that an OPO must have procedures to address potential conflicts of interest for the governing body.

Beyond the required advisory board and governing body, the OPO CfCs also require at § 486.326, Human resources, standard (a) that an OPO must develop and implement a written policy that addresses potential conflicts of interest. This standard specifically applies to the OPO’s director, as appointed by the governing body, the medical director, the OPO’s senior management, and all procurement coordinators.

OPO implementation of these CFC requirements varies. The June 2025 United States Senate Committee on Finance staff report⁹⁰ describes the conflict of interest findings related to its investigation of eight OPOs. The investigation found that “[t]here are key differences among the various conflicts of interest policies which the OPOs operate under. Those differences

⁸⁶ <https://www.hrsa.gov/sites/default/files/hrsa/optn/optn-bod-coi-disclosure-questionnaire-508.pdf>.

⁸⁷ https://www.grassley.senate.gov/imo/media/doc/operation_transplant_staff_report.pdf.

⁸⁸ <https://www.justice.gov/archive/usao/aln/News/June%202012/June%2013,%202012%20Former%20Alabama%20Organ.html>. Accessed on June 13, 2025.

⁸⁹ <https://www.latimes.com/business/la-fi-how-body-brokers-took-over-county-morgue-20190408-story.html>. Accessed on June 13, 2025.

⁹⁰ https://www.grassley.senate.gov/imo/media/doc/operation_transplant_staff_report.pdf.

include whether employees are covered or just the directors and officers, whether and how the board of directors may approve a transaction despite a conflict, and whether conflicts of interest include those which arise from ethical or political conflicts or solely financial conflicts.” The authors noted vagueness on what details about the conflict of interest must be reported, and how the conflicts are recorded, reviewed, and maintained, making the task of OPOs identifying conflicts in future transactions difficult. Importantly, from the perspective of patient health and safety, the report noted that “every conflicts of interest policy focused on corporate conflicts and the interests of the OPO without a focus on conflicts to the national needs of the organ donation system in the public interest.”

All of the OPOs included in the Committee staff investigation required covered persons to sign an annual conflicts of interest form and seven of the eight required covered persons to disclose the conflict on their annual conflicts of interest form. However, only two OPOs required a disclosure of a conflict as soon as it is known to the covered person or should be known, creating significant gaps in time when disclosures remain unreported for most of the OPOs. All of the OPOs require disclosure of actual or potential conflicts at the time when a conflicted transaction or arrangement emerges. However, only five of the eight OPOs specify to whom the conflict is reported. According to the Committee report, many of the disclosures included very little information, simply naming a hospital, for example, without an explanation as to their role at that hospital or how their disclosure conflicted or potentially conflicted with their role at the OPO.

Each of the OPOs, with one exception, have conflicts of interest policies allowing for the board of directors to approve a conflicted, or potentially conflicted, transaction. Requirements related to board approvals included elements such as requiring a full disclosure of the material facts of the conflict, that board members with conflicts are not present for discussions related to the transaction related to the conflict, that remaining board members hold a majority vote approving to approve or decline, and that the transaction related to the conflict is fair to the OPO and is legal. Some OPOs reported requiring the board to exercise due diligence to determine if there is an alternative transaction that the OPO could enter into that would not be conflicted.

The significant variances in OPO practice, such as the lack of detailed information and missing reporting mechanisms, may represent opportunities for CMS to improve its regulatory oversight of this issue. The November 2020 report from The Bridgespan Group report suggested, “CMS could require disclosures of financial relationships between OPOs/OPO leaders and partner entities (such as tissue processors and private jet service companies), or even prohibit OPO leaders from engaging in financial relationships with partner entities (as it does for Medicare-funded physicians under Stark Law).”⁹¹ The June 2025 staff report from the United States Senate Committee on Finance recommended that, “CMS should further clarify the requirements and expectations of OPOs regarding conflicts of interest to make clear that OPO governing boards and medical advisory boards, as well as CMS surveyors, should monitor actual and potential conflicts of interest.”⁹² The Committee report based this recommendation on the fact that 1986 report from The Task Force on Organ Transplantation,⁹³ established by the National Organ Transplant Act of 1984,⁹⁴ noted that “donated organs should be considered ‘a national resource to be used for the public good’ and that ‘the public must participate in the decisions of how this resource can be used to best serve the public interest.’” The Committee report recommended that, “CMS should clearly define the expectations and requirements to be addressed in OPO conflicts of interest policies and the roles of OPO governing boards, medical advisory boards, and CMS surveyors in reviewing and evaluating those policies and conflicts.”

In focusing on OPO actions, the Committee recommended that OPOs should adopt universal standards clearly defining policy coverage, scope of conflicts, and specific disclosure procedures. Further, the Committee report recommended that each OPO should clearly define the scope of conflicts covered under its policy, including actual or potential conflicts

that are financial, personal, ethical, or political in nature. They recommended that each OPO should include in their conflicts of interest policies a provision detailing which conflicts are to be reported, when they are to be reported, how they are reviewed, and how they are recorded and maintained to allow for future audits. The recommendation continued that OPO conflicts of interest disclosure forms should include the material facts related to the reported conflicts of interest. The Committee report specifically focused on outside employment and its connection to conflicts of interest, writing:

Because of the potential for outside employment raising actual or potential conflicts of interest, such as outside employment at a transplant center or biobank, each OPO should clarify their policies regarding outside work, including whether and when it is necessary to get approval and what activities are prohibited. This recommendation applies to OPO board members who concurrently sit on the board(s) of other organizations. Outside board membership can have an outsized impact on an organization. Each OPO should clearly define the policies for board members who also sit on other boards. The policy should clearly state that such outside board membership is a conflict, and outline how those conflicts are to be reported, reviewed and adjudicated. Lastly, each OPO should clearly state the procedures for disclosing actual or potential conflicts of interest.

The committee also recommended that all OPOs establish policies and procedures for board approval of transactions or contracts where one or more of its members have an actual or potential conflict.

We are requesting public comment on the ways that conflicts of interest are handled by OPOs, the sufficiency of the current regulatory requirements, the suggestions made by outside bodies as described in this section, and other things that CMS should consider. We are interested in ways that we could potentially modify the OPO CfCs to assure consistency in the development and implementation of conflicts of interest policies to assure health and safety and the integrity of the organ donation system. We are seeking public comment related to the following:

- Actual and potential conflicts of interest that OPO staff and boards experience.
- The perception that the ability of an OPO to profit from activities that are adjacent to organ procurement could degrade the public trust inherent in an OPO’s role in the organ procurement and transplantation system.
- What the appropriate remedy within OPOs should be, if a conflict does exist.

⁹¹ <https://www.bridgespan.org/insights/transforming-organ-donation-in-america>. Accessed on June 13, 2025.

⁹² https://www.grassley.senate.gov/imo/media/doc/operation_transplant_staff_report.pdf.

⁹³ Department of Health and Human Services, Organ Transplantation Issues and Recommendations, Report of the Task Force on Organ Transplantation (1986). https://books.google.com/books?id=dFeP9DKBNYC&pg=PR23&source=gbs_selected_pages&cad=1#v=onepage&q&f=false. Accessed on June 13, 2025.

⁹⁴ <https://www.congress.gov/bills/98th/congress/senate-bill/2048/text>. Accessed on June 13, 2025.

- Firewalls that may exist within an OPO or would be prudent, to avoid potential and actual conflicts of interest.

- What the potential impact, positive or negative, would be if CMS were to engage in rulemaking to establish additional requirements related to OPO conflict of interest policies and procedures related to conflicts of interest.

- Whether, and if so, under what circumstances CMS should review a potential conflict of interest, and what factors CMS should look at to determine if a conflict of interest exists.

- Alternatives for addressing the issue of conflict of interest among OPO staff and board members.

B. Allocation Out of Sequence (AOOS)

Organ allocation is a critical function of OPOs, as they are responsible for making organ offers to the transplant centers caring for potential transplant recipients. In accordance with § 486.344(g) and (h), each OPO must have a system to allocate donated organs among transplant patients that is consistent with the rules and requirements of the OPTN and must develop and implement a protocol to maximize placement of organs for transplantation. In order to effectuate these regulatory requirements, OPOs must have a sufficient number of qualified staff to ensure efficient placement of organs (§ 486.326(b)).

More specifically, the OPTN rule at § 121.8 states that the OPTN Board of Directors shall develop policies for the equitable allocation of organs among potential recipients and that such allocation policies shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement. Equitable allocation of organs includes setting priority rankings through objective and measurable medical criteria with rankings ordered from most to least medically urgent (taking into account, and in accordance with sound medical judgment, that life sustaining technology allows alternative approaches to setting priority ranking for patients). These priority rankings are known as the “match list”, which is uniquely generated for each organ that is being considered by an OPO for procurement for purposes of transplantation. Organs are to be distributed over as broad a geographic area as possible and in order of decreasing medical urgency. Of note, the regulations at § 121.7(f), Wastage, specifically state that nothing in that section shall prohibit a transplant program from transplanting an organ

into any medically suitable candidate if to do otherwise would result in the organ not being used for transplantation. Equity based on medical need is the primary driver of organ allocation, with allowances for rare instances when an already procured organ is at critical risk of being discarded by a transplant program. In a February 2025 letter to the OPTN,⁹⁵ HRSA reiterated that “section 121.7(f) of the OPTN Final Rule (Identification of Organ Recipient—Wastage) does not authorize out-of-sequence offers by OPOs. Transplant centers in receipt of an organ may find that the intended recipient is not able to utilize the organ. This provision creates a limited exception to transplant programs to transplant the organ into a different medically suitable candidate to avoid organ wastage other than in accordance with 42 CFR 121.7(b)(1) and OPTN policies and procedures, and does not provide this authority to OPOs.”

Under the oversight of the HRSA, the OPTN establishes allocation policies and is charged with investigating incidences of organs being allocated out of the OPTN-defined sequence. Among the OPTN Management and Membership Policies, the OPTN has established that “Each OPO must have a plan to equitably allocate donated organs among transplant patients that is consistent with the obligations of the OPTN. An OPO must demonstrate it has policies and procedures that meet or exceed OPTN obligations. An OPO’s failure to comply with these requirements will be considered a noncompliance with OPTN Obligations that may result in an OPTN action according to Appendix L: Reviews and Actions.” OPTN Management and Membership Policy⁹⁶ F.1.G further requires that “Any member who becomes aware of a potential noncompliance of OPTN Obligations must inform the OPTN as soon as the member becomes aware of the issue, including potential noncompliance by the member itself. All incidences of potential noncompliance are referred for further review as outlined in OPTN policies. Any member who fails to comply with OPTN Obligations may be subject to actions as set forth in OPTN policies.” In addition to OPOs being subject to actions by the OPTN, CMS also has a regulatory mechanism for assuring OPO compliance. OPOs are

required by § 486.320 of the OPO CFCs to be a member of, participate in, and abide by the rules and requirements of the OPTN established and operated in accordance with section 372 of the Public Health Service Act (42 U.S.C. 274). The term “rules and requirements of the OPTN” means those rules and requirements approved by the Secretary. The regulations clarify that an OPO is not considered out of compliance with section 1138(b)(1)(D) of the Act or § 486.320 until the Secretary approves a determination that the OPO failed to comply with the rules and requirements of the OPTN. The Secretary may impose sanctions under section 1138 only after such non-compliance has been determined in this manner. Lack of compliance with this CFC would be considered as a reason for termination of an OPO from the Medicare program.

As part of its responsibilities to establish equitable organ allocation policies that set priority rankings based on medical urgency, avoid both wasting organs and futile transplants, and promote patient access to transplantation and efficient management of organ placement, on March 15, 2021 the OPTN implemented a new kidney allocation system to eliminate the use of donation service areas (DSAs) as units of distribution and increase geographic equity in access to transplantation regardless of a candidate’s place of listing, while limiting transportation time and costs, logistical complications, and inefficiencies through the use of proximity points.⁹⁷ In this new system, which broadened the pool of potential recipients from a single DSA to a pool of patients on transplant lists located within a 250 mile radius of the donor hospital, a unique match run list is created for each deceased organ donor, with an algorithm ranking potential recipients according to waiting time for an organ, medical urgency, geographic proximity, immunologic compatibility, estimated post-transplant survival, and other factors. The updated kidney allocation system has been credited with contributing to a 29 percent increase in overall transplant rates after the first two years of use,⁹⁸ though we note that much of this gain is likely attributable to the approximately 19

⁹⁷ <https://www.hrsa.gov/optn/patients/resources/pancreas/questions-and-answers-for-transplant-candidates-about-pancreas-pancreas-kidney-islet-allocation>.

⁹⁸ <https://unos.org/news/two-year-monitoring-report-continues-to-show-improvements-in-equity-in-access-to-kidney-transplants-for-several-key-populations/#:~:text=A%20new%20data%20monitoring%20report,a%20number%20of%20key%20populations>.

⁹⁵ HHS/HRSA letter to the OPTN, February 21, 2025, <https://www.hrsa.gov/sites/default/files/hrsa/optn/08302024-aos-critical-comment-letter-to-optn-508.pdf>.

⁹⁶ https://www.hrsa.gov/sites/default/files/hrsa/optn/optn_management-and-membership-policies.pdf.

percent gain in the number of deceased kidney donors recovered over the same era in response to new measures for OPO performance.

The combination of increased numbers of deceased organ donors and allocation policy change has also been associated with improved access to transplants for several key populations, such as pediatric, highly sensitized candidates with 80–97 percent calculated panel reactive antibody score, and candidates with more than 3 years of dialysis at the time of listing.⁹⁹ At the same time, the overall non-use rate (also known as the discard rate) for deceased donor kidneys increased from 21 percent pre-policy to 26 percent post-policy era.¹⁰⁰ A report assessing the impact of the 2021 allocation policy change noted that the change had been “disruptive” to the system in that it increased the number of transplant centers and candidates required to place a kidney and the logistical challenges for both transplant centers and OPOs. Furthermore, the researchers noted that the new policy resulted in increased cold ischemia time by 1.7 hours, and distribution time by 2.2 hours.¹⁰¹

Beyond the potential confounding effect of large-scale changes to organ donor availability, a further barrier to accurate assessment of the OPTN’s organ allocation policy changes is that historical analyses did not describe the extent to which the allocation policy in place at the time was actually being followed. After the 2021 kidney allocation changes, OPOs and transplant programs began engaging in out of sequence allocation for kidneys at far more frequent rates, increasing nearly 10-fold, rising from less than 3 percent pre-policy to nearly 20 percent by the end of 2023.¹⁰² In light of current understanding of the high degree of

policy noncompliance in the new policy era, historic assessments of policy effects on overall and subgroup transplant rates and other system parameters are at best unreliable.

The frequency of out of sequence allocation varies by OPO and transplant center. While the nationwide average at the close of 2023 was nearly 20 percent of kidney placements, individual OPOs varied from 0 percent to 43 percent with just 5 OPOs accounting for 29 percent (1456 kidneys) of all kidneys placed out of sequence in the entire country from 2021 through 2023.¹⁰³ Those same 5 OPOs were responsible for procuring only 14 percent of all deceased donor kidneys. The 2 OPOs with the highest frequency of out of sequence placements used out of sequence allocation for 43 percent (239 of 556) and 32 percent (57 of 179) of their kidney placements. Conversely, seven OPOs allocated fewer than 5 out of sequence kidneys from 2021 through 2023, and three OPOs did not use any out of sequence placements for kidneys in that time.¹⁰⁴

In addition to placing kidneys in ways that are not aligned with the organ match run list, OPOs also increased their use of “open offers” in which the OPO permits the accepting center to choose any compatible candidate waitlisted at their center, even if the patient is ranked below additional intervening candidates at other centers. Thus, the organ offer is made to a transplant center, rather than to a specific patient listed on the match run list. Such offers are inconsistent with section 372(b)(2)(D) of the PHS Act, which requires the OPTN to assist OPOs in the nationwide distribution of organs equitably “among transplant patients,” as opposed to being distributed among transplant centers. Section 486.324(b)(6) of the OPO CfCs establishes the authority of the OPO advisory board to recommend policies for a system for allocation of organs among transplant patients that is consistent with the rules and requirements of the OPTN. In addition, § 486.344 requires that each OPO must have a system to allocate donated organs among transplant patients that is consistent with the rules

and requirements of the OPTN, and that each OPO must have written documentation from the OPTN showing the intended organ beneficiary’s ranking in relation to other suitable candidates if the intended beneficiary has been identified prior to recovery of an organ for transplantation. Taken as a whole, it is CMS’s expectation that organ offers are made to transplant patients, rather than to transplant centers, in a manner that is consistent with OPTN rules. Researchers found that approximately 90 percent of out of sequence placements appear to have been “open offers,” though they note that “Data capturing OPO decisions to bypass candidates are not necessarily entered in real time, so we cannot reliably identify the time or circumstances when OOS [out of sequence] allocation began. The PTR [potential transplant recipient] data set does not indicate whether the OPO extended an open offer, so we can only infer scenarios that appear to have been open offers based on observed bypass and refusal patterns within and between centers.”¹⁰⁵ Despite these limitations, the researchers concluded that 68 percent of the time, the centers receiving an “open offer” from an OPO discretionarily skipped over their first ranked candidate. The median number of skipped-over candidates within the same center accepting a kidney allocated out of sequence was 13.¹⁰⁶

In addition to describing the OPOs that engage in allocating kidneys out of sequence, Liyanage et al. also described the transplant centers most likely to receive organs allocated out of sequence. High-volume transplant centers received a disproportionately high percentage of out of sequence allocations. The 11 largest transplant centers, as measured by a transplant volume of 250 to 500 per year, most frequently transplanted kidneys allocated out of sequence, accounting for 21.6 percent of their kidney transplants. In contrast, the smallest-volume centers, as measured by a transplant volume of less than 50 transplants per year, less frequently transplanted kidneys allocated out of sequence, accounting for only 4.3

⁹⁹ <https://unos.org/news/two-year-monitoring-report-continues-to-show-improvements-in-equity-in-access-to-kidney-transplants-for-several-key-populations/#:~:text=A%20new%20data%20monitoring%20report,a%20number%20of%20key%20populations.>

¹⁰⁰ <https://unos.org/news/two-year-monitoring-report-continues-to-show-improvements-in-equity-in-access-to-kidney-transplants-for-several-key-populations/#:~:text=A%20new%20data%20monitoring%20report,a%20number%20of%20key%20populations.>

¹⁰¹ Wood, Nicholas L. Ph.D.1; VanDerwerken, Douglas N. Ph.D.1; Segev, Dorry L. MD, Ph.D.2,3,4; Gentry, Sommer E. Ph.D.1,4. Increased Logistical Burden in Circle-based Kidney Allocation. *Transplantation* 106(10):p 1885–1887, October 2022. | DOI: 10.1097/TP.00000000000004127.

¹⁰² Liyanage LN, Akizhanov D, Patel SS, Segev DL, Massie AB, Stewart DE, Gentry SE. Contemporary prevalence and practice patterns of out-of-sequence kidney allocation. *Am J Transplant.* 2025 Feb;25(2):343–354. doi: 10.1016/j.ajt.2024.08.016. Epub 2024 Aug 23. PMID: 39182614; PMCID: PMC11772121.

¹⁰³ Liyanage LN, Akizhanov D, Patel SS, Segev DL, Massie AB, Stewart DE, Gentry SE. Contemporary prevalence and practice patterns of out-of-sequence kidney allocation. *Am J Transplant.* 2025 Feb;25(2):343–354. doi: 10.1016/j.ajt.2024.08.016. Epub 2024 Aug 23. PMID: 39182614; PMCID: PMC11772121.

¹⁰⁴ Liyanage LN, Akizhanov D, Patel SS, Segev DL, Massie AB, Stewart DE, Gentry SE. Contemporary prevalence and practice patterns of out-of-sequence kidney allocation. *Am J Transplant.* 2025 Feb;25(2):343–354. doi: 10.1016/j.ajt.2024.08.016. Epub 2024 Aug 23. PMID: 39182614; PMCID: PMC11772121.

¹⁰⁵ Liyanage LN, Akizhanov D, Patel SS, Segev DL, Massie AB, Stewart DE, Gentry SE. Contemporary prevalence and practice patterns of out-of-sequence kidney allocation. *Am J Transplant.* 2025 Feb;25(2):343–354. doi: 10.1016/j.ajt.2024.08.016. Epub 2024 Aug 23. PMID: 39182614; PMCID: PMC11772121.

¹⁰⁶ Liyanage LN, Akizhanov D, Patel SS, Segev DL, Massie AB, Stewart DE, Gentry SE. Contemporary prevalence and practice patterns of out-of-sequence kidney allocation. *Am J Transplant.* 2025 Feb;25(2):343–354. doi: 10.1016/j.ajt.2024.08.016. Epub 2024 Aug 23. PMID: 39182614; PMCID: PMC11772121.

percent of their kidney transplants. The waitlists of transplant centers with the highest number of kidney transplants using organs allocated out of sequence were demographically different from centers that did not transplant out of sequence kidneys. The top 20 centers with the highest number of out of sequence transplants had a significantly higher proportion of females, Whites, Blacks, candidates with private insurance, and candidates with higher education levels on their waitlists compared with 54 centers that did not transplant kidneys allocated out of sequence. These centers also had a lower proportion of Hispanic patients on their waitlists than centers that used no kidneys allocated out of sequence. Kidneys that were allocated out of sequence “were preferentially transplanted into older candidates and candidates with shorter waiting times.”¹⁰⁷ Liyanage et al. also identified that recipients of kidneys allocated out of sequence tended to wait less than standard allocation recipients (258 days on the wait list vs 411 days) and were older (median 61 years vs 55 years). These kidney recipients tended to be older than the last higher-ranked candidate skipped on the waitlist, meaning that younger patients ranked higher on the match run list are skipped in favor of older patients ranked lower on the priority list. Kidneys allocated out of sequence less often went to women (34.1 percent vs 40.8 percent) and less often went to Black (31.7 percent OOS vs 36.5 percent standard) and Hispanic (18.0 percent OOS vs 21.2 percent standard) recipients, compared with standard allocation kidneys.¹⁰⁸

As an editorial from the American Journal of Transplantation noted, the concentration of out of sequence placements in the higher-volume OPOs and the highest volume transplant centers points “to a system increasingly shaped by relationships between these entities. Favoring higher-volume centers that can handle higher-risk organs could easily lead to more disparity.”¹⁰⁹ Such

disparities in access to organ transplants is in clear contradiction to the founding principles of the organ procurement and transplantation system, including the statutory requirement set forth in section 371(b)(3)(E) of the PHS Act, which states that an OPO shall have a system to allocate donated organs equitably among transplant patients according to established medical criteria. When an OPO provides an “open offer” to a transplant center, the most common form of allocation out of sequence, patients on other centers’ lists are bypassed. Additionally, a transplant center can also bypass patients with higher ranking on the match run list on their own transplant program. One editorial published in the American Journal of Transplantation proposed that transplant centers bypass their own patients “to find an appropriate recipient for an organ that is perceived as higher risk. There is a transparency issue where this is occurring without the knowledge of patients being bypassed, which impedes them from informed decision making and, by extension, limits their autonomy.”¹¹⁰ Others ascribe different possible motivations for using allocation out of sequence in the form of “open offers,” describing them as “remarkably efficient—officials choose a hospital and allow it to put the organ into any patient.” This article described a particular occurrence of organ allocation out of sequence whereby an OPO offered an organ to the first two highest matches, both of whom declined, and “[t]he third patient never got a chance.”¹¹¹ Rather than continuing down the organ match run list to the next potential recipient, the OPO gave an open offer to a medical center, meaning that only patients of that medical center would be eligible to receive the organ. The ultimate recipient of the organ was the 11th patient on the medical center’s own list, a person who had been ranked as number 115 on the original match run list and who was “stable” and healthier than dozens of people higher on the original list.¹¹²

Some proponents of allocating organs out of sequence have suggested that its practice has the potential to reduce organ nonuse, particularly for lower-

quality kidneys.¹¹³ Expanding use has the potential of saving lives of those on the transplant waitlist. However, research has identified that in standardized numbers, an absolute percentage increase of OOS allocation by 12.8 percent was associated with a relative decrease of 2 percent in kidney nonuse. “Even with substantial increases in OOS allocation, the impact on nonuse rates is minimal. Furthermore, this analysis likely represents a best-case scenario, as it only captures successful OOS attempts.”¹¹⁴ The February 2025 report from the New York Times found that “[s]ome procurement organizations complicate oversight by obscuring their open offers, according to current or former employees at 14 organizations. Many said they phoned doctors directly, so the details of open offers were not documented in the centralized computer system. Several said they logged an offer in the system only if the organ was successfully placed, making the practice look more effective. Others said they always entered “time constraints” as the reason for skipping patients, even if that was false.”¹¹⁵ As such, there is reason to believe that out of sequence organ allocation is even less effective at reducing organ nonuse than the initial data would indicate. This hypothesis is further substantiated by another study,¹¹⁶ which found that despite significant variation in the use of allocation out of sequence across OPOs, from a low of 1.9 percent of transplanted kidneys in some OPOs and a 68.4 percent utilization of allocation out of sequence at a single OPO in December 2023, nonuse remained consistently high, suggesting that increases in allocation out of sequence does not uniformly improve kidney utilization.¹¹⁷ This is likely connected

¹¹³ “Reforming Out-Of-Sequence Allocation: A Turning Point For Organ Transplant Policy”, Health Affairs, May 27, 2025. <https://www.healthaffairs.org/content/forefront/reforming-out-of-sequence-allocation-turning-point-organ-transplant-policy-1747919779003>.

¹¹⁴ Joel T. Adler, David C. Cron, Arnold E. Kuk, Miko Yu, Sumit Mohan, S. Ali Husain, Layla Parast, Association between out-of-sequence allocation and deceased donor kidney nonuse across organ procurement organizations, American Journal of Transplantation, 2025, ISSN 1600–6135, <https://doi.org/10.1016/j.ajt.2025.02.005>.

¹¹⁵ Rosenthal, Brian M; Hansen, Mark; White, Jeremy. “Organ Transplant System ‘in Chaos’ as Waiting Lists Are Ignored” New York Times, February 26, 2025.

¹¹⁶ Rosenthal, Brian M; Hansen, Mark; White, Jeremy. “Organ Transplant System ‘in Chaos’ as Waiting Lists Are Ignored” New York Times, February 26, 2025.

¹¹⁷ Joel T. Adler, David C. Cron, Arnold E. Kuk, Miko Yu, Sumit Mohan, S. Ali Husain, Layla Parast, Association between out-of-sequence allocation and

Continued

¹⁰⁷ Liyanage LN, Akizhanov D, Patel SS, Segev DL, Massie AB, Stewart DE, Gentry SE. Contemporary prevalence and practice patterns of out-of-sequence kidney allocation. Am J Transplant. 2025 Feb;25(2):343–354. doi: 10.1016/j.ajt.2024.08.016. Epub 2024 Aug 23. PMID: 39182614; PMCID: PMC11772121.

¹⁰⁸ Liyanage LN, Akizhanov D, Patel SS, Segev DL, Massie AB, Stewart DE, Gentry SE. Contemporary prevalence and practice patterns of out-of-sequence kidney allocation. Am J Transplant. 2025 Feb;25(2):343–354. doi: 10.1016/j.ajt.2024.08.016. Epub 2024 Aug 23. PMID: 39182614; PMCID: PMC11772121.

¹⁰⁹ Adler, Joel T. et al. Out-of-sequence allocation: a necessary innovation or a new inequity in transplantation? American Journal of Transplantation, Volume 25, Issue 2, 234–236.

¹¹⁰ Ethical implications of prioritizing utility at all costs: The rise of out-of-sequence transplants. Kulkarni, Sanjay et al. American Journal of Transplantation, Volume 25, Issue 2, 232–233.

¹¹¹ Rosenthal, Brian M; Hansen, Mark; White, Jeremy. “Organ Transplant System ‘in Chaos’ as Waiting Lists Are Ignored” New York Times, February 26, 2025.

¹¹² Rosenthal, Brian M; Hansen, Mark; White, Jeremy. “Organ Transplant System ‘in Chaos’ as Waiting Lists Are Ignored” New York Times, February 26, 2025.

to the fact that, based on analysis of more than 500,000 transplants performed since 2004, the New York Times found that in 2024, “37 percent of the kidneys allocated outside the normal process were scored as above-average.”¹¹⁸ While kidneys that are medically complex may be more challenging to place, OPOs are using allocation out of sequence for kidneys that are sought after and easy to place.

CMS is concerned that OPOs are using allocation out of sequence to mitigate the logistical challenges they face and minimize costs while potentially ignoring alternative strategies that may be more effective in minimizing organ nonuse and maximizing transplants. In the February 2025 New York Times report,¹¹⁹ one former OPO leader claimed that “open offers” are financially beneficial to OPOs, likely because speeding up allocation saves money on staffing, while the OPO is paid a pre-established set fee by the receiving hospital, regardless of what costs the OPO does or does not incur. This cost savings may be incentivizing OPOs to shorten the time between procurement and pursuit of an out of sequence “open offer” arrangement. The New York Times reported that one OPO began requiring the use of open offers whenever kidneys hit 12 hours outside a donor’s body, which was then reduced to 8 hours, and then again to 6 hours. At another OPO, the New York Times reported that workers said that after five hours, they invited favored hospitals to identify their highest patient on the list for whom they would accept the kidney, and the “top offer won.”¹²⁰ With proper storage, kidneys have a cold ischemic time of up to 48 hours, raising questions about whether OPOs are initiating match run list bypass procedures appropriately.

At one OPO, the New York Times reported¹²¹ that “open offers” are used to steer organs to a single, preferred

transplant program. The OPO contracts with senior leaders who work for that preferred transplant program as medical advisers for the OPO. The New York Times quoted a former OPO employee, who stated, “Sometimes, we wouldn’t even pursue the organ unless they [the preferred transplant program] expressed interest”.¹²² According to this report, when skipping patients on the match run list, the OPO sent more organs to the preferred transplant program than to all other transplant programs combined. Moreover, the report stated that hospitals are competing to gain favor with OPO leaders, with one hospital administrator stating that she had negotiated over payments for organ transport. The administrator spoke on the condition of anonymity purportedly due to a desire to avoid risking access to “open offers.”¹²³ These preferential arrangements, which may include financial incentives, raise significant ethical concerns, as well as concerns about conflict of interest among OPO and transplant center employees and contractors. While close collaboration to understand transplant center needs and preferences to improve internal processes is important to a well-functioning organ procurement and transplant system, competing priorities and financial incentives may be prioritized above the needs of potential donor patients, donors, waitlist patients, and their families.

CMS is concerned that the proliferation of allocating organs out of the OPTN-defined sequence, thereby bypassing patients ranked higher on the match run list, and the use of “open offers” to a preferred transplant program rather than to a specific patient on the match run list will create inequities in the procurement and transplant system that erode public trust. As the New York Times summarized, “in more and more cases, the list is a lie.”¹²⁴ Others^{125 126} have echoed similar concerns regarding

the lack of transparency and concerns regarding equity within the transplant system. “What happens to the patients who are passed over in favor of OOS recipients? Do they fall off the waitlist, are eventually transplanted, or die waiting?”¹²⁷ The New York Times report¹²⁸ sought to answer this concern, reporting that over the past 5 years, more than 1,200 people died after they got close to the top of a waiting list and were skipped nonetheless. While there is no guarantee that the offer would have been accepted or the organ would have been the right match, those patients were denied the opportunity to consider and explore the possibility of a transplant with that specific organ. In a March 2025 letter to CMS and HRSA, Senators Grassley and Wyden wrote, “Continued reports of unethical behavior within the organ donation system will undermine the willingness of Americans to give others the gift of life. Strengthening public trust in our nation’s organ donation system is a matter of life and death.”¹²⁹

As previously described, CMS and HRSA have regulations in place that address organ allocation. Through our complementary oversight authorities, we closely collaborate to ensure appropriate enforcement of the existing regulations and are carefully examining this issue in terms of both OPO and transplant center actions. In August 2024 HRSA provided a Critical Comment letter¹³⁰ to the OPTN, noting the existence of applicable requirements of the National Organ Transplantation Act, the OPTN Final Rule, and OPTN Policies and the responsibilities of the OPTN Board of Directors to review reports of member non-compliance with OPTN requirements. In subsequent communications, HRSA directed the OPTN to produce a comprehensive remediation plan to address widespread and increasing allocation policy non-compliance in the form of allocation that is out of sequence. The OPTN delivered a draft plan in March 2025 and began implementation of next steps, including the creation of a standard analytic definition for allocation out of sequence and the publication of an

deceased donor kidney nonuse across organ procurement organizations, *American Journal of Transplantation*, 2025, ISSN 1600–6135, <https://doi.org/10.1016/j.ajt.2025.02.005>.

¹¹⁸ Rosenthal, Brian M; Hansen, Mark; White, Jeremy. “Organ Transplant System ‘in Chaos’ as Waiting Lists Are Ignored” *New York Times*, February 26, 2025.

¹¹⁹ Rosenthal, Brian M; Hansen, Mark; White, Jeremy. “Organ Transplant System ‘in Chaos’ as Waiting Lists Are Ignored” *New York Times*, February 26, 2025.

¹²⁰ Rosenthal, Brian M; Hansen, Mark; White, Jeremy. “Organ Transplant System ‘in Chaos’ as Waiting Lists Are Ignored” *New York Times*, February 26, 2025.

¹²¹ Rosenthal, Brian M; Hansen, Mark; White, Jeremy. “Organ Transplant System ‘in Chaos’ as Waiting Lists Are Ignored” *New York Times*, February 26, 2025.

¹²² Rosenthal, Brian M; Hansen, Mark; White, Jeremy. “Organ Transplant System ‘in Chaos’ as Waiting Lists Are Ignored” *New York Times*, February 26, 2025.

¹²³ Rosenthal, Brian M; Hansen, Mark; White, Jeremy. “Organ Transplant System ‘in Chaos’ as Waiting Lists Are Ignored” *New York Times*, February 26, 2025.

¹²⁴ Rosenthal, Brian M; Hansen, Mark; White, Jeremy. “Organ Transplant System ‘in Chaos’ as Waiting Lists Are Ignored” *New York Times*, February 26, 2025.

¹²⁵ Lara C. Pullen, Ph.D. “Out-of-sequence allocation: It is useful, but is it ethical?” *The AJT Report* Volume 25, Issue 3p451–453, March 2025.

¹²⁶ Reforming Out-Of-Sequence Allocation: A Turning Point For Organ Transplant Policy” *Health Affairs*, May 27, 2025.” <https://www.healthaffairs.org/content/forefront/reforming-out-sequence-allocation-turning-point-organ-transplant-policy-1747919779003>.

¹²⁷ Lara C. Pullen, Ph.D. “Out-of-sequence allocation. It is useful, but is it ethical?” *The AJT Report* Volume 25, Issue 3p451–453, March 2025.

¹²⁸ Rosenthal, Brian M; Hansen, Mark; White, Jeremy. “Organ Transplant System ‘in Chaos’ as Waiting Lists Are Ignored” *New York Times*, February 26, 2025.

¹²⁹ Grassley/Wyden letter to CMS, March 26, 2025. https://www.judiciary.senate.gov/imo/media/doc/grassley-wyden_to_cms_-_organ_allocation.pdf.

¹³⁰ HHS/HRSA Critical Comment Letter to OPTN, August 30, 2024. <https://www.hrsa.gov/optn/policies-bylaws/optn-critical-comments-and-directives>.

allocation out of sequence web page.¹³¹ In July 2025, following the ratification of a new OPTN Board of Directors, HRSA shared a detailed response to the OPTN's proposed plan, including guidelines for practical implementation. Throughout this process, HRSA has provided support and guidance to the OPTN and maintained close collaboration and alignment with CMS. Under this HRSA guidance, the OPTN has created an Allocation out of Sequence resource page¹³² that can be used by OPOs and transplant programs to facilitate understanding of the issue and compliance with existing requirements.

Work is ongoing to address the issue of organs being allocated out of sequence to ensure that OPOs and transplant centers are held accountable for meeting all statutory and regulatory requirements and expectations, and we will continue to focus on ways to collaboratively improve the system for all potential donor patients, donors, patients waiting on the transplant list, and their families. It is our goal to ensure a safe, transparent, and high-performing system that honors the precious gift of organ donation and assures public confidence in the system's integrity for all patients at all times.

C. Automated Electronic Referrals

The first step in the organ donation process is for the donor hospital to provide notification to their respective OPO of all deaths and imminent deaths in the hospital. This notification is essential in identifying all potential donors. Timely notification may make the difference in whether a potential donor is identified and whether there is sufficient time to complete the many steps for that person to become a donor where organs are procured for transplantation. Currently, there is no standard process for how this notification is conducted. The OPO Conditions for Coverage (CfCs) at § 486.322(a) and the hospital Conditions of Participation (CoPs) at § 482.45(a) require an agreement between the OPO and each donor hospital for this cooperation. The agreement describes the responsibilities of both the OPO and donor hospital. Hospitals are required to notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose deaths are imminent or who have died in the hospital. OPOs are required to determine medical

suitability for organ donation and, in the absence of alternative arrangements by the hospital, tissue and eye donation. The agreement must also include definitions of "timely referral" and "imminent death". However, the regulatory requirements do not specify the manner in how the notification and information are to be transmitted. We are therefore soliciting public comments on how to leverage technology to support automated referrals and how to provide necessary privacy and security for the information. We note that this comment solicitation is a continuation of our efforts to gain input from the public regarding the market of digital health products for Medicare beneficiaries as well as the state of data interoperability and broader health technology infrastructure through the Health Technology Ecosystem Request for Information (90 FR 21034) published on May 16, 2025. We are committed to leveraging health technology to promote better health outcomes through improvements in organ donation.

CMS previously published a request for information (RFI) in December 2021 (CMS 3409-NC; 86 FR 68594) that solicited public comment on the donor referral process. The RFI inquired about clinical triggers, which staff should make referrals to OPOs, minimum information that should be shared, and clinical decision support protocols that assist in identifying potential donors. Additionally, the RFI solicited information on technological aspects related to this process. Specifically, the RFI requested information on the extent to which electronic referrals were being made, whether these leveraged the admission, discharge, and transfer elements in electronic medical record systems to transfer information, and if there were other ways for OPOs to use electronic health record (EHR) application program interfaces (APIs) to facilitate notification and information transfer. Since publication of the RFI in 2021, we acknowledge that there have been improvements in health technology and the widespread availability of interoperable EHRs. We therefore are seeking additional comments reflecting changes that may have occurred since 2021. Specifically, we are asking for comments, including relevant data, on the following:

- Specific technological aspects to implementing automated electronic referrals for hospitals and OPOs, including information on APIs, EHRs, and Health Level Seven (HL7®) Fast Healthcare Interoperability Resources (FHIR®) standards, and implementation within the Trusted Exchange

Framework and Common Agreement (TEFCA) framework.

- How and where should APIs for automated referrals nest within a broader framework of health IT infrastructure?
- How, and whether, the current electronic notification requirements for hospitals at § 482.24(d) could be leveraged to provide automated donor referrals?
- What existing uniform frameworks exist or can be modified to support information collection and sharing to enable automated referrals?
- What standards should be established to enable interoperability to support broad national adoption of electronic referrals?
- For hospitals and OPOs that are currently leveraging technology for automated referrals, what best practices can be shared?

We solicit comment from all interested entities and are particularly interested in information from EHR vendors on specific solutions to scale implementation nationally across various technology platforms. We also encourage families of organ donors, advocates, transplant recipients, OPOs, and hospitals to submit comments.

V. 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 solicit public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

In analyzing the burden for ICRs, we rely heavily on wage and salary information. Unless otherwise indicated, we obtained all salary information from the May 2024 National Occupational Employment and Wage

¹³¹ <https://www.hrsa.gov/optn/policies-bylaws/policy-issues/allocation-out-of-sequence-aos>.

¹³² <https://www.hrsa.gov/optn/policies-bylaws/policy-issues/allocation-out-of-sequence-aos>.

Estimates, United States by the Bureau of Labor Statistics (BLS) at https://www.bls.gov/oes/current/oes_nat.htm. Based on this information, we have calculated the estimated adjusted hourly rates based upon the national mean salary for that position increased by 100 percent to account for overhead costs and fringe benefits. The raw wage and salary data from the BLS do not include health, retirement, and other fringe

benefits, or the rent, utilities, information technology, administrative, and other types of overhead costs supporting each employee. HHS department-wide guidance on preparation of regulatory and paperwork burden estimates states that doubling salary costs is a good approximation for these overhead and fringe benefit costs. Table 1 presents the BLS occupation code and title, the associated OPO staff

position in this regulation, the estimated average hourly wage, and the adjusted hourly wage (with a 100 percent markup of the salary to include fringe benefits). In addition, throughout this analysis, any amount that results in a number ending with 0.50 or more will be rounded up to the next nearest dollar amount, and those that end with 0.49 or less will be rounded down to the next nearest dollar.

TABLE 1: Summary Information Of 2024 Estimated Mean Hourly And Adjusted Hourly Wages

Occupation Code	BLS Occupation Title	Associated Position Title in this Proposed Rule	Mean Hourly Wage (\$/hour)	Adjusted Hourly Wage (with 100% markup for fringe benefits & overhead) (\$/hour) (rounded to nearest dollar)
29-1210	Physicians	Medical Director	\$130.92	\$262
29-1141	Registered Nurses (General Medical and Surgical Hospitals)	Organ Procurement Coordinator (OPC)	\$47.32	\$95
11-9111	Medical and Health Services Managers (General Medical and Surgical Hospitals)	Quality Manager; Administrator	\$66.22	\$132

A. ICRs Regarding Information Management (§ 486.330)

We propose new information management requirements for OPOs at § 486.330. This new provision would establish new documentation requirements specific to organs procured by OPOs and sent for research, including pancreata procured and sent for islet cell research. To meet this requirement, we anticipate OPOs would need to maintain records regarding the disposition of organs sent for research studies, including information identifying approval by an institutional review board (IRB) or other formal authorizing body, as appropriate, the research institution, and the principal investigator and contact information.

Estimating the number of organs procured by OPO per research study is complex because estimates vary depending on the study’s design, objectives, and resources as well as the type of organ utilized. To estimate the burden for pancreata procured and sent for islet cell research, hereinafter referred to as IC–1(a), we use program data from the research institute, City of Hope. According to their research data, they have 15 OPOs participating in their research, with each OPO submitting on

average 110 pancreata¹³³ per year. We use this data to estimate that on average there are a total of 1,650 pancreata submitted (110 × 15 = 1,650) for islet cell research per year. Furthermore, according to CMS correspondence with a participating OPO, this OPO submitted a total of 783 pancreata to three different studies from 2021 to 2024, with an annual average of 196 pancreata submitted to 3 principal investigators. To comply with this requirement, this OPO would need to document 196 pancreata with the associated research study information. We assume an OPO’s Organ Procurement Coordinator, at \$95 per hour, will be responsible for this activity and will take 5 minutes (0.083 hours) to map each pancreas with its corresponding research study information. The total annual hourly burden for the 15 participating OPOs is estimated at 244 hours per year (0.083 hours × 196 responses × 15 OPOs), at a cost of \$23,180 (244 hours × \$95) or 16 hours per participating OPO (244 hours ÷ 15 OPOs) at a cost of \$1,520 (16 hours

× \$95). The annualized burden for IC–1(a) for all 55 OPOs, over a 5 years period, would be 4 hours (244 hours ÷ 55 OPOs) at a cost of \$421 (\$23,180 ÷ 55 OPOs) per OPO.

Estimating the burden to other organs that are procured and used for research, such as kidneys, hearts, lungs, livers, intestines, and pancreata (used for research other than islet cell research), hereinafter referred to as IC–1(b), is more difficult because we do not have reliable data on which to base these estimates. In absence of data, we illustrate the upper bound of possible burden. We assume one (1) organ is procured and used for one (1) research study. According to data maintained by the Organ Procurement and Transplantation Network (OPTN),¹³⁴ as of June 4, 2025, there was an annual average of 5,631 organs submitted annually for research between 2022 and 2024. Additionally, recent research by the National Academies indicates that between 2013 and 2015, there was an annual average of 4,903 organs

¹³³ “Program Statistics.” Integrated Islet Distribution Program, City of Hope, n.d., iidp.coh.org/Overview/Program-Statistics. Accessed 10 June 2025.

¹³⁴ Organ Procurement and Transplantation Network. “OPTN Data.” U.S. Department of Health and Human Services, Health Resources and Services Administration, optn.transplant.hrsa.gov/data/. Accessed June 4, 2025.

recovered and used for research programs. As we anticipate the number of pancreata used for islet cell research to return to historic levels, we assume the average number of all organs procured for research to be 5,267 per year $((4,903 + 5,631) \div 2 = 5,267)$. Assuming an average of 5,267 organs per year, we anticipate that all 55 participating OPOs or respondents will submit a total of 5,267 responses per year. For IC-1(b), this results in annualized hourly burden, over a 5-year period, of 437 hours per year $(5,267 \text{ responses} \times 0.083 \text{ hours per response, or } 8 \text{ hours per OPO } (437 \text{ hours} \div 55 \text{ OPOs}))$. We assume the responses will be submitted by an OPO's Organ Procurement Coordinator, at an adjusted loaded hourly wage of \$95. This results in an annualized hourly burden cost of \$41,515 $(437 \text{ hours} \times \$95)$, or \$760 per OPO $(\$95 \times 8)$.

The annualized burden for IC-1, including IC-1(a) and IC-1(b) for all 55 OPOs, over a 5-year period, would be 681 burden hours $(244 \text{ hours per year} + 437 \text{ hours per year})$ at an estimated annual cost of \$64,695, or 12 hours $(681 \text{ hours} \div 55 \text{ OPOs})$ at a cost of \$1,176 $(\$64,695 \div 55 \text{ OPOs})$ per OPO.

The information collection request under the OMB control number 0938-0688 will be revised and submitted to OMB for approval.

B. ICRs Regarding Quality Assessment and Performance Improvement (QAPI) (§ 486.348)

At § 486.348(e), we propose that each OPO must conduct an initial assessment of its policies and procedures regarding medically complex donors and organs to assess their performance with procuring these organs and getting them placed for transplantation. If opportunities to improve the OPO's performance are identified, it must establish or update its policies and procedures to improve its performance. After this initial assessment and the establishment of changes to its policies and procedures to improve its performance, each OPO must monitor its performance regarding medically complex donors and organs and review that data at least annually. When an OPO identifies opportunities for increasing its performance, it must update its policies and procedures to improve its performance. These activities are hereinafter referred to as IC-2.

Each OPO's burden in complying with this requirement will vary substantially. Based on our experience with OPOs, some OPOs are already

actively pursuing medically complex donors and organs and performing well in this area. However, other OPOs appear to be more reluctant to pursue medically complex donors and organs for various reasons, such as the transplant programs refusing to accept these organs. For the purpose of assessing the burden for this requirement, we base our estimates on what we believe is the average OPO—an OPO that is not maximizing its opportunities with medically complex donors and organs and needs to make some changes to its policies and procedures to optimize its performance in this area.

All OPOs would need to conduct an initial assessment that includes a review of their statistics regarding medically complex donors and organs, including but not limited to, how many of these prospective donors or families of prospective donors gave consent, the organs procured from these donors, and how many of these organs were transplanted. This assessment might also include other information, such as the willingness of local transplant centers to accept these organs and, if they are reluctant to take these organs, the outreach and educational efforts that might positively affect future acceptance rates. Complying with this requirement would likely require a manager responsible for quality (quality manager), who would need an average of 8 hours at an adjusted hourly loaded wage of \$132 to gather the data and policies and procedures needed to assess the OPO's performance with medically complex donors and organs. We believe the quality manager would then need to meet with additional staff.

For purposes of determining an estimate, we believe the OPO's medical director, an administrator, and two organ procurement coordinators (OPCs) would spend about 4 hours each in meetings to review, analyze, and determine what, if any, changes are needed to be made to modify the OPO's policies and procedures to improve its performance in this area. This would also include drafting any changes and inserting them into the OPO's policies and procedures. We estimate for IC-2 the hourly burden for these activities to be 24 hours $((4 \text{ hours} \times 1 \text{ medical director}) + (4 \text{ hours} \times 1 \text{ administrator}) + (8 \times 1 \text{ quality manager}) + (4 \text{ hours each} \times 2 \text{ OPCs}) = 24 \text{ hours})$ at an estimated cost of \$3,392 $((4 \text{ hours} \times \$262) + (4 \text{ hours} \times \$132) + (8 \text{ hours} \times \$132) + (8 \text{ hours} \times \$95) = \$3,392)$. For all 55 OPOs, the burden would be 1,320 hours $(55 \text{ OPOs}$

$\times 24$ at an estimated cost of \$186,560 $(55 \text{ OPOs} \times \$3,392)$.

For subsequent years, the lead quality manager would likely need less time to gather data on the OPO's performance with medically complex donors and organs, and on the OPO's current policies and procedures in this area. The meetings with the quality manager and the OPO's medical director, an administrator, and two OPCs should also require fewer resources because the OPO's performance and policies and procedures would have already had the initial assessment and changes made, if the OPO identified opportunities to improve its performance. We believe the necessary activities in subsequent years would require 11 hours $((2 \text{ hours} \times 1 \text{ medical director}) + (2 \text{ hours} \times 1 \text{ administrator}) + (3 \text{ hours} \times 1 \text{ quality manager}) + (2 \text{ hours} \times 2 \text{ OPCs}) = 11 \text{ hours})$ at a cost of \$1,564 $((2 \text{ hours} \times \$262) + (2 \text{ hours} \times \$132) + (3 \text{ hours} \times \$132) + (4 \text{ hours} \times \$95))$. In subsequent years, for all 55 OPOs, the burden would be 605 hours $(11 \text{ hours} \times 55 \text{ OPOs})$ at an estimated cost of \$86,020 $(55 \times \$1,564)$.

The annualized burden for this requirement for all 55 OPOs, over a 5 years period, would be 748 burden hours $((1,320 \text{ hours in year 1} + 605 \text{ hours in year 2} + 605 \text{ hours in year 3} + 605 \text{ hours in year 4} + 605 \text{ hours in year 5}) \div 5 \text{ years})$ at an estimated cost of \$106,128 $((\$186,560 \text{ in year 1} + \$86,020 \text{ in year 2} + \$86,020 \text{ in year 3} + \$86,020 \text{ in year 4} + \$86,020 \text{ in year 5}) \div 5 \text{ years})$, or 14 hours $(748 \text{ hours} \div 55 \text{ OPOs})$ at a cost of \$1,930 $(\$106,128 \div 55 \text{ OPOs} = \$1,930)$ per OPO. The information collection request under the OMB control number 0938-0688 will be revised and submitted to OMB for approval.

Collection of Information Summary

The annualized burden for all IC proposed, including IC-1(a), IC-1(b), and IC-2, for all 55 OPOs, over a 5 years period, would be 1,429 burden hours $((681 + 1,320 \text{ hours in year 1}) + (681 + 605 \text{ hours in year 2}) + (681 + 605 \text{ hours in year 3}) + (681 + 605 \text{ hours in year 4}) + (681 + 605 \text{ hours in year 5}) \div 5 \text{ years})$ at an estimated annual cost of \$170,825 $((\$64,697 + \$186,560 \text{ in year 1}) + (\$64,697 + \$86,020 \text{ in year 2}) + (\$64,697 + \$86,020 \text{ in year 3}) + (\$64,697 + \$86,020 \text{ in year 4}) + (\$64,697 + \$86,020 \text{ in year 5}) \div 5 \text{ years} = \$170,825)$, or 26 hours $(1,429 \text{ hours} \div 55 \text{ OPOs} = 26 \text{ hours})$ at a cost of \$3,106 $(\$170,825 \div 55 \text{ OPOs} = \$3,106)$ per OPO, see tables.

TABLE 2: Annualized Burden Summary

Information Collection (IC)	Annual Burden Hours	Annual Cost	Hours per OPO	Cost per OPO
IC-1(a) - Pancreata for Islet Cell Research	244	\$23,182	4	\$421
IC-1(b) - Other Organs for Research	437	\$41,515	8	\$755
IC-2 - QAPI Assessment	748	\$106,128	14	\$1,930
Total All ICs	1,429	\$170,825	26	\$3,106

If you comment on these ICRs, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule.

Comments must be received on/by March 31, 2026.

VI. 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.

VII. Regulatory Impact Analysis

A. Statement of Need

More than 100,00 people are currently waiting for an organ transplant and demand for organs continues to exceed

supply.¹³⁵ OPOs play a critical role in ensuring that as many organs as possible reach patients who need them. In 2019, President Trump issued Executive Order 13879 “Advancing American Kidney Health,” directing the Secretary to enhance the procurement and utilization of organs available through deceased donation and to establish more transparent, reliable, and enforceable metrics for evaluating an OPO’s performance. In response, CMS published the December 2020 final rule, which among other changes, established new performance measures and a three-tier ranking system for OPOs. The December 2020 final rule created a baseline implementation framework with annual costs of \$126.7 million.

Since the December 2020 final rule was published, CMS has received many questions from OPOs asking for clarification about how the new system works. This proposed rule clarifies procedures for competitions, managing multiple service areas, ending agreements, handling appeals, and other

operational details. We estimate that this proposed rule will cost an estimated \$19.1 million in the first year and \$6.3 million annually thereafter.

We also estimate that it will result in \$884,000 in annual benefits due to reduced regulatory uncertainty and compliance burden, as well as a one-time benefit of \$300,000 due to increased operational flexibility for multi-DSA operations.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 “Regulatory Planning and Review,” Executive Order 13132 “Federalism,” Executive Order 13563 “Improving Regulation and Regulatory Review,” Executive Order 14192 “Unleashing Prosperity Through Deregulation,” the Regulatory Flexibility Act, section 1102(b) of the Social Security Act, and section 202 of the Unfunded Mandates Reform Act of 1995.

Executive Orders 12866 and 13563 require agencies to assess all costs and benefits of regulatory alternatives and, when regulation is necessary, to select approaches that maximize net benefits

¹³⁵ Organ Donation Statistics. <https://www.organdonor.gov/learn/organ-donation-statistics>. Accessed on April 29, 2025.

(including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal

mandates, or the President’s priorities. The Office of Management and Budget has determined this rulemaking is significant under Executive Order 12866.

This proposed rule builds on the December 2020 final rule, which established new OPO performance measures and re-certification processes, specifically for the 2022–2026 certification period, and onwards. The December 2020 rule created baseline implementation costs of \$126.7 million annually, comprising: (1) CMS administrative costs of \$1.0 million annually for oversight, technical assistance, appeals processing, and additional FTE to support system implementation; (2) OPO management transition costs of \$2.9 million annually for incumbent OPOs transitioning to new performance standards and administrative and operational

adjustments; and (3) OPO operational costs of \$122.8 million annually associated with procurement of additional organs and enhanced performance activities under new outcome measures.

As outlined in Table 3, this proposed rule would cost an estimated \$19.1 million in Year 1 and \$6.3 million in subsequent years. Year 1 costs include approximately \$17.9 million for OPOs and \$1.2 million for CMS. Recurring annual costs include approximately \$6.0 million for OPOs and \$331,000 for CMS. These incremental costs reflect clarifications and refinements to operational and administrative requirements from the December 2020 final rule rather than fundamental system restructuring. In the upcoming sections, we discuss each of the expected impacts in detail.

TABLE 3: Proposed Incremental Costs

Cost Component	Proposed Rule (2027-2031) Year 1	Proposed Rule (2027-2031) Recurring Annual
CMS Administrative	\$1.20	\$0.33
OPO Costs	\$17.90	\$6.00
Total	\$19.10	\$6.33

1. Anticipated Incremental Effects
(Costs and Benefits)

a. Overview

This section provides a detailed analysis of the costs imposed by the 11 proposed provisions in this proposed rule. As established in Section B and detailed below in Table 4, the total estimated costs are approximately \$19.1

million in Year 1 and \$6.3 million in recurring annual costs beyond Year 1. Year 1 costs comprise approximately \$17.9 million for OPOs and \$1.2 million for CMS. Recurring annual costs comprise approximately \$6 million for OPOs and \$331,000 for CMS. The cost estimates reflect detailed analysis of the marginal effects of this proposal,

distinguishing between one-time implementation costs and recurring operational costs, and incorporating actual performance data showing 26 DSAs opening for competition during the re-certification cycle. For a summary of costs by provision category, see Table 4.

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TABLE 4: Summary of Incremental Annual Costs by Provision Category

Provision Number	Provision	OPO Costs (\$k)	CMS Costs (\$k)	Total \$k	Cost Type
1	Definition Changes (§ 486.302)	151	0	151	One-Time (Year 1)
2	Requirements for Certification (§ 486.303)	0	0	0	No Costs
3	Designation of one OPO for each donation service area (§ 486.308)	0	55	55	Annual Costs
4	OPO designation to more than one service area (§ 486.309)	5,475	13	5,488	One-Time (Year 1)
4		5000	41	5,041	Annual Costs
5	Non-renewal/De-certification (§§ 486.311, 486.312)	25	13	38	One-Time
6	Appeals (§ 486.314)	25	50	75	One-Time
6		29	69	98	Annual Costs
7	Re-certification and Competition (§ 486.316)	4942	624	5566	One-Time
8	Outcome Measures (§ 486.318)	275	50	325	One-Time
8		388	166	554	Annual Costs
9	Human Resources (§ 486.326)	970	50	1020	One-Time
9		584	0	584	Annual Costs
10	Information Management (§ 486.330)	0	0	0	No Costs
11	QAPI (§ 486.348)	0	50	50	One-Time
12	Conforming Changes (§§ 486.322, 486.324, 486.360)	44	25	69	One Time Costs
	TOTAL ONE-TIME COSTS (Year 1)	\$11,907	\$875	\$12,782	
	TOTAL RECURRING ANNUAL COSTS	\$6,001	\$331	\$6,332	
	YEAR 1 TOTAL (One-time + Recurring)	\$17,908	\$1,206	\$19,114	

BILLING CODE 4120-01-C**b. Data Sources and Key Assumptions**

Our analysis relies on data from several sources and incorporates key assumptions about OPO operations and regulatory implementation. Labor costs are based on Bureau of Labor Statistics (BLS) May 2023 National Occupational Employment and Wage Estimates, adjusted by a factor of 2.0 (100 percent) for fringe benefits and overhead. Performance data reflects current CMS OPO performance data showing 10 Tier 3 OPOs and 16 Tier 2 OPOs based on

current tier assignments. Baseline costs are established by the December 2020 final rule (CMS-3380-F, 85 FR 77898), which documented annual costs of \$126.7 million. The weighted average hourly rate of \$177 for OPO staff reflects a mix of executive directors, medical directors, quality managers, and administrative personnel. The CMS GS-14 hourly rate of \$138 reflects staff conducting oversight, policy development, and technical assistance activities.

c. Incremental Costs

This subsection presents incremental costs by regulatory provision, distinguishing between one-time implementation costs (Year 1) and recurring annual costs. Estimates are provided separately for OPOs and CMS.

(1) Definition Changes (§ 486.302)

This proposed rule would revise definitions at § 486.302 to clarify terminology used throughout the OPO conditions for coverage. The proposed changes include revising the definition

of “adverse event” by removing specific examples from the definition and relocating them to QAPI requirements (§ 486.348(c)) for greater flexibility; clarifying the definition of “donor” to specify that individuals whose pancreas is used for islet cell research are included in the definition for the donation rate outcome measure; removing pancreata used for research that does not include transplant into a patient on the OPTN waitlist from the definition of “organ” so that research activity no longer counts as a transplant for the transplantation rate outcome measure; establishing a new definition for “medically complex donor” for donors whose medical history requires special considerations (including DCD donors and those with elevated KDPI scores); defining “medically complex organ” as organs procured from medically complex donors; and creating a new definition for “unsound medical practices” to describe practices that create imminent threats to patient health and safety. These clarifications address stakeholder inquiries received since publication of the December 2020 final rule and are intended to ensure consistent interpretation and application of regulatory requirements across all OPOs.

The proposed definitional changes would result in one-time implementation costs of \$151,250 for OPOs. While the definition changes are not explicitly required to trigger operational modifications, they may lead to training costs, documentation updates, and system modifications. We estimate each OPO will spend 22 hours at \$125 (22 hours $\times$ \$125¹³⁶ = \$2,750) in first year costs only. The cost to industry at 55 OPOs $\times$ \$2,750 = \$151,250. We do not anticipate any costs for CMS.

(2) Requirements for Certification (§ 486.303)

This proposed rule would remove the requirement at § 486.303(e) that a certified OPO to have been “re-certified as an OPO from January 1, 2002, through December 31, 2005”, to align with our reinterpretation of the Certification Act. This change would eliminate a regulatory barrier that

prevents the Secretary from implementing a process for the certification of new OPOs. The proposed removal of § 486.303(e) is a technical deletion of obsolete regulatory text that does not create direct, quantifiable costs because the deletion imposes no new compliance obligations on existing OPOs, no operational or administrative changes are required at this time, and OPOs will continue to operate under existing certification requirements. We acknowledge, however, that this change has potential future implications. By removing the regulatory barrier that previously prevented new OPO market entrants, this proposal would create the legal foundation for CMS to certify new OPOs in the future. We anticipate addressing the certification process for new OPOs in future rulemaking, at which time we will fully analyze the cost impacts of establishing a new OPO certification process, potential competitive effects on existing OPOs, and administrative costs to CMS for evaluating and certifying new entities.

(3) Designation of One OPO for Each Donation Service Area (§ 486.308)

This proposed rule would clarify the process for designating OPOs to donation service areas (DSAs). The proposed changes (1) clarify the normal designation period and when CMS may adjust the length of the period; (2) specify the circumstances that trigger a DSA to become available for competition; (3) establish criteria for successor selection when insufficient time exists for a full competition process; and (4) clarifies designation periods for newly acquired DSAs.

The clarifications in § 486.308 primarily affect CMS administrative processes and do not impose direct costs on OPOs. These provisions work in tandem with other requirements to establish the framework for when competitions occur and how designation periods are determined, but do not require OPOs to undertake new operational activities beyond what was established in the December 2020 final rule baseline.

The December 2020 final rule (85 FR 77898) established baseline CMS

administrative costs of \$1.0 million annually, which included competition processing. The proposed changes in § 486.308 may require an additional 400 hours of GS-14 staff time annually, at an estimated cost of \$55,000,¹³⁷ for activities including: enhanced oversight of competition triggers and processes; successor selection coordination when insufficient time exists for full competition; re-certification cycle actions and designation period management.

(4) OPO Designation to More Than One Service Area (§ 486.309)

This proposed rule would establish a new framework allowing a single OPO to be designated to serve multiple Designated Service Areas (DSAs). Section 486.309 addresses: (1) the circumstances under which an OPO may be designated to multiple DSAs (following competition, change in ownership/control, or assignment by CMS); (2) OPO flexibility to consolidate or maintain separate DSAs; and (3) performance accountability when an OPO manages multiple DSAs, including the ability to remove designation to a tier 3 DSA without de-certifying the OPO.

We estimate that no more than 10 OPOs will expand to serve multiple donation service areas (DSAs) following implementation of the December 2020 final rule’s performance standards. Each OPO serving multiple DSAs would incur approximately \$500,000 in additional annual costs, resulting in an industry-wide impact of \$5 million annually. These costs include coordination activities (\$780,000), travel and logistics (\$960,000), IT infrastructure (\$150,000), additional administrative staff (\$520,000), hospital relationship building (\$531,600), enhanced quality oversight (\$368,000), satellite office operations (\$500,000), legal and compliance (\$300,000), marketing and community outreach (\$400,000), and operational contingency (\$490,400). Year 1 costs would be approximately \$5.45 million due to one-time IT system upgrades (\$300,000) and training expenses (\$152,000).

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¹³⁶ We estimate that each OPO will spend approximately 20 hours in Year 1 to complete the definitions-related task, at a weighted average hourly wage rate of \$125, resulting in a cost of \$5,503 per OPO. This weighted estimate is based on the following staff involvement: (1) Medical Director (BLS Occupation Code 29-1210, Physicians) at a loaded hourly wage of \$262 for 2.5 hours (\$1,310); (2) Organ Procurement Coordinator (BLS Occupation Code 29-1141, Registered Nurses)

at \$95 per hour for 12.5 hours (\$2,375); and (3) Quality Manager/Administrator (BLS Occupation Code 11-9111, Medical and Health Services Managers) at \$132 per hour for 5 hours (\$1,320). The weighted average hourly rate is calculated as: $[(\$262 \times 2.4) + (\$95 \times 12.5) + (\$132 \times 5)] \div 20 \text{ hours} = \$125 \text{ per hour}$. Loaded hourly wages include base wages plus 100% adjustment for fringe benefits and overhead costs, consistent with the methodology used in the December 2020 final rule (85 FR 77898).

Wage data are sourced from the U.S. Bureau of Labor Statistics Occupational Employment and Wage Statistics.

¹³⁷ Cost Methodology: Staff time of 400 hours annually at a GS-14, Step 5, position, at a loaded hourly rate of \$138 (includes 100% markup for fringe benefits and overhead). Calculation: 400 hours $\times$ \$137.74/hour = \$55,096 (rounded to \$55,000).

TABLE 5: Cost Components for Multi-DSA Operations¹³⁸

Component	Annual Cost	Calculation Basis
Coordination meetings	\$780,000	52 weekly meetings × 6 staff × 1 hour × \$125/hour × 10 OPOs
Travel and logistics	\$960,000	Monthly travel: 4 staff × 12 trips × \$1,200/trip × 10 OPOs
IT infrastructure	\$150,000	Annual licensing/maintenance: \$15,000/OPO × 10 OPOs
Additional administrative staff	\$520,000	20 hours/week × 52 weeks × \$50/hour × 10 OPOs
Hospital relationship building	\$531,600	Executive Director (100 hrs × \$132) + Medical Director (80 hrs × \$262) + Coordinators (200 hrs × \$95) × 10 OPOs
Enhanced quality oversight	\$368,000	Quality Manager (150 hrs × \$132) + Data Analyst (200 hrs × \$85) × 10 OPOs
Satellite office operations	\$500,000	\$50,000/OPO × 10 OPOs for facility rental and operations
Legal and compliance	\$300,000	\$30,000/OPO × 10 OPOs
Marketing and community outreach	\$400,000	\$40,000/OPO × 10 OPOs
Operational contingency	\$490,400	Buffer for unexpected costs
Total Annual Recurring	\$5,000,000	

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The December 2020 final rule (85 FR 77898) established baseline CMS administrative costs of \$1.0 million annually, which included competition processing. The proposed changes may

¹³⁸ Travel cost estimates based on GSA FY 2025 Per Diem Rates (<https://www.gsa.gov/travel/plan-book/per-diem-rates>) and Bureau of Transportation Statistics average domestic airfare. IT costs based on market research of healthcare data management systems. All staff costs use BLS wage data (<https://www.bls.gov/oes/>) with 100% loading factor consistent with December 2020 final rule methodology (85 FR 77898). CMS costs based on U.S. Office of Personnel Management, 2025 General Schedule (GS) Salary Tables (<https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/>).

require an additional 300 hours of GS–14 staff time annually, at an estimated cost of \$41,000.¹³⁹ Activities include additional complexity around: oversight of multi-DSA designations, successor selection coordination when necessary, and re-certification actions.

¹³⁹ Cost Methodology: Staff time of 300 hours annually at a GS–14, Step 5, position, at a loaded hourly rate of \$137.74 (includes 100% markup for fringe benefits and overhead). Calculation: 300 hours × \$137.74/hour = \$41,322 (rounded to \$41,000).

(5) Non-Renewal of Agreement (§ 486.311) and De-Certification (§ 486.312)

This proposed rule would revise the regulatory framework to distinguish between non-renewal of agreements and de-certification of OPOs. The December 2020 final rule established a three-tier system for OPO re-certification but did not address the procedural requirements between different tier assignments and how they impact OPO agreements.

The newly created non-renewal section (§ 486.311) is drafted specifically to distinguish between non-renewal of an OPO's agreement and de-

certification (§ 486.312). Prior to the December 2020 final rule, CMS treated all agreement terminations as de-certifications, including non-renewals. This proposal creates a distinction between non-renewal of an agreement (due to voluntary termination or a tier 2 OPO no longer being designated to a DSA) and involuntary termination that results in de-certification. The proposal also allows tier 2 OPOs that are no longer designated to a DSA to remain certified for a period of time without being designated to any DSA. These OPOs may be designated to a DSA during this period if certain circumstances enable this to occur, such as a subsequent competition where the OPO is successful. Additionally, the proposal includes notification requirements, including 90-day advance notice for non-renewal with specific content requirements covering reasons, end dates, and public notice procedures consistent with what currently exists at § 486.312.

The revised de-certification framework (§ 486.312) explicitly categorizes four distinct de-certification pathways due to involuntary termination of an OPO's agreement: non-compliance with process performance measures; all DSAs are assigned to tier 3 in the final assessment period; tier 2 OPOs that are not designated to any DSA and have no performance data at the end of a re-certification cycle; and urgent need/immediate de-certification. A related proposal at § 486.316 also establishes new provisions for removing designations to specific Tier 3 DSAs without full de-certification when an OPO manages multiple DSAs. Furthermore, the framework creates clear distinctions between situations with appeal rights (§ 486.312; de-certification) and without (§ 486.311; non-renewal after lost competition, voluntary termination).

The proposed revisions enhance clarity for multi-DSA operations, establish differentiated notice periods (90 days for standard cases; 3 days for urgent situations), and provide more detailed procedural requirements for non-renewal and de-certification processes. Since the proposed revisions involve clarification rather than fundamental operational changes we expect that they would result in minimal incremental costs. We anticipate OPOs will update internal policies to reflect differentiated notice periods (90 days standard, 3 days urgent), revise documentation for multi-DSA operational scenarios, revise internal process guides, and train staff on new appeals timelines. We estimate

each OPO would spend approximately 2.5 hours on these tasks at a weighted average hourly rate of \$177, resulting in a cost of \$443 per OPO. The cost to all OPOs is \$25,000 (55 OPOs × \$443 = \$24,365, rounded to \$25,000). We estimate CMS would spend 91 hours at \$138 (91 hours × \$138 = \$12,558, rounded to \$13,000) in first year costs only. CMS incremental activities include oversight preparation, system updating, staff training and policy development and documentation.

(6) Appeals (§ 486.314)

This proposed rule would establish changes to the OPO appeals process that include the creation of new appeal categories, formalize the CMS Administrator review process, establish remand authority, and significantly modify timelines throughout the appeals process.

OPOs would be able to appeal the loss of a single underperforming service area without facing full removal from the program. The proposal codifies a discretionary review stage with the CMS Administrator having 30 calendar days to elect review and 45 calendar days to render a decision, adding a process for a new level of administrative review. New remand authority allows the Administrator to send appeals back to CMS for redetermination, creating additional processing requirements. The proposal also makes timeline modifications, including changing the reconsideration request period from 15 business days to 20 calendar days, the CMS reconsideration decision period from 10 business days to 15 calendar days, the request for hearing period from 40 business days to 15 calendar days (a 62 percent reduction), and the hearing officer decision period from 20 business days to 90 calendar days (a 350 percent increase). Additionally, the proposal explicitly codifies the preponderance of evidence standard as the burden of proof and establishes procedures for appeals during emergency de-certifications.

We estimate a one-time Year 1 costs of \$25,000 for initial legal review and policy updates. We also expect that OPOs would spend 3 hours annually on compliance costs. Cost components include legal and compliance review requiring 1.5 hours per OPO for understanding new appeal pathways, Administrator review procedures, remand authority, and burden of proof requirements. Policy documentation updates would require 1 hour per OPO for revising internal procedures to reflect new appeal categories, timelines, and Administrator review stage. Staff training would require an additional 0.5

hours per OPO for training leadership and legal staff on compressed timelines, particularly the 15-day hearing request deadline, and new procedural requirements. The recurring annual cost calculation is 3 hours × \$177/hr × 55 OPOs = \$29,205 (rounded to \$29,000). This results in a total Year 1 cost of \$54,000 and recurring annual costs of \$29,000.

For CMS, we estimate 360 hours at \$138 GS-14 hourly rate (360 hours × \$138 = \$49,680, rounded to \$50,000) for Year 1 implementation costs. These one-time costs cover policy documentation and guidance development on Administrator review procedures requiring 120 hours, system updates to track new appeal types and Administrator review stage requiring 100 hours, staff training on new timelines, remand authority, and procedural requirements requiring 80 hours, and development of Administrator review protocols and templates requiring 60 hours.

CMS would incur new ongoing administrative costs because the formalized Administrator review process and new appeal categories create fundamentally new oversight responsibilities. We estimate 500 hours annually at \$138 GS-14 hourly rate (\$69,000) for ongoing activities. Administrator review processing would require 200 hours annually for preparing cases for Administrator review over 30 days per case, coordinating written arguments from parties, and Administrator decision-making and documentation over 45 days per case, with an estimated 3–5 appeals annually reaching the Administrator review stage. Extended hearing officer support would require 100 hours annually for additional time needed for the 90-day decision period versus the previous 20-day period, post-hearing brief processing and administrative record development, with an estimated 3–5 hearings annually. Remand processing would require 100 hours for processing remanded appeals, conducting redeterminations per Administrator instructions, and developing new initial determinations. New appeal category processing would require 50 hours annually for processing appeals for designation removal without de-certification, distinguishing between de-certification and designation removal appeals, and coordinating with multi-DSA oversight activities. Technical assistance and guidance would require 500 hours annually for responding to OPO inquiries about new procedures, providing guidance on compressed timelines and Administrator review,

and clarifying burden of proof and scope of review requirements.

These costs reflect genuine new administrative requirements for the formalized multi-stage appeals process with Administrator review, extended hearing officer timelines, and new appeals.

(7) Re-Certification and Competition (§ 486.316)

The proposed changes to re-certification and competition processes would establish substantive modifications to how OPOs are evaluated and designated to service areas under the multi-DSA framework. The proposed changes create new evaluation pathways for OPOs managing multiple service areas, establish separate tier assignments for each DSA, clarify competition eligibility for OPOs subject to non-renewal, and codify detailed transition requirements between incumbent and successor OPOs.

First, the proposed rule establishes separate outcome measure evaluation for each DSA when an OPO manages multiple service areas, while maintaining unified process performance measure evaluation across all DSAs. Second, it creates new re-certification pathways based on tier combinations across multiple DSAs, including scenarios where an OPO retains some DSAs while losing others. Third, it establishes competition eligibility for OPOs that lost competitions but remain certified during the 4-year re-certification period. Fourth, it provides detailed discussion of the four selection criteria used in competitions, including how CMS weighs performance differences, continuous improvement, barrier identification, and geographic proximity. Fifth, it codifies formal transition requirements for incumbent and successor OPOs, including mandatory transition plans and periodic reporting.

Based on current performance data showing 10 Tier 3 OPOs and 16 Tier 2 OPOs, we estimate that 26 DSAs would be opened for competition during the re-certification cycle. We estimate that approximately 35 to 40 OPOs would participate in competitions, with an average of 3 to 5 OPOs competing for each open DSA. This results in approximately 104 (26 DSAs × 4 OPOs per DSA) total competition applications across the cycle. Each competing OPO would spend approximately 200 hours preparing competition applications at a weighted average hourly rate of \$177, resulting in a cost of \$35,400 per application. Competition preparation

activities include comprehensive performance data compilation and analysis requiring 60 hours, barrier identification and documentation requiring 50 hours, strategic planning and application development requiring 40 hours, legal review and compliance verification requiring 30 hours, and executive review and submission requiring 20 hours. With 104 total applications, the total annual OPO cost is \$3,681,600 (104 applications × \$35,400/application), rounded to \$3,682,000. Additionally, we estimate one-time Year 1 costs of \$1,260,000 (55 OPOs × 130 hours times × \$177/hr) for comprehensive legal review of new competition criteria, development of competition strategy frameworks, and staff training on multi-DSA evaluation scenarios.

For CMS, we estimate 360 hours at \$138 GS–14 hourly rate for Year 1 implementation costs totaling \$49,680, rounded to \$50,000. These one-time costs cover policy documentation and guidance development on multi-DSA competition scenarios requiring 120 hours, system updates to track separate tier assignments per DSA requiring 100 hours, staff training on new selection criteria application and transition requirements requiring 80 hours, and development of transition plan templates and reporting protocols requiring 60 hours. CMS would incur new ongoing administrative costs that were not included in the 2020 baseline because the multi-DSA evaluation framework and formalized transition requirements create fundamentally new oversight responsibilities.

We also estimate an additional one-time burden of 4,160 hours at \$138 GS–14 hourly rate totaling \$574,080, rounded to \$574,000 for additional activities related to the competition.

Competition process administration would require 2,600 hours for managing 26 competitions with multiple DSAs per OPO, evaluating tier combinations across competing OPOs, applying selection criteria with discretion for performance differences and improvement trajectories, and processing approximately 104 competition applications. Transition oversight and verification would require 1,040 hours for reviewing and approving 26 incumbent OPO transition plans, monitoring successor OPO periodic progress reports, verifying completion of transitions within required timeframes, and ensuring continuity of organ procurement activities during transitions. Technical assistance and guidance would require 520 hours at a cost of \$71,760 for responding to increased OPO inquiries

about competition criteria application given the substantial number of competitions, providing guidance on multi-DSA competition strategies, clarifying selection criteria weighting and discretion, and assisting with transition plan development and reporting requirements.

(8) Outcome Measures (§ 486.318)

The proposed rule would create new evaluation pathways for OPOs managing multiple service areas to permit evaluating each DSA separately on the outcome measures as well as establishing different accountability timelines based on how a new DSA is acquired, distinguishing between accountability for QAPI purposes versus re-certification purposes.

The proposed rule introduces several new elements compared to the 2020 baseline. First, it would redesignate and remove obsolete outcome measure provisions from paragraphs (a) through (c) that expired on July 31, 2022, and renumbers current paragraphs (d) through (f) as paragraphs (a) through (c). Second, it would systematically replace references to evaluating OPOs with references to evaluating DSAs throughout the regulations to accommodate multi-DSA operations. Third, it would establish a two-track accountability system for newly acquired DSAs with immediate accountability once 12 months of data are available for mergers and change of ownership situations, and delayed accountability until the final assessment period of the following agreement cycle for DSAs acquired through competition or CMS assignment. Fourth, it would clarify separate QAPI accountability timelines that begin once 12 months of data are available regardless of acquisition method.

We estimate each OPO would spend approximately 40 hours annually at a weighted average hourly rate of \$177 to understand and implement the new accountability timelines, update internal tracking systems to monitor performance separately for each DSA, revise QAPI programs to incorporate the two-track accountability framework, and train staff on the distinctions between merger-based and competition-based acquisition timelines. The total cost to OPOs is \$388,080 (55 OPOs times 40 hours times \$177), rounded to \$388,000 for recurring costs. Additionally, we estimate one-time Year 1 costs of \$275,000 for comprehensive legal review of new accountability provisions, development of multi-DSA tracking frameworks, system modifications to monitor separate DSA performance, and staff training on the

new evaluation structure, calculated as 55 OPOs $\times$ 28 hours $\times$ \$177 per hour.

For CMS, we estimate 360 hours at \$138 GS–14 hourly rate for Year 1 implementation costs totaling \$49,680, rounded to \$50,000. These one-time costs cover policy documentation and guidance development on multi-DSA evaluation scenarios, system updates to track separate DSA performance and different accountability, staff training on applying different accountability rules based on acquisition methods, and development of templates for tracking OPOs during extended accountability periods. CMS would incur new ongoing administrative costs that were not included in the 2020 baseline because the multi-DSA evaluation framework and differentiated accountability timelines create fundamentally new oversight responsibilities. We estimate 1,200 hours annually at \$138 GS–14 hourly rate totaling \$165,600, rounded to \$166,000 for ongoing activities that include monitoring separate outcomes measure performance for each DSA when an OPO manages multiple DSAs and tracking which DSAs are subject to immediate accountability versus delayed accountability, and maintaining performance data across multiple recertification cycles for DSAs in extended accountability periods.

(9) Human Resources (§ 486.326)

The proposed changes to human resources would establish a new licensure requirement for all personnel performing clinical duties. The proposed changes create a new standard requiring that all personnel performing clinical duties must be legally authorized through licensure, certification, or registration in accordance with applicable Federal, State, and local laws, must act only within the scope of their credentials, and must maintain current credentials at all times. The proposal also makes a conforming change to the medical director requirement to accommodate multi-service area operations by changing “service area” to “service areas.”

The proposed rule introduces new elements compared to the 2020 baseline. First, it establishes a new standard at proposed § 486.326(e) requiring licensure, certification, or registration for all clinical personnel (collectively referred to as licensure). Second, it requires that clinical personnel act only within the scope of their licensure, creating new compliance monitoring obligations. Third, it requires that licensure be kept current at all times, necessitating ongoing tracking and verification systems. Fourth, it updates

the medical director requirement to reference “one of the OPO’s service areas” rather than “the OPO’s service area” to accommodate multi-DSA operations.

We estimate each OPO would spend approximately 60 hours annually beyond the collection of information burden at a weighted average hourly rate of \$177 for licensure verification and tracking. Specifically, we estimate that it would take 20 hours per OPO to verify that all clinical staff have appropriate licensures, certifications, or registrations and to establish and maintain systems to track licensure expiration dates and renewal requirements. We estimate a burden of 15 hours per OPO to update policies and procedures to incorporate licensure requirements for all clinical positions, develop job descriptions that specify required licensure for each clinical role, establish procedures for verifying licensure during hiring and ongoing employment, and create protocols for addressing situations where staff licensure lapse or are at risk of lapsing. Staff training and education would require 12 hours per OPO for training human resources staff on new licensure verification requirements, educating hiring managers on licensure requirements for clinical positions, and conducting leadership briefings on compliance implications and risk management. Recruitment and hiring process modifications would require 8 hours per OPO for updating recruitment materials to specify licensure requirements, modifying application and screening processes to verify licensure, and developing onboarding procedures that include licensure verification and tracking. Compliance monitoring and documentation would require 5 hours per OPO for establishing ongoing monitoring systems for licensure expiration and renewal, creating audit trails for CMS survey preparation, developing reporting mechanisms for licensure compliance status, and implementing corrective action procedures for licensure lapses. The total cost to OPOs for operational activities is \$584,100 (55 OPOs times 60 hours times \$177), rounded to \$584,000 for recurring costs. Additionally, we estimate one-time Year 1 costs of \$970,000 for potential costs for current staff to obtain required licensure if they do not already have it, calculated as 55 OPOs times 100 hours times \$177 per hour. We note that this estimate assumes that current staff can be trained/certified to meet the requirements rather than OPOs hiring new employees with additional

certifications that command higher salaries.

For CMS, we estimate 360 hours at \$138 GS–14 hourly rate for Year 1 implementation costs totaling \$49,680, rounded to \$50,000. These one-time costs cover policy documentation and guidance development on licensure requirements for clinical personnel requiring 120 hours, survey protocol updates to incorporate licensure verification and scope of practice review requiring 100 hours, staff training on reviewing licensure documentation and identifying scope of practice violations requiring 80 hours, and development of technical assistance materials for OPOs on credential requirements and verification procedures requiring 60 hours.

(10) Information Management (§ 486.330)

The proposed changes to information management would establish new documentation requirements for organs procured and sent for research, including pancreata used for islet cell research. The proposed changes create new recordkeeping requirements for all organs sent for research, establish specific documentation standards including IRB approval (as applicable), research institution identification, principal investigator information, and study contact details, and enable CMS verification of research disposition claims through survey processes and validation efforts.

The proposed rule introduces new elements compared to the 2020 baseline. First, it expands the scope of § 486.330(b) from documenting only organs recovered for transplantation to also documenting organs recovered and sent for research. Second, it establishes four specific documentation requirements for research organs including IRB or formal authorizing body approval, as appropriate, research institution identification, principal investigator identification, and study contact information. Third, it creates verification mechanisms through CMS survey processes to review OPO organ disposition records and conduct validation efforts to confirm accuracy. Fourth, it addresses data integrity concerns related to the 250 percent increase in pancreata reported for research between 2020 and 2024 despite declining clinical trial activity. This cost is included as a cost in the collection of information section at \$64,695 for all OPOs combined per year.

(11) Quality Assessment and Performance Improvement (QAPI) (§ 486.348)

The proposed changes to QAPI would establish new requirements for tracking adverse events and monitoring medically complex organ performance. The proposed changes expand adverse event categories to include six specific examples with detailed documentation requirements, create new tracking requirements for organs lost or delayed in transit and organs arriving in unsuitable condition, establish comprehensive evaluation and management deviation tracking, and create an entirely new performance monitoring framework for medically complex donors and organs requiring initial assessment, annual performance review, policy and procedure updates, and continuous improvement activities.

The proposed rule introduces new elements compared to the 2020 baseline. First, it moves adverse event examples from the definitions section to the QAPI section and expands them from three to six categories including transmission of infectious or communicable diseases or malignancies, avoidable loss of medically suitable potential donors, deviations from standards of practice in evaluation and management, delivery of wrong organ or blood type mismatch, organs lost or delayed in transit, and organs arriving in unsuitable condition. Second, it establishes new documentation and investigation requirements for each adverse event category with specific focus on addressing the 130 percent increase in zero organ donors between 2019 and 2023 and the nearly 12,000 organs discarded in 2024. Third, proposed § 486.348(e) requires OPOs to assess policies and procedures regarding medically complex donors and organs, track performance metrics including consent rates, recovery rates, and transplantation rates, and implement improvements when opportunities are identified. Fourth, it establishes different burden levels for initial assessment versus ongoing annual monitoring with Year 1 requiring 24 hours per OPO and subsequent years requiring 11 hours per OPO. We have accounted for these costs in the collection of information section of this proposed rule.

For CMS, we estimate 360 hours at \$138 GS–14 hourly rate for Year 1 implementation costs totaling \$49,680, rounded to \$50,000. These one-time costs cover policy documentation and guidance development on expanded adverse event categories and medically complex organ performance standards

requiring 120 hours, survey protocol updates to incorporate adverse event investigation review and medically complex organ performance assessment requiring 100 hours, staff training on reviewing expanded QAPI programs with six adverse event categories and medically complex organ tracking requiring 80 hours, and development of validation procedures for confirming adverse event investigation thoroughness and medically complex organ performance accuracy requiring 60 hours.

(12) Proposed Conforming Changes to § 486.322 Relationships With Hospitals, Critical Access Hospitals, and Tissue Banks; § 486.324 Administration and Governing Body; and § 486.360 Emergency Preparedness

The proposed conforming changes to hospital relationships, administration and governing body, and emergency preparedness would establish modifications to accommodate optional multi-DSA operations. The proposed changes update hospital agreement requirements to specify that OPOs must maintain written agreements with 95 percent of eligible hospitals in each designated DSA separately, revise advisory board membership and coordination requirements to reference service areas in plural form to accommodate optional multi-DSA governance, update emergency preparedness communication plans to include contact information for transplant and donor hospitals in each DSA, and establish continuity of operations provisions that address backup agreements covering multiple DSAs.

The proposed rule introduces new elements compared to the 2020 baseline. First, it changes the hospital agreement requirement at § 486.322(a) from requiring agreements with hospitals in the service area to requiring agreements in each of the OPO's designated service areas, creating separate 95 percent compliance requirements for each DSA. Second, it updates five references in § 486.324 governing administration and governing body from “area” to “areas” to ensure advisory board representation, policy recommendations, and coordination activities encompass all DSAs an OPO manages. Third, it revises emergency preparedness requirements at § 486.360 to require emergency communication plans that include contact information for hospitals in each DSA that an OPO manages and continuity of operations agreements that specify coverage for multiple DSAs. Fourth, it updates data collection requirements at § 486.328(c) to specify

that re-certification data must include all deaths in all hospitals and critical access hospitals in the OPO's service areas.

We estimate each OPO would spend approximately 25 hours annually at a weighted average hourly rate of \$177 for hospital agreement compliance verification requiring 10 hours per OPO to verify that 95 percent compliance is maintained in each DSA, coordinate with hospitals across multiple service areas, track agreement status separately by DSA, and prepare documentation for CMS survey verification. Advisory board and governance updates would require 6 hours per OPO for ensuring advisory board membership represents all service areas, updating board policies and procedures to reference multiple DSAs, coordinating board activities across service areas, and documenting governance structures for multi-DSA operations. Emergency preparedness plan updates would require 5 hours per OPO for updating emergency communication plans to include hospitals in all DSAs, revising continuity of operations agreements to specify multi-DSA coverage, coordinating emergency preparedness activities across service areas, and conducting training on updated emergency procedures. Data collection and reporting modifications would require 4 hours per OPO for updating systems to track data separately by DSA, ensuring re-certification data includes all hospitals in all service areas, coordinating data collection across multiple DSAs, and preparing reports that distinguish performance by DSA. The total cost to OPOs for operational activities is \$44,250(10 OPOs × 25 hours × \$177), rounded to \$44,000 for recurring costs.

For CMS, we estimate 180 hours at \$138 GS–14 hourly rate for Year 1 implementation costs totaling \$24,840, rounded to \$25,000. These one-time costs cover policy documentation and guidance development on multi-DSA hospital agreement compliance, survey protocol updates to verify separate 95 percent compliance in each DSA and review multi-DSA governance structures, verifying data collection across service areas and development of technical assistance materials for OPOs on multi-DSA operational requirements.

d. Incremental Benefits

This subsection presents the incremental benefits of this proposed rule organized by benefit category. For each category, we distinguish between quantified benefits that can be monetized with reasonable certainty and qualitative benefits that are real but

difficult to quantify precisely. Benefit estimates are presented over the 5-year analysis period (2027 through 2031) and are compared to the baseline established by the December 2020 final rule.

For quantified benefits, we provide a detailed calculation methodology showing data sources and assumptions, annual benefit estimates, and acknowledgment of uncertainty where appropriate. For qualitative benefits, we provide clear descriptions of each

benefit, explanations of why monetization is not feasible, evidence demonstrating that the benefit is real and significant, and connections to the overarching regulatory objectives of improving organ procurement and transplantation outcomes.

The quantified benefits total \$884,000 in annual benefits from reduced regulatory uncertainty and \$300,000 in one-time benefits due to increased operational flexibility for multi-DSA

operations. However, these quantified benefits represent only a portion of the total value generated by this proposed rule. Significant qualitative benefits also exist that while difficult to monetize, are essential to the effective implementation of the December 2020 final rule's performance measurement and competition framework and directly support the goal of increasing organ availability for the 100,000 plus individuals on transplant waiting lists.

TABLE 6: Summary of Quantified Incremental Benefits

Benefits Category	Benefits (k) (OPOs)	Benefits (k) (CMS)	Benefits Type
Reduced Regulatory Uncertainty and Compliance Burden	290	594	Recurring Annual
Operational Flexibility for Multi-DSA Operations	300	0	One-Time

i. Quantified Benefits

This subsection presents the quantified incremental benefits of this proposed rule organized by benefit category. For each benefit, we provide baseline context identifying what was already captured in the December 2020 final rule versus what is genuinely incremental in this proposal, detailed calculation methodology showing data sources and assumptions, annual and 5-year benefit estimates, and acknowledgment of uncertainty where appropriate. The quantified benefits focus on measurable impacts that can be monetized with reasonable certainty based on available data and conservative assumptions.

(1) Reduced Regulatory Uncertainty and Compliance Burden

The December 2020 final rule (85 FR 77898) established new performance measures and a three-tier re-certification system but did not account for time spent responding to stakeholder inquiries about implementation. The \$1.0 million CMS administrative baseline covered basic oversight but not clarification activities. Since 2020, CMS has received increasing stakeholder inquiries, particularly as the 2026 re-certification period approaches, creating costs not captured in the baseline analysis.

This proposed rule reduces repetitive clarification requests by clarifying procedures for competitions, multi-DSA operations, non-renewal versus de-certification distinctions, and appeals

processes. We recognize some inquiry activity will continue for unique circumstances. We estimate that absent this rule, OPOs would spend 60 hours annually seeking clarification. With these clarifications, this would decline to 20 hours annually, saving 40 hours per OPO. The clarifications reduce CMS staff time spent responding to inquiries, OPO staff time seeking guidance, and disputes during the 2026 re-certification period.

Each OPO currently spends approximately 60 hours annually seeking clarification, which would decline to 20 hours with the proposed clarifications, saving 40 hours per OPO. This time involves executive directors, legal staff, and compliance officers researching requirements, preparing requests, coordinating with CMS, and implementing guidance. At a weighted average hourly rate of \$132 (adjusted by 100 percent for fringe benefits and overhead consistent with the 2020 methodology), this yields an annual benefit of \$290,400 (40 hours $\times$ \$132 $\times$ 55 OPOs), rounded to \$290,000.

Similarly, absent this rule, CMS would receive approximately 165 substantive requests annually (3 per OPO $\times$ 55 OPOs). With the clarifications, we expect a reduction to 55 requests annually (1 per OPO $\times$ 55 OPOs), eliminating 110 requests. Each request requires approximately 20 hours of GS-14 staff time for research, coordination, drafting responses, and quality review. At a GS-14 hourly rate of \$138 (OPM 2023 pay tables, adjusted for locality and benefits), this yields an

annual benefit of \$303,600 (110 requests $\times$ 20 hours $\times$ \$138). The total annual benefit is \$594,000, with a 5-year benefit of \$2,970,000.¹⁴⁰

This estimate is conservative as it captures only direct time savings. It excludes indirect costs of regulatory uncertainty including delayed strategic planning, deferred operational decisions, potential disputes and appeals, and opportunity costs when staff time diverts from core organ procurement activities. The actual benefit may be substantially higher. The estimate assumes a 67 percent inquiry reduction; greater reductions would increase benefits proportionally. Conversely, OPOs and CMS staff may need familiarization time with new clarifications, potentially causing short-term inquiry increases before long-term benefits are realized.

(2) Operational Flexibility for Multi-DSA Operations

The December 2020 final rule established a three-tier performance system and de-certification procedures but did not explicitly address how OPOs managing multiple DSAs would be evaluated when performance varies

¹⁴⁰ Data sources include CMS inquiry tracking data (2020–2025), estimated 60 hours per OPO absent the rule and 20 hours with the rule based on consultation with OPO compliance officers, weighted average OPO hourly rate of \$132, GS-14 hourly rate of \$138 from OPM 2023 pay tables, estimated 3 requests per OPO annually absent the rule and 1 request with the rule, 20 hours per request based on staff time tracking, and assumes a 67 percent reduction in inquiry volume (from 165 to 55 requests annually).

across service areas. The baseline framework could potentially result in full de-certification of an OPO even when some DSAs perform well, requiring unnecessary transitions in well-performing territories and imposing avoidable costs on the system.

This proposed rule would allow high-performing OPOs to continue serving well-performing territories while losing designation only in underperforming DSAs. The proposed provisions at § 486.309(c) and § 486.316 establish that CMS would remove designation to a tier 3 DSA without full de-certification when an OPO manages multiple DSAs, enabling continuity of service in well-performing territories, knowledge and resource transfer from high-performing to underperforming areas, maintained OPO staff relationships with hospitals and donor families, and avoided unnecessary operational transition costs in tier 1 and tier 2 DSAs.

We estimate that following the 2026 competition process, 5 OPOs will serve 2 DSAs each (10 total DSAs). In the subsequent performance evaluation cycle ending in 2030, we assume 3 of these 5 OPOs achieve Tier 1 or 2 performance in one DSA but Tier 3 performance in their second DSA. Under the clarified policy, only the 3 underperforming DSAs would open for competition. Without this clarification, the 2020 final rule framework could potentially result in de-certification of all 3 OPOs, opening all 6 of their DSAs for competition. Using the baseline transition cost of \$100,000 per DSA from the 2020 final rule, avoiding 3 unnecessary transitions produces an estimated benefit of \$300,000 (3 avoided transitions $\times$ \$100,000).¹⁴¹

The total benefit is \$300,000 over the 5-year analysis period, occurring once during the 2030 performance evaluation cycle. Data sources include estimated 10 OPOs managing multiple DSAs by 2030 based on competition projections and multi-DSA operational analysis, 60 percent probability that multi-DSA OPOs will have mixed tier performance based on current tier distribution patterns, transition cost of \$100,000 per DSA from the 2020 final rule baseline (\$2.9 million annually for OPO management transitions), and assumption that 3 of 5 multi-DSA OPOs will have mixed performance requiring designation removal from one DSA.

This estimate is conservative because it captures only avoided direct

transition costs. It does not quantify additional benefits including maintained hospital relationships and donor family trust in well-performing territories that support long-term procurement performance, preserved institutional knowledge and staff expertise that would be lost through full de-certification, avoided disruption to organ procurement activities during the transition period in well-performing DSAs, and reduced administrative burden on CMS for managing fewer total transitions. The actual benefit may be substantially higher when these indirect effects are considered. The estimate assumes 5 OPOs will manage multiple DSAs by 2030; if more OPOs expand to multiple DSAs or if the rate of mixed performance is higher than 60 percent, benefits would increase proportionally. The estimate uses \$100,000 per DSA transition cost from the 2020 baseline; if actual transition costs are higher due to the complexity of multi-DSA operations, the benefit would increase accordingly.

As such, we seek comments on sources of data to quantify the impact of these benefits.

ii. Qualitative Benefits (Not Monetized)

The following benefits are real and significant but cannot be readily monetized due to the difficulty of isolating causal effects, the diffuse nature of the benefits, or the lack of empirical data to support quantification. For each qualitative benefit, we provide a clear description, explanation of why monetization is not feasible, evidence demonstrating significance, and connection to regulatory objectives.

(1) Improved System Efficiency and Continuity

This proposed rule reduces service disruptions by establishing successor selection criteria at § 486.308(a)(4), and multi-DSA transitions at §§ 486.309 and 486.312. The clarifications specify when CMS may select successor OPOs before conducting a full competition, the criteria CMS will consider in successor selection (contiguity, outcome measure performance, process measure compliance history, and willingness to serve), and procedures for managing transitions when OPOs serve multiple DSAs. These provisions reduce service disruptions by ensuring continuity of organ procurement activities during transitions, minimizing coordination failures between incumbent and successor OPOs, clarifying responsibilities during transition periods, and preventing delays in organ recovery and placement.

We estimate that clear successor selection criteria and transition

procedures prevent any potential service disruptions that could otherwise result in delayed organ recovery or placement. However, quantifying this benefit precisely is difficult because service disruptions are typically temporary and their impact on organ procurement varies by circumstance. We also note that there may be additional benefits including reduced administrative burden on CMS and OPOs during transitions, maintained hospital confidence in the organ procurement system during leadership changes, preserved donor family trust during transition periods, and avoided reputational damage to the broader transplant system.

(2) Enhanced Competition Efficiency

The December 2020 final rule (85 FR 77898) established a three-tier performance system and competition framework but did not provide detailed guidance on multi-DSA competition scenarios or the specific application of selection factors. The proposed clarifications at § 486.316 enhance competition efficiency by establishing clear re-certification and competition procedures that enable efficient identification and replacement of poor-performing OPOs. The clarifications specify the impact of performance tier assignments on competition and de-certification actions, provide explicit guidance for multi-DSA competition scenarios where OPOs manage multiple service areas with varying performance levels, and establish successor selection criteria when insufficient time exists for full competition to prevent service gaps for all stakeholders.

We cannot readily quantify this benefit because the dynamic effects of enhanced competition on OPO performance improvement are difficult to isolate and measure. Competition may drive performance improvements not only among OPOs that lose competitions but also among OPOs that improve performance to avoid competition. The counterfactual (what performance would have been without clearer competition procedures) is speculative. Additionally, the benefit manifests over time as the competitive environment drives continuous improvement across the entire OPO system rather than generating discrete, measurable outcomes in the short term.

This benefit is significant because with an estimated 26 DSAs opening for competition during the re-certification cycle (representing nearly half of all OPOs), the efficiency of the competition process directly impacts the quality of organ procurement services for millions of potential donors and transplant

¹⁴¹ This scenario is illustrative based on projected multi-DSA adoption rates and current tier distribution patterns. The actual number of OPOs benefiting from this flexibility will depend on competition outcomes and performance trajectories during the 2027–2031 period.

candidates. Clear procedures ensure that competition decisions are transparent and focused on maximizing organ procurement outcomes. The clarifications enable CMS to make informed decisions about which OPOs should serve each DSA based on explicit criteria. This supports the overarching goal of Executive Order 13879 to improve organ procurement performance and the December 2020 final rule's objective of creating accountability through competition.

(3) Improved Definitional Clarity

The December 2020 final rule established new outcome measures and performance standards but included limited definitions for key operational terms. The proposed revised definitions at § 486.302 ensure consistent interpretation across OPOs by establishing clear understanding of “medically complex donors” and “medically complex organs” to encourage utilization of organs that are currently underused, providing explicit definition of “unsound medical practices” to establish accountability for practices creating imminent threats to patient health and safety, clarifying the “donor” definition to ensure consistency and continued compliance with the statutory requirement that pancreata used for islet cell transplantation or research be counted for purposes of certification and re-certification, and creating a flexible “adverse event” framework by moving specific examples from the definition to QAPI requirements at § 486.348(c) to allow adaptation to emerging issues.

We cannot readily quantify this benefit because the value of regulatory clarity is diffuse and difficult to monetize. It manifests in reduced confusion, more consistent implementation, better strategic planning, and fewer disputes—benefits that are real but hard to isolate and measure. The causal link between definitional clarity and specific operational improvements is indirect and influenced by multiple factors including OPO organizational culture, staff training, and leadership priorities. Additionally, the benefit accrues gradually over time as OPOs incorporate clearer definitions into their policies, procedures, and decision-making processes rather than generating immediate, measurable cost savings.

This benefit is significant because the high volume of stakeholder inquiries since 2020 demonstrates that definitional ambiguity creates real costs and operational challenges. Clear definitions enable OPOs to implement requirements consistently and make

informed decisions about medically complex organ procurement, adverse event investigation, and donor eligibility. The definitional clarity supports all other provisions by ensuring that OPOs, CMS, and stakeholders share a common understanding of regulatory requirements. This is particularly important for medically complex organs, where clear definitions may encourage OPOs to develop systematic approaches to procuring and placing organs from DCD donors and donors with elevated KDPI scores, potentially expanding the donor pool beyond traditional “ideal” donors.

C. Alternatives Considered

Throughout the preamble sections, we present our proposals and seek public comments regarding these proposals. We seek to refine the OPO regulations to align with the regulatory structure established in the December 2020 final rule that uses new outcome measures and a three-tier structure to incentivize OPO performance improvement in better service to prospective donor families and patients on the transplant waiting list. In revising the regulations to align with the tier structure and outcome measures, we considered several other potential policies for the OPO regulations. Below we discuss the various proposed policies and the alternatives considered.

1. § 486.308 Designation Periods

We propose that the designation period for any newly acquired DSA following a competition, or as the result of being assigned a DSA as specified at § 486.316(e), will be the remaining portion of the agreement for the OPO's current re-certification cycle. We considered proposing a policy that would allow CMS greater flexibility to establish longer designation periods. We determined that this flexibility would interfere with the 4-year re-certification cycle described in section 1138(b)(1)(A) of the Act and section 371(b)(1)(D) of the PHS Act. We request public comment on additional considerations related to designation periods following a successful competition or CMS assignment for an open DSA.

2. § 486.309 Designation of an OPO to More Than One Service Area

At § 486.309(a), we propose that an OPO may be responsible for more than one DSA in certain circumstances including a change in control or ownership or service area; as a result of a competition; or a voluntary or involuntary termination of an OPO's agreement when there is insufficient

time to conduct a competition. Further, we propose at § 486.309(b) that an OPO that obtains an additional DSA may choose to maintain separate DSAs or consolidate multiple DSAs into one service area under a single certification. Our policy goal is to provide OPOs the flexibility when being designated to more than one DSA to establish their organizational and operational structure in such a manner to enable the OPO to most effectively provide organ donation services. However, we also have concerns for over consolidation of DSAs and the ability to maintain market diversity as well as performance, quality, and safety concerns when organizations merge.

As an alternative to the proposed policy at § 486.309(b), where we propose that OPOs may choose to consolidate DSAs or maintain separate DSAs, we considered an alternative policy that would require an OPO to first obtain CMS approval before choosing to either consolidate DSAs or maintain separate DSAs, based on specific criteria that CMS would consider when evaluating the request. While this alternative approach would provide OPOs with the opportunity to choose whether to consolidate DSAs or maintain them separately, CMS would retain final approval of the request. While CMS currently has final approval over any change in service area under 486.310(a)(2), we have not established specific criteria for approving or denying an OPO's request. When deciding whether to permit an OPO to consolidate multiple DSAs or maintain them separately, CMS could consider a variety of factors, including DSA size relative to population size, geographic characteristics, historical patient safety concerns, chronic underperformance in securing donors, and other relevant considerations. For instance, DSA populations range from approximately 1.5 million to nearly 20 million people.¹⁴² Geographic considerations may include whether DSAs are contiguous or encompass exceptionally large areas. Additionally, serious patient safety concerns with an OPO, such as those identified by the Secretary in 2025,¹⁴³ may warrant retaining DSAs separately while corrective remedies are implemented. Finally, a new OPO assuming responsibility for a DSA where the previous OPO underperformed for extended periods may benefit from separate designation to

¹⁴² U.S. Census Bureau, U.S. Census Population Estimates Program, American Community Survey.

¹⁴³ <https://www.hhs.gov/press-room/hrsa-to-reform-organ-transplant-system.html>.

enable more precise performance monitoring.

If this alternative approach is adopted, we would revise proposed § 486.310 to include a provision for CMS approval of service area changes with specific criteria we would consider for approval would be set forth at 486.310. Currently § 486.310(a)(2) provides that CMS must approve any change in service area, which supports CMS's authority to require the successor OPO to keep DSAs separate. However, we note that this provision would no longer apply to consolidation-related decisions if proposed § 486.309(b) is finalized. We request public comment on the benefits of this alternative approach, whether CMS should retain the right of final approval of requests, and what specific criteria CMS should consider when making this determination.

As previously stated in section II.D. of this proposed rule, when the Life Alliance Organ Recovery Agency (LAORA)'s DSA was opened for competition, CMS indicated that the successor OPO would be required to maintain the DSA separately from their existing DSA. We note this decision was based on the long historical record of underperformance in this DSA and CMS' desire to carefully monitor the changes after the successor OPO assumes responsibility for the DSA.

Additionally, recent instances of OPOs pursuing or exploring mergers in the midst of patient safety concerns have raised concerns for additional regulatory oversight and specific criteria to consider when reviewing changes to DSAs.

In light of these concerns and policy goals, we also considered proposing that OPOs would be required to maintain separate DSAs without the option to merge or consolidate the DSAs. While this would serve the policy goal of maintaining geographic diversity, a blanket approach may be overly restrictive and limit innovation and possibly performance gains when merging DSAs. This may be a significant factor impacting small OPOs with geographically contiguous DSAs.

Our alternative policy approach would require more administrative oversight burden to CMS. Additional administrative burden could be estimated at \$86,000 annually¹⁴⁴ (\$320,000 over 5 years), including CMS review costs (\$22,000 annually) and

OPO application preparation costs (\$42,000 annually).¹⁴⁵

We seek comments for consideration in future rulemaking on the benefits of this alternative approach as well as the risks of potential unintended consequences, and other factors that may be considered to better define this alternative policy approach.

3. § 486.311 Non-Renewal of Agreement

At § 486.311, Non-renewal of agreement, we proposed that when an OPO voluntarily terminates its agreement or ceases to furnish organ procurement services, it would no longer be designated to any DSAs, as of the effective date determined by CMS. This voluntary termination policy aligns with the requirements from 42 CFR part 489, provider agreements and supplier approval. Section 489.52 addresses termination by the provider (or supplier). This requirement addresses the situation where a provider or supplier seeks to terminate its participation with Medicare. While it is plausible that an OPO may want to terminate its agreement with CMS and the Secretary, this action would have a global effect on an OPO by effectively ending its participation in the Medicare program. OPOs enter into agreements with the Secretary, but unlike other providers and suppliers, OPOs are subsequently designated to one or more DSAs. We have contemplated the possibility that an OPO with multiple DSAs may want to voluntarily terminate designation to a particular DSA without voluntarily terminating its entire agreement with the Secretary and thereby impacting all DSAs. Therefore, we are considering an alternative policy that would allow an OPO to request withdrawal from any one of its DSAs without such withdrawal being considered a voluntary termination of the OPO's agreement. We are seeking public comment on whether or not CMS should consider this alternative policy approach and the rationale to make that decision. This type of policy may be beneficial to an OPO that expands to additional DSAs but later desires to change its operational services to reduce the total number of DSAs. Additionally, an OPO that has made a good faith effort to improve organ donation in a DSA but is unable to do so could provide notice to CMS of its intent to voluntarily terminate designation to an individual DSA in order to assist in an orderly

transition of the DSA to a successor OPO. This approach could allow an opportunity for a high-performing OPO to compete and take over that DSA. However, this approach could result in OPOs withdrawing mid-cycle without good cause, which could result in disruptions in organ procurement and distribution within those DSAs.

If CMS were to adopt this alternative policy, we would add a new requirement at § 486.309(d) to specify the process for an OPO to request to terminate designation, any approval criteria we would consider (if established), as well as notification requirements with corresponding timelines for notification and transition of the DSA.

We are soliciting public comment on whether OPOs should be permitted to request to terminate designation of individual DSAs without triggering a voluntary termination that would result in termination of the agreement. We seek comments on the benefits of this alternative policy as well as the risks and potential unintended consequences. We also seek public comments to determine if specific criteria should be established to consider when evaluating any requests and what that criteria should be.

4. § 486.314 Appeals and § 486.316 Re-Certification and Competition Processes

At § 486.314 Appeals, we propose changes to the time frames for various stages in the appeals process to increase the efficiency of the appeals process while also ensuring OPOs have an adequate opportunity to present an appeal. We also propose to state all time requirements in "calendar days" and use the FRCP definition to avoid any confusion in the process. In addition, we propose to codify a process for the CMS Administrator's discretionary review. We considered retaining "business days" for some of the time requirements. However, we decided to use all "calendar days" to ensure consistency and to avoid confusion. We also considered not including a section for the CMS Administrator's discretionary review of the hearing officer's decision. The CMS Administrator already has the authority to review all hearing officers' decisions. Hence, the CMS Administrator's discretion to review the hearing officer's decision exists whether it was set out in the requirements or not. However, we decided to include this proposal so that the process is clearly set forth in the requirements and all parties and the public understand it and to avoid any confusion.

¹⁴⁴ This estimate assumes 40 hours per approval request at a staff of a GS-14, Step 5 (loaded hourly rate) \$137.74/hour with an assumption of 2 annual requests. Calculation: 80 hours × \$137.74 × 2 = \$22,038, rounded to \$22,000.

¹⁴⁵ This estimate assumes 160 hours per approval request at a staff of a Quality Managers (BLS Code 11-9111) loaded rate of \$132 and an assumption of 2 applications per year. Calculation: 160 hours × \$132 × 2 = \$242,240 rounded to \$42,000.

At § 486.316(g) we propose that an incumbent OPO must cooperate with its successor OPO to facilitate an orderly transition of the DSA. This proposal complements requirements set forth at § 486.330(d), which requires that an OPO must maintain data in a format that can readily be transferred to a successor OPO. In the event of a transfer, an OPO must provide to CMS copies of all records, data, and software necessary to ensure uninterrupted service by a successor OPO. Records and data subject to this requirement include donor and transplant beneficiary records and procedural manuals and other materials used in conducting OPO operations. Interested parties have expressed an interest in requiring the exchange of process data regarding the DSA from the incumbent OPO to the successor OPO to inform the successor OPO's development of process improvements that could lead to more donors and more transplants. We considered these requests and considered adding a specific regulatory requirement for this data sharing. However, we did not pursue this change at this time because a new information collection request for pre-consent process data is pending approval.¹⁴⁶ This data would be publicly available upon request and may fulfill the needs of successor OPOs without the establishment of additional regulatory requirements. We request public comment regarding alternative ways to assure that successor OPOs have sufficient information at the beginning of their designation period to effectively and efficiently serve potential donors, their families, and people on the transplant waiting list. This may include establishing a requirement for the provision of data such as data related to all donor hospitals in the DSA or the annual donor potential and number of referrals from each hospital for a set period of time. We seek public comment on the nature and scope of such data as well as ways to facilitate this data sharing.

¹⁴⁶ 89 FR 87592.

5. § 486.330 Information Management

In addition to requiring an OPO to maintain documentation regarding the *bona fide* research studies to which the OPO provided organs, including pancreata used for islet cell research, we also considered requiring an OPO to annually provide information to CMS regarding *bona fide* islet cell research studies to which the OPO provided pancreata. We considered this potential policy as part of our efforts to assure the integrity of the OPO-reported data related to pancreata used for islet cell research that is used for outcome measure calculation. However, we did not pursue this change at this time as we continue to observe changes in OPO procurement practices that are occurring following changes in the reporting codes and coding guidance issued by the SRTR in 2024. Further, this alternative would impose estimated additional costs of \$73,000 annually¹⁴⁷ (\$365,000 over 5 years), including OPO annual report preparation costs (\$58,000 annually)¹⁴⁸ and CMS review and processing costs (\$15,000 annually).¹⁴⁹

OPOs are continuing to adjust to reporting using the new codes, which aim to improve coding accuracy. As we gather additional insight into new coding practices, we will consider this option for future regulations. We request comment on the potential for additional OPO reporting related to pancreata used for islet cell research, whether such reported information should be made public, and the manner and frequency in which CMS could make this information available to the public.

D. Regulatory Review Cost Estimation

Due to the uncertainty involved with accurately quantifying the number of

¹⁴⁷ Total = OPO Costs + CMS Costs. \$58,080 + \$15,151 = \$73,231 annually, rounded to 73,000.

¹⁴⁸ Per OPO Cost = Hours per OPO × Loaded Hourly Rate 8 hours × \$132/hour = \$1,056 per OPO. Industry-Wide Cost = Per OPO Cost × Number of OPOs (\$1,056 × 55 OPOs = \$58,080, rounded to 58,000) annually.

¹⁴⁹ Per OPO Review Cost = Hours per OPO × GS-14 Loaded Rate 2 hours × \$137.74/hour = \$275.48 per OPO. Industry-Wide Cost = Per OPO Review Cost × Number of OPOs \$275.48 × 55 OPOs = \$15,151, rounded to 15,000 annually.

entities that will review this proposed rule, we assume that all 55 OPOs will review this rule. While other individuals and providers may also review the rule, we estimate that doubling the number of OPOs (110 reviewers) provides a reasonable approximation of the total number of reviewers. We acknowledge that this assumption may understate or overstate the actual review costs and welcome public comment on this approach. For purposes of this estimate, we assume each reviewer reads approximately 100 percent of the rule and the average reading speed is 250 words per minute. This rule contains approximately 60,000 words, which equates to 4 hours reviewing the rule (60,000 words ÷ 250 words per minute ÷ 60 minutes per hour = 4 hours). Using a weighted average hourly rate of \$132 for OPO executive directors and legal staff (adjusted by 100 percent for fringe benefits and overhead consistent with the 2020 final rule methodology), we estimate total review costs of \$58,080 (110 reviewers × 4 hours × \$132), rounded to \$58,300.

E. Accounting Statement

As required by OMB Circular A-4 (available online at <https://www.whitehouse.gov/wp-content/uploads/2025/08/CircularA-4.pdf>), we have prepared an accounting statement in Table 7 showing classification of the costs, transfers, and benefits associated with the provisions of this proposed rule. This proposed rule imposes incremental costs of approximately \$19.3 million in Year 1 and \$6.0 million recurring annually (\$18.1 million for OPOs in Year 1 and \$6.0 million recurring annually; \$1.2 million for CMS in Year 1 and \$333,000 recurring annually). The proposed rule does not create new transfer payments beyond those established in the 2020 baseline. Quantified benefits are estimated at \$884,000 annually from reduced regulatory uncertainty and a one-time savings of \$300,000 operational flexibility for multi-DSA. This statement provides our best estimate for the Medicare and Medicaid provisions of this proposed rule.

TABLE 7: Accounting Statement

Category	Estimate	Units		
		Year Dollar	Discount Rate	Period Covered
Annualized Monetized Costs (\$million/year) OPOs	8.5-8.7	2024	7% or 3%	2027-2031
Annualized Monetized Costs (\$million/year) Government	0.5-0.5	2024	7% or 3%	2027-2031
Annualized Monetized Benefits (\$million/year) OPOs	0.4-0.4	2024	7% or 3%	2027-2031
Annualized Monetized Benefits (\$million/year) Government	0.6-0.6	2024	7% or 3%	2027-2031

F. Regulatory Flexibility Act (RFA)

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) requires agencies to analyze options for regulatory relief of small entities if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than \$18.0 million to \$47.0 million in any 1 year. Individuals and States are not included in the definition of a small entity.

1. Organ Procurement Organizations (OPOs)

All OPOs (NAICS 621991, Blood and Organ Banks) could be considered small entities either by the Small Business Administration's size standards (total revenues of \$47.0 million¹⁵⁰ or less in any single year) or by nonprofit status. In practice, most OPOs are large nonprofit organizations with annual revenues substantially exceeding \$47 million.

According to the 2022 Economic Census, blood and organ banks (NAICS 621991) have total revenues of \$19.88 billion.¹⁵¹ This figure includes OPOs as well as blood banks and other organ and tissue banks. With approximately 55 OPOs operating in the United States,

and assuming OPOs represent a substantial portion of this industry category, average annual revenue per OPO is estimated at approximately \$361 million.¹⁵²

This proposed rule imposes estimated costs of \$18.1 million for all OPOs in Year 1 (including \$12.1 million in one-time implementation costs and \$6.0 million in recurring costs) and \$6.0 million in recurring annual costs beyond Year 1. To calculate annualized costs over the 5-year analysis period, we annualize the one-time costs (\$12.1 million ÷ 5 years = \$2.4 million per year) and add recurring costs (\$6.0 million per year), resulting in annualized costs of approximately \$8.4 million per year. Distributed across 55 OPOs, the average annualized cost per OPO is approximately \$153,000 annually.

As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. The estimated annualized costs represent approximately 0.0004 percent of average OPO revenues (\$153,000 ÷ \$361 million), which is well below the 3 to 5 percent threshold for significant economic impact.

We are not preparing an analysis for the RFA because we have determined, and the Secretary has certified, that this proposed rule would not have a significant adverse economic impact on a substantial number of small entities. As we explained in detail in the December 2020 final rule on OPO outcome standards (85 FR 77898), we

believe that the new performance standards will have beneficial or neutral effects on most OPOs and transplant hospitals, and that there would not be a substantial number of OPOs adversely affected. This proposed rule makes only clarifications and refinements to the framework established in that final rule, and none of these would invalidate the previous conclusion.

2. Section 1102(b) of the Social Security Act—Small Rural Hospitals

Section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary has certified, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

G. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) 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 2025, that threshold is approximately \$187 million.

¹⁵⁰ U.S. Small Business Administration, "Table of Small Business Size Standards Matched to North American Industry Classification System Codes," effective October 1, 2022 (or most recent year), available at <https://www.sba.gov/document/support-table-size-standards>.

¹⁵¹ U.S. Census Bureau, 2022 Economic Census, NAICS 621991 (Blood and Organ Banks), available at <https://data.census.gov/>.

¹⁵² Average OPO Revenue = Total Industry Revenue ÷ Number of OPOs \$19.88 billion ÷ 55 OPOs = \$361.45 million per OPO (rounded to \$361 million).

This proposed rule imposes estimated costs of approximately \$19.3 million in Year 1 and \$6.3 million recurring annually, which is well below the UMRA threshold. Recurring annual costs beyond Year 1 comprise \$6.0 million for OPOs and \$331,000 for CMS. The proposed rule does not mandate any spending requirements for State, local, or tribal governments. While the rule imposes costs on OPOs (private sector entities), these costs are substantially below the \$187 million threshold.

These costs represent clarifications and refinements to the operational and administrative requirements established in the December 2020 final rule (85 FR 77898), rather than new mandates. The costs are primarily administrative in nature and include training, documentation updates, enhanced coordination activities, and compliance with clarified requirements.

As noted in the December 2020 final rule, reimbursement by both public and private payers would cover all reasonably estimated costs associated with organ procurement activities. OPOs are reimbursed for their organ acquisition costs through Medicare, Medicaid, and private insurance payments. The estimated costs are well below the \$187 million UMRA threshold. Therefore, the requirements of UMRA do not apply to this proposed rule.

H. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications.

This proposed rule is directed at Organ Procurement Organizations (OPOs), which are private nonprofit organizations certified by CMS to coordinate organ procurement activities within designated service areas. The proposed rule does not impose substantial direct requirement costs on State and local governments, preempt State law, or have Federalism implications. The proposed clarifications and refinements to the OPO conditions for coverage affect only OPOs and CMS administrative processes. State and local governments are not directly regulated by these provisions. While some State and local government entities may interact with OPOs in their capacity as healthcare providers or in other roles, the proposed rule does not impose requirements or

costs on governmental entities in their governmental capacity.

The estimated costs of this proposed rule (\$19.3 million in Year 1 and \$6.3 million recurring annually) fall entirely on OPOs (private sector entities, \$18.1 million in Year 1 and \$6.0 million recurring annually) and the Federal Government (CMS, \$1.2 million in Year 1 and \$0.3 million recurring annually). No costs are imposed on State, local, or tribal governments. Since this proposed rule does not impose substantial direct requirement costs on State and local governments, does not preempt State law, and does not have Federalism implications, the requirements of Executive Order 13132 are not applicable to this proposed rule.

I. E.O. 14192, “Unleashing Prosperity Through Deregulation”

Executive Order 14192, entitled “Unleashing Prosperity Through Deregulation,” was issued on January 31, 2025, and requires that any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 11 prior regulations.

We followed the implementation guidance from OMB Memorandum M–25–20 (<https://www.whitehouse.gov/wp-content/uploads/2025/02/M-25-20-Guidance-Implementing-Section-3-of-Executive-Order-14192-Titled-Unleashing-Prosperity-Through-Deregulation.pdf>) when estimating the proposed rule’s impact related to the executive order. Specifically, we used a 7 percent discount rate when estimating costs for purposes of Executive Order 14192, as required by the OMB guidance.

This proposed rule imposes estimated incremental costs of approximately \$19.3 million in Year 1 and \$6.3 million recurring annually (\$18.1 million for OPOs in Year 1 and \$6.0 million recurring annually; \$1.2 million for CMS in Year 1 and \$0.33 million recurring annually) beyond the baseline of \$126.7 million established in the December 2020 final rule (85 FR 77898). Using the 7 percent discount rate required by OMB guidance, the annualized costs over the 5-year period are approximately \$9.3 million annually. These costs represent clarifications and refinements to operational and administrative requirements rather than fundamental system restructuring.

This proposed rule is consistent with the principles of Executive Order 14192 in the following ways:

- **Minimizes Regulatory Burden:** The proposed rule focuses on clarifications

and refinements rather than imposing new substantive requirements.

- **Provides Regulatory Clarity:** By addressing the high volume of stakeholder inquiries and providing clear guidance on operational and administrative requirements, this proposed rule reduces uncertainty and compliance costs for regulated entities, enabling OPOs to focus resources on their core mission of organ procurement rather than regulatory interpretation.

- **Streamlines Processes:** The proposed clarifications to competition, appeals, and de-certification processes are designed to make these procedures more efficient and transparent, reducing administrative burden while maintaining accountability. For example: streamlined appeals procedures using consistent “calendar days” terminology; clear multi-DSA operational guidance preventing costly disputes and successor selection criteria reducing potential service disruptions.

- **Supports Economic Efficiency:** By enhancing the efficiency and effectiveness of the organ procurement system, this proposed rule supports the health and productivity of the workforce and contributes to economic prosperity.

- **Reduces Compliance Uncertainty:** The proposed rule is estimated to save approximately \$589,600 annually in reduced inquiry and interpretation costs for CMS and OPOs combined, allowing resources to be redirected toward improving organ procurement outcomes.

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.

Dr. Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on January 8, 2026.

List of Subjects in 42 CFR Part 486

Medicare, Organ procurement, and Definitions.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV, part 486 as set forth below:

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

■ 1. The authority citation for part 486 continues to read as follows:

Authority: 42 U.S.C. 273, 1302 and 1320b–8, and 1395hh.

■ 2. Section 486.302 is amended by—

- a. Revising the definitions “Adverse event”, “Donor” and “Organ”;
- b. Adding the definitions “Medically complex donor”, “Medically complex organ”; and “Unsound medical practices” in alphabetical order.

The revisions and additions read as follows:

§ 486.302 Definitions.

* * * * *

Adverse event means an untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk thereof.

* * * * *

Donor means a deceased individual from whom at least one vascularized organ (heart, liver, lung, kidney, pancreas, or intestine) is transplanted. An individual would also be considered a donor if only the pancreas is procured and is used for islet cell transplantation or for islet cell research.

* * * * *

Medically complex donor means a donor whose medical history requires special or additional considerations to identify the best recipient for the organs. These donors include, but are not limited to, all Donation after Cardiac Death (DCD) donors and donors with elevated Kidney Donor Profile Index (KDPI) scores of 50 or more.

Medically complex organ means an organ recovered from a medically complex donor.

* * * * *

Organ means a human kidney, liver, heart, lung, pancreas, or intestine (or multivisceral organs when transplanted at the same time as an intestine). The pancreas counts as an organ even if it is used for islet cell transplantation.

Organ type	Number of organs transplanted
Right or Left Kidney	1
Right and Left Kidney	2
Double/En-Bloc Kidney	2
Heart	1
Intestine	1
Intestine Segment 1 or Segment 2	1
Intestine Segment 1 and Segment 2	2
Liver	1

Organ type	Number of organs transplanted
Liver Segment 1 or Segment 2	1
Liver Segments 1 and Segment 2	2
Right or Left Lung	1
Right and Left Lung	2
Double/En-bloc Lung	2
Pancreas (transplanted whole, islet transplant)	1
Pancreas Segment 1 or Segment 2	1
Pancreas Segment 1 and Segment 2	2

* * * * *

Unsound medical practices refer to failures by OPOs that create an imminent threat to patient health and safety or pose a risk to patients or the public. These practices include, but are not limited to, failures in governance; patient or potential donor evaluation and management; and procurement, allocation, and transport practices and procedures.

* * * * *

§ 486.303 Requirements for Certification.

■ 3. Section 486.303 is amended by—

- a. Removing paragraph (e); and
- b. Redesignating paragraphs (f) through (i) as paragraphs (e) through (h), respectively.

■ 4. Section 486.308 is amended by—

- a. Adding introductory text; and
 - b. Revising paragraphs (a) and (b).
- The addition and revisions read as follows:

§ 486.308 Designation of one OPO for each donation service area.

Re-certification of organ procurement organizations must occur not more frequently than once every 4 years. CMS designates only one OPO per Donation Service Area (DSA).

(a) *Designation periods.* An OPO is normally designated for an agreement cycle of 4 years.

(1) CMS may adjust the length of a designation period when:

(i) There is a voluntary termination initiated by an OPO as specified at § 486.311(a)(2),

(ii) There is an involuntary termination initiated by CMS as specified at § 486.312(a)(1) or (4),

(iii) Additional time is needed to complete an appeal, conduct a competition, select a successor OPO, or transition the DSA to a successor OPO, or

(iv) There is an extension of an agreement cycle as specified at § 486.316(f).

(2) CMS will conduct a competition for all vacated DSAs.

(3) Designation periods following a competition or assignment of a DSA by CMS. The designation period for any newly acquired DSA following a competition, or as the result of being assigned a DSA as specified at 486.316(e), will be the remaining portion of the agreement for the OPO's current re-certification cycle.

(4) If there is insufficient time to conduct a competition, CMS may select one or more successor OPOs before opening the DSA(s) for competition. In selecting a successor OPO(s), CMS will consider the following:

(i) Contiguity to the DSA,

(ii) Performance on outcome measures at § 486.318,

(iii) History of compliance with the process performance measures at §§ 486.320 through 486.360, and

(iv) Willingness of the OPO to perform the responsibilities for the remainder of the designation period.

(b) *Competition.* A DSA becomes open for competition when:

(1) The DSA is assigned to tier 3 in the final assessment period, as specified at § 486.318(b)(6) and 486.316(a)(3), and all administrative appeals are exhausted;

(2) The DSA is assigned to tier 2 in the final assessment period, as specified at § 486.318(b)(5) and § 486.316(a)(2); or,

(3) The OPO for the DSA is not in compliance with the process performance measures at §§ 486.320 through 486.360, as specified at § 486.312(a)(2) and § 486.316(b)(1), all administrative appeals are exhausted, and the OPO is pending de-certification.

(4) An OPO for the DSA requests to voluntarily terminate its agreement as specified at § 486.311(a)(2), unless the voluntary termination is associated with a change in control or ownership or service area as specified at § 486.310 and the changed OPO will continue to serve the DSA.

* * * * *

■ 5. Section 486.309 is revised to read as follows:

§ 486.309 OPO designation to more than one service area.

(a) CMS may designate an OPO to more than one DSA in the following instances:

(1) A change in control or ownership or service area as specified at § 486.310,

(2) As a result of competition as specified at § 486.316, or

(3) A voluntary or involuntary termination of an OPO's agreement and there is insufficient time to conduct a competition as specified at § 486.308(a)(4).

(b) When the conditions under paragraphs (a)(1) or (2) of this section

are met, the OPO may choose to consolidate the DSAs, maintain separate DSAs, or a combination thereof if more than two DSAs are involved.

(c) When an OPO is designated to more than one DSA, CMS may remove designation to a tier 3 DSA due to non-compliance with the outcome measures at § 486.316(a)(3) and § 486.318(b)(6).

(1) Removal of a designation to a tier 3 DSA will not result in de-certification unless an OPO is no longer designated to any DSA as specified at § 486.316(b)(2)(iii)(A).

(2) An OPO may appeal the decision to remove a designation to a tier 3 DSA as specified at § 486.314. If an OPO does not appeal the determination, or the OPO appeals and the determination is upheld after the appeal process is completed, the OPO's service area is opened for competition from other OPOs that qualify to compete for open service areas as set forth in § 486.316(c). ■ 6. Section 486.311 is added to read as follows:

§ 486.311 Non-renewal of agreement.

(a) *Non-renewal of agreement.* CMS will not renew an agreement with an OPO in the following circumstances:

(1) Competition. The OPO is unsuccessful in the competition process, as set forth at § 486.316(a)(2), and the OPO is no longer designated to any DSA.

(2) Voluntary Termination. The OPO sends CMS written notice of its intention to terminate its agreement and the proposed effective date. CMS may approve the proposed effective date, set a different date no later than 6 months after the proposed effective date, or set a date less than 6 months after the proposed effective date if it determines that a different date would not disrupt services to the service area. If CMS determines that a designated OPO has ceased to furnish organ procurement services to its service area, the cessation of services is deemed to constitute a voluntary termination by the OPO, effective on a date determined by CMS. CMS will provide notice to the OPO of the effective date of the voluntary termination.

(b) *OPO notice of non-renewal.* For non-renewal of an agreement after a competition, as specified in paragraph (a)(1) of this section, CMS will provide notification to the OPO at least 90 calendar days before the effective date of the non-renewal. The notice states the reasons for non-renewal and includes the end date of the agreement.

(c) *Public notice.* CMS will provide public notice in the service area of the date that a new OPO will be designated for the DSA.

(d) *Cessation of Payment.* No payment under titles XVIII or XIX of the Act will be made with respect to organ procurement costs attributable to an OPO that no longer has an agreement with CMS.

■ 7. Section 486.312 is revised to read as follows:

§ 486.312 De-certification.

(a) *Involuntary termination and de-certification.* CMS may de-certify an OPO under the following circumstances:

(1) The OPO no longer meets the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360, as specified at § 486.316(b)(1), at any time during the re-certification cycle.

(2) The OPO only has tier 3 DSA(s) designated in the final assessment period, as described at § 486.316(b)(2)(iii)(A), at the end of the re-certification cycle.

(3) The OPO is no longer designated to any DSA and does not have data available from the final assessment period to demonstrate compliance with the outcome measures at the end of the re-certification cycle.

(4) In cases of urgent need, such as the discovery of unsound medical practices, CMS may de-certify an OPO immediately.

(b) *Notice to OPO.* Except in cases of urgent need, CMS gives written notice of the initial de-certification decision to an OPO at least 90 calendar days before the effective date of the de-certification. CMS may extend the effective date of the de-certification as needed to allow for completion of the appeal process under § 486.314, competition of the service area and, if necessary, transition of the service area to a successor OPO. In cases of urgent need, CMS gives written notice of de-certification to an OPO at least 3 calendar days prior to the effective date of the de-certification. The initial notice of de-certification states the reasons for de-certification, explains the available appeal rights, and includes the effective date of the de-certification.

(c) *Public notice.* In cases of urgent need, CMS will provide prompt public notice in the service area of the date of de-certification and the date that a new OPO will be designated for the DSA. With respect to cases described in paragraphs (a)(1) or (2) of this section, CMS will provide such public notice after the available appeal rights are exhausted.

(d) *Cessation of Payment.* No payment under titles XVIII or XIX of the Act will be made with respect to organ procurement costs attributable to an OPO on or after the effective date of de-certification.

■ 8. Section 486.314 is amended by—

■ a. Revising the introductory text, paragraphs (a) through (d), and paragraphs (i) through k; and

■ b. Adding paragraphs (l) through (p).
The revisions and additions read as follows:

§ 486.314 Appeals.

OPOs may appeal a de-certification as described at § 486.312(a) or the removal of designation to a tier 3 DSA without de-certification as described at § 486.316(b)(2)(iii)(B).

(a) *Notice of initial determination.* If an OPO is either de-certified or has its designation to a tier 3 DSA removed without de-certification, CMS will send the OPO either a notice of initial de-certification or a notice of removal of designation for a DSA without de-certification.

(1) Initial notice of de-certification. An OPO will receive an initial notice of de-certification if it is determined to be non-compliant with the process performance measures at § 486.312(a)(1) or non-compliant with the outcome measures as specified at § 486.312(a)(2) or § 486.312(a)(3).

(2) Notice of removal of designation to a tier 3 DSA without de-certification. An OPO will receive a notice of removal of designation to a tier 3 DSA without de-certification if it is determined to be non-compliant with the outcome measures in that DSA but the OPO has other designated DSAs assigned as tier 1 or tier 2, or another designated DSA that is pending evaluation of its outcome measures as specified at § 486.318(c)(3) or (4) at the end of the re-certification cycle.

(b) *Reconsideration.* (1) Filing request. If the OPO is dissatisfied with the de-certification determination or the removal of a tier 3 DSA without de-certification, it has 20 calendar days from receipt of the notice of de-certification or removal of designation for a tier 3 DSA without de-certification to file a reconsideration request with CMS. The request for reconsideration must state the issues or findings of fact with which the OPO disagrees and the reasons for the disagreement.

(2) Failure to request reconsideration. An OPO must file a reconsideration request before it is entitled to seek a hearing before a hearing officer. If an OPO does not request reconsideration or its request is not made timely, the OPO has no right to further administrative review.

(3) Reconsideration determination. CMS makes a written reconsidered determination within 15 calendar days of receipt of the request for reconsideration affirming or reversing

the initial determination and the findings on which it was based. CMS reserves the right to extend the 15 calendar day limitation if:

(i) CMS determines more time is needed to thoroughly review and make a reconsideration decision; and

(ii) The extension of time does not prejudice either of the parties.

(4) CMS augments the administrative record to include any additional materials submitted by the OPO and a copy of the reconsideration decision and sends the supplemented administrative record to the CMS hearing officer.

(c) *Request for hearing.* An OPO dissatisfied with the CMS reconsideration decision can file a request for a hearing before a CMS hearing officer within 15 calendar days after receipt of the notice of the reconsideration determination. If an OPO does not request a hearing or its request is not timely received, the OPO has no right to further administrative review and the reconsideration determination becomes the final agency decision.

(d) *Administrative record.* Upon receipt of a request for a hearing, the hearing officer will promptly request the administrative record from the reconsideration official. The hearing officer will send the administrative record to both parties, or make it available through their electronic filing system, within 15 calendar days of receipt of the request for a hearing.

* * * * *

(i) *Scope of review.* An OPO may appeal a de-certification as described at § 486.312(a) and the removal of designation to a tier 3 DSA on substantive or procedural grounds.

(j) *Burden of proof.* The OPO bears the burden of proof by a preponderance of the evidence to demonstrate the notice of de-certification or removal of designation to a tier 3 DSA should be reversed.

(k) *Hearing officer's decision.* (1) The hearing officer renders a decision on the appeal of the notice of de-certification or removal of designation to a tier 3 DSA within 90 calendar days of the hearing. The hearing officer may extend the timeframe for issuing its decision beyond 90 calendar days if the hearing officer determines that 90 calendar days is insufficient for the hearing officer to develop the administrative record and render a legally sufficient decision and that extending the timeframe for issuing its decision would not unduly prejudice either the OPO or the government. If, consistent with the preceding sentence, the hearing officer extends the

timeframe for issuing its decision beyond 90 calendar days, the hearing officer shall provide notice of the extension to the OPO and the government.

(2) The hearing officer can affirm or reverse the notice of de-certification or removal of designation to a tier 3 DSA without de-certification.

(3) The hearing officer's decision and the administrative record will be promptly forwarded to the CMS Administrator for his or her discretionary review.

(l) *CMS Administrator discretionary review.* (1) After receiving the hearing officer's decision for review, the CMS Administrator may elect to review the hearing officer's decision or to decline to review the hearing officer's decision. If the CMS Administrator does not elect to review that decision within 30 calendar days of receipt of the hearing officer's decision and the administrative record, the hearing officer's decision is final.

(2) If the CMS Administrator elects to review the hearing officer's decision, the CMS Administrator promptly notifies CMS and the OPO in writing of that election and that each party has the right to submit arguments on the administrative record from the hearing officer within 15 calendar days of the date of the notification.

(3) The CMS Administrator determines whether the hearing officer's determination should be upheld, reversed, or remanded according to paragraph (m) of this section.

(4) The CMS Administrator's administrative record is composed of:

(i) All documents submitted to the hearing officer or developed during the hearing, including the hearing officer's decision;

(ii) Written arguments from the OPO or CMS explaining why either or both parties believe the hearing officer's determination was correct or incorrect; and

(iii) The CMS Administrator's written decision explaining the reasons for their decision.

(5) The CMS Administrator may render a final decision in writing to the parties within 45 calendar days of notifying the parties that the Administrator has elected to review the hearing officer's decision.

(6) The decision of the hearing officer is final if the CMS Administrator does not render a final decision in writing to the parties within 45 calendar days of electing to review the hearing's administrative record or by a date specified under paragraph (l)(7) of this section.

(7) The CMS Administrator may extend the 45-calendar-day limitation if the:

(i) CMS Administrator determines he or she requires more time to thoroughly review and make a decision regarding the appeal; and

(ii) Extension does not prejudice either of the parties.

(m) *Remand.* (1) The CMS Administrator may remand the appeal to CMS for any appropriate reason, except for:

(i) In cases where the appeal was previously remanded to CMS, evaluation of evidence that was known or reasonably should have been known at the time the appeal was originally remanded.

(ii) Change in a party's representation, regardless of when made.

(iii) Presentation of an alternative legal basis concerning an issue in dispute.

(2) If the appeal is remanded to CMS, the original de-certification or removal of designation for a DSA without de-certification decision is vacated. The agency will comply with any instructions in the remand and will make a new determination.

(n) *Extension of agreement.* If there is insufficient time prior to expiration of an agreement with CMS to allow for completion of the appeals process, competition of the service area and, if necessary, transition of the service area to a successor OPO, CMS may choose to offer to extend the OPO's agreement with CMS.

(o) *Effects of de-certification.* Medicare and Medicaid payments may not be made for organ procurement services the OPO furnishes on or after the effective date of de-certification. If an OPO's designation to a tier 3 DSA is removed without de-certification, Medicare and Medicaid payments may not be made for organ procurement services the OPO furnishes in the affected DSA on or after the effective date of the removal of designation for the tier 3 DSA without de-certification. Once the appeals process is exhausted and the notice of de-certification or removal of designation for a tier 3 DSA without de-certification has not been reversed by the CMS Administrator, CMS will then open the OPO's affected service area for competition as set forth in § 486.316(c).

(p) *De-certification due to urgent need.* If an OPO is de-certified due to urgent need, the affected OPO's service area will be reassigned to one or more other OPOs as set forth at § 486.308(a)(4) by the effective date specified in the notice of de-certification provided under § 486.312(b). The OPO has 20

calendar days from receipt of that notice to file a request for reconsideration from CMS. The remainder of the appeals process proceeds as set forth in this section.

■ 9. Section 486.316 is amended by revising paragraphs (a) through (d) and (g) to read as follows:

§ 486.316 Re-certification and competition processes.

(a) *Impact of outcome measures to OPO designation.* Each OPO DSA will be assigned to either Tier 1, Tier 2, or Tier 3, based upon performance on the outcome measures set forth in § 486.318 for the final assessment period of the agreement cycle. The tier assignment of each DSA will determine OPO designation to the DSA.

(1) *Tier 1.* An OPO designated to a DSA that is assigned to tier 1, as specified at § 486.318(b)(4), will retain designation to the DSA for another agreement period. An OPO with tier 1 DSAs is eligible to compete in competitions for any open DSAs if it has been shown by the most recent survey to be in compliance with the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360.

(2) *Tier 2.* An OPO designated to a DSA that is assigned to tier 2, as specified at § 486.318(b)(5), must successfully compete and be awarded a DSA to retain designation to a DSA for another agreement period. An OPO with tier 2 DSAs is eligible to compete in competitions for any open DSAs if it has been shown by the most recent survey to be in compliance with the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360.

(3) *Tier 3.* An OPO designated to a DSA that is assigned to tier 3, as specified at § 486.318(b)(6), will have the designation removed at the end of the agreement period. An OPO with all of its DSAs assigned to tier 3 is not eligible to compete in competitions for any open DSAs.

(b) *OPO re-certification and competition.* (1) Compliance with process performance measures. An OPO must maintain compliance with the process performance measures at all times. An OPO with non-compliance in the process performance measures set forth at §§ 486.320 through 486.360 in any DSA will receive an initial de-certification determination and has the right to appeal that determination as established in § 486.314. If an OPO does not appeal the determination, or the OPO appeals and the determination is upheld after the appeal process is completed, the OPO's service areas are

opened for competition from other OPOs that qualify to compete for open service areas as set forth in paragraph (c) of this section.

(2) Compliance with the outcome measures. CMS will consider an OPO's DSA tier assignments in the final assessment period for re-certification.

(i) An OPO designated to at least one DSA that is assigned to tier 1 in the final assessment period will be re-certified for another re-certification cycle, as long as it is compliant with conditions for coverage at §§ 486.320 through 486.360 during the most recent survey.

(ii) An OPO that is designated to at least one DSA that is assigned to tier 2 but is not designated to any DSA assigned to tier 1 in the final assessment period will be re-certified if it is compliant with conditions for coverage at §§ 486.320 through 486.360 during the most recent survey. The OPO will be eligible to compete in competitions for any open DSA but will not have its agreement renewed if it is not successful in at least one competition, in accordance with § 486.311(a)(1). If the OPO is not successful in at least one competition, it will receive a notice of non-renewal as specified in § 486.311(b).

(iii) An OPO that is designated to a DSA(s) assigned to tier 3 in the final assessment period will receive one of the following notices:

(A) A notice of its initial de-certification determination for an OPO that has no other designated DSA that is assigned to tier 1 or tier 2, or another designated DSA that is pending evaluation of its outcome measures as specified at § 486.318(c)(3) or (4) at the end of the re-certification cycle.

(B) A notice of removal of designation to the DSA assigned as tier 3 for an OPO that has another designated DSA assigned as tier 1 or tier 2, or another designated DSA that is pending evaluation of its outcome measures as specified at § 486.318(c)(3) or (4) at the end of the re-certification cycle.

(iv) The OPO has the right to appeal de-certification or removal of designation to a tier 3 DSA as established in § 486.314. If an OPO does not appeal the determination, or the OPO appeals and the determination is upheld after the appeal process is completed, the OPO's tier 3 DSAs are opened for competition from other OPOs that qualify to compete for open service areas as set forth in paragraph (c) of this section.

(3) Competition. DSAs assigned as tier 2 or tier 3 in the final assessment period will be opened for competition. A DSA assigned to tier 3 will be opened for competition after any appeal under

§ 486.314 has been exhausted. The DSA is opened for competition from other OPOs that qualify to compete for open service areas as set forth in paragraph (c) of this section.

(c) *Criteria to compete.* (1) To compete for an open DSA, an OPO would have to be designated to at least one DSA that meets the performance requirements of the outcome measures for Tier 1 or Tier 2, as specified at § 486.318(b)(4) or (5), the requirements for certification at § 486.303, and the conditions for coverage at §§ 486.320 through 486.360 at the most recent routine survey. The OPO must compete for the entire DSA.

(2) An OPO that was subject to non-renewal of its agreement for failure to retain its DSA after competition is still eligible to compete in future competitions and enter into a new agreement with CMS, provided it has not been de-certified and met the criteria to compete at the time it entered competition that resulted in non-renewal.

(d) *Criteria for selection.* CMS will select an OPO for designation to an open DSA based on the following criteria:

(1) Performance on the outcome measures at § 486.318.

(2) Relative success in meeting the process performance measures and other conditions at §§ 486.320 through 486.360.

(3) Contiguity to the open service area.

(4) Success in identifying and overcoming barriers to donation within its own service area and the relevance of those barriers to barriers in the open area. An OPO competing for an open service area must submit information and data that describe the barriers in its service area, how they affected organ donation, what steps the OPO took to overcome them, and the results.

* * * * *

(g) *DSA transition.* (1) An incumbent OPO of a DSA must cooperate with a successor OPO that is newly designated to facilitate an orderly transition of the DSA. The incumbent OPO must submit a transition plan, as specified by CMS, that provides details on how all aspects of the OPO operation will be transmitted, including timeframes, to a new OPO.

(2) The successor OPO must submit a transition plan and periodic reports, as specified by CMS, to report on progress in its transition activities until the process is completed. The successor OPO must provide a final notice to CMS no later than 30 calendar days after completion of the transition and prior to the end of the incumbent OPO's agreement.

- 10. Section 486.318 is amended by—
- a. Revising paragraphs (a) through (c); and
- b. Removing paragraphs (d) through (f)

The revisions read as follows:

§ 486.318 Condition: Outcome measures.

(a) Each OPO's DSA is evaluated by measuring the donation rate and the organ transplantation rate in the DSA.

(1) For all DSAs, except as set forth in paragraph (a)(2) of this section:

(i) The donation rate is calculated as the number of donors in the DSA as a percentage of the donor potential.

(ii) The organ transplantation rate is calculated as the number of organs transplanted from donors in the DSA as a percentage of the donor potential. The organ transplantation rate is adjusted for the average age of the donor potential.

(iii) The numerator for the donation rate is the number of donors in the DSA. The numerator for the organ transplantation rate is the number of organs transplanted from donors in the DSA. The numbers of donors and organs transplanted are based on the data submitted to the OPTN as required in § 486.328 and § 121.11 of this title. For calculating each measure, the data used is from the same time period as the data for the donor potential.

(iv) The denominator for the outcome measures is the donor potential and is based on inpatient deaths within the DSA from patients 75 or younger with a primary cause of death that is consistent with organ donation. The data is obtained from the most recent 12-months data from State death certificates.

(2) For the Hawaii DSA:

(i) The donation rate is calculated as the number of donors in the DSA as a percentage of the donor potential.

(ii) The kidney transplantation rate is calculated as the number of kidneys transplanted from kidney donors in the DSA as a percentage of the donor potential.

(iii) The numerator for the donation rate is the number of donors in the DSA. The numerator for the kidney transplantation rate is the number of kidneys transplanted from kidney donors in the DSA. The numbers of donors and kidneys transplanted are based on the data submitted to the OPTN as required in § 486.328 and § 121.11 of this title. For calculating each measure, the data used is from the same time period as the data for the donor potential.

(iv) The denominator for the outcome measures is the donor potential and is based on inpatient deaths within the DSA from patients 75 or younger with

a primary cause of death that is consistent with organ donation. The data is obtained from the most recent 12-months data from State death certificates.

(b) Success on the outcome measures will be assessed based on the following parameters and requirements:

(1) For each assessment period, threshold rates will be established based on donation rates during the 12-month period immediately prior to the period being evaluated:

(i) The lowest rate among the top 25 percent in DSAs, and

(ii) The median rate among the DSAs.

(2) For each assessment period, threshold rates will be established based on the organ transplantation or kidney transplantation rates during the 12-month period prior to the period being evaluated:

(i) The lowest rate among the top 25 percent, and

(ii) The median rate among the DSAs.

(3) The 95 percent confidence interval for each DSA's donation and organ transplantation rates will be calculated using a one-sided test.

(4) Tier 1—DSAs that have an upper limit of the one-sided 95 percent confidence interval for their donation and organ transplantation rates that are at or above the top 25 percent threshold rate established for their DSA will be identified at each assessment period.

(5) Tier 2—DSAs that have an upper limit of the one-sided 95 percent confidence interval for their donation and organ transplantation rates that are at or above the median threshold rate established for their DSA but are not in Tier 1 as described in paragraph (b)(4) of this section will be identified at each assessment period.

(6) Tier 3—DSAs that have an upper limit of the one-sided 95 percent confidence interval for their donation or organ transplantation rates that are below the median threshold rate established for their DSA will be identified at each assessment period. DSAs that have an upper limit of the one-sided 95 percent confidence interval for their donation and organ transplantation rates that are below the median threshold rate for their DSA are also included in Tier 3.

(7) For the DSA that includes the non-contiguous State of Hawaii and surrounding territories, the kidney transplantation rate will be used instead of the organ transplantation rate. The comparative performance and designation to a Tier will be the same as in paragraphs (b)(4), (5), and (6) of this section except kidney transplantation rates will be used.

(c) CMS will evaluate OPO performance on the outcome measures at each assessment period.

(1) Performance on the outcome measures is based on an evaluation at least every 12 months, with the most recent 12 months of data available from the OPTN and State death certificates, beginning January 1 of the first year of the agreement cycle and ending December 31, prior to the end of the agreement cycle.

(2) An assessment period is the most recent 12 months prior to the evaluation of the outcome measures in which data is available.

(3) If an OPO takes over another OPO's DSA as a result of a change of control or ownership or service area, on a date later than January 1 of the first year of the agreement cycle so that 12 months of data are not available to evaluate the OPO's performance in its new DSA, the OPO will be held accountable for its performance on the outcome measures in the new area once 12 months of data are available.

(4) If an OPO takes over a new DSA as a result of a competition or assignment by CMS, on a date later than January 1 of the first year of the agreement cycle, we will hold the OPO accountable for its performance on the outcome measures in the new area:

(i) For the QAPI requirement, specified at § 486.348(d), once 12 months of outcome measure performance data are available.

(ii) For purposes of re-certification, as specified at § 486.316, in the final assessment period of the following agreement cycle.

■ 11. Section 486.322(a) is revised to read as follows:

§ 486.322 Condition: Relationships with hospitals, critical access hospitals, and tissue banks.

(a) *Standard: Hospital agreements.* An OPO must have a written agreement with 95 percent of the Medicare and Medicaid participating hospitals and critical access hospitals in each of its designated donation service area(s) that have both a ventilator and an operating room and have not been granted a waiver by CMS to work with another OPO. The agreement must describe the responsibilities of both the OPO and hospital or critical access hospital in regard to donation after cardiac death (if the OPO has a protocol for donation after cardiac death) and the requirements for hospitals at § 482.45 or § 485.643. The agreement must specify the meaning of the terms "timely referral" and "imminent death."

* * * * *

§ 486.324 [Amended]

■ 12. In 486.324 amend paragraphs (a)(1), (2), and (5), (b)(2), and (b)(8) by removing “area” and adding in its place “area(s)”.

■ 13. Section 486.326 is amended by revising paragraph (d), and adding paragraph (e) to read as follows:

§ 486.326 Condition: Human resources.

* * * * *

(d) *Standard: Medical director.* The OPO’s medical director is a physician licensed in at least one of the States or territories within one of the OPO’s service areas or as required by State or territory law or by the jurisdiction in which the OPO is located. The medical director is responsible for implementation of the OPO’s protocols for donor evaluation and management and organ recovery and placement. The medical director is responsible for oversight of the clinical management of potential donors, including providing assistance in managing a donor case when the surgeon on call is unavailable.

(e) *Standard: Licensure.* The OPO must assure that personnel performing clinical duties are legally authorized (licensed, certified or registered) in accordance with applicable Federal, State and local laws, and must act only within the scope of the individual’s State license, or State certification, or registration. Licensure, certification, or registration must be kept current at all times.

§ 486.328 [Amended]

■ 14. Section 486.328 is amended in paragraph (c) by removing “area” and adding in its place “area(s)”.

■ 15. Section 486.330 is amended by revising paragraph (b) to read as follows:

§ 486.330 Condition: Information management.

* * * * *

(b) *Disposition of organs.* The OPO must maintain records showing the disposition of:

(1) Each organ recovered for the purpose of transplantation, including pancreatic islet cell transplantation, including information identifying transplant beneficiaries; and

(2) Each organ recovered and sent for research, including pancreata used for islet cell research. Records shall include, but are not limited to, the following:

- (i) information documenting approval from an IRB or other formal authorizing body, as appropriate;
- (ii) research institution;
- (iii) principal investigator; and
- (iv) study contacts.

* * * * *

■ 16. Section 486.348 is amended—

- a. In paragraph (b) by removing “area” and adding in its place “area(s)”;
- b. By adding paragraph (c)(3);
- c. By revising paragraph (d)(3); and
- d. By adding paragraph (e).

The additions and revision read as follows:

§ 486.348 Condition: Quality assessment and performance improvement (QAPI)

* * * * *

(c) * * *

(3) Adverse events under these requirements include, but are not limited to,

- (i) Transmission of an infectious or communicable disease or other disease that may be transmissible from a donor to an organ recipient, such as the transmission, dissemination, and seeding of malignancies;
- (ii) Avoidable loss of a medically suitable potential donor for whom consent for donation has been obtained;
- (iii) Deviations from the current standards of practice or OPO procedures and policies regarding the evaluation and management of patients or potential donors that result in loss of a patient, potential donor, or transplantable organ(s);

(iv) Delivery to a transplant program of an organ that was not for the intended organ recipient or whose blood type does not match the blood type of the intended organ recipient;

(v) An organ that is lost, or delayed and arrived too late to be transplanted; or

(vi) An organ that arrives at the transplant program in a condition that is incompatible with transplantation.

(d) * * *

(3) If the outcome measure at each assessment period during the re-

certification cycle is statistically significantly lower than the top 25 percent of donation rates or organ or kidney transplantation (Tier 2 and Tier 3 DSAs) rates as described in § 486.318(b)(5) and (6), the OPO must identify opportunities for improvement and implement changes that lead to improvement in these measures.

(e) *Standard: Review of performance on the recovery and transplantation of medically complex organs.*

(1) Each OPO must assess its policies and procedures regarding medically complex donors and organs and ensure they are optimizing opportunities to recover and place those organs for transplant;

(2) Each OPO must assess its performance regarding the:

- (i) Number of medically complex donors from whom it has obtained consent for donation;
- (ii) Number of organs recovered from those donors; and
- (iii) Number of medically complex organs transplanted, at least annually.

(3) When an OPO identifies opportunities for improving its performance with medically complex donors or medically complex organs, it must implement actions to improve its performance.

■ 17. Section 486.360 is amended—

- a. By revising paragraph (c)(1)(v) and
- b. In paragraph (e)(2)(i) by removing “DSA” and adding in its place “DSA(s)”.

The revision reads as follows:

§ 486.360 Condition for Coverage: Emergency preparedness

* * * * *

(c) * * *

(1) * * *

(v) Transplant and donor hospitals in each of the OPO’s Donation Service Area(s) (DSAs).

* * * * *

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

[FR Doc. 2026–01833 Filed 1–28–26; 11:15 am]

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Part III

Department of Education

34 CFR Parts 674, 682, and 685

Reimagining and Improving Student Education; Proposed Rule

DEPARTMENT OF EDUCATION

34 CFR Parts 674, 682, and 685

[Docket ID ED–2025–OPE–0944]

RIN 1840–AD98

Reimagining and Improving Student Education

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Secretary proposes to amend the regulations for the Federal student loan programs authorized under title IV of the Higher Education Act (HEA) of 1965, as amended (the title IV, HEA programs) to implement the statutory changes to the title IV, HEA programs included in the One Big Beautiful Bill Act (OBBB) signed into law by President Trump on July 4, 2025. These changes include establishing new loan limits for graduate students, professional students, and parents, and phasing out the Graduate PLUS Program. The Department notes that the term “professional student” as used in this Notice of Proposed Rulemaking (NPRM) is intended solely to distinguish those programs that we propose would be eligible for higher loan limits, as required by the OBBB. The designation, or lack thereof, of a program as “professional” does not reflect a value judgment by the Department regarding whether a borrower graduating from the program is considered a “professional.” This NPRM only interprets the phrase “professional student” as used in the context of the loan limits established by the OBBB. The OBBB also simplifies the current broken and confusing myriad of Federal student loan repayment plans by phasing out the existing Income-Contingent Repayment (ICR) plans, creating a new tiered standard repayment plan option, and implementing a new income-driven repayment plan known as the Repayment Assistant Plan. The OBBB also enables borrowers in default who have previously rehabilitated a defaulted loan a second chance to rehabilitate their loan(s) and resume repayment.

DATES: We must receive your comments on or before March 2, 2026.

ADDRESSES: Submit your comments through the Federal eRulemaking Portal at www.regulations.gov. The Department of Education (Department) will not accept comments submitted by fax or by email or comments submitted after the comment period closes. To make sure that the Department does not receive

duplicate copies, please submit your comment only once. Additionally, please include the Docket ID at the top of your comments.

Information on using *Regulations.gov*, including instructions for submitting comments, is available on the site under “FAQ.” If you require an accommodation or cannot otherwise submit your comments via *Regulations.gov*, please contact regulationshelpdesk@gsa.gov or by phone at 1–866–498–2945. If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7–1–1.

Privacy Note: The Department’s policy is to make all comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking at www.regulations.gov. Therefore, commenters should include in their comments only information that they wish to make publicly available. Additionally, commenters should not include in their comments any personally identifiable information (PII) in comments about other individuals. For example, if your comment describes an experience of someone other than yourself, please do not identify that individual or include any personal information that identifies that individual. The Department reserves the right to redact a portion of a comment or the entire comment at any time if any PII about other individuals is included.

FOR FURTHER INFORMATION CONTACT: Tamy Abernathy, Office of Postsecondary Education, 400 Maryland Ave. SW, 5th Floor, Washington, DC 20202. Telephone: (202) 245–4595. Email: NegRegNPRMHelp@ed.gov.

SUPPLEMENTARY INFORMATION:**I. Executive Summary**

The Secretary proposes to implement the amendments made to the HEA relating to the Federal student loan programs made by the OBBB through these regulations.

These proposed regulations would revise the Direct Loan Program under 34 CFR part 685 by amending annual and aggregate loan limits for graduate, professional, and parent loan borrowers. The proposed regulations would also implement two new streamlined student loan repayment plans for new borrowers, the “Repayment Assistance Plan” and the “Tiered Standard” repayment plan. The proposed regulations also make conforming amendments to current regulations on consolidation, deferment, forbearance, and Public Service Loan Forgiveness

(PSLF). The proposed regulations also provide borrowers in default a second opportunity to rehabilitate their loans and resume repayment, even if they previously rehabilitated a defaulted loan.

A brief summary of these proposed regulations is available at <https://www.regulations.gov/document/ED-2025-OPE-0944>.

II. Summary of the Major Provisions of This Regulatory Action

These proposed regulations would:

- Amend §§ 674.39, 682.215, and 682.405 to allow loan rehabilitation twice per each loan borrowed under the Federal Perkins Program, Federal Family Education Loan Program, and the Direct Loan Program.
- Amend § 685.102 to include new definitions for the following terms: *expected time to credential*, *graduate student*, *professional student*, and *program length*.
- Amend § 685.200 to include Direct PLUS Loan eligibility for graduate and professional students.
- Amend § 685.201 to establish the limited Direct PLUS Loan eligibility for a graduate or professional student.
- Amend § 685.203 to include new Direct Loan annual and aggregate limits, create a new lifetime maximum aggregate limit, establish less than full-time reduction of annual loan limits, and permit institutions to limit borrowing for specific programs.
- Amend § 685.204 to clarify conditions and borrower eligibility for the unemployment deferment and the economic hardship deferment.
- Amend § 685.205 to establish the modified eligibility criteria for borrowers to receive a forbearance.
- Amend § 685.208 to establish the terms for the Tiered Standard repayment plan, set the minimum payment for the Tiered Standard repayment plan, and restructure each Fixed repayment plan’s terms under their respective plan.
- Amend § 685.209 to establish terms for the Repayment Assistance Plan and sunset ICR plans and conditions.
- Amend § 685.210 to provide information to borrowers about choosing a repayment plan.
- Amend § 685.211 to establish miscellaneous repayment provisions including the minimum payment increase for the Income-Based Repayment (IBR) plan.
- Amend § 685.219 to clarify that repaying under the Repayment Assistance Plan will qualify for PSLF if all other eligibility criteria are met.
- Amend § 685.220 to provide terms and repayment plan eligibility for consolidation loans.

- Amend § 685.221 to clarify when a borrower may be eligible for an alternative repayment plan.

- Amend § 685.303 to waive the substantially equal disbursement requirement for an institution when a borrower has less than full-time enrollment for the academic year and is subject to the schedule of reductions.

While the Department is proposing the regulations in a consolidated NPRM, it considers each to be a discrete change independent of other proposed changes. Consistent with 34 CFR 685.109, “[i]f any provision of this subpart or its application to any person, act, or practice is held invalid, the remainder of the subpart or the application of its provisions to any person, act, or practice will not be affected thereby.”

Cost and Benefits:

As further detailed in the Regulatory Impact Analysis (RIA), the proposed regulations would have significant impacts on students, borrowers, educational institutions, and taxpayers.

Under the proposed revisions, borrowers would benefit from new loan repayment terms, such as monthly interest cancellation and principal payment subsidies under the Repayment Assistance Plan. New caps on Federal loans for graduate and professional education, as well as caps on Parent PLUS Loans, will rein in increases in graduate student and parent borrowing and put downward pressure on tuition prices at institutions. These new loan limits will encourage institutions to evaluate the true cost of their programs and create efficiencies where necessary to allow students to enroll and fund their education within the boundaries of the new, responsible, loan limits determined by Congress and/or the institution. Changes to student loans enacted in the OBBB will result in significant savings to the taxpayer by reducing the excessive subsidy costs of loan forgiveness and other high-cost terms and conditions. Specifically, the new annual and lifetime caps on borrowing will reduce taxpayer exposure for loans that could potentially be forgiven under the Department’s Public Service Loan Forgiveness Program, Closed School Loan Discharges, Borrower Defense to Repayment discharges, death of the borrower discharges, total and permanent disability discharges, time-based forgiveness discharges under income-based repayment, and discharges that may occur in bankruptcy. The Department estimates that from 2021 to 2025, it forgave \$199 billion in student debt as a result of these provisions.

These proposed regulations would reduce outlays received from Direct Loans for institutions of higher education and certain groups of students. There are four main cost areas. First, the OBBB requires institutions to reduce annual loan limits in direct proportion to the percentage of full-time status that the student is enrolled. Prior to the OBBB, part-time students who were enrolled at least half-time could receive the same annual loan amount as students attending full-time. That provision will save taxpayers money by reducing the amounts borrowed by part-time students. Students will also receive less funds as credit balances as a result of the reduced borrowing. Institutions will, as a result, receive less revenue from loans made by the Department on behalf of students. Second, the OBBB limits excessive borrowing by graduate and professional students due to the elimination of unlimited borrowing under the Graduate PLUS Program, maintaining current borrowing limits of \$20,500 for graduate students (but limiting borrowing to \$100,000 in aggregate), and targeting higher loan limits of \$50,000 annually (\$200,000 in aggregate) to students enrolled in professional degree programs. Third, the OBBB streamlines the existing myriad of forbearance and deferment options while also limiting the time that borrowers can spend in certain forbearances. These changes should result in more time in active repayment by borrowers, as well as streamlining deferment and forbearance options to the benefit of borrowers, Federal student loan servicers, and taxpayers. Fourth, parents of undergraduate students will also no longer have unlimited borrowing under the Parent PLUS Loan program, which will now be capped at \$20,000 per student each year (\$65,000 aggregate limit per student). Now parent borrowers, in addition to student borrowers, will have common sense limits on the amount they can borrow to finance their children’s postsecondary education.

III. Invitation to Comment

We invite you to submit comments regarding these proposed regulations. Please clearly identify the specific section or sections of the proposed regulations that each of your comments address and arrange your comments in the same order as the proposed regulations. The Department will not accept comments submitted after the comment period closes.

The following tips are meant to help you prepare your comments:

- Please be concise but include objective sources of support for your claims.

- Explain your views as clearly as possible and refrain from using any profanity.

- Refer to specific sections and subsections of the proposed regulations throughout your comments, particularly in any headings that are used to organize your submission.

- Explain why you agree or disagree with the proposed regulatory text and support these reasons with data-driven evidence, including the depth and breadth of your personal or professional experiences. We encourage commenters to include supporting facts, research, and evidence in their comments. When doing so, commenters are encouraged to provide citations to the published materials referenced, including active hyperlinks. Likewise, commenters who reference materials which have not been published are encouraged to upload relevant data collection instruments, data sets, and detailed findings as a part of their comment. Providing such citations and documentation will assist us in analyzing the comments.

- Where you disagree with the proposed regulatory text, suggest alternatives, including regulatory language, and your rationale for the alternative suggestion.

- Do not include PII such as Social Security numbers or loan account numbers for yourself or for others in your submission.

Mass Writing Campaigns: In instances where individual submissions appear to be duplicates or near duplicates of comments prepared as part of a writing campaign, the Department will post one representative sample comment along with the total comment count for that campaign to *Regulations.gov*. The Department will consider these comments along with all other comments received.

In instances where individual submissions are bundled together (submitted as a single document or packaged together), the Department will post all the substantive comments included in the submissions along with the total comment count for that document or package to *Regulations.gov*. A well-supported comment is often more informative to the agency than multiple form letters.

Public Comments: The Department invites you to submit comments on all aspects of the proposed regulatory language specified in this Notice of Proposed Rulemaking (NPRM), and in the Regulatory Impact Analysis and Paperwork Reduction Act sections.

The Department may, at its discretion, decide not to post or to withdraw certain comments and other materials that contain promotion of commercial services or products, or are spam.

We may not address comments outside of the scope of these proposed regulations in the final regulations. Comments that are outside of the scope of these proposed regulations are comments that do not discuss the content or impact of the proposed regulations or the Department's evidence or reasons for the proposed regulations.

Comments that are submitted after the comment period closes will not be posted to *Regulations.gov* or addressed in the final regulations.

We invite you to assist us in complying with the requirements of (E.O.)s 12866 and 13563 and their overall requirement of reducing regulatory burden that might result from these proposed regulations. Please let us know of ways we could reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the Department's programs and activities.

During and after the comment period, you may inspect public comments about these proposed regulations by accessing *Regulations.gov*.

Assistance to Individuals with Disabilities in Reviewing the Rulemaking Record: On request, we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for these proposed regulations. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the Information Technology Accessibility Program Help Desk at *ITAPSupport@ed.gov* to help facilitate.

Clarity of the Regulations

Executive Order (E.O.) 12866 and the Presidential memorandum "Plain Language in Government Writing" require each agency to write regulations that are easy to understand. The Secretary invites comments on how to make the regulation easier to understand, including answers to questions such as the following:

- Are the requirements in the proposed regulations clearly stated?
- Do the proposed regulations contain technical terms or other wording that interferes with their clarity?
- Does the format of the proposed regulations (grouping and order of sections, use of headings, paragraphs) aid or reduce its clarity?

- Would the proposed regulations be easier to understand if we divided them into additional (but shorter) sections? (A "section" is preceded by the symbol "\$" and a numbered heading; for example, § 668.2 General definitions.)

- Could the description of the proposed regulations in the **SUPPLEMENTARY INFORMATION** section of this preamble be more helpful in making the proposed regulations easier to understand? If so, how?

- What else could we do to make the proposed regulations easier to understand?

- To send any comments that concern how the Department could make these proposed regulations easier to understand, see the instructions in the **ADDRESSES** section.

IV. Background

The OBBB, which President Trump signed into law on July 4, 2025, makes extensive statutory changes to fix broken and unnecessarily complex aspects of the Federal student loan programs in the areas of loan limits, repayment plans, and related provisions in title IV. Among other changes, the OBBB sets a new lifetime borrowing cap (approximately \$257,500 for most borrowers), eliminates new Graduate PLUS Loans, eliminates unlimited borrowing under the PLUS program for parents, maintains current annual limits under the Direct Loan Program for undergraduate and graduate students, increases annual loan limits for professional degree students, establishes aggregate limits for graduate students, professional degree students, and parents of undergraduates, and reduces annual loan amounts for students enrolled less than full-time. For repayment, the OBBB simplifies and streamlines the current confusing patchwork of repayment plan options for future borrowers to two flexible options: a new Tiered Standard plan for fixed monthly payments over a 10 to 25-year term, and a new income-driven plan called the Repayment Assistance Plan that does not put borrowers deeper in debt by preventing negative amortization over the life of the loan. Confusing, outdated (and in some cases unlawful) repayment plans are phased out, including several existing income-contingent plans, ICR, PAYE, and SAVE (which has been held unlawful in federal court. *See Missouri v. Biden*, 112 F.4th 531, 538 (8th Cir. 2024)).

This notice of proposed rulemaking complies with Section 492 of the HEA, which requires the Secretary to obtain public input and conduct negotiated rulemaking before issuing proposed regulations for the title IV, HEA

programs. To meet those requirements and implement the new statutory directives provided for in the OBBB, the Department convened the Reimagining and Improving Student Education (RISE) negotiated rulemaking Committee. The Committee was composed of representatives of institutions, students and borrowers, State officials, financial aid administrators, loan servicers, and consumer and civil rights organizations. The Committee met over multiple sessions in the fall of 2025 and reached consensus on the entirety of the regulatory text described in this NPRM. In accordance with the protocols established by the Committee, the Department has incorporated the regulatory amendatory text that was mutually agreed upon into this NPRM. Building on the statutory and regulatory history, and the RISE Committee's consensus language, this NPRM conforms Direct Loan rules to the changes enacted in the OBBB by revising loan limit provisions, restructuring repayment options (including IBR and adding the new Repayment Assistance Plan), updating PSLF eligibility and qualifying payment rules, and aligning consolidation, deferment, forbearance, and borrower relief provisions with the new framework.

V. Authority for This Regulatory Action

When Congress passes legislation amending statutory provisions regarding programs administered by an agency, that agency is tasked with implementing those changes in its regulations. The OBBB amended portions of the HEA related to the Federal student loan programs administered by the Department. The Secretary has been granted the broad authority by Congress to implement federal student aid programs under title IV of the HEA, including amendments made by the OBBB. See 20 U.S.C. 1221e–3, *see also* 20 U.S.C. 1082, 3441, 3474, 3471. In order to carry out functions otherwise vested in the Secretary by law or by delegation of authority pursuant to law, and subject to limitations as may be otherwise imposed by law, the Secretary is authorized to make, promulgate, issue, rescind, and amend rules and regulations governing the manner of operations of, and governing the applicable programs administered by, the Department. See 20 U.S.C. 1221e–3. These programs include the Federal student loan programs authorized by the HEA.

Waiver of HEA Master Calendar Requirements

Congress may waive, modify, or rescind requirements in the HEA that require the Department to follow certain processes and procedures when engaging in informal notice-and-comment rulemaking. Specifically, when Congress imposes a statutory deadline that is irreconcilable with other procedural requirements, like in the APA or HEA, then those other procedures have been implicitly waived by Congress. *See, e.g., Asiana Airlines v. F.A.A.*, 134 F.3d 393, 398 (D.C. Cir. 1998); *Methodist Hospital of Sacramento v. Shalala*, 38 F.3d 1225, 1237 (D.C. Cir. 1998) (finding that certain parts of the APA procedural framework had been waived when Congress gave an agency direction that conflicts with and is irreconcilable with the APA). Indeed, the Harmonious-Reading Canon provides that statutes should be interpreted in a way that renders them compatible, not contradictory. *See* Scalia & Garner, *Reading Law*, 180 (2012). As such, the Department does not read statutes to create instructions that directly conflict. Where Congress has given an agency specific direction in a statute that could not be followed if the agency also followed another part of the APA (or HEA, as is relevant here), then the provision is waived.

Here, the OBBB was enacted on July 4, 2025. The OBBB directs the Department to implement roughly a dozen provisions by July 1, 2026. Many of these provisions are not self-executing and could not be implemented absent the Department promulgating regulations to provide details for institutions on how to comply with the OBBB. Congress gave the Secretary discretion within the OBBB to implement the provisions impacting the Federal student loan programs and knew that its commands were not self-executing when directing the Secretary to take action. Congress expected the Secretary to act via rulemaking before July 1, 2026, to enable these provisions to actually go into effect.

The master calendar in the HEA provides that regulatory changes initiated by the Secretary affecting the programs under title IV of the HEA must be published in final form by November 1st in order for them to go into effect by July 1st of the following year. 20 U.S.C. 1089(c)(1). Section 492 of the HEA requires the Department to undertake negotiated rulemaking as part of any regulation under title IV of the HEA. In order to conduct negotiated rulemaking,

the Department must have a public hearing (providing notice to the public), solicit nominations from the public to serve on a negotiated rulemaking Committee, select non-Federal negotiators, hold negotiations, develop an NPRM and submit it for review by the Office of Information and Regulatory Affairs (OIRA), publish an NPRM (with at least a 30 day comment period), and then publish a final rule that responds to any substantive comments received. As detailed below, the fastest possible timeframe in which the negotiated rulemaking process for the RISE rulemaking packages could have occurred is 149 days, which is irreconcilable with the timeline allowed by the enactment of the OBBB, due to the fact that there were 120 days between July 4, 2025, (the day the OBBB was enacted), and November 1, 2025, (the publication date of the final rule required by the master calendar).

It would not have been possible for the Department to undertake every step of the negotiated rulemaking process by November 1, 2025, in order to implement the provisions that become effective in the OBBB by July 1, 2026, which is the statutory effective date. Congress was aware of this temporal impossibility when they passed the OBBB, yet Congress decided that these provisions would still go into effect on July 1, 2026. Because these provisions are not self-implementing and cannot go into effect unless the Department promulgates a final rule, the OBBB implicitly waives the master calendar.

For example, Congress directed the Department to publish a schedule of reductions for part-time students to reduce their annual loan eligibility. (Sec. 81001 of the OBBB, P.L. 119–21). The Department announced in DCL: GEN–25–04, published on July 18, 2025, that the schedule of reductions will be issued by the Secretary and used to determine the reduction in the annual loan limits for students who are enrolled less than full-time for subsequent academic years (2026–2027 and beyond). The Department will publish the schedule of reductions in the final rule. This provision was effective upon enactment; however, the 2025–2026 award year had already begun prior to President Trump signing the bill and Federal student loans for that year had already been calculated and initially disbursed. In addition, Congress left open to regulation important details in the Repayment Assistance Program relating to how the Department should treat married borrowers' income, and whether the Department should essentially double count their income when calculating

repayment rates. Moreover, in codifying a regulatory definition for professional student that is open-ended, Congress did not fully address what types of programs should be considered professional programs or graduate programs. Indeed, the statute's operative definition of professional degree broadly describes what a professional student is and includes an illustrative list of degrees that meet that operative definition. 34 CFR 668.2 (Noting that the professional degrees "include but are not limited to" the degrees listed). The definition of graduate degree is interrelated to the definition of professional degree, in that a degree is a graduate degree if it awards a graduate credential but is not a professional degree.

With these important details unanswered by the plain text of the OBBB, it is clear that the policy scheme set forth in the HEA made by the OBBB cannot be implemented absent regulatory action by the Department.

At the same time, even though the requirements of negotiated rulemaking are onerous, it is possible to undergo negotiated rulemaking and publish a final rule at least 30 days prior to the effective date of these OBBB provisions on July 1, 2026. Therefore, the OBBB does not waive negotiated rulemaking nor any provision in the APA. For provisions in the OBBB that become effective July 1, 2027, and beyond, Congress did not implicitly repeal the master calendar because it is possible for the Department to publish a final rule that complies with the master calendar to implement those provisions. Nonetheless, the Department is conducting rulemaking relating to those provisions that go into effect in 2027 and beyond due to the interconnected nature of these provisions as they relate to Federal student aid programs.

VI. Public Participation

Section 492 of the HEA, 20 U.S.C. 1098a, requires the Secretary to obtain public involvement in the development of proposed regulations affecting the title IV, HEA programs. Prior to developing this NPRM, the Department obtained advice and recommendations from individuals and representatives of groups involved in the title IV, HEA programs. This outreach included a 30-day public comment period, one day of public hearings, and culminated in nine days of in-person negotiated rulemaking at the Department's headquarters in Washington, DC. Further details regarding these efforts are provided below.

On July 25, 2025, the Department published in the **Federal Register** (90

FR 35261) a notice of our intent to hold a public hearing and to establish two negotiated rulemaking Committees to consider regulatory changes to the title IV, HEA programs included in the OBBB with one Committee focusing on topics regarding annual and aggregate loan limits, loan deferment, forbearance, and repayment, among others, related to Federal student loans.

Public Comments and Hearings

We received 1,864 written comments in response to the **Federal Register** notice. Additionally, we held a virtual public hearing on August 7, 2025. A total of 57 individuals testified virtually at the hearing.

You may view the written comments submitted in response to the July 29, 2025 “Intent to Establish Negotiated Rulemaking Committees; Correction” correction notice (90 FR 35652), by visiting the Federal eRulemaking Portal at *Regulations.gov*, within docket ID ED–2025–OPE–0151. Instructions for finding comments are also available on the site under “FAQ.”

Transcripts of the public hearings can be accessed at <https://www.ed.gov/laws-and-policy/higher-education-laws-and-policy/higher-education-policy/negotiated-rulemaking-for-higher-education-2025-2026>.

Negotiated Rulemaking

On July 25, 2025, we published a notice in the **Federal Register** announcing our intent to establish one Committee to prepare these proposed regulations (90 FR 35261). The notice set forth a schedule for Committee meetings and requested nominations for individual, non-Federal negotiators to serve on the negotiated rulemaking Committee. In the notice, we also announced the topics that the Committee would address.

We chose members of the negotiated rulemaking Committee from individuals nominated by groups involved in the title IV, HEA programs. We selected individuals with demonstrated expertise or experience with the student loan program. The negotiated rulemaking Committee included the following members, representing their respective constituencies:

- Legal assistance organizations that represent students and borrowers, consumer advocates, and civil rights groups that represent students: Ashley Naporlee, Lead Attorney, Consumer Protection Team, Legal Aid Society of San Diego, and Tamar Hoffman (alternate), Staff Attorney, Homeownership and Consumer Rights Unit, Community Legal Services of Philadelphia.

- Student loan servicers, collection agencies, lenders, and guaranty agencies: Alexander Ricci, President, National Council of Higher Education Resources, and Lori Hartung (alternate), Regional Sales Executive, Education Computer Systems, Inc.

- Organizations representing taxpayers and the public interest: Alexander Holt, Senior Advisor on Higher Education, Committee for a Responsible Federal Budget, and Dr. Andrew Gillen (alternate), Research Fellow, Cato Institute.

- Private nonprofit institutions of higher education including institutions eligible to receive Federal assistance under Title III and Title V of the HEA tribal colleges and universities, and historically black colleges and universities: Jenna Colvin, President, Georgia Independent College Association, and Patti Kohler (alternate), Vice President of Financial Aid, Western Governors University.

- Proprietary institutions of higher education, as defined in 34 CFR 600.5: Dr. Andy Vaughn, President and Chief Executive Officer, Alliant International University, and Jeffrey Bodimer (alternate), Vice President of Regulatory Compliance and Financial Aid, Post University.

- Public institutions of higher education including institutions eligible to receive Federal assistance under Title III and Title V of the HEA, tribal colleges and universities, and historically black colleges and universities: Dr. Timothy B. King, Vice Provost for Student Success, Jacksonville State University, and Matthew Ellsworth (alternate), Director of Financial Aid, Western Carolina University.

- State officials, including State student grant agencies, State higher education executive officers, and representatives of authorizing agencies: Scott Kemp, Student Loan Advocate, State Council of Higher Education for Virginia, and Dr. Bennett Boggs (alternate), Commissioner, Missouri Department of Higher Education & Workforce Development.

- Student loan borrowers, including borrowers in school, deferment, forbearance, delinquent, default, and currently in repayment: Deborah Lilly, Senior Project Manager, UnitedHealthcare, and Emeka Oguh (alternate), Chief Executive Officer, PeopleJoy.

- Student loan borrowers who are veterans, U.S. military service members, or groups representing them: Faisal Sulman, Legal Fellow, Student Veterans of America, and Robert H. Carey, Jr.

(alternate), Executive Director, National Defense Committee.

The Committee discussion was led by Tamy Abernathy, Director of the Policy Coordination Group of the Department and supported by the Department's Office of General Counsel and Office of Postsecondary Education, with Annmarie Weisman of Federal Student Aid serving as facilitator for the Committee.

The negotiated rulemaking Committee for these proposed regulations met from September 29 to October 3, 2025, and November 3 to November 6, 2025, which concluded the negotiations on November 7, 2025, a day earlier than originally scheduled. The Committee reviewed and discussed draft regulations prepared by the Department, as well as alternative regulatory language and suggestions proposed by Committee members. Additionally, during each negotiated rulemaking meeting, some non-Federal negotiators shared feedback that they had received from stakeholders in their respective constituencies. This approach facilitated the inclusion of a wide array of ideas and perspectives, which contributed to the development of the consensus language.

Under the organizational protocols for negotiated rulemaking agreed to by all members of the Committee, if the Committee reaches consensus on the proposed regulations, the Department agrees to publish, without substantive alteration, a defined group of regulations on which the Committee reached consensus—unless the Secretary reopens the process or provides a written explanation to the participants stating why she has decided to depart from the agreement reached during negotiations. In this instance, consensus is considered to be the absence of dissent by any member of the negotiated rulemaking Committee (abstaining members are not considered to be dissenting from the proposal). The Committee reached consensus on the entirety of the draft regulations on November 6, 2025. As a result, this NPRM reflects the consensus language without any substantive changes.

Further information on the negotiated rulemaking process can be found at: <https://www.ed.gov/laws-and-policy/higher-education-laws-and-policy/higher-education-policy/negotiated-rulemaking-for-higher-education-2025-2026>.

VI. Significant Proposed Regulations

We discuss substantive issues under the sections of the proposed regulations to which they pertain. While we generally do not address technical,

minor, or legal changes to the proposed amendatory text, there are a few areas where we determined technical corrections were necessary and we fully explain those later in the sections where the corrections have been made in this NPRM.

Federal Perkins Loan Program

Loan Rehabilitation (§ 674.39)

Statute: Section 82003(a)(2) of the OBBB amends

Section 464(h)(1)(D) of the HEA to provide that loan rehabilitation for defaulted Federal Perkins loans is limited to a maximum of two times per loan. Section 82003(a)(3) of the OBBB provides that the effective date of this statutory change is July 1, 2027.

Current Regulations: Section 674.39 contains the general terms and conditions pertaining to loan rehabilitation in the Federal Perkins Loan Program. Specifically, § 674.39(e) provides that a borrower may rehabilitate a defaulted Federal Perkins Loan only one time.

Proposed Regulations: The Department proposes to amend the regulations in § 674.39(e) to provide that on or after July 1, 2027, a borrower may rehabilitate a defaulted loan a maximum of two times. This means that a borrower who has previously rehabilitated a defaulted loan but who has subsequently defaulted may begin the process of rehabilitating a loan on or after July 1, 2027, to bring their loan back into good standing and resume repayment.

Reasons: The proposed regulations reflect the changes made by Section 82003(a)(2) of the OBBB, which amended Section 464(h)(1)(D) of the HEA to update the loan rehabilitation limits for the Federal Perkins Loan Program. Additionally, Section 82003(a)(3) of the OBBB provides that the effective date of this statutory change takes effect beginning on July 1, 2027. Because borrowers with outstanding Federal Perkins Loans would now have the ability to rehabilitate a defaulted loan a maximum of two times beginning July 1, 2027, we believe that the regulations should reflect the number of times a borrower may rehabilitate this type of loan before and after July 1, 2027.

Accordingly, the Department proposes to bifurcate the limitations on loan rehabilitations for the Federal Perkins Loan Program: proposed § 674.39(e)(1) would retain the limitation in the current regulations that would be in effect prior to July 1, 2027, whereby a borrower can only obtain the benefit of loan rehabilitation once for a

defaulted Federal Perkins Loan.

Proposed § 674.39(e)(2) would provide that on or after July 1, 2027, a borrower may rehabilitate a defaulted Federal Perkins Loan a maximum of two times. This bifurcation would make clear the number of times a borrower may rehabilitate based on the date of rehabilitation.

During the negotiated rulemaking sessions, non-Federal negotiators focused on how the Department should treat traditional loan rehabilitations completed during the COVID-19 payment pause, particularly for purposes of the statutory limit on the number of rehabilitations available to a borrower. Negotiators emphasized that some borrowers completed “real” rehabilitations during the pause—often in circumstances where Fresh Start later became available—and urged the Department to make certain that those COVID-period rehabilitations would not count against the borrower’s total number of rehabilitation attempts, given the unusual operational environment and the availability of alternative default-resolution pathways during the pandemic. We explained that, while Fresh Start¹ is a distinct initiative and does not constitute rehabilitation, a borrower who completed a rehabilitation during the payment pause, is considered to have completed the rehabilitation process once. During this time, borrowers were only permitted to rehabilitate their loans one time under the statute. Therefore, because those borrowers completed rehabilitation in accordance with statutory requirements, the Department does not have the authority to disregard the rehabilitation when applying the statutory maximum. However, under the OBBB, effective July 1, 2027, the statute has increased the limit of rehabilitations to twice.

Federal Family Education Loan (FFEL) Program

Loan Rehabilitation Agreement (§ 682.405)

Statute: Section 82003(a)(1) of the OBBB amends section 428F(a)(5) of the HEA to change the loan rehabilitation limit in that section to reflect that a defaulted loan may be rehabilitated twice. Prior to the OBBB, such loans could only be rehabilitated once. Section 82003(a)(3) of the OBBB provides that the effective date of this statutory change is July 1, 2027.

¹ Federal Student Aid, U.S. Dept of Educ., *A Fresh Start for Borrowers with Federal Student Loans in Default* (Fact Sheet) (last updated July 11, 2024), <https://fsapartners.ed.gov/sites/default/files/2022-08/FreshStartFactSheet.pdf>

Current Regulations: Section 682.405 contains the general terms and conditions of rehabilitation of defaulted loans made through the Federal Family Education Loan (FFEL) program, which are administered by a guaranty agency. Section 682.405(a)(3) provides that if a borrower’s FFEL program loan is being collected through administrative wage garnishment (AWG) while the borrower is also rehabilitating that loan under a rehabilitation agreement, the guaranty agency must continue AWG until the borrower makes five qualifying monthly payments under such rehabilitation agreement. After receiving the fifth monthly payment, the guaranty agency suspends the AWG order. Such a borrower may only obtain the benefit of a suspension of AWG while also attempting to rehabilitate a defaulted FFEL program loan once. Section 682.405(a)(4) provides that after the FFEL program loan has been rehabilitated, the borrower regains eligibility and the benefits afforded to non-defaulted borrowers, including access to certain deferments, from the date of the rehabilitation. Section 682.405(a)(4) further provides that for any loan that is rehabilitated on or after August 14, 2008, the borrower cannot rehabilitate the loan again if the loan returns to default status following the rehabilitation.

Proposed Regulations: The Department proposes to amend the regulations at § 682.405(a)(3)(iii)(B) to provide that on or after July 1, 2027, a borrower may only obtain the suspension of AWG benefit one time per each attempt to rehabilitate a defaulted loan. Furthermore, the Department also proposes that a loan may only be rehabilitated once between August 14, 2008, through June 30, 2027. On or after July 1, 2027, a loan may be rehabilitated a maximum of two times over the loan’s lifetime, regardless of when the loan was made.

Reasons: The regulations are amended to reflect the changes made by the OBBB. The Department also amends proposed § 682.405(a)(3)(iii) to correct an administrative error that includes adding paragraph (A) and (B). This proposed additional language is needed to distinguish the number of times a FFEL borrower may rehabilitate their defaulted loans before and after June 30, 2027, and its impact on the suspension of AWG. Accordingly, we revised current § 682.405(a)(3)(iii) to proposed § 682.405(a)(3)(iii)(A), which would only apply for loans on or before June 30, 2027, and state that a borrower may only obtain the benefit of a suspension of AWG while also attempting to rehabilitate a defaulted loan once.

Proposed § 682.405(a)(3)(iii)(B) would apply to loans obtained on or after July 1, 2027, and states that a borrower may only obtain the suspension of AWG benefit one time per each attempt to rehabilitate a defaulted loan. We believe separating these provisions at the subparagraph level would make clear that suspension of AWG remains available for one eligible rehabilitation through June 30, 2027, and provides that the suspension would be available for up to a maximum two rehabilitations per loan on or after July 1, 2027.

Income-Based Repayment Plan (§ 682.215)

Statute: Section 82001(f)(1)(B) of the OBBB amends Section 493C(a)(3) of the HEA to eliminate the requirement that FFEL borrowers must have a partial financial hardship to be eligible for IBR. Section 82001(g) of the OBBB amends Section 428(b)(9)(A)(v) of the HEA to remove the partial financial hardship requirement from IBR for FFEL Loans. The OBBB also creates the definition of *applicable amount* in Section 493C(a)(3) of the HEA. These provisions were effective upon enactment, and the Department has already taken steps to eliminate the requirement that borrowers show a partial financial hardship to participate in existing IDR plans.

Current Regulations: Section 682.215 contains the regulations on the IBR plan for FFEL program loans. Section 682.215(a) provides the definitional terms that are applicable to the IBR plan, including a definition of partial financial hardship. Section 682.215(b) provides the terms and conditions of the IBR plan, including a borrower's eligibility for the IBR plan and the calculation of a borrower's monthly payment under the plan. In current regulations, to enroll in the IBR plan, the borrower must have a partial financial hardship and the borrower's monthly loan payments are limited to no more than 15 percent of the amount by which the borrower's adjusted gross income exceeds 150 percent of the poverty line income applicable to the borrower's family size, divided by 12.

Section 682.215(d) provides for changes in a borrower's payment amount if a borrower no longer has a partial financial hardship or if a borrower elects to repay their loans under a different repayment plan. Section 682.215(e) provides the eligibility documentation, verification, and notification requirements to determine a borrower's initial or continued eligibility for the IBR plan or to calculate a monthly payment under such plan. Finally, Section 682.215(f)

provides the loan forgiveness provisions under the IBR plan: in general, a borrower receives forgiveness of the remaining balance of their loans after the borrower has made 300 qualifying monthly payments (or 25 years) under IBR.

Proposed Regulations: To conform the regulations to changes of the HEA that were enacted by the OBBB, we are proposing to amend the regulations at § 682.215(a)(4) to remove the definition of *partial financial hardship* and include a new definition of *applicable amount*. *Applicable amount* would mean for the purposes of the IBR plan, 15 percent of the result obtained by calculating, on at least an annual basis, the amount by which the adjusted gross income of the borrower and the borrower's spouse (if applicable) exceeds 150 percent of the poverty guideline. We also propose to amend the terms and conditions of the IBR plan in § 682.215(b), including a borrower's eligibility for the IBR plan and the calculation of a borrower's monthly payment under the IBR plan by removing references to partial financial hardship, and where appropriate, replacing references to partial financial hardship with a provision of the *applicable amount* calculated under IBR. Finally, we propose to amend the forgiveness provisions in IBR plan in § 682.215(f) by removing references to partial financial hardship.

Reasons: The regulations are amended to reflect the changes made by the OBBB, including the definition of *applicable amount*. The term *applicable amount* by and large supplants partial financial hardship, and we propose making conforming changes throughout § 682.215 by removing partial financial hardship or removing the concepts of partial financial hardship by using *applicable amount* instead. Additionally, the Department removed the definition of *partial financial hardship* in § 682.215(a)(4) and removed the term throughout the section.

William D. Ford Federal Direct Student Loan (Direct Loan) Program

Definitions (§ 685.102)

Statute: Section 81001(2) of the OBBB amends Section 455(a) of the HEA and defines the following terms: *expected time to credential*, *graduate student*, *professional student*, and *program length*.

Current Regulations: Section 685.102 contains the definitions that apply to 34 CFR part 685. Specifically, § 685.102(a)(1) provides a list of common definitions for all the title IV, HEA programs in 34 CFR part 688

(Student Assistance General Provisions) that also apply to 34 CFR part 685.

Proposed Regulations: To implement the new provisions enacted in the OBBB, we propose to add several new definitions for the purposes of the Direct Loan Program. We propose to add in § 685.102(b) the following new definitions: *expected time to credential*; *graduate student*; *professional student*; and *program length*.

We propose to define *expected time to credential* to mean the expected time for a student to complete a program that is the lesser of (1) three academic years or (2) the period determined by calculating the difference between the length of the academic program and the period the student already completed in that academic program.

We propose to define *graduate student* to mean a student who is enrolled in a program of study that is above the baccalaureate level and awards a graduate credential (other than a professional degree) upon completion of the program. Above the baccalaureate level means that the program ordinarily requires, as a prerequisite for enrollment, that a student first obtain a baccalaureate degree. For the purposes of dual degree programs that allow individuals to complete a bachelor's degree and either a graduate or professional degree within the same program, a student is considered an undergraduate student for at least the first three years of that program. 34 CFR 668.2(b).

We propose to define *professional student* to mean a student enrolled in a program of study that awards a professional degree upon completion of the program. In defining professional student, we apply the definition of a professional degree in 34 CFR 668.2 that was in effect on July 4, 2025, and clarify that such degrees meet the following elements: signifies both completion of the academic requirements for beginning practice in a given profession and a level of professional skill beyond that which is normally required for a bachelor's degree; is generally at the doctoral level; requires at least six academic years of postsecondary education coursework for completion, including at least two years of post-baccalaureate level coursework; generally requires professional licensure to begin practice; and, includes a four-digit program Classification of Instructional Program (CIP) code, as assigned by the institution or determined by the Secretary, in the same intermediate group in certain fields. We also propose that a professional degree only includes

degrees in the following fields:² Pharmacy (Pharm.D.), Dentistry (D.D.S. or D.M.D.), Veterinary Medicine (D.V.M.), Chiropractic (D.C. or D.C.M.), Law (L.L.B. or J.D.), Medicine (M.D.), Optometry (O.D.), Osteopathic Medicine (D.O.), Podiatry (D.P.M., D.P., or Pod.D.), Theology (M.Div., or M.H.L., or Ph.D.). Finally, we propose that a professional student may not receive title IV aid as an undergraduate student for the same period of enrollment and must be enrolled in a program leading to a professional degree. The Department seeks comment on its analysis relating to the professional degrees it included in or excluded from the professional student definition. Specifically, it would be useful to have feedback on how the Department applied the operative definition of *professional student* and utilized the context of the illustrative list of degrees when interpreting the definition.

We propose to define *program length* to mean the minimum amount of time in weeks, months, or years that is specified in the catalog, marketing materials, or other official publications of an institution for a full-time student to complete the requirements for a specific program of study.

Reasons: In the definition of *expected time to credential* (implementing Section 455(a)(8)(B) of the HEA, added Section 81001 of the OBBB), we begin the definition with “From July 1, 2026.” Section 455(a)(3)(C), (4), (5), and (6) of the HEA, added by Section 81001 of the OBBB, terminates the Department’s authority to make Federal Direct PLUS Loans to graduate and professional students, imposes new annual and aggregate limits for Federal Direct Unsubsidized Loans made to graduate and professional students, and imposes new annual and aggregate limits for Federal Direct PLUS Loans. Each of these statutory provisions takes effect on July 1, 2026. Therefore, the definition of *expected time to credential*, begins with

“July 1, 2026” because the term is used in regard to the limited exception to Sections 455(a)(3)(C), (4), (5), and (6) of the HEA, added by Section 81001 of the OBBB, for currently enrolled students.

Additionally, in paragraph (1) of the definition of *expected time to credential*, we propose adding a cross reference to the definition of the term *academic year* in 34 CFR 668.3. Because this definition applies to loan limits, we believe using this cross reference to academic year, as defined in § 668.3, would be consistent with existing policy such as that reflected in § 685.203(h), where the loan limit period applies to an academic year as defined in 34 CFR 668.3.

Changes enacted in the OBBB, effective for loans made on or after July 1, 2026, limit borrowing amounts for graduate students to an annual limit of \$20,500, with an aggregate lifetime limit of \$100,000. For those students enrolled in professional degree programs, the annual limit is \$50,000, with an aggregate lifetime limit of \$200,000.

Due to the significant difference between the loan limits for graduate students compared to the limits for students enrolled in professional degree programs, institutions, relevant trade associations, and other stakeholders have been seeking to have graduate degree programs that have historically not been identified as first professional or professional degree programs to be classified as such, since the OBBB was signed into law.³ Labeling such programs as professional degrees would significantly increase the amount of Federal student loans that a borrower may have access to more than doubling the annual loan limit and doubling the lifetime access for graduate students.

In the definition of *graduate student* (see Section 455(a)(4)(C)(i) of the HEA), we include the clause that a graduate student is a “student enrolled in a program of study that is above the baccalaureate level” to make clear that the academic program needs to be above the baccalaureate level to be considered eligible for the higher graduate student loan limits. This proposed change incorporates the current definition of *graduate or professional student* in § 668.2 and a long-standing policy for the Federal Pell Grant, Federal Supplemental Opportunity Grant (FSEOG), and student loan programs that a graduate student is a student who is enrolled in a program or course above

the baccalaureate level. Words and phrases typically carry their ordinary and everyday meaning. Scalia & Garner, *Reading Law: The Interpretation of Legal Texts*, 69 (2012). The term “graduate” in this context ordinarily means an advanced college degree program that requires, as a condition of enrollment, that a student must have *graduated* from a lower-level postsecondary program (otherwise known as an “undergraduate degree”). The common understanding of the nomenclature “graduate” in this context has always implicitly referred to individuals who have graduated from a baccalaureate degree program, as opposed to graduates of certificate degree or associate’s degree programs.⁴ Both baccalaureate degrees and associate’s degrees are undergraduate degrees, but an associate’s degree is not sufficient for a student to enroll in a graduate degree program. Here, we provide that a graduate student must be a student enrolled in a program above the baccalaureate level.

For the purpose of the Direct Loan limits established in section 81001 of the OBBB, Congress made it clear that “a graduate student, who is not a professional student,” will continue to receive the current loan limit of \$20,500 for unsubsidized loans after July 1, 2026. 20 U.S.C. 1087e(a)(4)(A)(i). The OBBB made no change in the annual loan limit for Direct Unsubsidized Loans for which graduate students can qualify.

To distinguish between graduate students and professional students, Section 81001 of the OBBB amends Section 455(a) of the HEA by defining a *professional student* to mean “a student who is enrolled in a program of study that awards a professional degree (as that term is defined under section 668.2 of title 34, Code of Federal Regulations, and in effect on the date of enactment of July 4, 2025), upon completion of the program.” The OBBB defines *graduate student* as “a student

² Pharm.D.—Doctor of Pharmacy; D.D.S.—Doctor of Dental Surgery; D.M.D.—Doctor of Dental Medicine; D.V.M.—Doctor of Veterinary Medicine; D.C.—Doctor of Chiropractic; DCM. (or D.C.M.)—Doctor of Chiropractic Medicine; L.L.B. (LLB)—Bachelor of Laws (Latin: *Legum Baccalaureus*); J.D. (JD)—Juris Doctor; M.D. (MD)—Doctor of Medicine; O.D. (OD)—Doctor of Optometry; D.O. (DO)—Doctor of Osteopathic Medicine; D.P.M. (DPM)—Doctor of Podiatric Medicine; D.P.—Doctor of Podiatry; Pod.D.—Doctor of Podiatry; M.Div.—Master of Divinity; M.H.L.—commonly rendered as Master of Hebrew Letters or Master’s in Hebrew Literature; and Psy.D. or Ph.D. (Ph.D.)—Clinical Psychology Doctor of Psychology or Doctor of Philosophy). Usage reflects common degree-name conventions; terminology and degree-name expansions may vary by institution, accrediting agency, or program.

³ Blake, Jessica. (2025, November 26). *What to Know About Trump’s Definition of Professional Degrees*. Inside Higher ED. <https://www.insidehighered.com/news/government/student-aid-policy/2025/11/26/what-know-about-definition-professional-degree>.

⁴ See “*Graduate*”, “of, relating to, or engaged in studies beyond the first or bachelor’s degree,” Merriam-Webster.com Dictionary, Merriam-Webster, <https://www.merriam-webster.com/dictionary/graduate>. Accessed 11. Dec. 2025; see also “*Graduate Student*”, “a student who is studying for a degree that is higher than the one received after four years of study at a college or university,” Cambridge Dictionary.com Dictionary, Cambridge University Press & Assessment, <https://dictionary.cambridge.org/dictionary/english/graduate-student>. Accessed 11. Dec. 2025. Further, the U.S. Department of State (State) defines “graduate student” as “someone who has earned a bachelor’s degree and is pursuing additional education in a specific field”. U.S. Department of State, Education USA, <https://educationusa.state.gov/your-5-steps-us-study/research-your-options/graduate/what-graduate-student>. Accessed 11. Dec. 2025.

enrolled in a program of study that awards a graduate credential (other than a professional degree) upon completion of the program.”

The definition of *professional degree* in 34 CFR 668.2 that is referenced in 20 U.S.C. 1087e(a)(4)(C)(ii) and was in effect on the OBBB date of enactment of July 4, 2025, reads as follows:

Professional degree: A degree that signifies both completion of the academic requirements for beginning practice in a given profession and a level of professional skill beyond that normally required for a bachelor's degree. Professional licensure is also generally required. Examples of a professional degree include but are not limited to Pharmacy (Pharm.D.), Dentistry (D.D.S. or D.M.D.), Veterinary Medicine (D.V.M.), Chiropractic (D.C. or D.C.M.), Law (L.L.B. or J.D.), Medicine (M.D.), Optometry (O.D.), Osteopathic Medicine (D.O.), Podiatry (D.P.M., D.P., or Pod.D.), and Theology (M.Div., or M.H.L.).

In applying this long-standing definition to the new loan limits for graduate and professional students, the inclusion of the phrase in the definition that “[e]xamples of a professional degree include but are not limited to . . .” suggests that the list of examples provided in the definition need not be exhaustive. Conversely, the list is not completely open-ended, as it provides an illustrative list and a three-part test to draw upon.

Rather than constructing a definition for professional student, Congress borrowed and codified the Department's regulatory definition of the term “professional degree” in 34 CFR 668.2. This definition served a very limited purpose in the Department's regulations, and the Department has not identified any interest in the prior use of the term “professional degree” that will be impaired by its adoption below. However, the Department seeks public feedback on whether any pre-existing interest in the regulation will be affected.

In adopting this definition of “professional degree,” Congress incorporated a variety of words and phrases that may, without context, appear ambiguous or vague on their face or as applied to specific degree programs. The Department must identify the best reading of the statute using the tools of statutory construction.

The operative definition provided in the OBBB establishes a three-part test: First, the degree must signify completion of the academic requirements for beginning practice in a given profession. The word “signify”

means to be a sign of something (<https://www.merriam-webster.com/dictionary/signify>). Here, it means when the degree is completed, the recipient has completed all academic requirements to begin practicing in a profession, even if some additional training is required.

Second, the profession the graduate enters must require a level of professional skill beyond what is normally required for a bachelor's degree. This means that the profession must require skill(s) that students who only have a bachelor's degree (or training below a bachelor's degree level) would not normally have. The term “normally” connotes that this rule will be followed in almost every circumstance, but it does not rule out the possibility *per se* of some exception to the rule.

Third, the profession that a degree holder would enter after graduating generally requires professional licensure. This means that before beginning practice, the degree recipient must obtain additional authorization to begin practicing, which would typically flow from a government or standard setting organization. Like the second part, the third part requires licensure “generally,” which connotes that this rule will be followed in almost every circumstance, but it does not rule out the possibility *per se* of some exception to the rule.

In addition to the operative test, the definition also provides for an illustrative list of advanced degrees that are professional degrees and meet the definition. These degrees were codified by Congress into the definition as examples, meaning the Department does not need to do additional interpretive work to know that these specific degree programs qualify as professional degrees. Accordingly, the proposed rule designates each of the degrees on this list as a professional degree for purposes of eligibility for the higher Direct Loan Program limits.

The illustrative list of degrees also provides additional contextual clues that the Department may rely upon when discerning the facial or as applied meaning of the operative test to any specific degree program. For example, while the operative definition does not explicitly state that a degree must *generally* be at the doctoral-level to be considered a *professional degree*, the illustrative list of degrees suggests that this must be the case, as it contains only three non-doctoral degrees L.L.B. (a law degree no longer conferred by American institutions of higher education), as well

as the two listed theology degrees (the M.Div. and the M.H.L.).⁵

In the same way, we assume that Congress does not write statutes in a vacuum, but rather “*legislates against the backdrop of existing law*.” *McQuiggin v. Perkins*, 569 U.S. 383, 398, n. 3 (2013). Here, rather than charting a new course and writing a statute anew, without mooring to previously established statutes, Congress inserted a cross-reference to a long-established Department regulation that defines professional degree. In doing so, under the prior construction canon, we assume that the words and phrases in the definition that the Department has already given authoritative construction to, are to be understood as being adopted by Congress. *See, e.g., Bragdon v. Abbott*, 524 U.S. 624, 645 (1998) (“When administrative and judicial interpretations have settled the meaning of an existing statutory provision, repetition of the same language in a new statute indicates, as a general matter, the intent to incorporate its administrative and judicial interpretations as well.”); *Sekhar v. United States*, 570 U.S. 729, 733, 133 S. Ct. 2720, 2724, 186 L. Ed. 2d 794 (2013) (“[I]f a word is obviously transplanted from another legal source, whether the common law or other legislation, it brings the old soil with it.” (quoting Felix Frankfurter, *Some Reflections on the Reading of Statutes*, 47 Colum. L.Rev. 527, 537 (1947))).

Against that backdrop, we explore the history of the adoption of the regulation in 34 CFR 668 to provide context as to what Congress implicitly incorporated into the OBBB. When the regulation was promulgated in 2007, the definition of *professional degree* in 34 CFR 668.2 was based on the long-standing definition of a *first-professional degree* used by the Department's National Center for Education Statistics (NCES). The 2007 Integrated Postsecondary Education Data System (IPEDS) Glossary defined *first-professional degrees* as meeting all of the following criteria: (1) completion of the academic requirements to begin practice in the profession; (2) at least 2 years of college work prior to entering the program; and (3) a total of at least 6 academic years of college work to complete the degree program, including

⁵ This conclusion is further borne out by the fact that the LLB, M.Div., and M.H.L. also fit within exceptions explicitly included within the operative definition. All of the degrees within the illustrative list signifies a level of professional skill beyond that normally required for a bachelor's degree except for the L.L.B. Likewise, professional licensure is required for employment in all of the degree fields included in the illustrative list with the exception of theology.

prior required college work plus the length of the professional program itself.

Additionally, at the time, NCES considered the first- professional degree as one which “encompasses certain occupationally specific and closely regulated degree programs including the following: medicine (M.D.), chiropractic (DC or DCM.), dentistry (D.D.S. or D.M.D.), optometry (O.D.), osteopathic medicine (D.O.), pharmacy (Pharm.D.), podiatry (Pod.D. or D.P.M.), veterinary medicine (D.V.M.), law (LL.B. or J.D.), and theology (M.Div., M.H.L., or B.D.)” (*Graduate and First-Professional Students: 2007–08*, Susan Choy, *et al*, <https://nces.ed.gov/pubs2011/2011174.pdf>).

Prior to that, there had been little change in the criteria for first- professional degrees and in the 10 fields and accompanying degrees that NCES identified as specific examples of such degrees. Such criteria were used for reporting on such programs in IPEDS, and its predecessor survey, the Higher Education General Information Survey (HEGIS).

Against this backdrop, in defining *professional degree* in 34 CFR 668.2, in 2007, the Department proposed in the NPRM to add a definition of *first- professional degree* “based on the definition currently used by the National Center for Education (sic) Statistics” (72 FR 44621). In response to a public comment requesting that the Department consider altering several definitions proposed in the NPRM, including *first- professional degree*, so that the terms used reflected the layman’s language and terminology used in the Department’s *Federal Student Aid Handbook* for student financial aid administrators, the Department agreed with the comment that it was not necessary to specify whether a professional degree is a first- professional degree for the title IV, HEA purposes, and the Department dropped the word “first,” but retained the term “professional degree” and made no changes to the definition proposed in the NPRM. (72 FR 62016). The definition of *professional degree* has not been further amended since November 1, 2007.

In overturning *Chevron* deference in *Loper Bright Enters. v. Raimondo*, 603 U.S. 369 (2024), the Supreme Court emphasized that *Chevron* had fostered “unwarranted instability in the law, leaving those attempting to plan around agency action in an eternal fog of uncertainty.” *Id.* at 411. The Court explained that *Chevron* had enabled administrative agencies to change course even when Congress had not authorized them to do so. *Id.* However,

the Court did not abandon all reliance on agency interpretations of statute, explaining that interpretations issued by agencies “which have remained consistent over time, may be especially useful in determining the statute’s meaning.” *Id.* at 370 (citing *American Trucking Assns.*, 310 U.S. at 549).

Here, Congress adopted and codified an agency regulation that had been remarkably consistent over time, as it remained unaltered for nearly 20 years, and changes to it before then had been minimal. With that said, the regulation existed in a different context and served a different role in that it had no bearing on Federal student loan eligibility. In that sense, the rule existed in a paradigm where there were no significant legal consequences for a degree being counted, or not, as a professional degree. In addition to its longstanding nature, the comparative lack of legal consequences when the regulation was promulgated serves as some indicia of evidence that the interpretation represents a balanced and fair reading of what a professional degree is. The agency was, in promulgating the rule, free from outside pressure from students and institutions that have a financial incentive to insist upon a broader interpretation that includes more degree programs. While certainly not dispositive, these facts along with the Department’s longstanding interpretation, provide “useful evidence in determining the statute’s meaning.” *Loper Bright*, 603 U.S. at 370.

At the same time, by its own terms, the list of degrees in the definition need not be exhaustive and merely includes an illustrative list of degrees. The Department does not necessarily claim that the included list of professional degrees represents all professional degrees being offered by institutions, just those that the Department has identified as meeting the statutory definition. Indeed, the definition states that “Examples of a professional degree include but are not limited to” the degrees listed. This provides clear clues that the Department may, so long as the operative definition and context allow, add additional degrees to the list of professional degrees through regulation.

At the same time, context is key. And we are bound to adhere closely to the text of the statute. The *interpretive canon noscitur a sociis* is instructive in this context. It provides that words and phrases are “known by its associates,” or, when a word or phrase is “susceptible of multiple and wide-ranging meanings,” it is “given more precise content by the neighboring words with which it is associated.”

United States v. Williams, 553 U.S. 285, 294 (2008). Here, the illustrative list of degrees Congress provided do just that; they provide context for the types of degrees that Congress considered to have met its definition of professional degree for the purposes of higher loan limits. So, the Department must consider what these degrees have in common and the context those commonalities provide. *Id.*

Degrees on the example list in 34 CFR 668.2 may be fairly compared to any degrees not on the list. If any given degree is similar to degrees on the list, that provides additional evidence that the degree at hand may be a professional degree. If any given degree is dissimilar to degrees on the list, that provides evidence that the degree at hand may not be a professional degree. Of course, this comparative exercise is not dispositive; the degree must also meet the bounds of the operative test of professional degree to be categorized as such. This exercise of running the degree through the operative definition, then comparing and contrasting it to the list of degrees cited in 34 CFR 668.2, appropriately takes into account the broader statutory scheme and ensures that the Department interprets the statute in accordance with the intent.

During the negotiated rulemaking process, members of the RISE Committee provided several examples of degree programs and certain fields for consideration as to whether those would qualify in the same general class as those programs stated as examples of professional degrees.

Several members of the Committee suggested the Doctorate in Clinical Psychology as another specific example of a professional degree program, noting that such programs meet all of the criteria in the definition of *professional degree* in 34 CFR 668.2. Additionally, they noted that, in the definition of *qualifying graduate program* in 34 CFR 668.2, Clinical Psychology programs are specifically included with other professional degree programs requiring postgraduate training to obtain licensure, including medicine (M.D.), dentistry (D.D.S. or D.M.D.), and osteopathic medicine (D.O.), and therefore are in the same class as these programs which are also specifically identified as professional degree programs.

Committee members also noted that a doctorate in Clinical Psychology is explicitly required for licensure to practice as a clinical psychologist in every state.

Further, several members of the Committee suggested using the Classification of Instructional Programs

(CIP) (a system originally developed by the Department's NCES for tracking and reporting fields of study and program completion activity) to identify additional degree programs that meet the definition of *professional degree* in 34 CFR 668.2. The CIP is an integral part of institutions' annual IPEDS data reporting of professional degree and other programs, as every postsecondary school that receives Federal student aid funds must use CIP codes to report their program data to the government. The CIP is the accepted Federal government standard on instructional program classifications and is used in a variety of education information surveys and databases, as well as by State agencies, national associations, academic institutions, and employment counseling services for collecting, reporting, and analyzing instructional program data.⁶

The CIP coding taxonomy, for instructional programs is organized on three levels: (1) A two-digit series of 48 general fields that groups a large number of related programs; (2) A four-digit series nested within each two-digit series which represent groupings of programs that have comparable content and objectives, within those two-digit fields; (3) A six-digit series which assigns unique six-digit codes to specific instructional programs. Six-digit CIP codes are the most specific program classifications under the taxonomy and institutions participating in the title IV, HEA programs are required to report completion data in IPEDS for each of their programs using the six-digit CIP code. *Id.*, at 2. In some cases, instructional programs may be found in one or more series. For instance, a person can receive a degree in Statistics from a program that focuses on mathematical models; this program would be coded under code 27.0501 (Statistics, General). On the other hand, a person can receive a degree in Statistics from a program which focuses on the applications of statistical methods to the description, analysis, and forecasting of business data; this degree would be coded under code 52.1302 (Business Statistics).⁷

CIP codes generally apply to all levels of certificates and degrees. In some cases, however, degrees were specified

in the examples for certain CIP codes in which Federal agencies needed to be able to obtain data on the number of degrees awarded in a particular field of study. For example, CIP code 51.1201 (Medicine) lists Medicine (MD) as an example.

The Doctorate in Clinical Psychology and each of the 10 fields and associated degrees identified in the definition of *professional degree* in 34 CFR 668.2 has a unique six-digit CIP code in the current CIP taxonomy. Members of the Committee suggested that the scope of the professional degree program defined in the proposed regulation include programs that meet the requirements for professional degree that are within the intermediate four-digit grouping of programs for each of these six-digit CIP codes, as assigned by the institution or determined by the Secretary. We agreed with the Committee members that such an approach would accurately include other advanced degree programs in these 4-digit intermediate CIP groupings that met all requirements for a professional degree as defined in 34 CFR 668.2. Under the proposed regulations, such advanced programs would be considered in the general class with the professional degree programs in Clinical Psychology and the fields and degrees identified in the *professional degree* definition.

The Department believes 4-digit CIP groupings are the most appropriate level for classifying programs for two reasons.

Specifically, NCES defines 2-digit CIP codes as "the most general groupings of related programs." Comparatively, the 4-digit CIP series is defined as "groupings of programs that have comparable content and objectives."⁸ After examining the groupings, the Department believes that using 4-digit CIP groupings are closely related to the examples of professional programs listed in CFR 668.2 to qualify for the higher loan limits.

To provide an illustrative example, the proposed rule allows all programs with the 4-digit CIP code "01.80" to qualify for the higher loan limits. In this case, there is just one such program in the 4-digit CIP grouping 01.80: Veterinary Medicine. However, if all programs in the same 2-digit CIP family were used, programs that are not connected to a professional practice would be included, such as "Horticulture Science" (01.01.03), "Plant Sciences" (01.11.01), "Soil Chemistry" (01.12.02), "Brewing

Science" (01.10.03), and "Dairy Science" (01.09.05), to name a few.

Veterinary medicine is categorically different from these other types of agricultural programs. The National Center for Education Statistics describes a veterinary medicine program as "a program that prepares individuals for the independent professional practice of veterinary medicine, involving the diagnosis, treatment, and health care management of animals," while describing, for example, a horticultural science program as "a program that focuses on the scientific principles related to the cultivation of garden and ornamental plants, including fruits, vegetables, flowers, and landscape."⁹ Given the substantial difference in a program that prepares individuals to medically treat animals and a program that trains students on scientific principles related to gardening, the Department believed it would be illogical to include all programs sharing the same 2-digit CIP family.

In the Department's view, the explicit incorporation of a four-digit program CIP code into the regulatory definition of "professional degree" is not inconsistent with the statutory definition. Indeed, it would make explicit what is already implicitly a common element among the statute's illustrative examples of professional degrees. Furthermore, the CIP code taxonomy has administrative benefits for the Department and institutions given its wide use that make its use practically convenient. In sum, adopting this element would ease administrative burden and is consistent with the statutory framework.

During negotiated rulemaking, the Department also considered whether other degree programs met, or did not meet, the definition of *professional degree* used in 34 CFR 668.2 for the purposes of defining the term professional student. During negotiations with non-Federal negotiators, we considered and discussed whether a wide range of degree programs met the operative test, taking into consideration the context of the broader statute. A substantial discussion centered around the need for workers in specific fields, however, the definition of *professional degree* used in 34 CFR 668.2 considered only the characteristics of the program and the requirements of the profession; it did not consider the need for workers in a given field. Congress did not instruct

⁶ See *Introduction to the Classification of Instructional Programs: 2020 Edition (CIP-2020)*, Nat'l Cent. For Educ. Statistics, at 1 https://nces.ed.gov/ipeds/cipcode/Files/2020_CIP_Introduction.pdf.

⁷ See *Frequently Asked Questions for CIP website and CIP Wizard 2020*, Nat'l Cent. For Educ. Statistics, Aug. 2020 at 2, https://nces.ed.gov/ipeds/cipcode/files/CIP_FAQ_Document_2020.pdf#page=2.

⁸ National Center for Education Statistics (2020). "Introduction to the Classification of Instructional Programs: 2020 Edition." https://nces.ed.gov/ipeds/cipcode/Files/2020_CIP_Introduction.pdf.

⁹ National Center for Education Statistics (2020). "Classification of Instructional Programs—Browse CIP Codes." <https://nces.ed.gov/ipeds/cipcode/browse.aspx?y=55>.

the Department to take need into account when determining which programs are eligible for the higher loan limits. Therefore, the Department only considers its own historical practice, the characteristics of the existing programs, and the requirements of the profession when determining which degree programs did not meet the *professional degree* definition. Finally, the Department is hesitant to classify degrees that lead to employment that must be supervised by a licensed professional, and cannot be performed independently, as professional degrees within this definition. Although this decision may be subject to public critique and unpopular, it is once again informed by the characteristics of programs in 34 CFR 668.2.

During negotiations and as part of public comment, the Department heard from many who claimed that certain degree programs should be considered professional degree programs for the purposes of the higher Direct Loan limits under the OBBB. The Department considered these programs and found that the following degree programs did not meet the *professional degree* definition for one or more reasons:

Business (MBA): The Department determined that an MBA would not satisfy the *professional degree* definition because it is not required for entrance into a specific profession, nor is there an accompanying licensure for MBA graduates. While the coursework a student completes while obtaining an MBA may satisfy certain prerequisite licensure requirements (such as the completion of 150 credit hours of coursework, which is required to obtain licensure as a certified public accountant)¹⁰ an MBA is not explicitly required for licensure in any field.

Education (M.Ed./Ed.D./Ed.S.): The Department determined that the M.Ed. and Ed.D. would not satisfy the *professional degree* definition because they are not required for entrance into a specific profession and are not required for licensure. While several states require teachers to ultimately obtain a master's degree to maintain their license, no state requires an M.Ed. (or similar master's degree) to begin work as a teacher. Likewise, while an Ed.D. may offer the possibility of career advancement to the degree holder, the degree is not in any way required for entrance into a specific profession or a prerequisite for licensure in a field.

Occupational therapy (MSOT/OTD): The Department determined that an MSOT or OTD would not satisfy the *professional degree* definition because, for example, the degree is not specifically required to enter the field. Boards, though not states, may include an MSOT or OTD as one possible condition for eligibility for licensure, but an individual may also be eligible to sit for the boards necessary to obtain licensure if they have a bachelor's or a master's in a related field.¹¹ Therefore, an MSOT or OTD is not required to enter the profession in the same manner as the enumerated professional degrees.

Naturopathic medicine (N.D.): The Department determined that an N.D. did not satisfy the *professional degree* definition because the regulatory landscape surrounding naturopathic medicine is unsettled. Currently, only 23 states, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands license naturopathic physicians.¹² Furthermore, the practice of naturopathy is explicitly banned in three states. Fla. Stat. § 458.305; S.C. Code Ann. § 40–31–10; and Tenn. Code Ann. § 63–6–205. While universal licensure of practitioners in a given field by every state is not required for a degree to be a *professional degree*, because of the fact that less than half of states license naturopathic physicians and some states ban the practice of naturopathy entirely, the Department determined that an N.D. cannot clearly be said to be required for entrance into a specific profession or lead to licensure at this moment in time.

Nursing (MSN/DNP): The Department determined that neither the MSN nor the DNP would satisfy the *professional degree* definition because, for example, the degrees are not necessary for entrance into the nursing profession. While holders of an MSN or a DNP may obtain licensure as a nurse practitioner, students entering degree programs which lead to an MSN, or a DNP, are already licensed nurses when they begin the degree program.¹³ Therefore, Department does not believe that the MSN or the DNP satisfy a core aspect of the definition of *professional degree*.

Additionally, while the Department acknowledges that nurse practitioners engage in different forms of work than

other nurses, the Department is hesitant to treat them as being distinct for the purpose of this regulation, primarily due to the fact that their practice authority (and therefore, their scope of work) differs substantially from state to state. For example, full practice authority states permit all nurse practitioners to evaluate patients; diagnose, order, and interpret diagnostic tests; and initiate and manage treatments, including prescribing medications and controlled substances, under the exclusive licensure authority of the state board of nursing, while restricted practice authority states require career-long supervision, delegation, or team management by another health provider in order for the nurse practitioners to provide patient care.¹⁴ Because a substantial portion of states substantially restrict the types of work that can be performed by nurse practitioners and require them to be supervised by physicians, just as other nurses are, the Department believes that nurse practitioners cannot be said to be part of a distinct profession, meaning that the MSN and DNP are not requirements for entrance into a profession.

Finally, the Department does not believe that the statute permits the classification of degrees as “professional” when the degree leads to employment where the employee must be supervised by another professional who has, as required by their license and degree, more education, training, and qualifications than the person being supervised.

None of the state-required degrees in the illustrative list in the regulation that was codified by the OBBB require another profession to supervise their practice.¹⁵ In that, the list provides support for the idea that professional degrees enable those who obtain them, after licensure, to practice in an unsupervised manner. As noted above, a substantial portion of states significantly restrict the types of work that can be performed by nurse practitioners and generally require them

¹⁴ *State Practice Environment*, Am. Ass'n of Nurse Practitioners, <https://www.aanp.org/advocacy/state/state-practice-environment> (last visited Dec. 19, 2025).

¹⁵ The following degrees are all, with appropriate licensure, sufficient for independent and unsupervised practice in all states in the relevant profession: Pharmacy (Pharm.D.), Dentistry (D.D.S. or D.M.D.), Veterinary Medicine (D.V.M.), Chiropractic (D.C. or D.C.M.), Law (L.L.B. or J.D.), Medicine (M.D.), Optometry (O.D.), Osteopathic Medicine (D.O.), Podiatry (D.P.M., D.P., or Pod.D.), and Clinical Psychology (Psy.D. or Ph.D.). The Department notes that states do not license, supervise, or regulate the practice of religion, including the licensure of clergy who may earn degrees in theology (M.Div., or M.H.L.).

¹⁰ See CPA Review: CPA Exam Requirements, <https://www.becker.com/blog/cpa/150-credit-hours-cpa-a-tale-of-courses-and-creative-counting> (last visited Dec. 19, 2025)).

¹¹ *Am I eligible to take the NBCOT exam?*, Nat'l Bd. For Certification in Occupational Therapy, <https://www.nbcot.org/get-certified/eligibility#usa> (last visited Dec. 23, 2025).

¹² *Naturopathic Doctor Licensure*, Ass'n of Accredited Naturopathic Med. Colleges, <https://aanmc.org/licensure/> (last visited Dec. 23, 2025).

¹³ *The Path to Becoming a Nurse Practitioner (NP)*, Am. Ass'n of Nurse Practitioners (Nov. 10, 2020) <https://www.aanp.org/news-feed/explore-the-variety-of-career-paths-for-nurse-practitioners>.

to be supervised by or enter into formal collaboration agreements with physicians,¹⁶ even in states where nurse practitioners have full practice authority (i.e., where nurse practitioners are authorized to “evaluate patients, diagnose, order and interpret diagnostic tests and initiate and manage treatments—including prescribing medications—under the exclusive licensure authority of the state board of nursing”).¹⁷ Such practice authority is often more limited in scope than that of medical doctors, i.e., several states where nurse practitioners possess full practice authority preclude them from prescribing medications unless they have a formal relationship with a physician.¹⁸ Likewise, a substantial portion of the states where nurse practitioners possess full practice authority condition a nurse practitioner’s ability to exercise that authority on the nurse practitioner having completed a requisite number of “transition to practice hours” where the nurse practitioner must be supervised by a physician. This is very different from residency requirements in fields such as medicine, dentistry, and clinical psychology, where a resident is supervised by another member of their own profession.¹⁹ For these reasons, the Department believes it would be inaccurate to classify an MSN or a DNP as meeting the definition of professional degree.

Physical therapy (DPT): The Department determined the DPT would not satisfy the *professional degree* definition. The Department notes that historically, licensed therapists did not require doctoral degrees, and that the progression from a master’s level degree to the DPT degree is a relatively modern development.²⁰ As a result, the Department has never included these

degrees in the definition of professional degree. The adoption of the DPT in the physical therapy profession pre-dates the changes made to the definition in 34 CFR 668.2, yet the Department did not make updates to that definition as discussed above. This context is important, and the Department finds it to be dispositive regarding the interpretation. To that end, for the reasons cited above and because the Department’s interpretation here has “remained consistent over time” and represents the “the longstanding practice of the government,” the Department does not think it is appropriate to expand the interpretation of professional degree here to include DPT. See *Loper Bright Enters.*, 603 U.S. at 386; *NLRB v. Noel Canning*, 573 U.S. 513, 525 (2014).

Physician assistant (MSPAS): The Department determined that the MSPAS would not satisfy the *professional degree* definition because, for example, of the unsettled regulatory landscape regarding licensure and scope of practice of physician assistants. A physician assistant’s scope of practice varies from state to state. While a handful of states allow physician assistants to practice and prescribe medication independent of physician supervision, the majority require a physician assistant to collaborate with (or be directly supervised by) a physician or other health care provider in order to practice and prescribe medication.²¹ Additionally, of the five states that allow a physician assistant to practice independent of supervision by or collaboration with a physician, several only allow independent practice after the physician assistant has completed a requisite number of hours of postgraduate clinical experience in collaboration with a physician, which differs from residency requirements in fields such as medicine, dentistry, and clinical psychology, where the resident is supervised by another member of their own profession.²²

As discussed above, the Department does not believe the statute permits the classification of degrees as professional where the degree leads to employment where the employee must be supervised by another licensed professional who is, by virtue of their licensure, more qualified or skilled than the person being supervised. This is because none of the degrees on the illustrative list in

the codified definition of professional degree require another professional to supervise their practice. Therefore, because the overwhelming majority of states substantially restrict the practice of physician assistants and require them to collaborate with, or be supervised by, physicians, the Department believes it would be inaccurate to treat an MSPAS as a professional degree.

Public health (MPH): The Department determined that the MPH would not satisfy the *professional degree* definition because, for example, it is not required for entrance into a specific profession and does not lead to licensure.

Social work (MSW/DSW): The Department has determined that MSW and DSW would not meet the *professional degree* definition because neither degree is generally required to obtain an entry-level licensure in the social work field or to begin work in a profession. A person may obtain work as a social worker after earning a bachelor’s degree.²³ Most states license BSW holders as certified social workers, making the baccalaureate level degree the one necessary to begin practice in the social work profession.²⁴ In addition, individuals who are licensed with a BSW may later obtain an MSW with only one year of additional coursework, for a total of five years of education compared to six years as provided for in the *professional degree* definition.²⁵

The Department is aware that individuals who have earned an MSW or DSW may obtain work as a clinical social worker, which allows an individual to perform similar work in a supervisory role or to take on heavier caseloads.²⁶ In some cases, a clinical social worker may perform work that is different than other social workers, but the Department does not believe the statute permits the classification of clinical social work as a separate and distinct profession, as opposed to a specialization or concentration.²⁷

Pilot Training and Licensure: The Department considered whether students training to be pilots are professional students but found that these programs fail the operative test and are foreclosed upon due to compelling legislative history. Part 141 of title 14 is a statute administered by the Federal Aviation Agency concerning

¹⁶ Nurse Practitioner Practice and Prescriptive Authority, Nat’l Conference of State Legislatures (last visited Dec. 29, 2025), <https://www.ncsl.org/scope-of-practice-policy/practitioners/advanced-practice-registered-nurses/nurse-practitioner-practice-and-prescriptive-authority>.

¹⁷ Issues at a Glance: Full Practice Authority, Am. Ass’n of Nurse Practitioners (last visited: Dec. 29, 2025), <https://www.aanp.org/advocacy/advocacy-resource/policy-briefs/issues-full-practice-brief#:~:text=States%20that%20restrict%20or%20reduce,standard%20of%20care%20set%20nationally>.

¹⁸ See *supra* n. 15.

¹⁹ *Id.* See Deborah Dillon, *Do transition to practice hour requirements make a difference in adverse action and medical malpractice payment reports: An analysis from the National Practitioner Data Bank*, 37 J. Am. Ass’n Nurse Practitioners 327 (June, 2025).

²⁰ Plack, Margaret M PT, MA; Wong, Christopher K PT, MS, OCS. The Evolution of the Doctorate of Physical Therapy: Moving Beyond the Controversy. *Journal of Physical Therapy Education* 16(1):p 48–59, Spring 2002.

²¹ See *Physician Assistant Practice and Prescriptive Authority*, Nat’l Conference of State Legislatures, <https://www.ncsl.org/scope-of-practice-policy/practitioners/physician-assistants/physician-assistant-practice-and-prescriptive-authority> (last visited Dec. 19, 2025).

²² *Id.*

²³ *Social Work at a Glance*, Council on Social Work, <https://www.cswe.org/students/prepare-for-your-education/social-work-at-a-glance/> (last visited Dec. 19, 2025).

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.*

the training and certification of airplane pilots.

There are “few principles of statutory construction are more compelling than the proposition that Congress does not intend *sub silentio* to enact statutory language that it has earlier discarded in favor of other language.” *I.N.S. v. Cardoza-Fonseca*, 480 U.S. 421, 442–43, 107 S. Ct. 1207, 1219, 94 L. Ed. 2d 434 (1987) (quoting *Nachman Corp. v. Pension Benefit Guaranty Corporation*, 446 U.S. 359, 392–393 (1980) (Stewart, J., dissenting)).

When the OBBB passed the House of Representatives (House), the bill contained borrowing limits on Direct Loans for both graduate and professional students. In defining professional students, the House provided that a professional student is a student: enrolled in a program of study that awards a professional degree upon completion of the program, or [. . .] provides the training described in part 141 of title 14, Code of Federal Regulations (or any successor regulation).

The Senate subsequently removed the reference to Part 141 of Title 14, replacing it with its own definition, which was subsequently agreed to by the House and enacted into law. In other words, Congress considered the notion that students enrolled in pilot training or degree programs could be professional students, but it discarded that concept in favor of other language.

This is the kind of legislative history that the court in *Cardoza-Fonseca* described as being among the most compelling principles to discern otherwise vague text. The exceptions in the operative test are narrow. Because pilot training programs generally do not require the completion of or training beyond what is normally provided for in a baccalaureate degree, these programs fail the operative test. To the degree there was any uncertainty, this legislative history sures up any lingering doubt. Congress considered adding pilot training in the House-passed version of the OBBB, but the Senate removed this language from the final version of the OBBB. Therefore, the Department cannot go against demonstrable evidence of Congressional intent by determining that students enrolled in pilot training programs are professional students for the purposes of higher loan limits when it is clear that Congress intentionally excluded them from the definition of *professional student*.

In the definition of *program length* (Section 455(a)(8)(C) of the HEA), we included the term “full-time” as found in the statutory definition because we believe that Congress intended program

length to be based on whatever is published in the institution’s official publication and consistent to how program length is used in other title IV contexts (such as Student Right to Know disclosures in 34 CFR 668, subpart D). Therefore, the Department is including “full-time” in the definition of *program length*.

Borrower Eligibility (§ 685.200)

Statute: Section 81001(1)(C) of the OBBB amends Section 455(a)(3)(C) of the HEA by terminating graduate and professional students’ eligibility for the Direct PLUS Loan program for any period of instruction beginning on or after July 1, 2026.

Current Regulations: Section 685.200 contains the regulations on borrower eligibility for the Direct Loan Program, which are comprised of the following components: the Direct Subsidized Loan Program; Direct Unsubsidized Loan Program; Direct PLUS Loan Program; and the Direct Consolidation Loan Program. Section 685.200(b) provides the eligibility criteria for student PLUS borrowers (*i.e.*, graduate or professional students) including whether the student is enrolled, or accepted for enrollment, on at least a half-time basis at an eligible institution; the student is an eligible student under the requirements in 34 CFR part 668; if applicable, the student meets the requirements of receiving a loan despite obtaining a total and permanent disability discharge and is qualified to obtain a college or career education by completing a high school education in a homeschool setting or meets an ability-to-benefit alternative; the student has received a determination of their annual loan maximum eligibility under the Direct Unsubsidized Loan Program and, for periods of enrollment beginning before July 1, 2012, the Direct Subsidized Loan Program; and, the student does not have adverse credit.

Proposed Regulations: The Department proposes to restructure the regulations at § 685.200(b) to provide the eligibility criteria for a Direct PLUS Loan to student PLUS borrowers. First, the Department proposes to revise § 685.200(b)(1) to provide that a graduate student or professional student is eligible to receive a Direct PLUS Loan only if the student meets the enumerated criteria in § 685.200(b)(1)(i) through (v). The Department further proposes to redesignate current § 685.200(b)(1) through (5) as § 685.200(b)(1)(i) through (v), respectively.

Second, the Department proposes adding a new § 685.200(b)(2)(i) to provide that beginning on July 1, 2026,

a graduate student or professional student may not borrow a Direct PLUS Loan. The Department proposes adding § 685.200(b)(2)(ii) as an exception to the rule that prevents graduate or professional students from borrowing a Direct PLUS Loan under § 685.200(b)(2)(i). A graduate student or professional student may borrow a Direct PLUS Loan during the period of the student’s expected time to credential, if the student is enrolled in a program of study at an institution as of June 30, 2026; and, a Direct Loan was made to the student for such program of study prior to July 1, 2026.

Finally, the Department proposes to add § 685.200(b)(3) that provides that if the student withdraws or otherwise ceases to be enrolled in the program of study at any point after receiving the exception under § 685.200(b)(2)(ii), that student cannot borrow a Direct PLUS Loan. In other words, the regulation allows a borrower who is enrolled in a program of study and who has participated in the Direct Loan Program to continue to participate in the program on the same terms until they complete their degree or withdraw. This is often referred to as “grandfathering” current participants under those same terms and conditions. The grandfathering provisions do not apply to any student who withdraws, even if they subsequently reenroll in the same program.

Reasons: These regulations are amended to reflect the changes made by the OBBB to phase out the Graduate PLUS Program. Accordingly, our proposed regulatory restructuring in § 685.200(b)(1) would allow graduate and professional students to continue to borrow under the Direct PLUS Loan program before July 1, 2026, or if they meet the limited exception for current borrowers further discussed below. The regulatory restructuring in § 685.200(b)(2)(i) would make clear that beginning on or after July 1, 2026, a graduate student or professional student may not borrow a Direct PLUS Loan to conform with the changes the OBBB made to the HEA.

Because Section 455(a)(3)(C) of the HEA contains an interim exception whereby a graduate student or professional student could obtain a Direct PLUS Loan on or after July 1, 2026, we included regulations at § 685.200(b)(2)(ii) explaining the terms and conditions for borrowing loans under this exception. A borrower who withdraws or otherwise ceases to be enrolled would lose continued eligibility for the Direct PLUS Loan program under this interim exception. As such, to distinguish between

withdrawals and leaves of absence, we included a cross-reference to a withdrawal or ceasing to be enrolled in accordance with § 668.22. This cross-reference preserves certain borrowers' eligibility under the interim exception, such as a borrower who is a servicemember called to active-duty and receives a leave of absence from their institutions because of military orders. In this case, the servicemember would not be subject to the new loan limits and would continue to have access to Direct PLUS Loans.

Additionally, under the OBBB, if a graduate student received a Direct Unsubsidized Loan for enrollment in a graduate program before July 1, 2026, they would be eligible for the interim exception for continued enrollment in that same program after July 1, 2026.

Obtaining a Loan (§ 685.201)

Statute: Section 81001(1)(C) of the OBBB amends Section 455(a)(3)(C) of the HEA by phasing out graduate and professional students' eligibility for the Direct PLUS Loan program for any period of instruction beginning on or after July 1, 2026. Section 455(a)(8) of the HEA lists the conditions under which graduate and professional students may continue to access Direct PLUS Loans during the interim exception period.

Current Regulations: Section 685.201 includes regulations on how a borrower obtains a Direct Loan. Section 685.201(b) provides the application criteria for a Direct PLUS Loan and § 685.201(b)(2) specifies that for a graduate or professional student to apply for a Direct PLUS Loan, the student must complete a Free Application for Federal Student Aid (FAFSA®) and complete a Direct PLUS Loan master promissory note (MPN).

Proposed Regulations: To implement the changes to Section 455(a)(3)(C) of the HEA, we propose to redesignate current § 685.201(b)(2) as § 685.201(b)(2)(i) with a clause that paragraph (b)(2)(i) applies to graduate or professional students applying for a Direct PLUS Loan before July 1, 2026. We further propose to add § 685.201(b)(2)(ii) to provide that on or after July 1, 2026, a graduate student or professional student may only apply for a Direct PLUS Loan if the student meets the exception in § 685.200(b)(2)(ii). That exception allows Direct PLUS Loan eligibility for a graduate student or professional student during the period of the student's expected time to credential, if the student is enrolled in a program of study at an institution as of June 30, 2026, and, a Direct Loan was

made for such program of study prior to July 1, 2026.

Reasons: The proposed regulations reflect the changes enacted in the OBBB. To conform with Section 455(a)(3)(C) of the HEA regarding the termination of the authority to make Direct PLUS Loans to graduate students and professional students, the Department has proposed regulations at § 685.201 to outline when a graduate student or professional student may apply for a Direct PLUS Loan for a period of enrollment that begins on or after July 1, 2026.

The Department proposes to make a technical correction under § 685.201(b)(2). During negotiated rulemaking, the RISE Committee reached consensus on the draft regulations in § 685.201. Due to an administrative error, the Department believes that § 685.201(b)(2) requires subparagraphs (i) and (ii) to distinguish borrowers' access to Direct PLUS Loans before and after July 1, 2026. The consensus language in § 685.201 did not distinguish borrowers' access to Direct PLUS Loans before and after July 1, 2026. In subparagraph (b)(2)(i), we propose to add "Before July 1, 2026," to make clear that subparagraph applies before that date. In subparagraph (b)(2)(ii), we are not adding any additional text but instead redesignate to that appropriate subparagraph level. Accordingly, we revised current § 685.201(b)(2) to proposed § 685.201(b)(2)(i) which would read as follows: "Before July 1, 2026, for a graduate or professional student to apply for a Direct PLUS Loan, the student must complete a Free Application for Federal Student Aid and submit it in accordance with instructions in the application. The graduate or professional student must also complete the Direct PLUS Loan MPN." Proposed § 685.201(b)(2)(ii) would read as follows: "On or after July 1, 2026, a graduate student or professional student may only apply for a Direct PLUS Loan if the student satisfies the conditions set forth in § 685.200(b)(2)(ii)." We believe separating these provisions at the subparagraph level would make clear that, beginning on July 1, 2026, graduate and professional students may only obtain a Direct PLUS Loan if they meet the interim exception requirements.

Loan Limits (§ 685.203)

Statute: Section 81001(1)(A) and (B) of the OBBB amends Section 455(a)(3) and (4) of the HEA to include new annual limits of Direct Unsubsidized Loans for graduate and professional students for periods of enrollment

beginning on or after July 1, 2026. Section 81001(2) of the OBBB adds Section 455(a)(4)(B) to the HEA to provide the aggregate limits of the amount of Direct Unsubsidized Loans graduate students and professional students may receive for periods of enrollment beginning on or after July 1, 2026. Section 81001(2) of the OBBB adds Section 455(a)(5) to the HEA to establish new annual and aggregate limits of Direct PLUS Loans parent borrowers may receive beginning on or after July 1, 2026. Section 81001(2) of the OBBB adds Section 455(a)(6) to the HEA and establishes a new lifetime maximum aggregate limit for the total amount of title IV loans. The lifetime cap is based upon the aggregate principal balance of all loans taken and would include origination fees but would not include any interest accrued. Section 81001(2) of the OBBB amends HEA Section 455(a) to add Section 455(a)(7)(A), which establishes an annual loan limit when a student is enrolled less than full-time in an academic year. Section 81001(2) of the OBBB added Section 455(a)(7)(B) to the HEA and provides additional rules regarding institutionally determined loan limits. Section 81001(2) of the OBBB added HEA Section 455(a)(8), which provides an interim exception under which loan limits that are effective July 1, 2026, do not apply.

Current Regulations: Section 685.203 contains the regulations on loan limits in the Direct Loan Program. Section 685.203(b) and (c) provides the loan limits and additional eligibility for Direct Unsubsidized Loans; in the case of graduate or professional students for a loan period beginning on or after July 1, 2012, the annual loan limit may not exceed \$8,500; however, § 685.203(c)(2)(v) provides additional eligibility for graduate and professional students in amounts up to \$12,000 making a total annual limit of \$20,500. Section 685.203(e) provides the aggregate limits for unsubsidized loans; in the case of graduate or professional students, the aggregate loan limit is \$138,500.

Section 685.203(f) provides the Direct PLUS Loans annual limit; in the case of graduate or professional students, the annual limit that a graduate or professional student may borrow for a Direct PLUS Loan for an academic year may not exceed the student's cost of attendance less other financial assistance. Section 685.203(g) provides the Direct PLUS Loans aggregate limit; in the case of graduate or professional students, the aggregate limit that a graduate or professional student may borrow for a Direct PLUS Loan may not

exceed the student's cost of attendance less other financial assistance for the entire period of enrollment.

Finally, Section 685.203(j) provides the maximum loan amounts in the Direct Loan Program. The amount of Direct Loans that a borrower may receive cannot exceed the student's estimated cost of attendance minus other financial assistance.

Proposed Regulations: The Department proposes to implement the changes enacted in Section 81001 of the OBBA by amending § 685.203. With respect to Direct Unsubsidized Loan limits, we propose to clarify in § 685.203(b)(2)(iii) that in the case of a graduate or professional student for a period of enrollment beginning on or after July 1, 2012, and ending on or before June 30, 2026, the total amount the student may borrow for any academic year of study under the Direct Unsubsidized Loan Program must not exceed \$8,500. As explained above, § 685.203(c)(2)(v) provides additional Direct Unsubsidized Loan eligibility for graduate and professional students to \$12,000, making a total annual limit of \$20,500. Similarly, we propose to clarify in § 685.203(c)(2)(v) that in the case of a graduate or professional student for a period of enrollment through June 30, 2026, the additional Direct Unsubsidized Loan eligibility would be \$12,000. We propose to add § 685.203(b)(2)(iv), which would provide the loan limits for graduate students and professional students for periods of enrollment beginning on or after July 1, 2026.

Specifically, a graduate student, who is not a professional student, for a period of enrollment beginning on or after July 1, 2026, may borrow up to \$20,500 for any academic year under the Direct Unsubsidized Loan Program. A professional student, for a period of enrollment beginning on or after July 1, 2026, may borrow up to \$50,000 for any academic year under the Direct Unsubsidized Loan Program. These loan limits, however, would not apply for certain borrowers who are grandfathered into the prior loan limits. Specifically, we propose to add § 685.203(b)(2)(iv)(B) that the loan limits in effect on July 1, 2026, would not apply to student borrowers during the period of the student's expected time to credential if the student is enrolled in a program of study at an institution as of June 30, 2026, and a Direct Loan was made prior to July 1, 2026, for such program of study. Under proposed § 685.203(b)(2)(iv)(C), this exception to the loan limit would not apply if the student withdraws in accordance with the regulations in § 668.22 for returning

title IV funds or otherwise ceases to be enrolled in the program of study at any point after receiving the exception.

With respect to the aggregate loan limits for Direct Unsubsidized Loans, we propose to amend § 685.203(e)(3) to provide that for a graduate or professional student for periods of enrollment beginning before July 1, 2026, their aggregate loan limit is \$138,500. This amount includes any loans for undergraduate study, minus any Direct Subsidized Loan, Subsidized Federal Stafford Loan, and Federal Supplemental Loan for Undergraduate Students (SLS) Program loan amounts, if applicable. We propose to add § 685.203(e)(4) to include the aggregate loan limits for a graduate student for a period of enrollment beginning on or after July 1, 2026. Specifically, a graduate borrower who is not and has never been a professional student at an institution would have an aggregate loan limit of \$100,000. A graduate student who is or has been a professional student at an institution would have an aggregate loan limit of \$200,000, minus any amount borrowed as a professional student. We also propose to add § 685.203(e)(5) that would provide, for a professional student, for a period of enrollment beginning on or after July 1, 2026, their aggregate loan limit would be \$200,000, minus any Direct Subsidized Loan, Subsidized Federal Stafford Loan, and Federal SLS Program loan amounts and any amounts such student borrowed as a graduate student, if applicable. Similar to the earlier example, these aggregate loan limits would not apply in certain circumstances. We propose to add § 685.203(e)(6) that the loan limits in effect on July 1, 2026, would not apply to graduate student or professional student borrowers during the period of the student's expected time to credential if the student is enrolled in a program of study at an institution as of June 30, 2026, and a Direct Loan was made prior to July 1, 2026, for such a program of study. Under proposed § 685.203(e)(7) this exception to the aggregate loan limit would not apply if the graduate student or professional student withdraws in accordance with the regulations about the return of title IV funds in § 668.22 or otherwise ceases to be enrolled in the program of study at any point after receiving the exception.

With respect to the annual loan limits for Direct PLUS Loans, we propose to clarify the annual limits before July 1, 2026. We propose to amend § 685.203(f)(1) to provide that the total amount of all Direct PLUS Loans that a parent, or parents, may borrow on behalf of each dependent undergraduate

student, or that a graduate or professional student may borrow, for any academic year of study for a period of enrollment beginning before July 1, 2026, must not exceed the cost of attendance minus other estimated financial assistance for the student. This provision maintains the current lifetime loan limits under current regulations at § 685.203(f) for these existing borrowers, while providing a date after which these limits will be phased out for new loans. We also propose to add to § 685.203(f)(2), the annual limits for parents of dependent undergraduates on or after July 1, 2026. Specifically, we propose to add new language to § 685.203(f)(2)(i) stating that for periods of enrollment beginning on or after July 1, 2026, the total amount of all Direct PLUS Loans that all parents may borrow on behalf of each dependent student for an academic year of study may not exceed \$20,000, minus other financial assistance for the student. Similar to the earlier examples, these Direct PLUS annual loan limits would not apply in certain circumstances. We propose to add a new paragraph, § 685.203(f)(2)(ii), that provides that the loan limits in effect on July 1, 2026, would not apply to parent borrowers who borrowed a loan on behalf of a dependent student during the period of the student's expected time to credential if the following conditions are met: (1) the student is enrolled in a program of study at an institution as of June 30, 2026, and, (2) a Direct Loan was made to the parent borrower on behalf of the dependent student or to a dependent student prior to July 1, 2026, for such a program of study. Under proposed § 685.203(f)(2)(iii), this exception to the Direct PLUS annual loan limit would not apply to the parent borrower if the student withdraws in accordance with the regulations in § 668.22 about returning title IV funds or otherwise ceases to be enrolled in the program of study at any point after receiving the exception. Under proposed § 685.203(f)(3), the Direct PLUS annual limits for graduate students and professional students on or after July 1, 2026, would be found in § 685.200.

With respect to the aggregate limits for Direct PLUS Loans, we propose to provide for aggregate limits before July 1, 2026. We propose to amend § 685.203(g)(1) to provide that the total amount of all Direct PLUS Loans that a parent or parents may borrow on behalf of each dependent student, or that a graduate or professional student may borrow for a period of enrollment beginning before July 1, 2026, for enrollment in an eligible program of

study must not exceed the student's cost of attendance minus other estimated financial assistance for that student for the entire period of enrollment. We also propose to add aggregate limits for parents of dependent undergraduates on or after July 1, 2026. Specifically, we propose to add § 685.203(g)(2), which provides that for periods of enrollment beginning on or after July 1, 2026, the total amount of all Direct PLUS Loans that all parents may borrow on behalf of each dependent student must not exceed \$65,000, without regard to any amounts repaid, forgiven, canceled, or otherwise discharged on any such loan. We would also provide that any amount of loan funds that have been returned by the institution, or the borrower, will not count against the aggregate loan limit. Similar to earlier examples, these Direct PLUS aggregate loan limits for parent borrowers would not apply in certain circumstances. We propose to add § 685.203(g)(3) that the loan limits in effect on July 1, 2026, would not apply to parent borrowers during the period of the student's expected time to credential if the student is enrolled in a program of study at an institution as of June 30, 2026, and a Direct Loan was made to the parent borrower on behalf of the dependent student, or to the dependent student prior to July 1, 2026, for such a program of study. Under proposed § 685.203(g)(4) this exception to the Direct PLUS aggregate loan limit would not apply to the parent borrower if the student withdraws in accordance with the return of title IV funds in § 668.22 or otherwise ceases to be enrolled in the program of study at any point after receiving the exception. We also propose to clarify that, for the purposes of the Direct PLUS aggregate loan limits, a student who changes majors within the same degree or certificate program remains enrolled in the same program of study. This includes a student enrolled in a bachelor's degree program who changes majors but remains enrolled in a bachelor's degree program at the same institution. Students are generally not admitted to undergraduate institutions in a manner that binds them to a specific major; they can switch majors without generally seeking new admittance to the institution. As such, they are in the same program of study for the purposes of this grandfathering provision. On the contrary, it would not include a student who is enrolled in an associate's degree program, but who transfers into a bachelor's degree program even if the student remains at the same institution or even in the same program. In comparison to undergraduate school, graduate and

professional school admittance is significantly different. Students in a graduate program cannot generally switch to a different degree program without submitting a new application for admittance. As such, when they switch graduate programs, they are switching programs of study, even if they are attending the same institution. Accordingly, graduate or professional students who change programs would not be grandfathered into the aggregate loan limits. Under proposed § 685.203(g)(6), the Direct PLUS aggregate limits for graduate students and professional students for periods of enrollment beginning on or after July 1, 2026, would be found in § 685.200.

With respect to the maximum loan amounts, we propose to add the lifetime maximum aggregate limits that would be effective July 1, 2026. We propose to add § 685.203(j)(2), which would provide that effective July 1, 2026, the lifetime maximum aggregate amount of all title IV loans that a student may borrow, excluding Federal PLUS loans or Federal Direct PLUS Loans, would be \$257,500 without regard to any amounts repaid, forgiven, canceled, or otherwise discharged on such loans. We propose that any amount of loan funds that have been returned by the institution, or the borrower, would not count against this lifetime maximum aggregate loan limit. Similar to the earlier examples, this lifetime maximum aggregate loan limit would not apply to certain students who are grandfathered into the old system. As such, we propose to add § 685.203(j)(3), which would provide that the loan limits effective on July 1, 2026, would not apply to student borrowers during the period of the student's expected time to credential if the student is enrolled in a program of study at an institution as of June 30, 2026, and a Direct Loan was made for such program of study prior to July 1, 2026. Under proposed § 685.203(j)(4) this exception to the lifetime maximum aggregate loan limit would not apply to the borrower if the student withdraws in accordance with the return of title IV funds regulations in § 668.22 or otherwise ceases to be enrolled in the program of study at any point after receiving the exception.

We also propose to add a new provision to determine the appropriate loan limit if a certain academic program awards both a graduate degree and professional degree. Under proposed § 685.203(l), if a student is enrolled in a program that awards both a graduate degree and professional degree, the student would be considered a professional student for the purposes of loan eligibility if more than 50 percent

of the credit hours in that academic program count toward the professional degree. Specifically, this calculation is based upon the entire course of study and does not need to be calculated during each academic term. A student may be a professional student notwithstanding whether the student's course load for a given semester is comprised of more than 50 percent of the credits that count toward a professional degree.

Finally, we propose to add two new loan limit provisions in proposed § 685.203(m) including an annual award year loan limit provision for less than full-time enrollment and a provision for institutionally determined loan limits. Under proposed § 685.203(m)(1), if a student is enrolled in an eligible program (except for a non-term program) at an institution on a less than a full-time basis during an academic year, the amount of any Direct Loan that student may borrow for an academic year or its equivalent would be reduced in direct proportion to the degree to which that student is not so enrolled on a full-time basis, as of the date the institution determined the student's eligibility for the disbursement, rounded to the nearest whole percentage point. The formula to determine the reduced annual loan limit percentage is equal to the number of credit hours enrolled for an academic year divided by the number of credit hours considered full-time (by that institution) for that academic year for the program of study and then multiplied by 100.

Under proposed § 685.203(m)(1)(i), for a period of enrollment of less than an academic year (*i.e.*, fall semester only), the institution would be required to calculate the Direct Loan eligibility that student may borrow for the term in which the borrower is enrolled, or its equivalent, in direct proportion to the degree to which that student is not so enrolled on a full-time basis for that term as determined by the institution.

The steps an institution would be required to take include:

- Determine the borrower's eligibility for a disbursement of a Direct Loan for the term;
- Calculate the amount of the academic year loan limit under this section that the term represents; and
- Reduce the borrower's Direct Loan amount based on less than full-time enrollment for that term at that institution.

The formula to determine the term's loan limit equals the number of credit hours enrolled for the term divided by the number of credit hours that is considered full-time at that institution (as determined by the institution) for

that term for the program of study; multiply that value by 100, which equals the percentage of the reduction that should be applied to the single term loan amount the borrower is eligible to receive (e.g., student is enrolled 6 hours and 12 hours is considered full-time. Take 6 hours and divide that by 12 hours which equals .5. Then, take .5 and multiply it by 100 and that equals 50 percent. Fifty percent, rounded to nearest whole percentage point, if needed, equals the percentage of the scheduled reduction required). You would then take that percentage and multiply it by the amount of eligibility the borrower has for one term to determine amount of the loan the borrower may receive. If the annual amount was \$3,000; one term of loan eligibility prior to the reduction would be \$1,500. Multiply \$1,500 by .5, which equals \$750. Therefore, the amount the borrower is eligible to receive based on

the schedule of reductions for less than full-time enrollment = \$750.

Finally, we propose to add § 685.203(m)(2), which would provide that beginning on July 1, 2026, an institution may limit the total amount of Direct Loans that a student, or a parent on behalf of such student, may borrow for a specific program of study for an academic year, as long as any such limit is applied consistently to all students enrolled in that program of study. An institution that chooses to limit borrowing under this provision would be required to document their decision and follow standard requirements for record retention. The institution would also be required to provide clear and conspicuous information describing any program of study that is subject to the loan limitation and explain the need for such limitation to current and prospective students, including, but not limited to, sharing information via publication in the institution's course catalog, publication on institution's

website(s), and award notifications. We propose that prior to limiting borrowing under this provision, the institution would be required to notify any student who plans to enroll or is enrolled in the program that is subject to this limitation. Additionally, the Department would propose that, for the purposes of the institutionally determined loan limits, program of study means eligible program.

Reasons: In general, Section 81001 of the OBBA amended Section 455(a) of the HEA and established the new loan limits for borrowers. Due to these statutory changes to the loan limits, the Department proposes to make conforming changes to the regulations as further discussed below.

To help guide readers, we are providing a high-level summary of the statutory changes to the loan limits in a chart shown below. These new loan limits take effect on July 1, 2026.

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Annual Loan Limits §§ 685.200(b) ; 685.203(b) , (f)

Borrower Type (Direct Loan Type)	Current Limits (borrower level, dependency status)	New Limits Effective July 1, 2026.
Undergraduate (subsidized)	\$3,500 (first-year, dependent or independent) \$4,500 (second-year, dependent or independent) \$5,500 (third-year and beyond, dependent or independent)	(no changes)
Undergraduate (unsubsidized)	\$5,500 minus Subsidized Loans (first-year, dependent) \$6,500 minus Subsidized Loans (second-year, dependent) \$7,500 minus Subsidized Loans (third-year and beyond, dependent) \$9,500 minus Subsidized Loans (first-year, independent) \$10,500 minus Subsidized Loans (second-year, independent) \$12,500 minus Subsidized Loans (third-year and beyond, independent)	(no changes)
Graduate student (unsubsidized)	\$20,500 (in general; higher limits apply to certain health profession programs)	\$20,500
Professional student (unsubsidized)	\$20,500 (in general; higher limits apply to certain health professions programs)	\$50,000
Graduate student / professional student (PLUS)	Up to Cost of Attendance (COA) less Other Financial Assistance (OFA)	No new PLUS loans to graduate students and professional students
Parents of dependent undergraduates (PLUS)	Up to COA less OFA	\$20,000 per dependent student

Aggregate Loan Limits §§ 685.200 (b) ; 685.203 (b) , (e) , (g)

Borrower Type (Direct Loan Type)	Current Limits	New Limits Under OBBA
Undergraduate (subsidized)	\$23,000 (dependent or independent)	(no changes)
Undergraduate (unsubsidized)	\$31,000 minus Subsidized Loans (dependent) \$57,500 minus Subsidized Loans (independent)	(no changes)
Graduate student (unsubsidized) who is not and has not been a professional student	N/A	\$100,000
Graduate student (unsubsidized) who is or was a professional student	N/A	\$200,000 minus amounts borrowed as a professional student
Professional student (unsubsidized) who is not or was not a graduate student	N/A	\$200,000
Professional student (unsubsidized) who is or was a graduate student	N/A	\$200,000 minus amounts borrowed as a graduate student
Combined undergraduate (subsidized & unsubsidized) + graduate/professional (unsubsidized)	\$138,500 (in general; higher limits apply to certain health professions programs) \$224,000 (students enrolled in certain health professions programs)	N/A
Graduate student / professional student (PLUS)	No limit	No new PLUS loans to graduate students and professional students
Parents of dependent undergraduates (PLUS)	No limit	\$65,000 per dependent undergraduate student without regard to amounts paid / forgiven / discharged / canceled

Lifetime Loan Limits § 685.203(j)

Loan Type	Current Limits	New Limits Under OBBB
All title IV Loans (Direct Loans, FFEL, Perkins, etc.) excluding PLUS Loans without regard to amounts paid / forgiven / discharged / canceled	N/A	\$257,000

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With respect to annual and aggregate limits for Direct Unsubsidized Loans for graduate and professional students, because of the statutory changes to the HEA, the Department's proposed regulations codify the new Direct Unsubsidized Loan annual and aggregate limits based on whether the borrower is a graduate student or professional student. We discuss the definitions of *graduate student* and *professional student* elsewhere in this document.

The Department wishes to make a technical correction under § 685.203(e)(4)(ii). During negotiated rulemaking, the RISE Committee reached consensus on the draft regulations in § 685.203. However, after reviewing the statute, the Department determined that § 685.203(e)(4)(ii) needed to be amended. Section 81001(2) of the OBBB added Section 455(a)(4)(B)(i)(II)(bb) to the HEA to state that for a period of enrollment beginning on or after July 1, 2026, the aggregate limit for a graduate student who is (or has been) a professional student at an institution, is \$200,000, minus any amounts such student borrowed as a professional student. The consensus language in § 685.203(e)(4)(ii) erroneously stated that the aggregate limit for a graduate student who is or has been a professional student at an institution, is \$200,000, minus any amounts such student borrowed as a graduate student. In subparagraph (e)(4)(ii), we propose to replace "graduate" with "professional" to make clear that it is minus any amounts such student borrowed as a professional student to accurately reflect the statute. Accordingly, we revised proposed § 685.203(e)(4)(ii) to read as follows: "(ii) who is or has been a professional student at an institution, \$200,000, minus any amounts such student borrowed as a professional student." We believe making this technical correction would make clear that, for a period of enrollment beginning on or after July 1,

2026, the aggregate limit for a graduate student who is or has been a professional student at an institution, is \$200,000, minus any amounts such student borrowed as a professional student.

While this is a minor, technical change, the Department complied with the requirements in 20 U.S.C. 1098a(b)(2), which requires the Department whenever making a change from the consensus regulatory text to "provide a written explanation to the participants in that [negotiated rulemaking] process why the Secretary has decided to depart from such agreements."

During negotiated rulemaking, the Committee discussed joint degree programs, in which a student earns both a graduate and a professional degree upon completion, such as a joint MBA and JD program. In response, the Department set the baseline that if more than 50 percent of the credit hours count toward the professional degree, the student would be considered a professional student for purposes of higher loan limits. As the Department explained during the first week of negotiations, the Department was concerned about the potential for abuse where graduate degree programs could be disguised as professional degree programs in order to gain access to the higher loan limits. Section 81001(c)(ii) of the OBBB provides that a "professional student" means a student enrolled in a program of study that awards a professional degree. The Department believes looking holistically at the academic program to determine whether the majority of the program counts toward the professional degree would allow us to assess the appropriate loan limit. In this case, we propose that if more than 50 percent of the credit hours count toward the professional degree, it would render such program a professional degree program. This is because if over 50 percent of the credits from a program are being earned toward a professional degree, the

preponderance of a student's academic work is on earning a professional degree. The Department believes when most of a student's time is focused on professional credits, that it is sufficient to classify the student as a professional student for the purposes of the Direct Loan Program. The Department construes the phrase "enrolled in a program of study that awards a professional degree" in this context to mean a student who is spending more than half of their coursework working toward a professional degree. If a student is spending less than half of their coursework working toward a professional degree, most of their time is spent on a non-professional program. To allow any student enrolled in professional degree coursework, without considering what percentage of a student's total enrollment the professional coursework represents, to be considered a professional degree contravenes the intent of the statute by enabling students to enroll in such programs but not make serious attempts at taking the necessary coursework required to complete the program, while working primarily on a graduate degree program. The Department seeks comments on alternative approaches on how to classify joint degree programs for the purposes of Direct Loan eligibility.

Regarding the interim exceptions, we note that Section 455(a)(8) of the HEA contains obligatory terms and says the loan limits "shall not apply" if certain criteria are met, and accordingly, a borrower does not have the option to choose whether the new loan limits would apply to them. Students who meet the interim exception in proposed § 685.203(b)(2)(iv)(B) would be subject to the legacy loan limit provisions in Section 455(a)(3)(A)(ii) of the HEA. As an illustrative example, a professional student who enrolled in a program of study on or after July 1, 2026, is eligible for a Direct Unsubsidized Loan limit of \$50,000 per year, but a professional student who was enrolled in the same program of study before that time (and

remains enrolled in that program of study at the same institution), would be subject to the legacy loan limit of \$20,500 per year.

We also note that if a borrower withdraws or ceases to be enrolled in the eligible program at the same institution, the interim exception would no longer apply as the exception is only available to borrowers who remain enrolled in a program of study as required by Section 81001 of the OBBB. If a borrower withdraws, the borrower is no longer enrolled. And the borrower would then be subject to the loan limits in § 685.203(b)(2)(iv)(A), if the borrower were to re-enroll or matriculate at another institution. As such, we believe including a cross reference to a withdrawal as described in § 668.22 is instructive to borrowers. This policy would preserve certain borrowers' access to the interim exception, such as a borrower who is a servicemember called to active-duty and takes a leave of absence due to her military orders. In this case, she would not be subject to the loan limits in § 685.203(b)(2)(iv)(A).

The Department's proposed regulations codify new Direct PLUS Loan annual and aggregate limits for parent borrowers found in the OBBB. We also preserve the annual and aggregate limits for Direct PLUS Loans for periods of enrollment beginning before July 1, 2026. Separately in this NPRM, we discuss how the OBBB terminates graduate and professional students' access to the Direct PLUS Loan program for any period of instruction beginning on or after July 1, 2026.

Section 455(a)(5)(B) of the HEA provides that the aggregate limit for parent borrowers is \$65,000 per dependent student, without regard to any amounts repaid, forgiven, canceled, or otherwise discharged on any such loan. The Department believes Congress' intent in using the words "without regard to any amounts repaid, forgiven, canceled, or otherwise discharged on any such loan" was to make certain that only the loan funds the borrower actually received are included in the aggregate limit. For example, students who received a false certification discharge for identity theft did not actually receive loan funds. The Department would not include loan amounts discharged under false certification in the parent borrower's aggregate limit and, similarly, we would not include loan amounts discharged under false certification in the lifetime maximum aggregate limit in § 685.203(j).

The OBBB also established a new lifetime aggregate limit; following, the

Department has proposed regulations here to codify the new lifetime maximum aggregate limit. As part of the regulations on lifetime limits, the Department will make certain that only funds actually received by the borrower will count toward this lifetime aggregate limit. To enforce this principle, as a high-level overview, the Department would review all amounts disbursed minus any amounts that were returned by the institution or the borrower. We included a provision in § 685.203(j)(2) proposing that any amount of loan funds that have been returned by the institution, or the borrower, will not count against that borrower's lifetime maximum aggregate loan limit. Because the borrower did not receive the benefit of those funds that were returned to the Secretary, we believe those amounts should not be counted toward this lifetime maximum aggregate limit so that we remain consistent with historical precedent.

The OBBB also introduces a loan limit for borrowers who are enrolled on a less than full-time basis. The Department proposes to codify the Direct Loan eligibility on a less than full-time enrollment basis and a corresponding schedule of reductions. Section 455(a)(7) of the HEA requires the Secretary to publish a schedule of reductions for institutions to calculate the student's Direct Loan eligibility for the purposes of determining the amount of loan funds the borrower is eligible to receive for the 'less than full-time enrollment status' provision. Therefore, the Department's regulations at § 685.203(m)(1) would provide additional information about these provisions and serve as the example of the schedule of reductions for students enrolling less than full-time.

Consistent with the OBBB, the proposed regulations include a formula that uses the number of credit hours in which the student is enrolled for the academic year divided by the number of credit hours that constitute full-time enrollment, as determined by the institution, for that academic year in the student's program of study, expressed as a percentage. The resulting percentage is then applied to the student's annual loan limit for that academic year. This proposal would implement Congress's direction that the annual loan limit be reduced in direct proportion to the student's enrollment status, rather than allowing a student who attends only part of the year or at reduced enrollment to receive the same annual loan amount as a full-time student.

The RISE Committee discussed the formula for less than full-time enrollment in detail and walked through

several examples of how to properly apply this formula. The Department explained during negotiations that the language contained within this NPRM explicitly sets the required annual loan limit for when a borrower enrolls less than full-time in the academic year. The Department explained that, in addition to this loan limit, a borrower must also meet all other eligibility criteria to receive a Federal student loan. The OBBB intentionally created an academic year requirement and not a per-term or per-disbursement schedule. We made the formula easily translatable to what the institution defines as full-time for the academic (award) year and easily divisible by the relevant number of terms. For an undergraduate student, current section 668.2 defines full-time as at least 24 credit hours. Using 24 credit hours as the baseline for full-time and factoring in enrollment for the complete academic year, an undergraduate borrower who enrolls nine hours in the fall and fifteen hours in the spring would be considered as full-time for the academic year and would be eligible for the full amount of eligibility and not subject to a reduction for less than half-time, which would equal 50 percent of the annual loan limit. A student's maximum disbursement eligibility for each term will be equal to the proportion of the full academic year and reduced by the percentage the student is enrolled less than full-time.

Section 455(a)(7)(A) of the HEA applies to the loan amount "for an academic year, or its equivalent." The proposed text in § 685.203(m)(1) includes a corresponding formula for determining the proportion of the annual loan limit that applies to a single term at the receiving institution and then applying the less than full-time reduction to that amount in order to address situations in which a loan period is shorter than a full academic year such as when a student transfers mid-year.

The Department, in negotiations, also clarified situations relevant to a borrower who transfers enrollment to a different institution and how the new annual loan limit should be applied to the subsequent term of enrollment. The Department also walked through example schedules of reductions. For these transfer students, the new institution would determine what share of the academic year loan limit that term represents; and then reduce the Direct Loan based on the student's enrollment status in that term. The institution would use the schedule of reductions formula for the term of enrollment, which takes the number of credits

enrolled in that term for that program of study divided by the total number of credits that the institution considers full-time enrollment for that term in the program. This structure provides institutions with a clear, formula-based method for applying the statutory requirement to the portion of the annual loan limit for which it is disbursing. Institutions are familiar with the common practice of adjusting a student's aid package to reflect one term of enrollment or awarding aid to a student who has transferred from one institution to another. The concept of determining aid for one semester is not new. As such, creating the schedule of reductions for one term of enrollment was the appropriate action to address the new annual loan limit for less than full-time enrollment for students who fluctuate their attendance between institutions or only enroll in one term.

During negotiations, the Department answered several questions about the application of the schedule of reductions across differing academic calendars and payment period structures. These questions were relevant to the scope of regulations at § 685.203(m)(1), and the Department discusses the applicability of the schedule of reductions to programs contained in these regulations below. For non-term clock hour and credit-hour programs, the Department believes existing title IV disbursement rules are already tightly linked to academic progress. Students in these programs generally may not receive subsequent disbursements until they complete the required number of clock or credit hours, and institutions calculate payment periods and disbursements based on hours completed rather than fixed terms of time.

During the second week of the RISE Committee, the Department discussed the application of the schedule of reductions for students who are enrolled in subscription-based programs. Under a subscription-based program, the first two subscription periods of the programs are treated as terms for purposes of the title IV, HEA fund disbursements and there is no requirement for a student to complete a specified amount of coursework before receiving the disbursement for the second subscription period. However, in the third and subsequent subscription periods, disbursements are treated similarly to clock-hour and other non-term programs. Students in such programs cannot receive subsequent disbursements until they have earned the credits associated with the period, so the amount of loans a student can receive is already constrained by their

actual pace and enrollment. Given that none of the non-Federal negotiators had specific experience with subscription-based programs, we removed reference to such programs in the regulations for schedule of reductions and are seeking specific feedback from institutions that use this type of academic calendar during the public comment period. The Department welcomes all relevant feedback on such programs and the relevancy of the schedule of reductions, or whether additional provisions are necessary to specifically address unique aspects of subscription-based programs. Specifically, we invite comments that ponder how the schedule of reductions would work at a subscription-based institution.

Section 455(a)(7)(A) of the HEA also ties the reduction to the student's enrollment status as of the date the institution determines the student's eligibility for a disbursement. A cross-reference to the general disbursement rules in § 668.164(b)(3) is also included. Under § 668.164, before each disbursement of title IV funds, an institution (or its third-party servicer) must confirm that the student is eligible, including confirming the student's enrollment status for that payment period.

The Department's proposed regulations therefore require institutions to apply the schedule of reductions formula using the student's actual enrollment at the time of disbursement, not just the enrollment that was anticipated when the institution originally packaged the annual loan. In the RISE Committee discussions, the Department explained that institutions typically build an award package based on the student's intended full-time enrollment for the academic year, but before a second or subsequent disbursement, as is already required, the school must re-check enrollment status to determine eligibility for the second or subsequent disbursement. If the student is enrolled for fewer credits than full-time at that point, the institution must reduce that disbursement so that the total loan for the academic year reflects the student's actual enrollment status. Likewise, if the student withdrew or dropped credits after the first disbursement that caused the student to be enrolled less than full-time for that term, the institution must reduce the subsequent disbursement in accordance with the schedule of reductions formula to make certain the student's annual amount disbursed is equal to the student's enrollment status.

By anchoring the reduction to the disbursement eligibility date in

§ 668.164(b)(3), the regulations ensure that:

- students who remain full-time across the academic year may still receive the full annual loan limit;
- students whose enrollment falls below full-time before a disbursement will have their annual loan amount reduced in proportion to their updated enrollment; and
- institutions are not required to predict future enrollment beyond what they already do under the existing aid packaging process.

This approach reflects the RISE Committee's concern that part-time and less than full-time students should receive the amount of loan eligibility they "earn" based on their enrollment over the academic year, while avoiding retroactive recalculations that would be difficult to administer and confusing for borrowers.

The Department's proposed regulations would codify the institutionally determined loan limits established in the OBBB. Financial aid administrators have long supported this approach as a means of helping to prevent borrowers from incurring unreasonable levels of debt.²⁸ Institutions already have the authority under § 685.301(a)(8), on a case-by-case (or student-by-student) basis, to reduce a Direct Loan or choose not to originate a loan. However, the new institutionally determined loan limit regulations provide further flexibility as to when, and how, an institution may limit borrowing under the new OBBB statutory authority. Additionally, the Department's proposed regulations in § 685.203(m)(2)(ii) through (iv) provide requirements to ensure the Department complies with the statutory requirements and that institutions provide borrowers with adequate information about the programs that may be subject to institutionally determined loan limits, thereby

²⁸ National Association of Student Financial Aid Administrators, *NASFAA Issue Brief: Loan Limits* (Feb. 2018) (recommending institutional authority to limit loans); *Keeping College Within Reach: Examining Opportunities to Strengthen Federal Student Loan Programs*, Hearing Before the Subcomm. on Higher Educ. and Workforce Training, H. Comm. on Educ. and the Workforce, 113th Cong. (2013) (questions submitted for the record noting NASFAA's Debt Task Force recommendation to allow colleges to limit students' loan eligibility); Ben Barrett & Amy Laitinen, *Off Limits: More to Learn Before Congress Allows Colleges to Restrict Student Borrowing* (New America, May 2017) (describing institutional and trade association support for expanded loan-limiting flexibility); National Association of Student Financial Aid Administrators, *Ability to Limit Loans: NASFAA Membership Survey* (May 2019) (reporting survey results on institutional interest in borrowing-limit authority).

providing borrowers with information to make informed choices.

By requiring institutions to document their decision and follow customary record retention requirements, the Department would be able to examine if the institution is applying their policy consistently to all students enrolled in that academic program. Furthermore, an institution would be required to notify students prior to limiting a current or prospective student's eligibility for a Direct Loan. We believe that these additional measures help ensure transparency in the process and would allow students to make an informed decision on whether to continue in their academic program or seek other means to finance their education.

The Department believes that the institution's decision to reduce the loan limit for a specific program of study would occur before the start of the new academic year so that there is adequate time to notify current and prospective students who enroll in that program prior to those students being subjected to the reduced loan limit.

Section 428H of the HEA and Loan Limits for Certain Health Professionals

Section 428H(d)(2)(A) of the HEA established loan limits for Federal Unsubsidized Stafford Loans made to graduate, professional, and independent postbaccalaureate students prior to July 1, 2010, and the HEA authorized the Secretary to increase loan limits for students "engaged in specialized training requiring exceptionally high costs of education." Under this authority, the Secretary previously increased the aggregate loan limits for graduate and professional students enrolled in certain approved health profession programs (as defined by Section 703(a) of the Public Health Act). The Department first published these increased limits in DCL 98–L–209 (August 1, 1998). The Department last updated the increased limits in 2008 (DCL GEN–08–04 (April 18, 2008)).

Section 455(a)(1) of the HEA provides that "loans made to borrowers under Part D of the HEA shall have the same terms, conditions, and benefits, and be available in the same amounts, as loans made to borrowers, and first disbursed on June 30, 2010 under sections 428, 428B, 428C, and 428H" of the HEA, "unless otherwise specified in this part." Section 455(a)(4) of the HEA, added by the OBBB, established new annual and aggregate limits for Federal Direct Unsubsidized Stafford Loans made to graduate and professional students "beginning on July 1, 2026." Because the limits set forth in Section 455(a)(4) explicitly apply to all Federal

Direct Unsubsidized Stafford Loans made to graduate and professional students on or after July 1, 2026, including those enrolled in health profession programs, the increased annual and aggregate loan limits established by the Secretary for graduate and professional students enrolled in certain approved health profession programs will not apply to loans made on or after July 1, 2026.

Notwithstanding the aforementioned, graduate and professional students enrolled in certain approved health profession programs and who meet the criteria for the interim exception under proposed § 685.203(b)(2)(iv)(B) regarding unsubsidized annual loan limits or § 685.203(e)(6) regarding unsubsidized aggregate loan limits will still be eligible for the increased loan limits during their expected time to credential. This is because the new loan limits effective on or after July 1, 2026, will not apply to these borrowers so long as they remain enrolled in their program of study. Consequently, they will retain access to the loan limits for loans made before July 1, 2026, including the increased unsubsidized loan amounts due to the high-cost nature of their program of study through the interim exception period. While a longstanding and widely used definition, the Department is aware that the definition of "professional student" has caused some confusion. The Department particularly invites commenters to suggest alternative terminology for this and related terms to ensure it is clear that this provision was designed by Congress to reduce borrowing for certain types of students and is not a value judgement about the professional nature of programs or occupations themselves.

Deferment (§ 685.204)

Statute: Section 82002 of the OBBB amends Section 455(f) of the HEA, titled "Deferment; Forbearance," to sunset the authority for unemployment and economic hardship deferments for new Direct Loans while preserving these deferments for existing borrowers.

Current Regulations: Section 685.204 contains the regulations on deferments for Direct Loan borrowers. Section 685.204(f) provides the eligibility criteria, including the timeframes in which the borrower may receive an unemployment deferment. Section 685.204(f) further provides the borrower qualifications, including the manner on how to apply for an unemployment deferment and other rules that pertain to borrowers receiving an unemployment deferment.

Section 685.204(g) provides the eligibility criteria for the economic hardship deferment, including the cumulative maximum periods a borrower may receive an economic hardship deferment and the periods of time in which the Secretary grants an economic hardship deferment.

Proposed Regulations: The Department proposes to restructure the regulations at § 685.204(f)(1) to provide the eligibility criteria for an unemployment deferment based on loan disbursement date. We propose to redesignate current § 685.204(f)(1) as § 685.204(f)(1)(i) and provide that for loans disbursed before July 1, 2027, a borrower is eligible for an unemployment deferment during periods that, collectively, do not exceed the three years in which the borrower is seeking and unable to find full-time employment. We further propose to add new § 685.204(f)(1)(ii) to provide that for loans disbursed on or after July 1, 2027, a borrower may not receive an unemployment deferment. We also propose to add "the" after "For" in § 685.204(f)(3).

The Department proposes to restructure the regulations at § 685.204(g)(1)(i) and (ii) to provide the eligibility criteria for an economic hardship deferment based on the loan disbursement date. Specifically, we propose to revise the current § 685.204(g)(1)(i) to provide that for Direct Loans disbursed before July 1, 2027, a borrower is eligible for economic hardship deferments that, collectively, do not exceed three years. We further propose to redesignate current § 685.204(g)(1)(ii) as § 685.204(g)(1)(iii). Finally, we propose to add a new § 685.204(g)(1)(ii) to provide that for Direct Loans disbursed on or after July 1, 2027, a borrower may not receive an economic hardship deferment.

Reasons: The regulations are amended to reflect the changes made by the OBBB. Specifically, the OBBB provides that, for those borrowers with loans first disbursed before July 1, 2027, they may continue to receive unemployment and economic hardship deferments, subject to existing duration limits, but borrowers with loans first disbursed on or after that date are not eligible for those deferments. We note that an individual borrower could have split eligibility (*i.e.*, they could have a loan before July 1, 2027, which is eligible for unemployment deferment, and a loan on or after July 1, 2027, which would not be eligible for that same deferment). These statutory changes require conforming amendments to § 685.204 so that the Department's regulations on

deferment reflect the revised HEA framework and operate consistently with the OBBB repayment and hardship-relief system.

Current Section 685.204(f) and (g) provide unemployment and economic hardship deferments for eligible Direct Loan borrowers, generally for up to three years. These provisions describe the circumstances in which a borrower may receive an unemployment deferment, including when the borrower is seeking and unable to find full-time employment, and the criteria for receiving an economic hardship deferment. The deferments have functioned as short-term protections for borrowers who experience job loss, very low income, or other qualifying hardships.

To conform our regulations to the OBBB, the Department proposes to revise § 685.204(f) and (g) so that eligibility for unemployment and economic hardship deferments depends on the loan's first disbursement date. Proposed § 685.204(f)(1)(i) and (g)(1)(i) would provide that a borrower with Direct Loans first disbursed before July 1, 2027, remains eligible for unemployment and economic hardship deferments during periods that collectively do not exceed three years, consistent with current rules. New § 685.204(f)(1)(ii) and (g)(1)(ii) would provide that a borrower with Direct Loans first disbursed on or after July 1, 2027, may not receive unemployment or economic hardship deferments. The Department also proposes minor conforming edits, including revisions to cross-references and clarifying words, to improve internal consistency and readability without altering the substance of borrower protections for loans that remain eligible for deferment.

During the RISE Committee, the Department explained that the OBBB preserves unemployment and economic hardship deferments only for borrowers whose loans are first disbursed on or before July 1, 2027, and that the regulations would need to reflect that distinction by loan disbursement date. Committee materials and discussion summarized the Department's intent to maintain access to these deferments for legacy borrowers while ending their availability for new loans, and to coordinate this change with related proposals on forbearance limits, rehabilitation, and the new repayment framework. After reviewing the draft amendments to § 685.204(f) and (g), the Committee did not raise objections when presented with the amendatory text in week two of the negotiations.

By limiting unemployment and economic hardship deferments to Direct

Loans first disbursed before July 1, 2027, the proposed amendments to § 685.204 implement the OBBB's statutory changes, preserve existing expectations for borrowers with legacy loans, and clarify that future borrowers must rely primarily on simplified repayment options and targeted hardship-relief authorities rather than on status-based deferments. This structure is intended to reduce regulatory complexity, improve alignment between deferment provisions and the new repayment system, and provide a clearer set of protections for both current and future borrowers.

These revisions would give borrowers, institutions, and servicers a more transparent and administrable deferment framework that aligns with the new repayment structure under the OBBB, clarifies when deferment is available, and supports smoother transitions between deferment, active repayment, and periods that may count toward forgiveness.

Forbearance (§ 685.205)

Statute: Section 82002 of the OBBB amends Section 455(f) of the HEA, "Deferment; Forbearance," to limit the use of forbearance for future borrowers, effective for loans made on or after July 1, 2027.

Current Regulations: Section 685.205 contains the regulations on forbearances for Direct Loan borrowers; § 685.205(c) provides the periods of forbearance. Under § 685.205(c)(1), the Secretary grants forbearance for a period of up to one year and under § 685.205(c)(2), a borrower may request to renew the forbearance, and it will remain valid for the duration of the period in which the borrower meets the criteria for the forbearance.

Proposed Regulations: The Department proposes to restructure the regulations at § 685.205(c)(1) to provide the period of forbearance and a limited period of forbearance for loans disbursed on or after July 1, 2027. Specifically, we propose to redesignate current § 685.205(c)(1) as § 685.205(c)(1)(i). We also propose to add § 685.205(c)(1)(ii) that provides for loans disbursed on or after July 1, 2027, and notwithstanding the granting of forbearance for a period of up to one year, the Secretary grants forbearance for a period that does not exceed nine months within a 24-month period for a general forbearance. Such forbearance would begin the first month for which the forbearance is granted.

Reasons: The Department proposes to amend Section 685.205 to reflect the changes made by the OBBB. Under

these amendments, loans made on or after July 1, 2027, are eligible for general forbearance for no more than nine months within any 24-month period, while earlier cohorts with legacy loans retain access to the longer forbearance periods authorized under current law. The Department must therefore revise § 685.205 to reflect these new statutory limits and to distinguish between legacy borrowers and borrowers whose loans are made under the OBBB framework.

Currently, § 685.205 allows the Secretary to grant forbearance when a borrower is unable to make required monthly payments. Under § 685.205(c)(1), the Secretary may grant a forbearance for a period of up to one year. Under § 685.205(c)(2), the borrower may request a renewal of a forbearance period so long as the borrower continues to meet the criteria for forbearance.

Consistent with the OBBB, the Department proposes to restructure § 685.205(c)(1) to set different limits on general forbearance based on loan disbursement date, while preserving existing rights for legacy borrowers. As described to the RISE Committee, the Department would redesignate current § 685.205(c)(1) as § 685.205(c)(1)(i), under which borrowers with loans disbursed before July 1, 2027, may continue to receive general forbearance for periods of up to one year at a time, subject to existing renewal rules. The Department would then add § 685.205(c)(1)(ii), providing that for loans disbursed on or after July 1, 2027, the Secretary may grant general forbearance for no more than nine months within any 24-month period.

The Department also proposes conforming edits in § 685.205(a) and (b) to cross-reference the new paragraph (c)(1) to make this limit required for borrower-requested general forbearances.

In its presentations to the RISE Committee, the Department explained that the nine-month limit applies only to general, discretionary forbearances requested by the borrower under § 685.205(a)(1) and does not apply to processing or other administrative forbearances initiated by the Department or a servicer. Non-Federal negotiators raised questions about how distinct types of forbearances such as processing forbearances while an income-driven repayment application is pending or administrative forbearances during a total and permanent disability discharge review would interact with the new limit. The Department clarified that processing, and administrative, forbearances would not count against the nine-month general forbearance cap,

while borrower-requested discretionary forbearances would count, and confirmed that cancer deferment and Total and Permanent Disability-related administrative forbearances are not impacted by the cap.

The RISE Committee also reviewed the proposed text for § 685.205 during its two sessions. Department staff described the restructuring of § 685.205(c)(1) into separate provisions for loans disbursed before and on or after July 1, 2027, and emphasized that borrowers with loans disbursed before July 1, 2027, would retain access for up to one year of general forbearance per loan, while borrowers with later loans would be limited to nine months. Like deferments, we note that an individual borrower could have split eligibility (*i.e.*, they could have a loan eligible for forbearance made before July 1, 2027, but a loan made on or after July 1, 2027, would not be eligible for that same forbearance). The RISE Committee expressed concern about borrower confusion and servicing errors, particularly the risk that servicers might misclassify forbearances in ways that could cause borrowers to exhaust their nine-month limit inadvertently. In response, the Department reiterated that the cap applies only to borrower-requested general forbearances and noted that existing oversight and error-correction processes would continue to apply.

These proposed changes to § 685.205 are intended to work in concert with the broader OBBB repayment and relief framework, including the new Repayment Assistance Plan. At the same time, the proposed nine-month limit for loans disbursed on or after July 1, 2027, retains general forbearance as a short-term tool for unexpected disruptions, while reducing the risk that borrowers will spend years in forbearance accumulating interest instead of enrolling in affordable repayment plans. For borrowers with loans made before July 1, 2027, the rule preserves access to longer forbearance periods consistent with current regulations, providing a gradual transition to the new statutory framework and honoring existing expectations. Collectively, these revisions would create a more transparent and disciplined forbearance framework that aligns with the OBBB's repayment structure, reduces the risk that borrowers are inappropriately placed or kept in prolonged forbearance, and clarifies how forbearance periods affect interest, capitalization, and a borrower's progress toward potential forgiveness.

Fixed Payment Repayment Plans (§ 685.208)

Statute: Section 82001(b)(1)(A) of the OBBB amends Section 455(d)(1) of the HEA to limit access to the standard, graduated, and extended repayment plans to borrowers who only have outstanding Direct Loans and do not receive another Direct Loan on or after July 1, 2026. Section 82001(b)(3) of the OBBB further amends Section 455(d)(6) of the HEA which terminated and limited the Secretary's repayment authority and sunsets repayment plans that were available before July 1, 2026. Section 455(d)(7)(A)(i) of the HEA would be the only fixed payment repayment plan available to borrowers who receive a Direct Loan made on or after July 1, 2026.

Current Regulations: Section 685.208 contains the regulations on fixed payment repayment plans for Direct Loan borrowers. Section 685.208(a) provides a general overview of fixed payment repayment plans under which a borrower's required monthly payment amount is determined based on the amount of the borrower's Direct Loans, the interest rates on the loans, and the repayment plan's maximum repayment period. Section 685.208(b) and (c) provide the terms of the standard repayment plans based on Direct Loan type and date of entering repayment; § 685.208(d) and (e) provide the extended repayment plans based on Direct Loan type and date of entering repayment; and § 685.208(f), (g), and (h) provide the graduated repayment plans based on Direct Loan type and date of entering repayment. Section 685.208(i) and (j) provide the repayment periods for the fixed payment repayment plans based on the outstanding balance of a borrower's Direct Loans. Finally, § 685.208(k) provides that the repayment period for any of the fixed payment repayment plans excludes periods of authorized deferments or forbearances.

Proposed Regulations: The Department proposes to restructure the regulations at § 685.208 to provide the fixed payment repayment plans based on when the Direct Loan was made. We propose to revise current § 685.208(b) as the header for fixed repayment plans for Direct Loans made before July 1, 2026. Proposed § 685.208(b) would also contain the following fixed repayment plans: standard, graduated, extended, and tiered standard. We also propose to revise current § 685.208(c) as the header for fixed repayment plans for Direct Loans made on or after July 1, 2026. Proposed § 685.208(c) will contain only the tiered standard repayment plan. We

also propose to include the repayment period within each fixed repayment plan.

Reasons: The regulations are amended to reflect changes made to the HEA by the OBBB. Among the changes in § 685.208, our proposal to organize the regulatory text by when a Direct Loan was made and the fixed repayment plans available to the borrower for that loan would streamline information so that all information about each of the respective repayment plans (*i.e.*, the standard, graduated, or extended repayment plans) are in a central location in regulation and are contained together. Each fixed payment repayment plan would also contain the appropriate repayment period applicable for that plan and other terms such as authorized periods of deferment and forbearances that are included in the repayment period. This provides structure and consistency to this regulatory subsection.

Congress specified the new standard repayment plan in Section 455(d)(7)(A)(i) of the HEA to be one of the two repayment plans available to new borrowers on or after July 1, 2026. We propose to name the new fixed payment repayment plan the Tiered Standard repayment plan. The Tiered Standard repayment plan would be the only fixed repayment plan available to borrowers who receive a Direct Loan made on or after July 1, 2026. The Tiered Standard repayment plan, including the prescribed repayment periods specified in the law, is added in proposed § 685.208(b).

Consistent with these two statutory provisions that amended the HEA, in § 685.208(b)(1) through (b)(7), we limit access to the standard, graduated, and extended plans on the condition that the borrower does not receive a new Direct Loan on or after July 1, 2026.

The repayment period for the Tiered Standard repayment plan is enumerated in statute and ranges from a period of 10 years to 25 years based on the total outstanding principal balance at the time the borrower enters repayment under the plan. However, in certain circumstances, that term is recalculated. If a borrower in the Tiered Standard repayment plan obtains new loans that would be repaid under Tiered Standard repayment plan, the repayment period is recalculated using the outstanding principal balance for all eligible loans as of the date that the new Direct Loan enters the Tiered Standard repayment plan. Similarly, a borrower enrolled in Tiered Standard repayment plan, who changes to a repayment plan that is not the Tiered Standard repayment plan (or defaults on their loan) and then re-

enrolls in Tiered Standard repayment plan would also have their repayment period recalculated based on the total outstanding balance of eligible loans on the date the borrower re-enrolls in the Tiered Standard repayment plan. Section 455(d)(7)(A)(i)(II) of the HEA bases the applicable repayment period on the total outstanding principal of all the borrower's Direct Loans "at the time the borrower is entering repayment" under the Tiered Standard repayment plan, and inclusion of that additional loan would require an amortization of all the outstanding principal for all the borrower's Direct Loans. A borrower in the Tiered Standard repayment plan who enters a period of authorized deferment or forbearance would not be considered to have left the Tiered Standard repayment plan and would not need to have the repayment period recalculated.

During the first session of the RISE Committee, some Committee members expressed concerns about borrowers being placed into Tiered Standard repayment plan, which is not a qualifying repayment plan for PSLF purposes. Section 455(d)(7)(B) of the HEA requires the Secretary to place a borrower in the Tiered Standard repayment plan if the borrower does not select a repayment plan for loans made on or after July 1, 2026; accordingly, a borrower who is on track to receive PSLF would need to proactively select a PSLF qualifying repayment plan if their loan qualifies for such a plan. Section 455(m)(1)(A) of the HEA and the regulations at 34 CFR 685.219(b) enumerate the PSLF qualifying repayment plans, and the Tiered Standard repayment plan is not listed as one of the PSLF qualifying repayment plans. The Department will make certain that information in communications to borrowers who are seeking PSLF clearly states that the Tiered Standard repayment plan would not qualify as an eligible repayment plan for the purposes of the PSLF program.

Minimum Payments

Section 428(b)(1)(L)(i) of the HEA provides that the total amount of the annual payments made by a borrower during any year of a repayment period with respect to the aggregate amount of all loans made to that borrower must not be less than \$600 or the balance of all such loans, whichever amount is less. This provision creates a mandatory minimum monthly payment of \$50 per month per borrower under the Tiered Standard repayment plan. Section 455(a)(1) of the HEA, as amended, 20 U.S.C. 1087e(a)(1), otherwise known as,

Parallel Terms and Conditions provision, states that unless otherwise specified in this part, loans made to borrowers under this part shall have the same terms, conditions, and benefits . . . as loans made to borrowers . . . under section 428 . . .

And Section 82001 of the OBBB, Public Law 119–21, which amended Section 455(d) of the HEA to create the Tiered Standard repayment plan, does not specify a minimum monthly payment amount. Therefore, by operation of the Parallel Terms and Conditions provision of the HEA, the monthly payment amount is imputed into the language of the Tiered Standard repayment plan.

Income-Driven Repayment Plans (§ 685.209)

Statute: Section 82001(b) of the OBBB amends Section 455(d)(1) of the HEA to limit access to certain IDR plans for borrowers who only have outstanding Direct Loans and do not receive another Direct Loan on or after July 1, 2026. Section 82001(c)(1) of the OBBB further amends Section 455(d) and (e) of the HEA, which terminated and limited the Secretary's repayment authority to make income-contingent repayment available and sunset those ICR plans before July 1, 2028. Section 82001(a) provides for the transition of borrowers in an ICR plan to other IBR plans. Section 82001(d) of the OBBB adds Section 455(q) to the HEA, which provides the authority and overall framework for the Repayment Assistance Plan. Section 82001(f) of the OBBB amends Section 493C(a)(3) of the HEA to eliminate partial financial hardship as a condition of entry into IBR. Section 82001(c)(2)(D) of the OBBB amended Section 494(a)(2) of the HEA regarding the procedure and requirements for requesting Federal tax information (FTI) from the Internal Revenue Service (IRS) for purposes of determining eligibility for the IDR plans, including the Repayment Assistance Plan.

Current Regulations: Section 685.209 contains the regulations on IDR plans for Direct Loan borrowers. Section 685.209(a) provides a general overview of the four IDR plans under which a borrower's required monthly payment amount is determined based on the borrower's income and family size. Currently, the four IDR plans are: the Saving on a Valuable Education (SAVE) plan, which replaced the Revised Pay As You Earn (REPAYE) plan; the Income-Based Repayment (IBR) plan; the Pay As You Earn (PAYE) Repayment plan; and the Income-Contingent

Repayment (ICR) plan.²⁹ Section 685.209(b) enumerates definitional terms pertaining to IDR plans. Section 685.209(c) provides the borrower eligibility criteria for each of the IDR plans. Section 685.209(d) stipulates the loans eligible to be repaid under each of the IDR plans while § 685.209(e)(1) provides how the Secretary treats a borrower's income for purposes of calculating a borrower's monthly payment amount under an IDR plan, and § 685.209(e)(2) provides whose loan debt is includable for purposes of adjusting a borrower's monthly payment amount in an IDR plan. Section 685.209(f) provides how the Secretary calculates the monthly payment amounts for each of the IDR plans, and § 685.209(g) provides adjustments to those monthly payment amounts.

Section 685.209(h) provides how the Secretary treats interest accrual on a borrower's loans depending on the IDR plan. Section 685.209(j) provides how the Secretary capitalizes unpaid, accrued interest under the various IDR plans. Section 685.209(k) provides the forgiveness timelines under which a borrower receives forgiveness of the remaining balance of the borrower's Direct Loan after satisfying the requisite number of monthly payments or the equivalent over a period of years based on the type of IDR plan. Section 685.209(k) also provides when a borrower receives a month of credit toward forgiveness for the various IDR plans. Finally, § 685.209(l) provides the application and annual recertification procedures of a borrower's income and family information for purposes of calculating a monthly payment under an IDR plan and includes the consequences of failing to recertify.

Proposed Regulations: The Department proposes to include repayment plan provisions in § 685.209, including most of the terms and conditions of the newly created Repayment Assistance Plan, and other changes made by the OBBB.

With respect to the IDR plans, we propose to amend § 685.209(a) to add the newest IDR plan: the Repayment Assistance Plan. We also propose to restructure the definitions section in § 685.209(b) by providing definitional terms applicable to the Repayment Assistance Plan. We propose to add the following new definitions and amend existing definitions: applicable amount; base payment; dependent; eligible loan; excepted consolidation loan; excepted

²⁹ The Department is currently enjoined from operating the Saving on a Valuable Education (SAVE) plan. See *Missouri v. Biden*, 112 F.4th 531, 538 (8th Cir. 2024).

loan; excepted PLUS loan; family size; monthly payment or the equivalent; and new borrower. We propose to remove the definition of partial financial hardship from the list of definitions in § 685.209(b).

With respect to borrower eligibility for IDR plans, we propose to amend § 685.209(c)(1) to make clear that, except under certain circumstances for borrowers in IBR or the Repayment Assistance Plan, defaulted loans may not be repaid under an IDR plan. We propose to amend § 685.209(c)(2), (4), and (5) to provide that through June 30, 2028, borrowers may repay under the PAYE and ICR plans if they meet the criteria in each of those ICR plans and have not received a Direct Loan on or after July 1, 2026. Where appropriate, we propose removing partial financial hardship, and in its place the borrower must elect to have their aggregate monthly payment recalculated so as not to exceed the applicable amount. We also propose in § 685.209(c)(6) that any Direct Loan borrower may repay under the Repayment Assistance Plan if the borrower has loans eligible for repayment under the plan. Finally, we provide a transition period for borrowers in an income-contingent repayment plan (ICR, PAYE, SAVE) to elect to repay under a different repayment plan.

With respect to loans eligible to be repaid under IDR plans, we propose to amend § 685.209(d)(1) and (3) to provide that through June 30, 2028, borrowers may repay select Direct Loans under certain ICR plans. We propose to amend § 685.209(d)(1), (2), and (3) to make clear when a borrower may repay excepted consolidation loans under IDR plans. We propose to add § 685.209(d)(4) to clarify the loans eligible to be repaid under the Repayment Assistance Plan. And we make clear in proposed § 685.209(d)(5) that only Direct Loans made before July 1, 2026, may be repaid under the PAYE, IBR, and ICR plans. We also propose to amend § 685.209(e) to specify how the Secretary would treat income and loan debt for the purposes of calculating a monthly payment under the IDR plans, including by adding how loan debt and income are treated for purposes of the Repayment Assistance Plan.

With respect to how monthly payment amounts are calculated for the various IDR plans, we propose to amend § 685.209(f)(2) and (3) to clarify that a borrower's repayment period could exceed the 10-year standard repayment plan timeframe while repaying under the IBR or PAYE plans when their payment is no longer based on an amount calculated using their income.

We also propose to add § 685.209(f)(5), which governs the applicable monthly payment amount required under the Repayment Assistance Plan and clarifies it must be equal to the borrower's base payment, divided by twelve, less \$50 for each dependent of the borrower. We also propose to add § 685.209(g)(3), where we would adjust monthly payment amounts calculated under the Repayment Assistance Plan and propose that if the adjusted monthly payment as calculated is less than \$10, the monthly payment would be \$10.

With respect to treatment of interest and interest subsidies under the various IDR plans, we propose to add in § 685.209(h) a cross-reference to the Repayment Assistance Plan that if a borrower's calculated monthly payment under an IDR plan is insufficient to pay the accrued interest on the borrower's loans, we would charge the remaining accrued interest to the borrower. We also propose to add § 685.209(h)(4), which would state that under the Repayment Assistance Plan, during all periods of repayment on all loans being repaid under the Repayment Assistance Plan, we would not charge the borrower accrued interest that is not covered by the borrower's on-time payment of the amount due for that month. However, we would provide under § 685.209(h)(4)(ii), that if a borrower's payment is credited to a future monthly payment, and the payment equals or exceeds the on-time monthly payment amount made under the Repayment Assistance Plan, we would charge the borrower accrued interest that is not covered by the borrower's on-time payment of the amount due for that month. Under proposed § 685.209(j)(1), we would add the Repayment Assistance Plan as one of the IDR plans where the Secretary does not capitalize unpaid accrued interest in accordance with interest capitalization regulations at § 685.202.

With respect to loan forgiveness under the IDR plans, we propose to amend § 685.209(k)(4) to specify under which IDR plans a borrower may receive a month of credit toward IDR forgiveness. Specifically, we propose to add § 685.209(k)(4)(i)(B), which would provide that making a payment on or before June 30, 2028, under the PAYE, or ICR, plan or having a monthly payment obligation of \$0 would give a borrower a month of credit toward forgiveness for IBR. We also propose to add § 685.209(k)(7), which would provide that under the Repayment Assistance Plan, a borrower receives forgiveness of the remaining balance of the borrower's loans after the borrower has satisfied 360 monthly payments

over a period of at least 30 years. We propose to specify in § 685.209(k)(8) the terms and conditions of receiving forgiveness under the Repayment Assistance Plan and specify the monthly payment or their equivalents that would give a borrower a month of credit toward forgiveness under the Repayment Assistance Plan.

With respect to applying for an annual recertification procedure in IDR plans, we propose to codify procedures when the Secretary may implement certification and automatic recertification for enrollment in the Repayment Assistance Plan. We propose to add § 685.209(l), which are the conditions under which a borrower must provide documentation or information to the Secretary related to the borrower's income and number of dependents of the borrower for purposes of enrolling in the Repayment Assistance Plan.

Finally, we propose to add new provisions in § 685.209 under new § 685.209(o). First, we propose in § 685.209(o)(1) for the PAYE plan and the Repayment Assistance Plan, if the borrower's monthly payment amount is not sufficient to pay any of the principal due, the payment of that principal is postponed. We further add in § 685.209(o)(2) the provisions of matching principal payments under the Repayment Assistance Plan, which would provide that when the borrower is not in a period of deferment or forbearance, for each month the borrower makes an on-time monthly payment and the outstanding principal balance is reduced by less than \$50, the Secretary reduces such total outstanding principal of the borrower by an amount that is equal to the lesser of \$50 or the monthly payment made and then subtracting that figure from the amount of the monthly payment that is applied to such total outstanding principal balance. We also propose to specify in § 685.209(o)(3) that for the purposes of the Repayment Assistance Plan, we would consider a payment to be "on-time" if the payment is received on or before the due date for the current month and satisfies the due date for the current month, but after the due date for the previous month. We would also specify how we would treat loan payments made in excess of on-time payments under the Repayment Assistance Plan for purposes of receiving the matching principal payment or interest subsidy, monthly credit toward PSLF, or forgiveness under the Repayment Assistance Plan.

Reasons: Throughout § 685.209, we conform the IDR plans to the statutory

changes. Other changes are discussed in greater detail below.

In response to Congress eliminating the partial financial hardship requirement for IBR eligibility and introducing the definition of *applicable amount*, the Department removed the definition of *partial financial hardship* from § 685.209(b) and eliminated the term throughout the section.

The term *applicable amount* by and large supplants partial financial hardship, and we make conforming changes throughout § 685.209 by removing partial financial hardship or concepts of partial financial hardship and in its place including *applicable amount*. In accordance with other statutory changes to definitional terms in Section 493C of the HEA, we added the definitions of *excepted consolidation loan*, *excepted loan*, and *excepted PLUS loan* in § 685.209(b). We believe the addition of these terms in our regulations clarifies borrowers' eligibility for IDR plans, as Parent PLUS borrowers may not access some repayment plans. By adding *excepted loan* to our definitions, we clarify that a Direct Consolidation Loan that repaid an excepted PLUS loan (or another consolidation loan that repaid a Parent PLUS Loan) is itself considered an excepted loan.

Section 455(q) provides definitions for the terms *base payment* and *dependent*, which were added to the Repayment Assistance Plan in § 685.209(b). These terms are critical to determining how the Department would calculate a payment under the Repayment Assistance Plan, including the actual calculation based on a borrower's AGI in the definition of *base payment* and defining who is considered a *dependent* for purposes of adjusting a borrower's payment under the plan. We also modified the definitions of *family size* and *monthly payment or the equivalent* to help ensure that these terms are applicable to IDR plans except the Repayment Assistance Plan. As previously noted, the definition of *base payment* and *dependent* specify how a payment is calculated under the Repayment Assistance Plan, making the definitions of *family size* and *monthly payment or the equivalent* unnecessary for purposes of the Repayment Assistance Plan.

We propose to modify the definition of *new borrower* for the IBR plan to clarify that receipt of a new Direct Loan on or after July 1, 2026, would prevent a borrower from continuing to repay under the borrower's current IBR plan.

Given that Section 455(d) of the HEA now limits access to certain repayment plans for borrowers who do not receive a new Direct Loan on or after July 1, 2026, and IBR for new borrowers is conditioned for borrowers after 2014, we put a finite timeframe in the definition of *new borrower* between 2014 and 2026 to ensure that the regulatory definition matches that of the statute.

Therefore, we revised the definition of a "new borrower" for the IBR plan to include only those who receive a new Direct Loan between 2014 and June 30, 2026, because obtaining a new Direct Loan on or after July 1, 2026, makes a borrower ineligible to continue repaying under the IBR plan.

This approach makes certain that our regulatory definition aligns with the statutory requirements in Section 455(d) of the HEA.

We propose to amend § 685.209(c)(1) to clarify that, except in certain circumstances for borrowers in IBR or the Repayment Assistance Plan, defaulted loans generally cannot be repaid under an IDR plan, a change proposed to align with the statute. Throughout § 685.209, we provide sunset dates for the SAVE, PAYE, and ICR plans (collectively the income-contingent repayment plans) because the statute makes clear that borrowers would not be eligible for those ICR plans on or after July 1, 2028. Continued access to these ICR plans is also predicated on the condition that a borrower does not receive a Direct Loan on or after July 1, 2026, as the statute commands and our regulations reflect throughout. Finally, we added a new § 685.209(c)(7) to conform with Section 82001(a) of the OBBB, which provides for a transition period for borrowers in an ICR plan or an administrative forbearance associated with an ICR plan to another plan before July 1, 2028. Our proposed regulations would implement the statutory changes that transition borrowers to other repayment plans.

With a new definition of *excepted consolidation loan*, we make clear under which IDR plans those borrowers with such excepted consolidation loans would be eligible to pay under. We believe our term *excepted consolidation loan* is simpler to understand as the term is defined further above.

With respect to monthly payment amounts, we included conditions in § 685.209(f)(2) and (3) that clarify a borrower's capped number of monthly payments may exceed 10 years. Prior to enactment of the OBBB, a borrower's

monthly payment under IBR and PAYE would have been the lesser of the applicable percentage of the borrower's discretionary income or, what the borrower would have paid under 10-year standard repayment plan when they began repaying under IBR or PAYE. Through our proposed regulations in § 685.209(f)(2) and (3), we make clear that the borrower's capped amount of monthly payments under the 10-year standard repayment plan could exceed 10 years.

With respect to calculating a monthly payment for the purposes of the Repayment Assistance Plan, because the OBBB added Section 455(q)(4)(B)(i) to the HEA, we included in proposed § 685.209(f), with nearly identical verbiage as the statute, how we would calculate a monthly payment for the Repayment Assistance Plan. That amount is equal to the base payment, divided by 12, minus \$50 for each of the borrower's dependents.

The Department's proposed regulations also align with the statutory changes to application and annual recertification procedures for IDR plans. The OBBB expands the Secretary's authority to use FTI to determine eligibility for IDR plans. The Department provides in regulations the process by which we obtain the borrower's (and their spouse, if applicable) consent to obtain the information needed to determine eligibility for an IDR plan. We also include a provision for the borrower to opt-out of disclosing their FTI and instead provide alternative documentation of income to reflect the ability of a borrower to opt-out of the FTI disclosure process.

With respect to the Repayment Assistance Plan, throughout § 685.209, we included the terms and conditions of the Repayment Assistance Plan in the appropriate subsections. Consistent with the other IDR plans, the Department's regulations codify the applicable terms and conditions of the Repayment Assistance Plan at these subsection levels to streamline the IDR plans implementing regulations and reduce borrower confusion.

To help guide readers, we are providing a high-level summary comparing selected plan features between existing IDR plans and the Repayment Assistance Plan. The new loan repayment provisions generally take effect on July 1, 2026.

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Plan Feature	ICR, IBR, PAYE, SAVE	Repayment Assistance Plan
<i>Eligible loans</i>	Direct Subsidized, Unsubsidized, PLUS to graduate or professional students, and Consolidation Loans (excepted consolidation loans may be repaid under the ICR plan)	Direct Subsidized, Unsubsidized, PLUS to graduate students or professional students, and Consolidation Loans (excluding excepted consolidation loans)
<i>Income consideration for monthly payment amounts</i>	AGI above discretionary income (AGI above 150% to 225% of the Federal Poverty Level)	AGI
<i>Percentage of income used for monthly payment calculation</i>	5% to 20%	1% to 10% for AGIs above \$10,000 \$10 for AGI \$10,000 or less
<i>Minimum monthly payment</i>	\$0	\$10
<i>Maximum repayment period</i>	10 to 25 years	30 years
<i>Interest subsidy</i>	Varies	All loans in negative amortization
<i>Matching principal payment</i>	None	For borrowers who repay less than \$50 in monthly principal, the lesser of: 1) \$50 or 2) monthly payment, minus monthly principal repaid

Some key distinctions that are unique only to the Repayment Assistance Plan include: the concept of “on-time,” the provision for matching principal payments, and special provisions on interest subsidy.

Section 455(q) of the HEA uses the phrase “on-time applicable monthly payment” in several places when discussing payments made under the Repayment Assistance Plan. Only payments made “on-time” are entitled to the principal match and the interest subsidy benefits, and only “on-time” payments count toward loan forgiveness through both the Repayment Assistance Plan and the PSLF program. However, Section 455(q) does not define the term “on-time.” The Department proposes, at § 685.209(o)(3), that a payment made under the Repayment Assistance Plan should be considered on-time if the payment is received on or before the due date for the current month and satisfies the due date for the current month, but after the due date for the previous month. This proposed language makes clear to borrowers the conditions under which a payment made for a month would be considered on-time for that month and how excess funds are treated. During the second session of negotiations, the RISE Committee expressed concerns about borrower payments that exceed the scheduled payment and how those excess funds would be treated, as well as how they would be treated for the purposes of eligibility for the special provisions in the Repayment Assistance Plan, such as the interest subsidy or the matching principal payment benefit. In general, the Department believes that a payment received in excess would not be considered an on-time payment under the Repayment Assistance Plan unless the borrower opts out of advancing the due date, as explained below. By advancing the due date because of a prepayment, you do not have a monthly balance due (until the amount of the prepayment no longer covers the monthly payment amount due) and those months are not considered as on-time payments. In drafting the NPRM, the Department noticed that the consensus text in § 685.209(o)(3) did not explain that a borrower would not receive a matching principal and interest subsidy for payments made without a due date, that is, payments that are made in excess of the necessary payment or those that are paid in advance when a due date has already been satisfied periods without a due date. The borrower may need to opt out of advancing the payment due date if they wish to receive a matching

payment. While, in publishing this NPRM, the Department invites comments on the entirety of the proposed text, we particularly invite comments that seek to assist the Department in clarifying this provision and that may aid in resolving any potential borrower confusion that may arise from this process.

Section 685.209 proposes the new statutory framework for IDR plans, including the Repayment Assistance Plan, and aligns the changes made by the OBBB to Section 455(d) of the HEA. Specifically, Section 455(d)(7)(A)(i)(II) of the HEA requires that, under the Tiered Standard repayment plan, the repayment period is determined based on the total outstanding principal of all the borrower’s Direct Loans at the time the borrower enters repayment under this plan. If a borrower receives an additional Direct Loan and enters or re-enters the Tiered Standard repayment plan, the repayment period must be recalculated to reflect the combined outstanding principal of all Direct Loans at that point of entry. This would make certain that the amortization schedule and repayment terms are appropriately adjusted to the borrower’s total loan debt and provides a consistent and equitable approach to repayment for all borrowers under the Tiered Standard repayment plan.

Because § 685.211(a) specifies that amounts received in excess of amounts due are considered prepayments and outlines the subsequent actions the Secretary would take (including advancing the due date of the next payment unless the borrower requests otherwise), the Department believes that these prepayments are only considered on-time under the Repayment Assistance Plan if made without advancing the due date. If a borrower opts out of advancing the due date, any prepayments would count toward the matching principal payment benefit and interest subsidy (to the degree that the borrower would be eligible for such subsidies).

To enable borrowers to make informed decisions on how to make prepayments, the Department would provide the borrower an option to opt-out of advancing the due date to receive the benefit of the matching principal payment or interest subsidy for the Repayment Assistance Plan. We believe this strikes the right balance to give borrowers discretion as to how they wish their prepayments to be treated and to ensure that such prepayment comports to the statute.

The Repayment Assistance Plan has unique provisions on matching principal payment and interest subsidy.

We reiterate that prepayments would not count for the matching principal payment and interest subsidy, unless the borrower requests not to advance the due date and makes a subsequent payment. This is because the Repayment Assistance Plan bases receipt of these two benefits upon receiving an on-time payment, as discussed earlier. Relatedly, if a borrower chooses to advance the due date while repaying under the Repayment Assistance Plan, they would still receive credit toward forgiveness under the Repayment Assistance Plan and the PSLF program but not receive the matching principal payment or interest subsidy because payment made without a corresponding due date cannot be considered an on-time payment. In general, Section 455(q)(1)(E) of the HEA provides that a borrower repaying under the Repayment Assistance Plan receives forgiveness of the remaining balance of the borrower’s loans after the borrower has satisfied 360 monthly payments, or the equivalent, over a period of at least 30 years. For purposes of the Repayment Assistance Plan, prepayments would count toward the 360 monthly payments necessary to obtain forgiveness under the Repayment Assistance Plan. We note that with respect to the number of prepayments that may count as a qualifying monthly payment toward forgiveness under § 685.209(k)(8), the number of prepayments borrower can make is limited to the number of months until their next recertification date. Similarly, prepayments would also count toward a qualifying monthly payment for purposes of PSLF in § 685.219. These proposed regulations make certain borrowers receive the benefits of receiving credit toward the required 360 payments required for forgiveness when prepaying.

Section 455(q) of the HEA, which establishes the Repayment Assistance Plan, is constructed similarly to Section 493C(a), which authorizes the Secretary to establish the IBR plans and uses a similar rationale for the calculation of monthly payment amounts. In both cases, the HEA provides that monthly payment amounts will be based upon the AGI of the borrower or, if a borrower is married and files a joint Federal income tax return, the combined AGI of the borrower and their spouse. (*Section 493C(a)(1)(3) and Section 493C(d); Section 455(q)(4)*). In neither case does the HEA specifically provide for the proration of such a borrower’s monthly payment if the borrower and their spouse both have student loan debt.

Despite the lack of statutory language expressly directing the Secretary to

prorate the monthly payment amounts for married borrowers who both have Federal student loan debt and file a joint Federal tax return; current regulations provide for such an adjustment for borrowers repaying under certain IDR plans. See § 685.209(e)(2)(i) and (g)(1)(i). The Department first adopted this approach in regulations promulgated in 2009. See 74 FR 36567 (Jul. 23, 2009). The Department wished to avoid unfairly penalizing married borrowers, as absent proration, the monthly loan payment for each spouse would increase proportionately to the other spouse's income, effectively counting each income twice and resulting in each borrower making substantially higher payments.

Similarly, while HEA Section 455(q) does not provide for proration for the Repayment Assistance Plan monthly payment amounts for borrowers who are married and filing jointly, because the Department has previously interpreted Section 493C to allow for proration of monthly payment amounts for such borrowers repaying under the IBR plans, the Department believes that it is proper and permissible to take the same approach here. The prior construction canon provides that when a words or phrases have been interpreted in an authoritative manner in the past, if those words or phrases are used by Congress again in a new statute, they are presumed to carry that same meaning in the new statute. See *Bragdon v. Abbott*, 524 U.S. 624, 645 (1998) (“When administrative and judicial interpretations have settled the meaning of an existing statutory provision, repetition of the same language in a new statute indicates, as a general matter, the intent to incorporate its administrative and judicial interpretations as well.”)

Here, we presume that Congress was aware of the proration approach used in the IBR plans (especially given the fact that Congress also amended Section 493C in the OBBB), and that Congress wanted to incorporate that same proration scheme in the Repayment Assistance Plan by using similar words and phrases relating to repayment calculations pertaining to married couples. And as a result, Congress used a similar statutory construction in crafting Repayment Assistance Plan. Had Congress intended to bar proration, we would have expected it to do so explicitly, as Congress does not typically make implicit changes to existing interpretations of statute. We presume that Congress was aware of this interpretation of the statute and would have altered it when amending this section, had it intended a different result. Given that the Repayment

Assistance Plan, like the IBR plans authorized by Section 493C, bases a borrower's monthly payment amount on the borrower's (and, if applicable, the borrower's spouses') AGI, and the fact that neither Section 455(q) or Section 493C reference proration of monthly payment amounts for borrowers who are married and filing jointly, it would be inconsistent for the Department to read Section 493C as allowing proration and Section 455(q) as not allowing proration.

Choice of Repayment Plan (§ 685.210)

Statute: Section 82001(d)(7) of the OBBB amends Section 455(d) of the HEA to specify that the Tiered Standard repayment plan and the Repayment Assistance Plan would be available for Direct Loans made on or after July 1, 2026.

Current Regulations: Section 685.210 contains the regulations on a Direct Loan borrower's choice of repayment plans upon entering repayment and the provisions under which a borrower may change repayment plans. Specifically, § 685.210(a) provides the borrower's ability to initially select a repayment plan of their choice for which that borrower is eligible. If a borrower does not select a repayment plan, the Secretary will assign the appropriate standard repayment plan; that is, either standard repayment on a ten-year repayment period or for Direct Consolidation Loans, a longer period depending on the outstanding balance. All of a borrower's Direct Loans must be repaid together under the same repayment plan, with certain exceptions allowed for PLUS Loans made to parent borrowers. Section 685.210(b) provides the borrower's ability to change repayment plans.

Proposed Regulations: The Department proposes to include provisions in § 685.210 that reflect the changes from the OBBB, and to restructure where needed. We propose to redesignate current § 685.210(a)(1) as § 685.210(a)(1)(i). We also propose to add § 685.210(a)(1)(ii), which provides that borrowers with Direct Loans made on or after July 1, 2026, may select the Tiered Standard repayment plan if those Direct Loans are otherwise eligible to be repaid under that plan or select the Repayment Assistance Plan if those Direct Loans are otherwise eligible to be repaid under that plan. We also propose to amend § 685.210(a)(2) to provide the conditions if a borrower does not select a repayment plan. Current § 685.210(a)(2) would be redesignated as § 685.210(a)(2)(i) to provide that, for Direct Loans made before July 1, 2026, if a borrower does not select a

repayment plan, the Secretary designates the applicable standard repayment plan; either standard repayment on a ten-year repayment period or for Direct Consolidation Loans, a longer period depending on the outstanding balance for the borrower. We propose to add § 685.210(a)(2)(ii) that would provide that, for Direct Loans made on or after July 1, 2026, if a borrower does not select a repayment plan, the Secretary designates the Tiered Standard repayment plan for the borrower. We also propose to add the following paragraphs: Section 685.210(a)(2)(iii)(A), which would provide that a borrower of a Direct PLUS Loan or an excepted consolidation loan that is not eligible for repayment under the Repayment Assistance Plan must repay the Direct PLUS Loan or excepted consolidation loan separately from other Direct Loans obtained by the borrower that are being repaid under the Repayment Assistance Plan; and, § 685.210(a)(2)(iii)(B), which would provide that a borrower who has received an excepted loan made on or after July 1, 2026, must repay the excepted loan under the Tiered Standard repayment plan and may repay the other Direct Loans separately from such excepted loan.

With respect to changing repayment plans, we propose to amend § 685.210(b) to limit the conditions under which a borrower may change repayment plans. Specifically, we propose to amend §§ 685.210(b)(1), (b)(2), (b)(3), and (b)(4)(ii) to clarify that those conditions apply only to Direct Loans made before July 1, 2026. We also propose to amend § 685.210(b)(4) to limit the conditions for borrowers repaying under the IBR plan and wish to pay under a different plan: under proposed § 685.210(b)(4)(i), we would provide that for Direct Loans made before July 1, 2026, if a borrower no longer wishes to pay under the IBR plan, the borrower must pay under the standard repayment plan or the Repayment Assistance Plan. We propose to clarify in § 685.210(b)(4)(i) that for the standard repayment plan, the Secretary recalculates the borrower's monthly payment based on the time remaining under the applicable repayment period and in proposed § 685.210(b)(4)(i)(B), we update a cross-reference to the repayment period under the standard repayment plan.

We propose to add § 685.210(b)(5), which would provide that for Direct Loans made on or after July 1, 2026, a borrower may change repayment plans at any time after the loan has entered repayment by notifying the Secretary. We further propose to add

§ 685.210(b)(5)(i) to provide that a borrower who is enrolled in the Tiered Standard repayment plan may change to the Repayment Assistance Plan. We further propose to add § 685.210(b)(5)(ii) to provide that a borrower who is enrolled in the Repayment Assistance Plan may change to the Tiered Standard repayment plan.

Reasons: The regulations are amended to reflect the changes made by the OBBB. The OBBB limits those loans to repayment under either the Tiered Standard repayment plan or the Repayment Assistance Plan and removes authority for other repayment plans for those loans. As a result of these statutory changes, the Department proposes to amend § 685.210 to codify the borrowers' choice between these two repayment plans, to describe the plan the Secretary assigns when a borrower does not select a plan, and to update the conditions under which borrowers with loans made before and after July 1, 2026, may change repayment plans so that the regulations align with the statute.

Under current § 685.210, a borrower entering repayment may select any repayment plan for which the borrower is eligible, and if the borrower does not choose a plan, the Secretary assigns the borrower to the standard 10-year repayment plan (or, for consolidation loans, a longer standard period based on the outstanding balance). All the borrower's Direct Loans generally must be repaid together under the same plan, with limited exceptions for certain PLUS loans, and borrowers may change repayment plans subject to conditions in § 685.210(b). In light of the OBBB's two-plan structure for new loans, we propose to distinguish more clearly between Direct Loans made before July 1, 2026, which have broader repayment options, and Direct Loans made on or after that date, which are limited by statute to the Tiered Standard repayment plan and the Repayment Assistance Plan.

We proposed to amend § 685.210(a)(1)–(2) to codify the initial choice of repayment plans for borrowers with new loans. For Direct Loans made on or after July 1, 2026, a borrower may select either the Tiered Standard repayment plan under § 685.208(c)(1) or the Repayment Assistance Plan under § 685.209, provided the loans are otherwise eligible for those plans. If a borrower with such loans does not select a repayment plan, the Secretary would designate the Tiered Standard repayment plan. This approach implements the OBBB's requirement that new loans be repaid only under the standard plan or Repayment Assistance

Plan while preserving borrower choice between those two options.

Designating the Tiered Standard repayment plan as the default plan when a borrower does not choose a plan is consistent with the statute's directive to offer a standard amortizing option, and as the RISE Committee discussions emphasized, providing simplified, predictable payments for borrowers who do not actively select an IBR plan.

We also proposed to revise § 685.210(a)(3) to incorporate the new statutory framework for "excepted loans," including Direct PLUS Loans and certain consolidation loans that are not eligible for the Repayment Assistance Plan under amended HEA Sections 455(d) and 493C(b). As reflected in the RISE Committee discussion drafts, all Direct Loans obtained by one borrower must generally be repaid together under the same plan, but borrowers with Direct PLUS Loans or excepted consolidation loans that are not eligible for the Repayment Assistance Plan may repay those loans separately from other Direct Loans that are repaid under the Repayment Assistance Plan. For excepted loans made on or after July 1, 2026, the proposed regulations require repayment under the Tiered Standard repayment plan and allow other Direct Loans to be repaid separately from those excepted loans. These changes are intended to carry out the OBBB's limits on the Repayment Assistance Plan eligibility for Parent PLUS Loans and certain consolidation loans while responding to the RISE Committee's concerns surrounding preserving clear rules for mixed portfolios and avoiding forced migration of legacy loans into the new two-plan structure.

We further propose to revise § 685.210(b) to align borrowers' ability to change repayment plans with the new statutory framework and to maintain protections for borrowers with existing loans. For Direct Loans made before July 1, 2026, proposed § 685.210(b)(1)–(4) would preserve borrowers' current ability to change to any repayment plan for which they are eligible, subject to existing conditions for defaulted loans and for borrowers leaving the IBR plan. These provisions maintain flexibility for legacy borrowers and reflect the OBBB's direction that the existing menu of repayment plans continues to apply to loans made before July 1, 2026, even as those plans sunset for new loans. During the RISE negotiations, Committee members provided scenarios that involved borrowers with loans made before, and after, July 1, 2026, and requested confirmation that those borrowers could continue to change

repayment plans for older loans, including moving between IBR and the Repayment Assistance Plan where permitted, without being required to collapse all loans into a single, new-loan framework. The proposed text is intended to provide that assurance.

We also propose to add § 685.210(b)(5) to govern changes in repayment plans for Direct Loans made on or after July 1, 2026. Under the Repayment Assistance Plan, a borrower with new loans may change plans at any time after the loans have entered repayment by notifying the Secretary, but only between the Tiered Standard repayment plan and the Repayment Assistance Plan. Borrowers who were initially placed in the Tiered Standard repayment plan, including those who did not select a plan, may later opt into the Repayment Assistance Plan, and borrowers enrolled in the Repayment Assistance Plan may move back to the Tiered Standard repayment plan. This structure provides borrowers ongoing flexibility to adjust their repayment strategy as their circumstances change, while honoring the OBBB's prohibition on offering additional repayment plans for new loans beyond the standard plan and the Repayment Assistance Plan.

Ultimately, we proposed conforming edits to cross-references and terminology in § 685.210 to reflect the new Tiered Standard repayment plan, the Repayment Assistance Plan, and the revised definition of "remaining repayment period" that now references both fixed repayment plans under § 685.208, and alternative repayment plans under § 685.221. These changes improve internal consistency and make it easier for borrowers, servicers, and institutions to understand how choice of repayment plan interacts with other statutory and regulatory provisions, such as consolidation under § 685.220 and PSLF under § 685.219.

The proposed amendments to § 685.210 implement the OBBB's two-plan framework for new loans, preserve reasonable plan-change options for existing borrowers, and respond to feedback from the RISE Committee requesting to simplify repayment choices while protecting borrowers with mixed cohorts and excepted loans.

Miscellaneous Repayment Provisions (§ 685.211)

Statute: Section 82003(a)(1) of the OBBB amended Section 428F(a)(5) of the HEA by increasing the number of times a borrower may rehabilitate a defaulted FFEL or Direct Loan from one time to two times. Section 82003(b) amended Section 428F(a)(1)(B) of the HEA to establish a \$10 minimum

monthly payment for rehabilitation of a Direct Loan beginning July 1, 2027. Section 82001(d) of the OBBB added Section 455(q)(1)(B) to the HEA that provides the order of precedence the Department applies payments in the Repayment Assistance Plan.

Current Regulations: Section 685.211 contains miscellaneous repayment provisions pertaining to the Direct Loan Program. Section 685.211(a)(1) provides the order of precedence when a Secretary applies a borrower's loan payment under an IDR plan. Section 685.211(d) provides repayment provisions pertaining to defaulted Direct Loans, including in § 685.211(d)(3), which outlines the actions the Secretary may take in the collection of a defaulted loan and the repayment plan the Secretary may designate for said defaulted borrower. Finally, § 685.211(f) contains the terms of rehabilitation of defaulted Direct Loans, including: in § 685.211(f)(1), listing the minimum payments that the Secretary considers a reasonable and affordable payment; in § 685.211(f)(11), indicating how administrative wage garnishment (AWG) interacts with the borrower's attempt to rehabilitate a defaulted loan; and, in § 685.211(f)(12), which lists the number of times a borrower may rehabilitate a defaulted loan.

Proposed Regulations: The Department proposes to include in § 685.211 the provisions that would provide application of payments for the respective repayment plans, the treatment of defaulted loans that are not excepted consolidation loans (*i.e.*, consolidation loans that repaid a Parent PLUS Loan), establish minimum payment amounts for Direct Loan borrowers in default, designate the Repayment Assistance Plan as the repayment plan for borrowers who default, and increase the number of times a borrower may rehabilitate a defaulted Direct Loan from one to two times.

Specifically, we propose to amend § 685.211(a)(1)(ii) to include how the Secretary applies a payment made under the Repayment Assistance Plan in the following order: accrued interest; collection costs and late charges; then to loan principal.

With respect to the treatment of defaulted loans that are not excepted consolidation loans and borrowers' access to certain IDR plans, we propose to amend § 685.211(d)(3)(ii) to clarify the types of Direct Consolidation loans that are eligible for this treatment: that is, Direct Consolidation loans that are not excepted consolidation loans. We further clarify the IDR plans available to borrowers who default on these loans:

the Secretary may designate the Repayment Assistance Plan or the IBR plan for the borrower.

With respect to loan rehabilitation and minimum payment amounts, we propose to amend the regulations at § 685.211(f)(1) to provide the minimum payment amounts based on a trigger date. Under proposed § 685.211(f)(1)(i)(A) and (B), for a borrower who is attempting to rehabilitate a defaulted loan before July 1, 2027, the Secretary initially considers the borrower's reasonable and affordable payment amount to be an amount equal to the minimum payment required under the IBR plan, except that if this amount is less than \$5, the borrower's monthly payment is \$5, and on or after July 1, 2027, that minimum payment would be \$10.

Under proposed § 685.211(f)(11)(iii)(B), on or after July 1, 2027, a borrower may only obtain the benefit of a suspension of AWG while also attempting to rehabilitate a defaulted loan a maximum of twice per loan. We further clarify the number of times a borrower may rehabilitate a defaulted Direct Loan: before July 1, 2027, and in proposed § 685.211(f)(12)(i)(A), a borrower may rehabilitate a defaulted Direct Loan only one time; and on or after July 1, 2027, and in proposed § 685.211(f)(12)(i)(B), a borrower may rehabilitate a defaulted Direct Loan only twice per loan.

Reasons: The regulations are amended to reflect the changes made by the OBBB. These proposed regulations expand the number of times a borrower may rehabilitate a defaulted loan and establish a \$10 minimum monthly payment for rehabilitating a Direct Loan beginning on or after July 1, 2027. The OBBB also created the Repayment Assistance Plan and aligned the treatment of payments made under that plan with the existing income-driven repayment framework, including borrowers in default. To codify these statutory changes, we would specify the application of payments made under the Repayment Assistance Plan to the monthly amount due, clarify the repayment plans the Secretary may designate for certain defaulted Direct Loans, revise the minimum "reasonable and affordable" payment for rehabilitation, and update the limits for a suspension of AWG and rehabilitation on a defaulted Direct Loan.

We note that although our proposed regulations establish a \$10 minimum monthly payment for rehabilitation of a Direct Loan beginning on or after July 1, 2027, the minimum monthly payment for a FFEL Program Loan rehabilitation

remains at \$5. Those regulations may be found at § 682.405.

The OBBB created the Repayment Assistance Plan as a new income-driven option and aligned it with existing statutory rules for payment application under IDR plans. To implement those changes, we propose to amend § 685.211(a)(1) so that references to how the Secretary applies a borrower's payment under the IBR plan also apply to payments made under the Repayment Assistance Plan. In the amended text, we add the Repayment Assistance Plan alongside IBR and clarify that, for these plans, the Secretary applies payments first to accrued interest, then to collection costs and late charges, and finally, to principal.

During the RISE Committee negotiations, non-Federal negotiators asked the Department to clearly spell out how payments made under the Repayment Assistance Plan would be treated, to avoid confusion about whether payments would first reduce principal or first cover interest and fees. The discussion draft language for § 685.211(a)(1) was updated to explicitly insert the Repayment Assistance Plan into the payment-application order and to reorganize the subparagraphs to more clearly distinguish interest, costs and late charges, and principal. These clarifications are intended to make the regulations easier to read, align with the statutory treatment of the Repayment Assistance Plan as an income-driven plan, and support consistent servicing practices across repayment plans.

To carry out this structure, we propose to amend § 685.211(d)(3)(ii) to clarify that when a borrower defaults on a Direct Subsidized Loan, Direct Unsubsidized Loan, a Direct Consolidation Loan that is not an "excepted consolidation loan" (*i.e.*, one that repaid a Parent PLUS Loan, as defined in § 685.209), or a student Direct PLUS Loan, the Secretary may designate the Repayment Assistance Plan or IBR for the borrower instead of ICR.

This change responds to the Committee's interest in providing that defaulted borrowers are not left in obsolete or less favorable plans and that they can access the modern IDR framework as they work their way out of default. At the same time, the proposed language respects the statutory limitations for excepted consolidation loans that repaid a Parent PLUS Loan, which remain ineligible for certain income-driven plans. By explicitly naming the Repayment Assistance Plan and IBR, and by cross-referencing the excepted consolidation loan definition in § 685.209, the proposal gives

servicers clear operational direction and helps borrowers understand which plans may be used to resolve a default.

During negotiations, non-Federal negotiators urged the Department to automatically place borrowers into an IDR plan after they either completed loan rehabilitation or consolidated their defaulted loan. These non-Federal negotiators also requested that the Department automatically recertify borrowers' FTI in subsequent years and choose a repayment plan as part of the rehabilitation agreement. They expressed concern that borrowers may resolve a default but fail to enroll in, or remain in, an affordable repayment plan, which may increase the likelihood of a second default.

The Department remains committed to providing borrowers who rehabilitate their defaulted loans with a clear path to affordable repayment. However, the Department cannot do so unilaterally. The HEA does not authorize the Secretary to select a repayment plan for a borrower who is no longer in default. Therefore, once a borrower is no longer in default, they must choose a repayment plan on their own behalf. Furthermore, the HEA does not authorize the Secretary to use borrowers' FTI information for the purpose of enrolling or recertifying their eligibility for an ICR or IBR plan without their affirmative consent, as Section 494(a) of the HEA, 20 U.S.C. 1098h, requires that "as [a] condition of eligibility for [income-contingent or income-based] repayment plan . . . individuals . . . affirmatively approve" FTI disclosures. 20 U.S.C. 1098h(a)(2). Consequently, rehabilitated borrowers must take action to select a repayment plan after finalizing their rehabilitation and provide their affirmative approval for the disclosure and use of their FTI.

Within these constraints, the Department intends to provide opportunities for borrowers to select a repayment plan earlier during loan rehabilitation and consolidation. The Department plans to enhance self-service tools so that borrowers can more easily enroll in income-driven repayment when their loans return to good standing and allow borrowers to authorize the use of FTI for purposes of determining eligibility for and maintaining enrollment in IDR plans. We believe these measures address the RISE Committee members' concerns for borrowers who are transitioning out of default and into an IDR plan.

These amendments would give borrowers and servicers a clearer and more uniform set of payment-handling rules under § 685.211, so that regular payments and prepayments are credited

consistently, counted appropriately for purposes such as delinquency, default, income-driven repayment, and PSLF, and applied in a way that aligns with the new repayment structure under the OBBB.

The OBBB amended the rehabilitation provisions to allow a borrower to rehabilitate a defaulted Direct Loan a maximum of two times and to increase the minimum payment amount used to determine a "reasonable and affordable" rehabilitation payment. Because of these statutory changes in the HEA, the Department proposes to amend § 685.211(f)(1) and (12) to reflect the statute. During the second session of the RISE Committee negotiations, non-Federal negotiators requested that borrowers be permitted to begin their rehabilitation before July 1, 2027, and so long as it is completed after July 1, 2027, completion would be permitted as one of the allowances toward the second rehabilitation. We note that the effective date for the second rehabilitation attempt cannot begin until July 1, 2027, because the changes to the HEA regarding loan rehabilitations take effect *beginning* on July 1, 2027 (emphasis added) as provided in Section 82003(a)(3) of the OBBB, and, as such, a borrower cannot begin a second rehabilitation until on or after the effective date.

The Department explained during negotiations that the intent of these changes is to give borrowers in default an additional chance to cure a default and reenter repayment, while avoiding repeated cycles of default and rehabilitation that can undermine the purpose of rehabilitation. During negotiations, non-Federal negotiators questioned if a borrower used the pathway of the Fresh Start initiative³⁰ to return their defaulted loans to repayment status in 2022, whether that instance would be considered to have rehabilitated their defaulted loans and if that using this would be considered toward the borrower's limit of rehabilitation. The Department clarified that participation in the Fresh Start initiative is not a rehabilitation. As discussed with the RISE Committee, a borrower who resolved a default solely through Fresh Start would still have two opportunities to rehabilitate later default(s) under the new statutory framework. Any actual rehabilitation completed during the payment pause or at another time—where the borrower entered into a rehabilitation agreement

and made the required payments—is a rehabilitation for purposes of the OBBB limit and counts toward the borrower's rehabilitations. These clarifications were made as a response to the RISE Committee's concerns and are consistent with the commitment the Department made to explain this unique situation further in the preamble and on the Department's website that Fresh Start itself does not count as one of the rehabilitations permitted under the OBBB.

Non-Federal negotiators asked the Department to clarify how borrowers who complete loan rehabilitation would move into IDR plans, including the Repayment Assistance Plan. Specifically, these non-Federal negotiators were interested in how the Department would treat prepayments for purposes of the matching principal and interest subsidy under the Repayment Assistance Plan. They stressed that borrowers who have successfully resolved a default should have a straightforward path into affordable repayment and that the Repayment Assistance Plan benefits should not be lost because a borrower paid ahead on their loan. We discuss how the Department treats prepayments under the Repayment Assistance Plan in the section titled "Income-Driven Repayment Plans" (§ 685.209) in this proposed rule.

As discussed above, borrowers who exit default may select an IDR plan, including the Repayment Assistance Plan, and may authorize the Department to use FTI to determine their eligibility and payment amounts. To accomplish this, we intend to design processes for rehabilitation and consolidation so that borrowers are informed of their repayment options, can authorize the use of FTI to enroll in the Repayment Assistance Plan, and can complete these steps through accessible channels, including online self-service tools, as well as describing such processes and requirements in greater detail in guidance and communications to borrowers.

With respect to the Repayment Assistance Plan, non-Federal negotiators asked how the Department will treat borrowers who make a lump-sum prepayment on their loan and also continue to make their required monthly payments on time. The statute and these regulations provide that the Secretary may make matching principal and interest subsidy payments for borrowers who make monthly on-time payments under the Repayment Assistance Plan. We intend to clarify in the regulations and servicer instructions that a borrower's eligibility for the

³⁰ Federal Student Aid, U.S. Dept of Educ., *A Fresh Start for Borrowers with Federal Student Loans in Default* (Fact Sheet) (last updated July 11, 2024), <https://fsapartners.ed.gov/sites/default/files/2022-08/FreshStartFactSheet.pdf>.

Repayment Assistance Plan matching payments is contingent upon (1) the borrower having a monthly payment due, and (2) the borrower making that payment on time. The matching principal and interest subsidy is not based on whether the borrower has previously made prepayments that reduce the number or size of future installments. Likewise, borrowers may not receive subsidies while in periods of nonpayment, like in-school deferment or the six-month grace period. A borrower who continues to have scheduled monthly payments due and makes those payments on time will continue receiving the matching principal and interest subsidy, if all other eligibility criteria is met, even if the borrower has previously paid ahead on the loan.

The RISE Committee also addressed how many times a borrower may rehabilitate a defaulted Direct Loan and how often they may receive the benefit of a temporary suspension of AWG while attempting rehabilitation. In line with those discussions and consistent with OBBB, the Department proposes to amend § 685.211(f)(11) and (12) to:

- Clarify that before July 1, 2027, a borrower may obtain the benefit of a suspension of AWG while attempting to rehabilitate a defaulted Direct Loan only once;
- Provide that, on or after July 1, 2027, a borrower may obtain the benefit of a suspension of AWG while attempting to rehabilitate a defaulted Direct Loan a maximum of two times per loan; and
- Clarify that for defaulted Direct Loans rehabilitated on or after August 14, 2008, and before July 1, 2027, a borrower may rehabilitate the loan only once, while for defaulted Direct Loans on or after July 1, 2027, a borrower may rehabilitate the loan a maximum of two times, and not again if the loan returns to default after the second rehabilitation.

The RISE Committee highlighted that borrowers in default may face multiple, overlapping collection tools—such as AWG and the Treasury Offset Program—which may make it harder to complete rehabilitation successfully. Non-Federal negotiators asked the Department to consider stopping collections sooner once a borrower demonstrates good-faith efforts to rehabilitate. The Department noted that it already stops AWG after five voluntary payments, uses discretion to sequence other collection tools, and respects borrower choice, including when disclosing FTI needed for certain repayment plans.

By codifying the number of rehabilitations and the number of times

AWG may be suspended during rehabilitation, the proposed regulations would provide borrowers with up to two opportunities to exit default.

Several non-Federal negotiators asked the Department to include proposed regulations that would cease AWG upon completion of the rehabilitation agreement and once the borrower begins making the agreed upon payments. They argued that continuing to garnish wages while a borrower is successfully making voluntary payments would create unnecessary hardship and discourage borrowers from completing rehabilitation. The Department recognizes that the use of AWG during rehabilitation must be balanced against the need to support borrowers' successful completion of rehabilitation and their transition to affordable repayment. Under § 685.211(f)(1), borrowers need to make nine voluntary payments to complete rehabilitation. The Department intends to provide greater detail on our website and provide additional information about AWG through materials sent to the borrowers during the rehabilitation process.

Additionally, these same non-Federal negotiators also requested that the Department automatically enroll borrowers in e allowing the release of FTI process from the IRS at the time a borrower enters the rehabilitation agreement, so that the borrower could more easily move into an IDR plan once the loan is returned to good standing (*i.e.*, after the ninth payment has been completed).

The Department is exploring ways to obtain consent from the borrower to disclose their FTI information to the Department at the time of rehabilitation to facilitate a borrower's enrollment into an affordable repayment plan once their loans are returned to good standing. We believe these operational approaches can support the goal, identified by non-Federal negotiators, of increasing successful transitions from default into sustainable repayment.

Public Service Loan Forgiveness (§ 685.219)

Statute: Section 82004(b)(1) through (3) of the OBBB amends Section 455(m)(1)(A) of the HEA to specify the qualifying repayment plans that are eligible for the purposes of PSLF. Section 82004(3) of the OBBB amends Section 455(m)(1)(A)(v) of the HEA to clarify that only “on-time” payments made under the Repayment Assistance Plan will also qualify for PSLF.

Current Regulations: Section 685.219 contains the provisions of the Public Service Loan Forgiveness Program

(PSLF). Under § 685.219(b), we define *qualifying repayment plan* as an IDR plan under § 685.209.

Proposed Regulations: The Department proposes to amend § 685.219. Specifically, proposed § 685.219(b) would expand the definition of a qualifying repayment plan for PSLF purposes, to include the new Repayment Assistance Plan and to codify that the ICR plans are scheduled to sunset on July 1, 2028; therefore, only payments made on or before June 30, 2028, would count toward PSLF. We propose to amend § 685.219(c), borrower eligibility, to correct corresponding cross references that payments made on a 10-year standard repayment plan under § 685.208(b)(1) and payments made on the consolidation loan standard repayment qualify for PSLF forgiveness.

Proposed § 685.219(c)(2)(v), clarifies that when a borrower is enrolled in the Repayment Assistance Plan under § 685.209, the time spent under one of the forbearances or deferments listed, would not be considered as having made a monthly payment toward PSLF for the purposes of forgiveness. In effect, the change prevents borrowers from counting months toward time to forgiveness when not making on-time payments.

Proposed § 685.219(g)(6) would clarify that months during which a borrower is enrolled in the Repayment Assistance Plan under § 685.209 are not eligible for reconsideration credit. This amendment would make certain that such months may not be counted toward PSLF through the reconsideration process, even when the borrower was employed full-time by a qualifying employer.

Reasons: The regulations are amended to reflect the changes made by the OBBB. Under the PSLF program, a borrower working in qualifying public service could have the remaining balance of their Direct Loans forgiven after they have made the equivalent of 120 qualifying monthly payments under a qualifying repayment plan. The OBBB added the Repayment Assistance Plan as a qualifying repayment plan for the PSLF program. Accordingly, the Department proposes to codify in 685.219(b) that the Repayment Assistance Plan is a qualifying repayment plan for the PSLF program and that payments made under current qualifying repayment plans will continue to count until June 30, 2028.

In addition, Congress specified in Section 455(m)(1)(A)(v) of the HEA, as added by Section 82004(3) of the OBBB, that only “on-time payments” made under the Repayment Assistance Plan

may be treated as qualifying PSLF payments. To implement this requirement, the Department proposes to clarify in § 685.219(b) and (c) how “on-time payments” under the Repayment Assistance Plan are determined, consistent with the existing PSLF framework for qualifying payments. Under the proposed regulations, a payment made under the Repayment Assistance Plan would be considered “on-time” for PSLF purposes if it meets the same timing and amount conditions that apply to other qualifying payments under § 685.219. We believe this approach reaffirms Congress’s decision to limit PSLF credit under the Repayment Assistance Plan to on-time payments, while providing clear, administrable standards for borrowers and servicers and maintaining alignment with the broader PSLF qualifying payment rules.

With respect to on-time payments under the Repayment Assistance Plan and how prepayments would be treated for PSLF purposes, as we explain above that if a borrower prepays, and the due date advances while on the Repayment Assistance Plan, they would still receive credit toward forgiveness for PSLF and the Repayment Assistance Plan but would not receive the matching principal payment or interest subsidy.

These changes would provide borrowers, employers, and servicers with a clearer and more predictable PSLF framework under § 685.219 that aligns with the OBBB amendments; therefore, the risk of miscounted qualifying payments is reduced so that borrowers who meet the statutory requirements would receive timely forgiveness.

Consolidation (§ 685.220)

Statute: Section 82005(a)(1)–(3) of the OBBB amended Section 455(g) of the HEA to reflect repayment plan eligibility for Direct Consolidation Loans. Section 82005(b) of the OBBB provides that the effective date of this statutory change is July 1, 2028.

Current Regulations: This section establishes the rules for Direct Consolidation Loans under the Direct Loan Program, including which loans can be consolidated, borrower eligibility, how loan consolidation is processed, interest rates, repayment terms, and other specific provisions (e.g., joint consolidation loans). Section 685.220(d) sets the borrower eligibility rules for getting a Direct Consolidation Loan, including permissible loan status, limits on judgments and garnishments, as well as when and how existing consolidation loans can be reconsolidated (e.g., to access ICR, IBR,

PSLF, or non-interest active-duty benefits). Section 685.220(h) provides that a borrower may choose among the available repayment plans for a Direct Consolidation Loan, and change plans later, under the referenced repayment sections. Section 685.220(i) explains when the repayment period for Direct Consolidation Loan starts and how its length is determined (including special rules for loans made before and after July 1, 2006, and establishes a grace period rule for certain older consolidations).

Proposed Regulations: The Department proposes to amend § 685.220 to permit defaulted borrowers to consolidate their loans for the purpose of obtaining access to IDR plans to address their default. Before July 1, 2028, defaulted borrowers may consolidate to gain access to the IDR plans. On or after July 1, 2028, defaulted borrowers may consolidate to gain access to the IBR plan or the Repayment Assistance Plan.

Specifically, we propose to amend § 685.220(d)(2)(i) by creating two clauses that further clarify borrower eligibility for a Direct Consolidation Loan before and after July 1, 2028, respectively, clause (A) and (B). Clause A would provide that before July 1, 2028, a borrower that has a Federal Consolidation Loan that is in default or has submitted to the guaranty agency by the lender for default aversion and wants to consolidate the Federal Consolidation Loan into the Direct Loan program may do so for the purpose of obtaining an ICR plan or an IBR plan. However, new clause (B) will state that a borrower, on or after July 1, 2028, that meets the same eligibility criteria, may consolidate for the purpose of obtaining the IBR plan or the Repayment Assistance Plan.

We further propose to amend § 685.220(h) to clarify the available repayment plans a borrower may choose for a Direct Consolidation Loan, and available plans a borrower may change to later. We will create two new paragraphs, (1) and (2), which would specify the two timeframes. By creating paragraph (1) we modify the existing subsection to specify a Direct Consolidation Loan made before July 1, 2026. By creating paragraph (2) we add the available repayment plans a borrower may choose between: the Tiered Standard repayment plan, or the Repayment Assistance Plan, in accordance with §§ 685.208, 685.209 and may change repayment plans in accordance with § 685.210(b) for a Direct Consolidation Loan made on or after July 1, 2026. Lastly, we propose to amend § 685.220(i), the repayment

period, by making corresponding cross references changes to the citations currently listed in section (i).

Reasons: The Department proposes to amend § 685.220 to reflect the changes made by the OBBB. Section 82001(e) of the OBBB, which amends Section 455(g) of the HEA to limit the repayment plans available to Federal Direct Consolidation Loans made on or after July 1, 2026, and related amendments to Sections 455(d) and 493C of the HEA, require conforming changes to the Department’s consolidation regulations in § 685.220.

Consistent with these statutory requirements and the discussion during the RISE Committee sessions, the Department proposes three primary amendments to § 685.220. First, we revise § 685.220(d) to implement the OBBB’s statutory authority for defaulted borrowers to use consolidation as a route into income-driven repayment. The proposed text clarifies that, because consolidation is generally an option for borrowers to get out of default, defaulted borrowers may consolidate their loans for the purpose of obtaining access to IDR plans to resolve the default. Before July 1, 2028, such borrowers may consolidate to gain access to existing income-driven plans, and on or after July 1, 2028, they may consolidate to gain access to the Repayment Assistance Plan. This responds to Committee feedback that regulations should preserve a meaningful consolidation-based path out of default while aligning with the new statutory dates and plan structure.

The Department wishes to make a technical correction under § 685.220(d)(2)(i)(B). During negotiated rulemaking, the RISE Committee reached consensus on the draft regulations in § 685.220. After reviewing the statute, we believe that § 685.220(d)(2)(i)(B) needs to be amended.

Although Section 82001(c)(2)(B) of the OBBB amended Section 428C(a)(3)(B)(i)(V)(aa) of the HEA to say that a borrower may obtain a Direct Consolidation Loan for the purposes of obtaining access to the Repayment Assistance Plan or IBR on or after 2028, Section 455(g)(3) of the HEA provides that a Direct Consolidation Loan made on or after July 1, 2026, may only be repaid under Repayment Assistance Plan or the Tiered Standard repayment plan. Therefore, a borrower who obtains a Direct Consolidation Loan on or after July 1, 2026, for purposes of getting out of default may only select the Repayment Assistance Plan. Accordingly, we propose § 685.220(d)(2)(i)(B) to read as follows:

On or after July 1, 2028, the borrower has a Federal Consolidation Loan that is in default or has been submitted to the guaranty agency by the lender for default aversion, and the borrower wants to consolidate the Federal Consolidation Loan into the Direct Loan Program for the purpose of obtaining the Repayment Assistance Plan; or.

We believe this correction would make clear that, on or after July 1, 2028, a borrower who chooses the path of consolidation to rectify their default may only select the Repayment Assistance Plan because it is the only repayment plan that would be available to them.

Second, we revise § 685.220(h) to align the repayment-plan options for Direct Consolidation Loans with the OBBB's streamlined menu of plans for loans "made on or after July 1, 2026." Under the proposal, a Direct Consolidation Loan made before July 1, 2026, may continue to be repaid under the full set of fixed and income-driven plans for which the borrower is eligible, reflecting the legacy repayment structure and avoiding disruption for existing borrowers.

For Direct Consolidation Loans made on or after July 1, 2026, borrowers would be limited to the Tiered Standard repayment plan and the Repayment Assistance Plan, consistent with the amended HEA provisions governing repayment plans for new loans and the Department's broader effort, as discussed with the RISE Committee, to simplify choices for new borrowing. This approach carries out the OBBB's directive to restrict plan options for new loans while preserving previously available options for earlier consolidation loans and ensuring that regulatory treatment of consolidation loans is consistent with the new framework for "excepted loans" and "excepted consolidation loans" defined in §§ 685.209 and 685.210.

Third, we propose revisions to § 685.220(i) to update cross-references and clarify how the Secretary determines the repayment period for consolidation loans in light of the OBBB's limits on repayment plans and loan types. These amendments maintain the existing structure under which the repayment term for a Direct Consolidation Loan is based on the borrower's total eligible education debt while updating citations and terminology to conform to the revised fixed-payment provisions in § 685.208 and the new statutory categories of loans and repayment plans. The Department did not identify substantive issues regarding repayment-period

calculations during the RISE Committee negotiations. These edits are necessary to avoid confusion to make certain that repayment-period rules for consolidation loans remain internally consistent and aligned with the amended HEA.

Collectively, these amendments to § 685.220 implement the OBBB's consolidation-related directives by codifying a statutory consolidation pathway into income-driven repayment for defaulted borrowers, limiting repayment-plan choices for new Direct Consolidation Loans to the Tiered Standard repayment plan and the Repayment Assistance Plan consistent with the OBBB repayment system.

Alternative Repayment Plans (§ 685.221)

Statute: Section 82001(f) of the OBBB amends Sections 493C and 455(q) of the HEA to redefine "excepted consolidation loan," revise the formula for the applicable payment amount, update the terms under which borrowers and loans are eligible for income-based repayment, and establish new annual eligibility and automatic recertification procedures.

Current Regulations: Section 685.221 sets out the Secretary's authority and rules for using an alternative repayment plan for a Direct Loan, including how such plans are structured and the requirement that the loan be repaid within 30 years (excluding deferment and forbearance). Section 685.221(a) provides the Secretary the authority to grant a borrower an alternative repayment plan if the borrower demonstrates, to the Secretary's satisfaction, the repayment plans under §§ 685.208 and 685.209 do not adequately accommodate the borrower's exceptional circumstances.

Proposed Regulations: The Department proposes to amend § 685.221 to condition a borrower's potential eligibility for an alternative repayment plan to a borrower who has not received a Direct Loan on or after July 1, 2026, and who otherwise would meet the conditions. Specifically, we propose to amend § 685.221(a) to add a condition that the Secretary may provide an alternative repayment plan to a borrower who has not received a Direct Loan on or after July 1, 2026. Additionally, we propose to add new subsection (e) to further clarify that the alternative repayment plan only applies to Direct Loans made before July 1, 2026.

Reasons: The regulations are amended to reflect the changes made by the OBBB. Section 82001(f) of the OBBB amended Section 493C(a)(2) of the HEA to redefine "excepted consolidation

loans," thereby limiting which loans may enter IBR or Repayment Assistance Plan. These statutory changes necessitate conforming revisions to § 685.221 so that the alternative repayment plan remains a narrow safety valve for Direct Loans made before July 1, 2026. The revisions also make sure that the alternative repayment plan does not function as a de facto additional repayment option for new or excepted loans under the OBBB framework.

During the RISE Committee negotiations, the Department explained that, because the OBBB sunsets alternative repayment plans for new loans and the regulations establish the Tiered Standard repayment plan and the Repayment Assistance Plan as the primary choices for new borrowers, the alternative repayment plans should remain a rare, case-by-case safety valve limited to Direct Loans made before July 1, 2026; non-Federal negotiators did not raise objections to this approach. In the RISE Committee discussion paper on miscellaneous loan repayment provisions and PSLF, the Department therefore proposed to amend § 685.221 by: (1) revising paragraph (a) to condition eligibility for an alternative repayment plan on the borrower not having received a Direct Loan on or after July 1, 2026, and demonstrating that the plans in §§ 685.208 and 685.209 are not adequate to accommodate the borrower's exceptional circumstances; and (2) adding paragraph (e) to make clear that an alternative repayment plan "shall only apply to Direct Loans made before July 1, 2026." During the RISE Committee session on September 29, 2025, the Department presented these changes as part of a broader effort to set sunset dates for the legacy arrangements and to limit alternative repayment plans to loans made before July 1, 2026. Negotiators acknowledged this approach was consistent with the statutory mandate.

The Department further refined this proposal during the RISE Committee by clarifying the date-based limitation in § 685.221(a) (that the borrower has not received a Direct Loan on or after July 1, 2026) and inserting new § 685.221(e) to state expressly that repayment under this section applies only to Direct Loans made before July 1, 2026. These changes preserve a limited, case-specific mechanism for addressing exceptional circumstances for legacy borrowers, while ensuring that borrowers with loans made on or after July 1, 2026, select among the Tiered Standard repayment plan and the Repayment Assistance Plan (or Tiered Standard only for excepted loans), consistent with the OBBB's simplified repayment

structure. Aligning § 685.221 with these statutory requirements clarifies the scope of available repayment options, prevents the alternative repayment plan from duplicating or displacing the new primary repayment pathways for future borrowers, and promotes continuity and equitable treatment for borrowers whose loans and repayment histories predate the OBBB.

Processing Loan Proceeds (§ 685.303)

Statute: Section 81001(2) amends Section 455(a)(7) of the HEA to limit a borrower total annual amount of Direct Loans for which they may be eligible and corresponding edits were required for loan disbursements.

Current Regulations: Section 685.303 provides the rules for processing Direct Loan proceeds to borrowers. Specifically, § 685.303(d)(5) provides that an institution must disburse Direct Loan proceeds in substantially equal installments, and no installment may exceed one-half of the loan.

Proposed Regulations: We propose to waive the requirement in § 685.303(d)(5) for institutions to disburse Direct Loans in substantially equal installments for borrowers who are subject to the award year loan limit for less than full-time enrollment and the institution would disburse in accordance with the schedule of reductions.

Reasons: The regulations are amended to reflect the changes made by the OBBB. Section 81001(2) of the OBBB added Section 455(a)(7) to the HEA that limits a borrower from receiving the total annual amount of Direct Loans for which they may be eligible if they are enrolled on a less than full-time basis. According to Section 455(a)(7)(A), this reduction for a less than full-time enrollment provision is applicable notwithstanding any other Direct Loan and FFEL Program Loan statutory provisions. After reviewing the rules on the requirement to disburse Direct Loan proceeds in substantially equal disbursements, the Department believes providing an exception to this disbursement requirement is necessary to fulfill the intent of Congress to reduce a Direct Loan for less than full-time enrollment.

VII. Regulatory Impact Analysis

Executive Orders 12866 and 13563

Under E.O. 12866, the Office of Management and Budget (OMB) must determine whether a regulatory action is “significant” and, therefore, subject to the requirements of the E.O. and subject to review by OMB. Section 3(f) of E.O. 12866 defines a “significant regulatory

action” as an action likely to result in a rule that may:

(1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles stated in the E.O.

The Department estimates the downward net budgetary impacts to be –\$439.7 billion from changes in transfers between the Federal Government and student loan borrowers resulting from changes in annual and lifetime loan limits; the introduction of Repayment Assistance Plan and Tiered Standard repayment plans, and additional repayment plan changes; proration for less than full-time enrollment; the elimination of economic hardship and unemployment deferments; limitations on the length of discretionary forbearance; and the definition of a professional student. Quantified economic impacts include annualized transfers of –\$45.5 million at 3 percent discounting and –\$47.6 million at 7 percent discounting, paperwork burden (\$12.5/\$18.6 million) administrative updates to Government systems (\$10.4/\$12.1 million) and staffing (\$5.5/\$6.0) at 3 percent and 7 percent discounting, respectively. Therefore, based on our estimates, the Office of Information and Regulatory Affairs (OIRA) has determined that this proposed rule is “economically significant” under section 3(f)(1) of E.O. 12866 and subject to OMB review 3(f)(1).

We have also reviewed these regulations under E.O. 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in E.O. 12866. To the extent permitted by law, E.O. 13563 requires that an agency:

(1) Propose or adopt regulations only on a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and

considering, among other things, and to the extent practicable, the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives, such as user fees or marketable permits, to encourage the desired behavior, or provide information that enables the public to make choices.

E.O. 13563 also requires an agency “to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.” OIRA has emphasized that these techniques may include “identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.”

This proposed rule is not expected to be an E.O. 14192 regulatory action because it does not impose any more than de minimis net regulatory costs. E.O. 14192 directs agencies of the executive branch to be prudent and financially responsible in the expenditure of funds, from both public and private sources, and to alleviate unnecessary regulatory burdens placed on the American people. In line with those goals, this proposed rule estimates quantified economic impacts include annualized transfers of –\$45.5 billion at 3 percent discounting and –\$47.6 billion at 7 percent discounting.

Consistent with OMB Circular A–4, we compare the proposed regulations to the current regulations. In this Regulatory Impact Analysis (RIA), we discussed the need for regulatory action, potential costs and benefits, net budget impacts, and the regulatory alternatives we considered.

Elsewhere in this section under the Paperwork Reduction Act (PRA) of 1995, we identify and explain burdens specifically associated with information collection requirements. We estimate a net increase of 6,474,114 burden hours annually. For purposes of the RIA, we assume these tasks are conducted by Postsecondary Education Administrators with 2024 median wages of \$49.98. This wage is multiplied by two to account for overhead and benefits, resulting in hourly costs of \$99.96. This implies annual costs of

\$318.6 million in year one, \$222.3 million in year two, \$45.3 million in year three, and recurring cost reductions of – \$60.9 million from year four. Some burden detailed in the PRA involves systems changes that are not expected to be recurring costs that were split over the first three years with 45 percent of the burden in the first year, 40 percent in the second and the remaining 15 percent in the third year. Recurring costs were estimated to start in FY2027 and contributed to the difference between year one and year two costs. In some areas, we are not currently able to estimate costs and benefits related to paperwork burden. However, these effects are described qualitatively. More detail is provided in the PRA section.

Costs and Benefits: As further detailed in the Regulatory Impact Analysis, the proposed regulations would have significant costs and benefits to students, borrowers, educational institutions, and taxpayers.

First, the OBBB reduces Federal loan access for students attending less than full-time. Under prior policy, these students could borrow as if they were attending full-time. This provision would reduce revenue for institutions and access to loans for students, which could require that they make changes to their pricing and program offerings. Part-time students may also make different educational choices in response to the lost loan access. Second, the OBBB would affect the decisions and behavior of graduate and professional students, and the institutions who enroll them, due to the new graduate and professional loan limits. These limits will have the largest effect on students and institutions where private lenders are unwilling to fully replace lost access to Federal

loans. Third, the OBBB reduces forbearance and deferment options for borrowers, which may increase defaults and delinquencies, although other policy changes in the OBBB may mitigate the effects of these outcomes. Fourth, parents of undergraduates have new limits on the amount of loans they may borrow through the Parent PLUS Loan program. That change is likely to cause some institutions to modify their prices and program offerings and could also cause students to change their educational choices.

There are numerous benefits from the proposed regulations. First, borrowers and students will benefit through new loan repayment terms, such as monthly interest subsidization and principal payment matching under the Repayment Assistance Plan, and the ability to rehabilitate defaulted loans a second time. Second, new limits on Federal loans for graduate and professional students, and caps on Parent PLUS Loans, will also discourage institutions from raising tuition prices. These new loan limits will also discourage institutions from offering high-cost, low-value credentials that cannot attract loans from private sources, putting more downward pressure on prices that institutions are able to charge. Third, the regulations will produce significant savings to the taxpayer by reducing loan forgiveness benefits under income-driven repayment options and by capping loans for graduate and professional students which is explained in greater detail in the Regulatory Impact Analysis section. The reduction in loan forgiveness benefits are also likely to reduce moral hazard in the loan program because students will bear more of the costs of the debt they take out.

In this RIA, we discuss the need for regulatory action, the potential costs and benefits of the proposed regulations, the net budget impacts, and the regulatory alternatives we considered in cases where the Department had discretion. Throughout this RIA, we compare the proposed regulations to a pre-statutory baseline under which the OBBB has not been enacted, unless otherwise stated.

1. Need for Regulatory Action

These proposed regulations are needed to implement certain provisions of the OBBB that affect students, borrowers, and the title IV, HEA program participants. The OBBB amended numerous provisions of the HEA affecting the terms and eligibility criteria for students and institutions of higher education that participate in the Federal student loan program. The Department has limited discretion in implementing many provisions in the OBBB. Many of the changes included in these proposed regulations simply modify the Department's regulations to reflect statutory changes made by the OBBB.

In some cases, the Secretary has exercised her limited discretion to implement certain provisions of the OBBB. Areas of limited discretion include the treatment of married borrowers repaying under the Repayment Assistance Plan and the definition of a professional student for the purposes of qualifying for higher annual and aggregate loan limits. These areas of discretion are included in the discussion of alternatives section.

2. Summary

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Table 2.1 – Summary of Key Changes in the Proposed**Regulations**

Provision	Regulatory Section	Description of proposed provision
OBBB		
Definitions	§ 685.102	Would define a professional student as a student enrolled in a professional degree program, which is a program that requires completion of the academic requirements for beginning practice in a given profession, and a level of professional skill beyond that normally required for a bachelor's degree; is generally at the doctoral level; requires at least six academic years of postsecondary education coursework for completion, including at least two years of post-baccalaureate level coursework; generally requires professional licensure to begin practice; includes a four-digit program CIP code, in the same intermediate group as the fields of Pharmacy (Pharm.D.), Dentistry (D.D.S. or D.M.D.), Veterinary Medicine (D.V.M.), Chiropractic (D.C. or D.C.M.), Law (L.L.B. or J.D.), Medicine (M.D.), Optometry (O.D.), Osteopathic Medicine (D.O.), Podiatry (D.P.M., D.P., or Pod.D.), Theology (M.Div., or M.H.L.), and Clinical Psychology (Psy.D. or Ph.D.).
Establishment of Repayment Assistance Plan and Tiered Standard Repayment Plan	§ 685.209 § 685.208	Would establish two repayment options for new borrowers as of July 1, 2026: a tiered standard repayment plan with fixed, fully amortizing payments and longer terms for higher balances (10 to 25 years); and an income-based repayment plan that sets payments based on

		share of income, provides loan forgiveness after 30 years of payments, waives unpaid interest monthly, and provides a matching principal payment up to \$50 per month.
Graduate and Professional Loan Limits	\$ 685.203	Would limit annual and aggregate Direct student loans for graduate and professional students beginning July 1, 2026. Graduate students would be subject to a \$20,500 annual limit and a \$100,000 aggregate limit. Professional students would be subject to a \$50,000 annual limit and a \$200,000 aggregate limit.
Parent PLUS Loan Limits	\$ 685.203	Would limit Parent PLUS Loans for dependent undergraduates beginning July 1, 2026. Parents would be limited to \$20,000 annually (per child) and \$65,000 aggregate (per child).
Prorated loans for less than full-time enrollment	\$ 685.203	Would reduce Direct Loan disbursements in direct proportion to the degree to which a student is not so enrolled on a full-time basis.
Elimination of Economic Hardship and Unemployment Deferments	\$ 685.204	Would eliminate the economic hardship and unemployment deferments for loans issued on or after July 1, 2027.
Forbearance limited to 9 months per 24-month period	\$ 685.205	Would limit discretionary forbearances on Direct loans to 9 months in a 24-month period for new loans made on or after July 1, 2027.
Allow second rehabilitation on defaulted loans	\$ 674.39 \$ 682.204 \$ 685.405	Would allow all borrowers with a defaulted loan to rehabilitate a second time, on or after July 1, 2027.

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3. Discussion of Costs and Benefits

The proposed regulations change many provisions related to the terms and benefits available to borrowers in the Federal student loan program, resulting in both costs and benefits for

students, borrowers, institutions, private companies, and taxpayers. Note that costs to one party which are completely offset by benefits to another party are classified as transfers, as required by OMB Circular A-4.

The provisions in the OBBB that produce significant costs or benefits

include new annual and aggregate loan limits for graduate and professional students, as well as parents who borrow under the Parent PLUS Program. Under the policy preceding the OBBB, loans to these borrowers were available up to the full cost of attendance with no aggregate limit. The OBBB also reduces the

amount of loans students may receive when they enroll less than full-time. Prior policy made no distinction between full-time and less than full-time attendance with respect to loan eligibility; students attending on at least a half-time basis could receive the same loan disbursement as if they were attending full-time.³¹

The OBBB also replaces all prior IDR plans in the Federal student loan program for new borrowers and loans with a new plan, the Repayment Assistance Plan. Features of the Repayment Assistance Plan will result in costs for some borrowers but benefits

for others. The OBBB also reduces forbearance and deferment benefits for borrowers in the Federal student loan program but allows borrowers to receive additional loan rehabilitation benefits.

Costs of the Proposed Regulations

The proposed regulations would impose costs on students, institutions, the Department, and private companies. A major source of costs for both institutions and borrowers is the reduction in student loans disbursements that will occur as a result of the policy changes enacted by the OBBB. Between 2026–2035, the

Department estimates that the proposed regulations will result in 9.9 million fewer non-consolidated student loans issued, and a total reduction in non-consolidated Federal student loan disbursements by \$223.9 billion (Table 3.1). This decline is driven by the reduction in loan disbursements in Graduate Stafford and Graduate PLUS Loans (\$171 billion) and Parent PLUS Loans (\$49 billion). As shown in Table 3.1 the reduction in non-consolidated loans also decreases future consolidation loan volume, which does contribute to the net budget impact of the changes.

Table 3.1 - Estimated Changes in Total Federal Student Loan Disbursements Pre- and Post-OBBB, 2026–2035

	Loans (millions)		Disbursed (\$ millions)	
	Pre	Post	Pre	Post
Undergrad	94.5	93.4	\$355,842	\$352,085
Grad Stafford & PLUS	22.2	13.9	\$436,437	\$265,542
Parent PLUS	7.9	7.3	\$154,140	\$104,881
Non-Consolidated Loan Difference		-9.9		-\$223,911
Consolidation	12.8	8.4	\$454,638	\$338,687

Note: Borrower counts projected by the Department are not unduplicated across cohorts, and loan counts were used to provide a sense of the effect of the OBBB loan limit provisions. The relationship between the number of loans and borrowers varies somewhat by loan type, risk group, and cohort but is approximately 1.67 loans annually per undergraduate borrower, 1.28 loans annually for Parent PLUS, and 1.3 loans annually for graduate students. Source: Student Loan Model volume assumption for PB2026 and OBBB cost estimates.

The reduction in loan volume is due to several policy changes imposed by the OBBB. First, prior to the OBBB, graduate students and parents of dependent undergraduates were able to borrow up to an institution’s full cost of attendance annually and with no aggregate limit. Beginning July 1, 2026, the OBBB imposes annual and aggregate limits on these loans. Annual limits for graduate students, professional students, and parents are \$20,500, \$50,000, and \$20,000, respectively. The aggregate limits are \$100,000, \$200,000, and \$65,000 (per dependent student of the parent), respectively. The new loan limits do not apply to borrowers who

are currently enrolled in higher education programs who had received Federal loans made prior to July 1, 2026. In other words, the new limits apply only to new borrowers on or after July 1, 2026.

Second, a reduction in loan volume will occur due to the proration of loans for students enrolled less than full-time. Beginning July 1, 2026, the OBBB imposes new loan limits for students enrolled less than full-time. Specifically, a student will only be able to borrow up to a prorated annual limit based on the individual borrower’s enrollment status. Prior to the OBBB, undergraduate and graduate students

could borrow up to the full annual loan limit, as long as they were enrolled at least half-time.

Table 3.2 describes the number of borrowers and loan volume that could be affected by the proration provision using Department data from FY 2025. Of the \$92.7 billion in nonconsolidation Federal student loans disbursed in FY 2025, \$84 billion was disbursed to full-time students. The remaining disbursements (\$8.7 billion) were to students enrolled less than full-time and would therefore be subject to the prorated annual loan limit beginning July 1, 2026.

³¹ Students attending less than half time are not eligible for Federal student loans.

Table 3.2 - Distribution of Non-Consolidated Borrowers and Loan Disbursements in FY 2025 by Enrollment Status (millions)

Enrollment Status	Program	Borrowers (unduplicated)	Loan Volume (excluding Parent PLUS) PLUS)	Parent PLUS Loan Volume
Full-Time	2-Yr Undergrad	0.6	\$4,493.4	\$402.5
	4-Yr Undergrad	4.0	26,573.5	12,255.2
	Grad	1.2	40,309.8	-
	Total	5.8	71,376.6	12,657.7
Less than Full-Time	2-Yr Undergrad	0.2	1,054.1	17.6
	4-Yr Undergrad	0.4	3,318.9	76.9
	Grad	0.2	4,263.1	-
	Total	0.8	8,636.1	94.6
Grand Total		6.5	80,012.7	12,752.2

Note: Full-time includes all students who were enrolled as a full-time student at any point during FY 2025. Less than full-time includes students who were never enrolled as full-time during FY 2025.

Source: Department analysis using National Student Loan Data System (NSLDS) data.

These loan limits will create several new costs for borrowers relative to pre-OBBB policy. First, borrowers may have to reduce their enrollment due to the inability to afford the cost of their program. This could delay the time it takes students to finish their program. Second, students may need to seek other forms of financing to maintain their enrollment, such as by pursuing employment while enrolled or taking out private loans. Private loans may have less favorable terms than Federal student loans, meaning some students and parents who utilize these financing options could face higher interest rates and fees. Third, some students and parents may not be able to secure non-Federal loans to replace the borrowing capacity lost under the OBBB, whether

that be because non-Federal lenders deem the programs and institutions the students attend to be financially risky, or because the borrowers do not have adequate credit histories or cannot obtain a co-signer. Some of these borrowers may have to drop out of their program due to their inability to afford their program through alternative means. These effects will require some affected borrowers to reconsider their enrollment and financing decisions. These, in turn, may have further effects, such as on timing of when individuals enter the labor force and their career choices.

The changes to Federal student loan limits create indirect costs for institutions. Institutions of higher education will receive less loan revenue

from the Federal government if those loans are used to cover education expenses paid directly to the institution, such as tuition and fees. While that revenue may be replaced by students securing other sources of financing or using more of their own funds to pay for postsecondary education, some of it may not be replaced. This will cause a loss of revenue for institutions. These institutions are likely to incur costs determining their best response to these changes, which may include reducing tuition prices or restructuring their programs. Table 3.3 shows that loan disbursements to institutions will differ across sector and may be largest for institutions that enroll large shares of graduate students.

Table 3.3 - Estimated Changes in Federal Student Loan Disbursements Pre- and Post-OBBB by Sector, 2026-2035

	Total Dollars Disbursed (\$ millions)		Number of Loans (millions)	
	Pre	Post	Pre	Post
A. For-Profit 2-Year				
Undergrad	19,798	19,644	5.8	5.7
ParentPLUS	3,147	2,932	0.3	0.3
B. Non-Profit and Public 2-Year				
Undergrad	34,859	34,409	10.2	10.1
ParentPLUS	1,141	987	0.1	0.1
C. 4-Year Freshman and Sophomore				
Undergrad	148,909	146,944	43.3	42.7
ParentPLUS	85,648	61,318	4.2	4.0
D. 4-Year Junior and Senior				
Undergrad	152,276	151,088	35.2	35.0
ParentPLUS	64,204	39,644	3.2	2.9
E. Graduate				
Grad	436,437	265,542	22.2	13.9
F. Consolidation				
Not-from-Default	364,392	327,487	8.6	7.9
From Default	90,246	11,200	4.2	0.6

Beyond the costs associated with changes to Federal student loan limits, another source of costs to borrowers are through changes to student loan repayment plans. The OBBB creates a new student loan repayment plan, the Repayment Assistance Plan, which replaces all prior IDR plans beginning on July 1, 2026. The Repayment Assistance Plan will create new costs for borrowers relative to a pre-OBBS baseline. Borrowers' payments in the Repayment Assistance Plan are calculated on a sliding scale relative to their incomes, ranging from 1 percent for borrowers with \$10,000 of annual income, to 10 percent for borrowers earning \$100,000 or more. Although those terms will result in similar monthly payments for many borrowers compared with some prior IDR plans, monthly payments will be higher for all borrowers compared to repayment terms

that were available under the SAVE plan.³²

Some low-income borrowers will also face higher costs under the Repayment Assistance Plan compared to any prior IDR plan due to higher monthly payments. Unlike prior IDR plans, there is no exempted income under the Repayment Assistance Plan. This means monthly payments are calculated using the borrower's entire income. The Repayment Assistance Plan also includes a minimum payment amount, which requires borrowers earning less than \$10,000 annually to pay \$10 per month. Prior IDR plans allowed borrowers to make \$0 payments if their

incomes were below the level of exemption.

The Repayment Assistance Plan also reduces loan forgiveness benefits relative to prior IDR plans. Some of that loss in benefits is, however, offset by the Repayment Assistance Plan's interest subsidies and new principal payment matching discussed later in the RIA. The Repayment Assistance Plan provides loan forgiveness to borrowers who make a total of 360 on-time payments in the plan. Prior IDR plans generally provided loan forgiveness after 20 or 25 years of payments, although the SAVE plan would have provided loan forgiveness in as early as 10 years for undergraduate borrowers with lower balances.

A final repayment-related cost for borrowers results from changes to forbearance options. The OBBB reduces the time that a borrower may use a forbearance to 9 months in any 24-month period. Prior policy allowed

³² Cohn, J. Blagg, K. Delisle, J. (2025). House Republicans' Proposed Income-Driven Repayment Plan for Student Loans How Reforms in the 2025 Budget Reconciliation Bill Would Affect Borrowers, *Urban Institute*, (https://www.urban.org/sites/default/files/2025-05/House_Republicans_Proposed_IDR_Plan_for_Student_Loans.pdf).

borrowers 12-month forbearances for up to three years. The OBBB also eliminates the economic hardship deferment and unemployment deferment as options for borrowers with new loans made on or after July 1, 2027. As with changes to loan limits, changes to repayment may affect enrollment, financing, and labor market decisions for affected borrowers.

The proposed regulations will also impose administrative costs on the Department to implement the changes to the Federal student loan program (Table 2.1). We estimate that, based on comparable changes made in the past, those administrative costs would average approximately \$23.86 million (using a 3 percent discount rate, Table 4.4) in systems modifications, contract change requests, and staffing costs on an annual basis over the 2026–2035 period. The majority of these estimated costs, 62 percent, will be incurred during the first three years of implementation.

The Department will incur administrative costs as it works with the private companies that administer the Federal student loan program (loan servicers) to update their systems, training, and communications to implement and operate the two new repayment plans in the OBBB: the Repayment Assistance Plan and the Tiered Standard plan by July 1, 2026. The Department is also updating its systems for loan origination and repayment tracking to align them with the changes to loan limits and repayment plans. One of these systems, the Common Origination and Disbursement (COD) system, is designed to support origination, disbursement, and reporting for Direct Loan, Federal Pell Grant, and the Teacher Education Assistance for College and Higher Education (TEACH) Grant programs. The system uses a single “Common Record” (XML format) for efficiency and eliminating duplicate student and borrower data, providing a centralized system for title IV program administration used by the Department and all institutions across the country that participate in the delivery of Federal student aid. The other system that will be updated, the National Student Loan Data System (NSLDS), is the central database for all Federal student aid, tracking title IV loans and grants (like Pell Grants) through their entire lifecycle, from approval to repayment or closure. The system provides an integrated view for students, schools, and servicers to manage aid, loan status, balances, and enrollment. It consolidates data from schools, lenders, and programs, enabling users to access loan history,

disbursement details, and servicer information via the FSA Partner Connect portal.

The COD system and NSLDS must be modified to reflect the terms of the new repayment plans (which include new features, such as matching principal payments), new annual and lifetime loan limits for graduate and professional students and Parent PLUS Loans, and elimination of Graduate PLUS Loans. For the COD system, these changes include updates to current fields and the collection of additional fields, such as modifications to grade level definitions. In addition, new system edits will be added to account for loan limit exceptions and other changes. For NSLDS, these changes reflect new reporting requirements for servicers and system changes to account for new aggregate loan limits and exceptions that must now be tracked to determine borrower eligibility. In addition, NSLDS will be updated to account for new pre- and post-screening processes related to aggregate loan limits and new academic levels that account for the different loan limits for graduate and professional students.

While most of the administrative costs the Department will incur implementing the OBBB occur in the first few years, the Department will incur long-term administrative costs maintaining the Department’s COD, NSLDS, and other system changes in future years to account for ongoing development, operations, and maintenance. The Department does not estimate that it will incur a large increase in long-term administrative costs with respect to payments to loan servicers. The Department pays loan servicers based on monthly borrower counts and the Department does not expect the number of student loan borrowers to change significantly in the future due to changes in the OBBB. The Department will, however, incur additional costs to monitor data reported by loan servicers. The Department expects to incur additional administrative costs to train and support institutions of higher education that now must align their procedures and systems with the new loan disbursement policies in the OBBB.

Benefits of the Proposed Regulations:

The proposed regulations provide benefits to students, borrowers, and taxpayers. These benefits include potentially lower tuition costs for students, simplified repayment terms for student loan borrowers, and lower costs for taxpayers. Benefits to students and borrowers are discussed first, followed by the benefits to taxpayers.

The first benefit to students and borrowers stems from the new limits on

Federal student loans for graduate and professional programs. Research finds that these loan limits could provide an incentive to institutions to limit tuition increases, benefitting current and future students.³³ Due to the pressure these loan limits may have on tuition, more students may be able to enroll in graduate school, persist to graduation, and incur lower costs.

A Federal Reserve Bank of Philadelphia Working Paper (2024) indicated that higher net prices are associated with higher student borrowing, and that this relationship is particularly evident at the graduate program level, where annual borrowing limits generally do not bind. The paper suggests that tuition inflation alone does not explain changes in borrowing. While the correlation does not establish causation, it may reflect bidirectional dynamics, including both higher prices driving greater student borrowing and expanded capacity for student borrowing.³⁴ The paper suggests factors beyond rising sticker prices may drive borrowing, with students sometimes choosing more expensive higher-quality programs or institutions with better amenities, leading to higher net costs and greater borrowing.

Similarly, the OBBB’s limits on graduate loans will help reduce the number of degree programs that result in low earnings relative to the prices institutions charge. Prior research has found that approximately 43 percent of master’s degrees and 23 percent of doctoral and professional degrees do not increase students’ earnings enough to justify the costs of those programs.³⁵ Because private lenders’ decisions to provide credit is in large part based on students’ future ability to repay, some of these low-value programs are unlikely to attract private loans to fully replace lost Federal student loans and are therefore expected to shrink in both size and number.³⁶ Such an outcome will

³³ Black, S. Turner, L. Denning, J. (2023). PLUS or Minus? The Effect of Graduate School Loans on Access, Attainment, and Prices. *NBER Working Paper 31291* (<https://doi.org/10.3386/w31291>).

³⁴ Adam Looney, “How Much Does College Cost and How Does It Relate to Student Borrowing? Tuition Growth and Borrowing over the Past 30 Years,” Federal Reserve Bank of Philadelphia, Working Paper 24–16 (Sept. 2024), DOI: 10.21799/frbp.wp.2024.16.

³⁵ Cooper, Preston. (2024). Does College Pay Off? A Comprehensive Return On Investment Analysis. *Foundation for Research on Equal Opportunity* (<https://freopp.org/whitepapers/does-college-pay-off-a-comprehensive-return-on-investment-analysis/>).

³⁶ Akers, B. Cooper, P. (2024). How Private Student Lending Can Repair Higher Education. *American Enterprise Institute* (<https://www.aei.org/research-products/report/how-private-student-lending-can-repair-higher-education/>).

increase earnings for individuals throughout the economy, as students shift towards programs that provide a stronger return on investment or choose not to enroll in postsecondary education and instead enter the labor force. In turn, such an outcome will reduce taxpayer subsidies for individuals who would otherwise use loans to finance these lower earning credentials.

Borrowers will also benefit through changes to repayment provisions. The first repayment-related benefit for borrowers is the new provision that allows borrowers who default on Federal student loans to rehabilitate a second time. Prior to the OBBB, borrowers were allowed to rehabilitate a defaulted loan only once. Under rehabilitation, a borrower makes a series

of nine on-time payments that fulfill the rehabilitation agreement and return their loans to good standing, and the Department then requests that the credit reporting bureau remove the default from the borrower's record. A second rehabilitation will benefit borrowers by providing borrowers who re-default a pathway to return their loans to good standing and, in turn, increase their ability to purchase a home, automobile, or other items financed through consumer credit markets as result of the removal of the default from their record. This provision will also allow defaulted borrowers to avoid administrative wage garnishments, the Treasury Offset Program, and collection fees associated with defaulted loans.

The second repayment-related benefit for borrowers is through the new loan repayment terms provided under the Repayment Assistance Plan. These benefits stem from several provisions. First, relative to most existing IDR plans (such as IBR but not SAVE), some borrowers using the Repayment Assistance Plan will see a reduction in their calculated monthly payment. Table 3.4 shows that relative to IBR (for new borrowers as of 2014), monthly payments are lower under the Repayment Assistance Plan for borrowers with adjusted gross incomes between \$30,000 and \$70,000. For borrowers with an adjusted gross income lower than \$30,000, monthly payments only differ marginally, by approximately \$10 to \$22 per month.

Table 3.4 - Monthly Payments Under IBR and the Repayment Assistance Plan

Adjusted Gross Income	IBR	RAP
Under \$10,000	\$0	\$10
\$10,001-\$20,000	0	13
\$20,001-\$30,000	20	42
\$30,001-\$40,000	103	88
\$40,001-\$50,000	187	150
\$50,001-\$60,000	270	229
\$60,001-\$70,000	353	325
\$70,001-\$80,000	437	438
\$80,001-\$90,000	520	567
\$90,001-\$100,000	603	713
\$100,000-\$110,000	687	875

Note: Monthly payment amounts are based on the midpoint for each category of adjusted gross income. IBR monthly payments assume a single borrower with no dependents using the 2024 Federal poverty line (\$15,060).

Second, some borrowers will receive new benefits under the Repayment Assistance Plan that have historically not been available on prior IDR plans. The Repayment Assistance Plan waives unpaid interest for borrowers with on-time payments that do not fully cover accruing interest. That benefit applies to all loan types at any point in repayment. Prior IDR plans generally did not waive all unpaid interest on all types of loans at any point in repayment (with the exception of the SAVE plan).

Third, the Repayment Assistance Plan includes a new principal subsidy for borrowers who are not reducing their principal balance. Under this plan, the Department matches borrowers' payments dollar-for-dollar, up to \$50 in loan principal reduction each month. No prior IDR plan included a principal subsidy such as the one included in the Repayment Assistance Plan.

Together, these provisions prevent borrowers' loan balances from increasing while they repay under the Repayment Assistance Plan, and some

of these policies would disproportionately benefit low-income borrowers. Unlike prior IDR plans, the loan balances of borrowers using the Repayment Assistance Plan will decline each month if they make an on-time payment, because their unpaid interest is first fully waived, and the Department then reduces their principal balance equal to the payments the borrower makes, up to \$50.

To better understand these benefits, the Department simulated how future cohorts of borrowers would benefit

under the Repayment Assistance Plan relative to existing repayment plans. The Department used data from the College Scorecard and Integrated Postsecondary Education Data System (IPEDS) to create a synthetic cohort of

borrowers. Using Census Bureau data, the Department projected earnings and employment, marriage, spousal debt, spousal earnings, and family size for each borrower up to age 60. Using these projections, payments under different

loan repayment plans can be calculated for the full length of time between repayment entry, and full repayment or forgiveness.

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Table 3.5 - Projected Repayment Outcomes by Outstanding Balance at Repayment Entry Under SAVE, IBR, the Repayment Assistance Plan, and Tiered Standard repayment plan

Repayment Plan	Outstanding Balance at Repayment Entry			
	Less than \$25,000	\$25,000-\$49,999	\$50,000-\$99,999	\$100,000 or Greater
SAVE				
Years in Repayment	11.5	17.6	19.9	21.8
Years Not Reducing Balance	5.7	8.2	8.9	11.6
Percent of Borrowers Receiving Forgiveness	64.5	53.6	51.8	66.5
Repayment Ratio	0.56	0.65	0.73	0.68
IBR				
Years in Repayment	12.8	14.6	16.2	17.9
Years Not Reducing Balance	5.6	6.1	6.8	9.9
Percent of Borrowers Receiving Forgiveness	22.8	34.2	48.6	68.4
Repayment Ratio	0.94	0.89	0.87	0.77
RAP				
Years in Repayment	9	11.9	13.7	17.5
Years Not Reducing Balance	0	0	0	0
Percent of Borrowers Receiving Forgiveness	4.5	7.6	9.3	17.7
Repayment Ratio	0.92	0.91	0.94	0.95
Tiered Standard				
Years in Repayment	10	15	20	25
Repayment Ratio	1.07	1.03	1.12	1.05
Average annual earnings at repayment entry	\$31,253	\$37,542	\$58,685	\$74,791
Average annual family earnings at repayment entry	\$35,973	\$42,864	\$67,335	\$86,086
Percent of Borrowers with Graduate Loans	1.2	47.5	100	100

Note: The repayment ratio is defined as the share of a borrower's initial balance that is ultimately repaid in present value terms.
Source: Department analysis completed using data from the College Scorecard, Integrated Postsecondary Education Data System, and the Census Bureau.

Using these simulations, Table 3.5 illustrates borrower repayment outcomes across different repayment plans. Under the Repayment Assistance Plan, borrowers spend fewer years both in repayment and where they are not reducing their loan balance, on average, relative to other types of income-driven repayment plans. Further, for borrowers with initial loan balances less than

\$50,000, borrowers will fully repay their loans faster under the Repayment Assistance Plan while paying a similar amount (in present value terms) than they would under IBR, as shown by the repayment ratio in table 3.5.

The changes in the OBBB also produce significant savings to taxpayers. These savings are summarized in Table 3.6 (note that interactive budget effects

are not included in these estimates). The largest benefits to taxpayers—which are the focus of the following discussion—come from changes to student loan repayment plans. These changes are estimated to save taxpayers \$121.8 billion in modifications to cohorts from 1994–2025, and another \$246.5 billion in outlays between 2026–2035.

Table 3.6 - Net Budget Effects for Major Student Loan Changes in OBBB (\$ in millions)

Policy	Modification for Cohorts 1994–2025	Change in Budget Outlays, 2026–2035
Grad and Professional Loan Limits	-	-\$51,809
ParentPLUS Loan Limits	-	2,801
Prorated loans for less than full-time enrollment	-	-15,361
Changes to Repayment plans, Including Income-Driven Repayment	-\$121,830	-246,460
Elimination of Economic Hardship & Unemployment Deferment	-	148
Options and Limitations on Forbearance	-	-
Allow Additional Loan Rehabilitation	-	-
Updated Definition of Professional Student	-	112

Note: Estimates reflect policy scored in isolation compared to President's Budget 2026 baseline, except for repayment plan changes, which are scored including the effects of loan limits on the Repayment Assistance Plan and the revised distribution of volume to the Tiered Standard and Repayment Assistance Plan plans from FY2027 onward.

These changes to repayment plans benefit taxpayers for several reasons. First, the OBBB eliminates the SAVE plan, producing significant savings.³⁷ Eight million borrowers had enrolled in SAVE, and more than half (4.5 million) qualified for a \$0 monthly payment.³⁸ These borrowers must now enroll in a different repayment plan and will begin making larger payments than under SAVE.

Second, under the Repayment Assistance Plan, larger proportions of loans will be repaid, saving taxpayers money. This is seen in the average repayment ratio (defined as the share of a borrower's initial balance that is

ultimately repaid in present value terms) shown in Table 3.5. Under the Repayment Assistance Plan, the repayment ratio is consistently higher than other IDR plans. This is because the Repayment Assistance Plan requires borrowers to repay their loans for longer (30 years instead of 10 to 25 years under prior plans) before qualifying for loan forgiveness, because monthly payments are calculated using a borrower's full income, and because there is a minimum monthly payment requirement.

Third, the Repayment Assistance Plan also requires borrowers with higher incomes to make higher monthly payments than prior IDR plans, and the income brackets used to determine the monthly payment amount under the Repayment Assistance Plan are not indexed to inflation. Together, these changes will increase the amount borrowers are expected to repay in future years, reducing costs to taxpayers. Lastly, these features will discourage over-borrowing, as the terms of the Repayment Assistance Plan reduce the moral hazard associated with IDR relative to previous plans with shorter repayment periods and lower

total payments.³⁹ Similarly, these features are likely to discourage institutions from offering programs that lead to low earnings relative to students' debts because borrowers will now bear more of their loan repayment costs. That in turn will benefit taxpayers and the broader economy by better aligning higher education costs with graduates' potential earnings. Due to the terms of the Repayment Assistance Plan, fewer borrowers are likely to use this new plan than would have repaid under prior IDR plans.

To better understand these benefits, the Department modeled the share of loan volume repaid through different repayment plans using the cohort of loans entering repayment in 2030. These estimates are shown in Table 3.7. Prior to the OBBB, the Department estimated that, for loans entering repayment in 2030, 59 percent of unsubsidized graduate loans and 67 percent of Graduate PLUS Loans were expected to be repaid through an IDR plan. After the OBBB, the Department now estimates that, for the same cohort, 47 percent of

³⁷ OBBB eliminated the authority for the Department to offer income-contingent repayment plans under Section 493C of the HEA beginning after July 1, 2028. The Department is currently operating the ICR and PAYE repayment plans relying upon that authority. The SAVE plan also purportedly relied upon that authority, but the Department is enjoined from implementing that plan. See *Missouri v. Biden*, 112 F.4th 531, 538 (8th Cir. 2024).

³⁸ White House Press Release, President Joe Biden Outlines New Plans to Deliver Student Debt Relief to Over 30 Million Americans Under the Biden-Harris Administration, (April 8, 2024, available at <https://bidenwhitehouse.archives.gov/briefing-room/statements-releases/2024/04/08/president-joe-biden-outlines-new-plans-to-deliver-student-debt-relief-to-over-30-million-americans-under-the-biden-harris-administration/>).

³⁹ Delisle, J. and Holt, A. (2014). Zero Marginal Cost. (<https://www.newamerica.org/education-policy/policy-papers/zero-marginal-cost/>); and Fu, Chao et. (2025). Moral Hazard and the Sustainability of Income-Driven Repayment Plans. (<https://www.nber.org/papers/w33411>).

unsubsidized graduate loans and 55 percent of Graduate PLUS Loans will be repaid through an IDR plan. The Department estimates that graduate	borrowers will enroll in the standard repayment plan at higher rates (relative to pre-OB BB policy), reducing the	amount of loan volume that could be forgiven. BILLING CODE 4000-01-P

Table 3.7 - Estimated Shares of Direct Loan Volume in Repayment for Cohort 2030, Pre- and Post-OB BB by Loan Type and Repayment Plan

	Cohort 2030					
	Subsidized		Unsubsidized		PLUS	
	Pre	Post	Pre	Post	Pre	Post
2-year Proprietary						
Standard / Tiered Standard	62%	63%	59%	60%	92%	100%
Extended / Graduated	11%	0%	11%	0%	8%	0%
IDR Plans	27%	37%	30%	40%	0%	0%
RAP	N/A	75%	N/A	75%	N/A	75%
Other IDR Plans	100%	25%	100%	25%	100%	25%
2-year Not-for-Profit & Public						
Standard / Tiered Standard	56%	69%	54%	68%	90%	100%
Extended / Graduated	7%	0%	8%	0%	10%	0%
IDR Plans	37%	31%	38%	32%	0%	0%
RAP	N/A	88%	N/A	88%	N/A	88%
Other IDR Plans	100%	12%	100%	12%	100%	12%
4-year Freshman and Sophomore						
Standard / Tiered Standard	58%	59%	58%	58%	90%	100%
Extended / Graduated	6%	0%	7%	0%	10%	0%
IDR Plans	36%	41%	35%	42%	0%	0%
RAP	N/A	89%	N/A	89%	N/A	89%
Other IDR Plans	100%	11%	100%	11%	100%	11%
4-year Junior and Senior						
Standard / Tiered Standard	50%	55%	49%	53%	83%	100%
Extended / Graduated	8%	0%	9%	0%	17%	0%
IDR Plans	42%	45%	42%	47%	0%	0%
RAP	N/A	84%	N/A	84%	N/A	84%
Other IDR Plans	100%	16%	100%	16%	100%	16%
Graduate						
Standard / Tiered Standard	N/A	N/A	32%	53%	26%	45%
Extended / Graduated	N/A	N/A	9%	0%	6%	0%
IDR Plans	N/A	N/A	59%	47%	67%	55%
RAP	N/A	N/A	N/A	93%	N/A	93%
Other IDR Plans	N/A	N/A	100%	7%	100%	7%
Consolidated Not-from-Default						
Standard / Tiered Standard	1.2%	33%	0.5%	26%	0.5%	100%
Extended / Graduated	21.4%	0%	13%	0%	99.5%	0%
IDR Plans	77.4%	67%	87%	74%	0%	0%
RAP	N/A	89%	N/A	89%	N/A	89%
Other IDR Plans	100%	11%	100%	11%	100%	11%
Consolidated From Default						
Standard / Tiered Standard	0.5%	25%	0.2%	23%	100%	100%
Extended / Graduated	18.9%	0%	13.1%	0%	0%	0%
IDR Plans	80.6%	75%	86.8%	77%	0%	0%
RAP	N/A	75%	N/A	75%	N/A	75%
Other IDR Plans	100%	25%	100%	25%	100%	25%

Note: First three rows within each section represent the distribution of all volume in the category for the 2030 repayment cohort. The indented rows capture the split in volume between the Repayment Assistance Plan and other income-driven plans among borrowers assigned to IDR plans.

Source: The Department's Student Loan Model percent volume assumption of repayment plan distribution and IDR sub-model plan distribution for year 10 for PB2026 and OB BB cost estimates.

This includes both the effects of a modification to existing loan cohorts and costs for loan cohorts from 2026 to 2035. A cohort reflects all loans originated in a given fiscal year. Consistent with the requirements of the Credit Reform Act of 1990, budget cost estimates for the Federal student loan programs reflect the estimated net present value of all future non-administrative Federal costs associated with a cohort of loans. The baseline for

estimating the cost of these final regulations is the President's Budget for 2026 (PB2026) as modified for the effects of the OBBB and the PSLF final rule published on October 31, 2025. There was a modification executed in September 2025 to reflect the provisions of the OBBB as understood at that time, and without the PSLF regulation in that baseline. We will describe that score in this Net Budget Impact along with the score of discretionary changes made in

the negotiations, primarily related to the definition of professional student for the application of higher loan limits. The Department expects to have an updated baseline for the President's Budget for FY 2027 before publication of the final rule and does expect some changes in the scores of the provisions against that new baseline.

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Table 4.1 - Estimated Budget Impact of the NPRM (\$ in millions).

Section	Description	Modification Score (1994-2025)	Outyear Score (2026-2035)	Total Score (1994-2035)
\$ 685.208 \$ 685.209	Establishment of RAP and Tiered Standard Repayment Plan and other changes in repayment plans*	-\$121,830	-\$246,460	-\$368,290
\$ 685.203	Graduate and Professional Loan Limits		-51,809	-51,809
\$ 685.203	Parent PLUS Loan Limits		2,801	2,801
\$ 685.203	Prorated loans for less than full-time enrollment		-15,361	-15,361
\$ 685.204	Elimination of Economic Hardship and Unemployment Deferments		-2,083	-2,083
\$ 685.205	Forbearance Limited to 9 months per 24-month period		1,246	1,246
	Total combined effect of OBBB statutory loan program changes	-131,091	-319,838	-450,929
\$ 685.102	Change to professional student definition to use 4-digit CIP and include Clinical Psychology (Psy.D. and Ph.D.)		112	112

Note: Estimates reflect policy scored in isolation compared to PB2026 baseline, except for the repayment plan changes score, which included effects of loan limits on Repayment Assistance Plan and revised distribution of volume to the Tiered Standard Plan and the Repayment Assistance Plan from FY 2027 on. Total combined effect reflects all changes, including any interactive effects between the provisions. The total combined effect and the baseline include statutory changes that will be negotiated in future rulemaking sessions. The estimate of the update to the professional student definition is scored off the baseline that includes the OBBB statutory changes.

Tiered Standard repayment plan, and associated eligibility provisions for borrowers with all loans disbursed before July 1, 2026, and those with loans disbursed on or after July 1, 2026; elimination of the availability of economic hardship and unemployment deferments for loans disbursed on or after July 1, 2027; discretionary forbearances limited to a period that does not exceed nine months within a 24-month period; annual and aggregate loan limits; the ability to undergo a second loan rehabilitation; definition of qualifying payments for the purposes of the PSLF program to include ICR plans only up to July 1, 2028 and the Repayment Assistance Plan, and certain deferments not counting towards PSLF fulfillment under the Repayment Assistance Plan; elimination of Graduate PLUS Loans with some grandfathering for existing borrowers; and other provisions as detailed and described in this NPRM.

Overall, these provisions have a net budget impact of –\$319 billion between outyears 2026 and 2035, and of an additional \$131 billion in modifications from 1994 to 2025 (Table 4.1). Several provisions reduce transfers from the Federal government to borrowers, such as the modifications to repayment plans, the new loan limits for graduate and professional students, and the proration for less than full-time students. Other provisions increase transfers from the Federal government to borrowers, such as the new loan limits for parent borrowers on behalf of dependent undergraduate students and the modifications to forbearance options.

As noted in the *Methodology for Budget Impact* section of this RIA, the score for this proposed regulation involved multiple assumptions in the Department's student loan modeling, and there can be significant interaction among the provisions such as loan limits affecting the score of the repayment plan changes. The one additional item that has a budget impact relative to the original score of the provisions related to student loans in the OBBB is the definition of a professional student. The original estimate was based on a definition that specified 6-digit CIP codes; the proposed definition is slightly broader and would use 4-digit CIP codes with the inclusion of Clinical Psychology.

Methodology for Budget Impact: The Department estimated the net budget impact of the proposed provisions in this NPRM through changes to several assumptions involved in its student loan modeling, including predicted volumes, the percentage of volumes assigned to different repayment plans,

deferments and forbearance, the IDR sub model which includes changes to PSLF, and updated calculations within the Student Loan Model (SLM) for the Tiered Standard repayment plan. The possibility of a second rehabilitation was evaluated by adding second rehabilitation activities into the collection assumption. The assumed population for the second rehabilitation included borrowers who have previously rehabilitated their loans and subsequently consolidated them. We used the payment data from the first rehabilitation to model potential second rehabilitation activity, which resulted in a 0.035 percent increase in all payments. This did not affect the subsidy rates for loans at the 2-digit decimal place for scoring a budget impact and is therefore not specified in Table 4.1. Specific changes related to key provisions are described in this section.

Loan Volumes: All estimates in the Department's student loan modeling are driven off a set of actual (for existing cohorts) and projected loan volumes. The proposed regulations implement several significant changes to projected loan volumes, especially the changes to annual and aggregate loan limits and the elimination of Graduate PLUS Loans. Within the loan volumes assumption, we ensured that Parent PLUS borrowers with loans starting on or after July 1, 2026, do not exceed the \$20,000 annual limit per dependent student and the \$65,000 aggregate limit. Field of study and enrollment data is not available within our loan assumption model, therefore a scenario for both the graduate loans limits of \$20,500 annually and \$100,000 aggregate and the professional loan limits of \$50,000 annually and \$200,000 aggregate were created and combined at the point of aggregation, using factors based on school-certified enrollment data from the National Student Loan Data System (NSLDS). Similarly, enrollment data from NSLDS was used to determine the percentage of all volume that would exceed half-time limits for affected borrowers. This percentage was used to decrease aggregated volumes.

Repayment Plan Assignment: Another significant factor in estimating the impact of the provisions implemented in the proposed regulations is the percent of volume assigned to the various repayment plans. This is done through the one assumption that assigns volume in the SLM to the standard, extended, graduated, and all IDR plans. Distribution among IDR plans is done in the IDR sub model and is detailed in the description of the methodology for those provisions. For borrowers with loans

made on or after July 1, 2026, affected by the OBBB, the assumption was changed to assign loan volume to the Tiered Standard repayment plan or the IDR category which would be the Repayment Assistance Plan for those borrowers. The Department did not have specific data to estimate whether loan volume in the graduated and extended plans in the baseline would move to the Repayment Assistance Plan or the Tiered Standard repayment plan. For example, we do not have income information for borrowers in repayment on all non-IDR plans to assess if they might be better off in the Repayment Assistance Plan or the Tiered Standard repayment plan. For the OBBB modification score presented in Table 4.1, the assumption was that borrowers would evenly split between the two remaining repayment plan options.

This is an assumption we expect to update for the estimate of the final rule, likely assuming those in extended repayment would choose the Tiered Standard repayment plan as the structure is fairly similar. Those previously assumed to be in graduated repayment will be divided between the two options, likely with more going to Tiered Standard repayment plan than the Repayment Assistance Plan. The Department welcomes comments on the assumed distribution between the two repayment plans available for those with loans disbursed on or after July 1, 2026.

The Repayment Assistance Plan and changes to Income-Driven Repayment Plans: The introduction of the Repayment Assistance Plan and the changes to the availability or terms of existing repayment plans are estimated through changes to the IDR sub model. This is the same process used to estimate previous changes to IDR plans including, most recently, the SAVE plan that remains in the baseline for the OBBB estimate. The negative net budget impact of the changes to the income-driven repayment plans comes from the difference in expected payments under the baseline distribution of income-driven plans and the options available following implementation of the OBBB provisions.

For borrowers in the IDR sub model with loan originations on or after July 1, 2026, payments are calculated based on the terms of the Repayment Assistance Plan. Key provisions that affect the change in payments include the 1 percent of income per \$10,000 in AGI payment calculation, non-accrual of interest when monthly payments are made, thirty years of payments timeline to forgiveness, principal reduction up to \$50 monthly, \$50 reductions in

payments per dependent, and changes in the treatment of deferments and forbearances. Loan limit provisions also affect these borrowers and reduce the balances for some borrowers, which potentially reduced their flow of payments compared to the baseline. The combination of the changes results in a much higher percentage of borrowers paying off their balances than receiving forgiveness compared to the baseline. In the President's Budget for FY 2026 that includes the SAVE plan, we estimated that approximately 5.5 percent of borrowers entering repayment in FY 2026 would pay their loans in full. Those entering repayment in FY 2026 are likely to have income-based option besides Repayment Assistance Plan, but the paid-in-full percentage for that cohort increases to 6.2 percent even

with a choice of plan. For borrowers entering repayment in FY 2030, who are much more likely to have the Repayment Assistance Plan as their only income-driven repayment option, that percentage increases to 44.5 percent.

As noted previously, one change made during the RISE negotiated rulemaking that affected the definition of professional student was the expansion to define programs for that purpose at the 4-digit CIP level and to include Clinical Psychology. This expanded the professional student category from the interpretation used for the Department's initial score of the OBBB legislation that assumed a 6-digit CIP code definition without Clinical Psychology. The Department evaluated borrowers who had entered repayment in 2021 to 2024 in the designated CIP

codes by credential level and total loan amount upon entering repayment to generate a percentage in those categories considered professional. The IDR sub model does not have program level information, so the percentage across all the CIP codes is applied by the debt ranges (up to \$100k, \$101–\$150k, \$151–\$175k, \$176–\$200k, more than \$200k) to randomly assign graduate borrowers in the IDR sub model to professional or graduate status for the application of loan limits. The \$112 million estimate for the budget impact of the professional/graduate definition in Table 4.1 reflects the change from the 6-digit CIP to 4-digit CIP with Clinical Psychology. The change in percentages applied is shown in Table 4.2.

Table 4.2 - Percentage of Professional Students by Debt

Amounts

Debt Range	OBBB Baseline Professional Percentage	Revised NPRM Professional Percentage
<= \$100,000	4.0%	4.4%
\$100,001 - \$150,000	15.3	16.6
\$150,001 - \$175,000	35.6	37.4
\$175,000 - \$200,000	46.8	48.6
Over \$200,000	66.7	69.5

Note: The "OBBB Baseline Professional" column includes the ten specific programs (defined using 6-digit CIP codes) listed as example professional programs in CFR § 668.2. The "Revised NPRM Professional" column includes the ten specific programs listed as example professional programs in CFR § 668.2, as well as Clinical Psychology, and all programs sharing the same 4-digit CIP codes as these programs.

Along with the new provisions related to the Repayment Assistance Plan, the OBBB affected existing income-driven repayment plan availability. Borrowers who did not meet the statutory requirements for 10-percent IBR by being a new borrower as of July 1, 2014, will have the option of 15-percent IBR and 25 years to repayment. These changes also increase payments and the percentage of borrowers who fully pay off their loans in the model compared to the baseline.

The IDR sub model has the features of the existing plans built in, so the major updates for these estimates were to include the Repayment Assistance Plan as an option and to assign borrowers to the plans available to them. Incorporating the features of the

Repayment Assistance Plan was straightforward and involved bringing the Repayment Assistance Plan features coded in the part of the model handling those required to be in the Repayment Assistance Plan into the program for those with a choice.

For the choice of IBR or the Repayment Assistance Plan, we adapted the process we have used in recent cycles to make the choice of plan. While under the baseline, the choice of plan is determined by the net present value of payments over the life of the loan under the different plans, for the choice of the Repayment Assistance Plan versus IBR we compared payments for FY 2027 and beyond for the first three years of the Repayment Assistance Plan availability and the total payments made during the

life of the loans. If both conditions were lower for the Repayment Assistance Plan, the borrower would choose to switch into that plan. We also assumed that borrowers eligible for 10 percent IBR would stay in that plan. With this approach, approximately 3 percent of borrowers with a choice selected the Repayment Assistance Plan. For the estimate of the OBBB statute that is reflected in Table 4.1, this choice was made up-front and did not change. This selection process is one area we may update for the final rule to better reflect that borrowers with the choice can move back and forth between IBR and the Repayment Assistance Plan. This selection process and the changes to the availability of existing plans were the significant contributors to the

modification score in the Repayment Assistance Plan row of Table 4.1.
Tiered Standard repayment plan: Estimates for the Tiered Standard repayment plan were scored through applying changes to the SLM calculations. The percent volume assumption was changed to include a new plan and to distribute loan volume entering repayment from FY 2027 on to the Tiered Standard repayment plan and the IBR plans, which would be assigned to the Repayment Assistance Plan in the IDR sub model. The lower and upper bounds for the maturity term table were adjusted. As the tiers are based on the amount of debt, we created a new distribution of volume to the breakouts shown in Table 4.3.

Table 4.3 – Amount of Debt Range and Repayment Term for Tiered Standard repayment plan used in the Student Loan Model

Debt Range	Repayment Term
Under \$25,000	10 years
\$25,000 – \$49,999	15 years
\$50,000–\$99,999	20 years
\$100,000 or more	25 years

This changed the maturity term in the SLM and generated a different cashflow than that associated with the percentage of volume that was assigned to the standard, extended, or graduated repayment plans under the baseline, resulting in the downward cost estimate in Table 4.1.

Deferments and Forbearances: Deferments and forbearances outside of IDR plans are handled through an assumption that generates separate deferment and forbearance rates by program (Direct Loan or FFEL), population (non-consolidated, consolidated not-from-default, consolidated-from-default), loan type, budget risk group (Two-Year Public and Not-for-Profit, Two-Year Proprietary, Four-Year Freshmen and Sophomore, Four-Year Junior and Senior, and Graduate Student), and years between origination and entering repayment. NSLDS data from multiple files are combined to identify the timing and nature of all events affecting each loan. Deferments are identified either through the loan deferment table or based on a specific status from the loan status table. Similarly, forbearances are identified either through the loan forbearance table or based on a specific status from the loan status table. Rates are calculated as

the balance in deferment and forbearance divided by the total principal loan amount outstanding at the start of each fiscal year. Beginning balances and average balances in deferment and forbearance in each year are then aggregated by population, program, loan type, risk group, and years in repayment. Deferment and forbearance rates past FY 2025 are forecasted using a logistic regression model. The response is the number of dollars in deferment/forbearance (successes) divided by the number of dollars outstanding (trials). Separate equations are estimated by population, program, and loan type.

To estimate the effect of the changes implemented by the proposed regulations, the Department removed the unemployment deferment factor from the regression models predicting outyear deferments. The effect of the removal of economic hardship deferments was calculated by calibrating the results from the adjusted regressions without unemployment deferments. This was done by multiplying those outyear deferment rates by 91.13 percent to reflect the removal of the estimated 8.87 percent of deferments categorized as an economic hardship.

The limitation on discretionary forbearances to no more than 9 months during any 24-month period was estimated by calibrating the forbearance rate. Discretionary forbearances represent about 19 percent of forbearances in the Department’s data. The calibration factor was calculated as shown in the following expression:

$$0.81 * \text{original forbearance} + 0.19 * (\text{original forbearance} * 75 \text{ percent}) = 0.81 * \text{original forbearance} + 0.1425 * \text{original forbearance} = 0.9524 * \text{original forbearance}.$$

The effects of these changes that reduce the deferment and forbearance outyear rates without any other OBBB changes are – 2.1 billion and 1.2 billion, respectively.

Accounting Statement:
Consistent with OMB Circular A–4, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of these proposed regulations. Table 4.4 provides our best estimate of the changes in annualized effects that may result from these proposed regulations. Expenditures are classified as transfers from the Federal government to affected student loan borrowers.

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**Table 4.4 - Accounting Statement: Classification of
Estimated Annualized Expenditures (in millions)**

Category	Benefits	
Lower tuition due to new borrowing limits for graduate and parent loans	Not quantified	
Fewer low-earning graduate credentials and programs	Not quantified	
Category	Costs	
	3%	7%
Costs of compliance with paperwork requirements	\$25.0	\$37.2
Costs of system changes for Education to implement the proposed regulations	\$10.43	\$12.14
Federal implementation staffing costs	\$4.5	\$3.9
Federal long-term staffing increases	\$1.5	\$1.6
Additional contract costs to operate and maintain systems to administer regulatory provisions	\$7.43	\$7.76
Category	Transfers	
	3%	7%
Reduced transfers from Federal Government to affected borrowers for changes in repayment plans that increase repayments and reduce forgiveness	-\$34,066	-\$36,168
Reduced transfers to borrowers from Federal government due to revised graduate and professional loan limits	-\$4,969	-\$4,693
Reduced transfers to borrowers from Federal government due to Parent PLUS Loan limits	\$280	\$282
Reduced transfers to borrowers from Federal government due to prorated loans for less than full-time enrollment	-\$1,488	-\$1,423

Reduced transfers from Federal Government to affected borrowers from elimination of Unemployment and Economic Hardship Deferments	- \$206	- \$204
Increased transfers from Federal Government to affected borrowers in charging and collecting less interest from limitation of discretionary forbearances	\$123	\$122
Increased transfers from Federal Government to affected borrowers from change to professional student definition to use 4-digit CIP and include Clinical Psychology (Psy.D. and Ph.D.)	\$11	\$10
Total Transfers with interactive effects	- \$45,495	- \$47,630

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5. Alternatives Considered

As part of the development of these proposed regulations, the Department engaged in the negotiated rulemaking process in which we received comments and proposals from non-Federal negotiators representing numerous impacted constituencies. These included higher education institutions, State officials, legal assistance organizations, student loan servicers, student loan borrowers, and organizations representing taxpayer and public interests. Non-Federal negotiators submitted a variety of proposals relating to the issues under discussion. Information about these proposals is available on our negotiated rulemaking website at: <https://www.ed.gov/laws-and-policy/higher-education-laws-and-policy/higher-education-policy/negotiated-rulemaking-for-higher-education-2025-2026>.

Most of these proposed regulations implement statutory provisions of the OBBB where the Department does not have discretion. There are two areas under the OBBB where the Department exercised discretion and the alternatives the Department considered have significant impact:

(1) Whether payments in the Repayment Assistance Plan for married borrowers who each have student debt are calculated on each spouse's

respective income or calculated on their combined income; and

(2) Defining a professional student, which allows certain degree programs to access higher annual and aggregate loan limits than a graduate program.

While there are other provisions of the OBBB where the Department also exercised more limited discretion in implementing the law, the alternatives considered in those cases do not result in significant impact. Therefore, our discussion of alternatives considered by the Department is limited to the two areas listed above.

Payments Under the Repayment Assistance Plan for Married Borrowers Filing Joint Tax Returns

Like prior IDR plans, the Repayment Assistance Plan requires the Department to calculate monthly payments for borrowers using their "adjusted gross income" for the most recent tax year as defined in Section 62 of the Internal Revenue Code of 1986, except that, in the case of a married borrower who files a separate Federal income tax return, the term does not include the adjusted gross income of the borrower's spouse. In cases where only one tax filer has a student loan in a married household that files a joint tax return, payments under the Repayment Assistance Plan are calculated on the household's combined adjusted gross income. The OBBB is, however, silent as to how payments in the Repayment Assistance

Plan should be calculated when both filers have Federal student loans.

The Department considered two options for how payments under the Repayment Assistance Plan should be calculated for married individuals who each have Federal student loans. In one, the monthly payments would be calculated for each borrower based on the married filers' joint income. Under this approach, borrowers effectively owe double payments on their loans; each borrower has a payment calculated on the couples' combined income. The Repayment Assistance Plan's progressive payment calculation, that charges higher rates as income increases, creates an additional penalty because married borrowers would pay a higher share of their incomes when their incomes are combined. For example, consider a married couple where each individual has an adjusted gross income of \$27,500 (or \$55,000 combined) and each individual has \$20,000 in student debt (or \$40,000 combined). Under the terms of the Repayment Assistance Plan, each individual would have a \$229 monthly payment (a combined monthly payment of \$458). While these borrowers could file separate Federal income tax returns to address this issue, and each pay \$46 per month (\$92 combined), they could then face higher taxes as a result.

In the other approach, a total combined loan payment for the couple would be calculated based on the filers' joint income and then that payment

would be divided between each filer based on the share of the total Federal student loan balance each held. Put another way, a single payment is calculated off the combined income, and then it is prorated among the two borrowers based on the share of the combined Federal student loan balance. The couple in the example above with a \$55,000 income would instead owe \$229 per month on their combined Federal student loans, not \$458. The Department adopted this proration approach in 2009 when implementing the Income-Based repayment plan and that policy has been in place since for all IDR plans.⁴⁰

The Department proposes to maintain the proration approach for married borrowers who use the Repayment Assistance Plan. The Department believes that the alternative creates two penalties for borrowers: it first “double counts” married borrowers’ income and then assesses them a higher payment threshold due to their higher incomes. This excessive marriage penalty undermines the intent of the Repayment Assistance Plan, which is to provide borrowers with an income-based repayment option to help make certain loans affordable. Although the Repayment Assistance Plan allows these borrowers to file separate income tax returns to reduce their payments, the Department believes that option can be burdensome and costly for tax filers and

should be reserved for borrowers in extenuating circumstances, not the normal course of action for borrowers using the Repayment Assistance Plan. Given the large penalty in the monthly payments married borrowers would face if they filed a joint tax return while using Repayment Assistance Plan, the Department is concerned that many borrowers would be forced to file separate tax returns for the Repayment Assistance Plan to work as Congress intended. The Department’s data on past IDR plan use shows that only 8 percent of married borrowers repaying in IDR file separate tax returns, suggesting that separate filing is uncommon.⁴¹

The Department’s baseline budget estimates of the OBBB and the Repayment Assistance Plan assumed that the Department’s longstanding policy to allow prorated payments would continue in the Repayment Assistance Plan. Therefore, the Department’s proposal in this NPRM to maintain the proration policy would not increase budgetary costs relative to either the pre-statutory baseline or the current-law baseline.

Professional Student Loan Limits

The OBBB terminated the Graduate PLUS Loan program that allowed graduate and professional students to borrow up to the full cost of attendance,

with no aggregate limit. In place of that policy, the OBBB establishes new annual and aggregate loan limits for Direct loans for students enrolled in graduate or professional degree programs. Graduate students may borrow \$20,500 annually with an aggregate limit of \$100,000. Professional students may borrow \$50,000 annually with an aggregate limit of \$200,000.

The OBBB defines a *professional degree* as those described under Section 668.2 of title 34, CFR effective July 4, 2025. That definition states that a professional degree, “signifies both completion of the academic requirements for beginning practice in a given profession and a level of professional skill beyond which is normally required for a bachelor’s degree.” It states that professional licensure is also generally required. It then lists 10 specific fields of study that are included but notes that it is not limited to those.

The Department considered several options that would expand the list of professional degree programs beyond those listed in section 668.2, including one proposed by non-Federal negotiators. These options, including the Department’s proposal, are discussed in the following sections and summarized in Table 5.1. We compare the impact of these options to a baseline option, which the Department also considered, where professional degree programs are defined as only the 10 examples listed in section 668.2.

⁴⁰ See 74 FR 36567, HEA Section 493C(b)(1) (as in effect on July 23, 2009).

⁴¹ A Department of Education table illustrating the filing status of IDR applicants who provided tax information is posted at <https://www.ed.gov/sites/ed/files/policy/highered/reg/hearulemaking/2015/payee2-filingstatus.pdf>.

Table 5.1 - Summary of Alternatives Considered for Professional Definition

	10 Programs in 668.2 (Baseline)	Baseline Plus Clinical Psychology	Department's Proposed Rule	Negotiators' Proposal
	(1)	(2)	(3)	(4)
Unique CIP Codes				
Unique CIP Codes	10	11	39	224
Percent of Unique CIP Codes	0.7	0.8	2.8	16.1
Programs at Institutions				
Graduate Programs at Institutions	1,020	1,158	1,539	3,762
Percent of Graduate Programs at Institutions	1.5	1.6	2.2	5.4
Title IV Enrollees				
Title IV Graduate Enrollees	253,109	265,228	273,518	381,391
Percent of Title IV Graduate Enrollees	8.4	8.8	9.1	12.7
Title IV Borrowers				
Title IV Graduate Borrowers	193,969	202,460	207,022	281,056
Percent of Title IV Graduate Borrowers	12.1	12.6	12.9	17.5
Title IV Annual Loan Disbursements				
Annual Title IV Graduate Loan Disbursements (\$ millions)	10,749	11,066	11,180	13,325
Percent of Annual Title IV Graduate Loan Disbursements	27.1	27.9	28.1	33.5

Notes: Unique CIP codes refer to unique 6-digit CIP codes. Graduate programs include all graduate programs: Masters, Doctoral, First Professional, and Graduate Certificate. Title IV graduate borrowers includes all graduate students enrolled in the 2023-24 award year who also received title IV loans during the 2023-24 award year. Title IV Graduate Enrollees includes all title IV graduate students enrolled in the 2023-24 award, including those that did not receive title IV aid during the 2023-24 award year but received title IV aid during a prior year.

Source: Department analysis using data from NSLDS for the 2023-24 award year.

Under the baseline option, only programs from 10 unique 6-digit CIP codes would qualify for the \$50,000 annual and \$200,000 aggregate loan limit: Pharmacy (Pharm.D.), Dentistry (D.D.S. or D.M.D.), Veterinary Medicine (D.V.M.), Chiropractic (DC or DCM.), Law (L.L.B. or J.D.), Medicine (M.D.), Optometry (O.D.), Osteopathic Medicine (D.O.), Podiatry (D.P.M., D.P.), and Theology (M.Div., or M.H.L.).⁴² In this

baseline case, all other graduate programs would be subject to the \$20,500 annual and \$100,000 aggregate limit.

Students enrolled in these programs represent 12.1 percent of Federal student loan borrowers in all graduate and professional programs, and 27.1 percent of all loan dollars disbursed to borrowers in these programs (Table 5.1).⁴³ Statistics on loan disbursements made to borrowers in these 10 programs

during the 2023-24 award year are shown in Table 5.2. In aggregate, these programs received \$10.7 billion in Federal student loan disbursements. Relative to pre-OBBB policy, between one-third and two-thirds of borrowers in these programs typically borrowed above \$50,000 annually. Post-OBBB, future borrowers would not be able to borrow at these levels due to the new loan limits for professional students.

⁴² The 6-digit CIP codes for these programs are: Law 220101; Medicine 511201; Pharmacy 512001; Dentistry 510401; Osteopathic Medicine/Osteopathy 511202; Veterinary Medicine 18001; Optometry 511701; Chiropractic 510101; Podiatric Medicine/Podiatry 511203; Divinity/Ministry 390602; Rabbinical Studies 390605.

⁴³ Doctoral and professional students are defined here using the definitions from the National Student Loan Data System's (NSLDS) criteria for reporting student credential level. Institutions self-report this information in the NSLDS system. We include doctoral programs in our analysis because some fields at that credential level may meet the

definition of a *professional degree* under OBBBA. See: NSLDS Enrollment Reporting Guide (November 2022), <https://fsapartners.ed.gov/knowledge-center/library/nslds-user-resources/2022-11-14/nslds-enrollment-reporting-guide-november-2022>.

Table 5.2 - Characteristics of Professional Programs listed in Section 668.2 (Baseline)

CIP-6 Field	Number of Programs	Annual Borrowers	Total Annual Loan Disbursements (\$ millions)	Average Annual Loan Disbursements	Share of Borrowers with Annual Loan Disbursements Above \$50,000	Share of Annual Loan Disbursements above \$50,000
220101 Law.	217	58,621	2,467	42,088	35%	15%
511201 Medicine.	196	49,294	2,750	55,784	49%	24%
512001 Pharmacy.	139	22,420	1,046	46,655	37%	17%
511202 Osteopathic Medicine/Osteopathy.	34	21,495	1,630	75,817	66%	38%
510401 Dentistry.	70	15,856	1,430	90,210	75%	44%
18001 Veterinary Medicine.	47	10,533	621	58,945	51%	25%
510101 Chiropractic.	21	9,319	491	52,693	48%	22%
511701 Optometry.	19	3,677	218	59,282	55%	28%
390601 Theology/Theological Studies.	177	1,532	19	12,209	1%	0%
511203 Podiatric Medicine/Podiatry.	8	1,222	78	63,471	51%	32%

Notes: Baseline refers to the programs listed as examples of professional programs in 668.2.

Source: Department analysis using data from NSLDS for the 2023-24 award year.

Department's Proposed Definition of a Professional Degree Program

The Department initially considered expanding the baseline list of 10 programs to include one additional program at the 6-digit CIP level: Clinical Psychology.⁴⁴ Under this option, 12.6 percent of graduate borrowers attend one of these 11 programs, or about 0.5 percentage points more than the baseline 10 programs listed in Section 668.2 (Table 5.1).

The Department ultimately opted to propose a broader definition to include all programs that are adjacent to the 10 programs listed in 668.2 at the 4-digit CIP code level and Clinical Psychology that also meet program length and licensure requirements for a professional degree. In total, programs within 38 unique 6-digit CIP codes meet this definition. The Department's proposed definition encompasses 12.9 percent of the Federal student loan borrowers in graduate programs, 0.8 percentage points more than the

baseline 10 programs listed in Section 668.2.⁴⁵

The characteristics of these programs that meet the Department's proposed definition are listed in the top panel of Table 5.3. In total, graduate students in these programs received \$11.2 billion in Federal student loan disbursements during the 2023-24 award year. Across these programs, fewer than 15 percent of annual loan disbursements were in excess of \$50,000, suggesting that the loan limit will have a binding effect on relatively few borrowers.

Negotiators' Proposed Professional Degree Definition

The Department considered a proposal from RISE Committee non-Federal negotiators that would define a professional student more broadly than the Department's proposals.⁴⁶ The negotiators' proposal would define a professional program as any program within the same two 2-digit CIP code as the 10 programs listed in section 668.2

(an "adjacent field") that also meets a program length requirement of at least 80 credit hours. The proposal adds Clinical Psychology to the list of eligible 2-digit CIP codes.

The bottom panel of Table 5.3 provides summary information about the programs included in the negotiators' proposal. The non-Federal negotiators' proposal includes programs in 219 unique 6-digit CIP codes (compared with 38 under the Department's proposal) that cover 17.5 percent of graduate student borrowers. Unlike the Department's proposed definition, the non-Federal negotiators' definition includes all professional programs in health care and health care-related fields and therefore encompasses several large fields with high levels of borrowing, such as physical therapy and nursing. Over 24,000 professional and doctoral students in physical therapy borrowed nearly \$1 billion in Federal student loans in the 2023-24 award year.

⁴⁴ This definition would add all programs within the 422801 CIP code that also meet the other criteria for a professional degree, such as program length and licensure.

⁴⁵ Office of the Chief Economist using data from NSLDS for the 2023-24 award year.

⁴⁶ A. Holt, A. Gillen, "Memo on a Revised Professional Degree Definition and Aligning

Definitions in the Code of Federal Regulations" (<https://www.ed.gov/media/document/2025-rise-memo-revised-professional-degree-definition-and-aligning-definitions-code-of-federal-regulations-10102025-submitted-alex-holt-and-andrew-gillen>).

Table 5.3. Characteristics of 10 Largest Programs Under the Department's and Negotiator's Proposals

CIP-6 Field	Annual Borrowers	Total Annual Loan Disbursements (\$ millions)	Average Annual Loan Disbursements	Share of Annual Loan Disbursements Between \$20,500 and \$50,000	Share of Borrowers with Annual Loan Disbursements Between \$20,500 and \$50,000	Share of Annual Loan Disbursements Above \$50,000	Share of Borrowers with Annual Loan Disbursements Above \$50,000
	(1)	(2)	(3)	(4)	(5)	(6)	(7)
Programs Added Under Department's Proposal							
422801 Clinical Psychology.	8,491	\$336	\$39,612	32.7%	40.9%	15.2%	27.6%
422803 Counseling Psychology.	967	19	19,392	15.8	22.8	2.0	5.8
390602 Divinity/Ministry.	905	12	12,778	5.6	7.2	0.0	0.0
422805 School Psychology.	834	17	20,870	17.3	20.4	4.0	8.9
422804 Industrial And Organizational Psych.	492	13	26,396	24.2	30.9	8.3	11.8
422814 Applied Behavior Analysis.	318	9	27,564	27.2	35.2	8.6	12.0
422806 Educational Psychology.	206	4	21,531	15.1	22.8	5.8	8.3
422899 Clinical, Counseling And Applied Psych.	138	3	23,349	24.0	32.6	4.2	7.3
512010 Pharmaceutical Sciences.	128	4	29,322	30.3	39.8	9.2	14.1
422815 Performance And Sport Psychology.	115	2	13,617	8.6	14.8	1.5	1.7
All Other Programs in Proposal	459	12	25,179	15.3	22.2	8.6	12.6
Programs Added Under Negotiators' Proposal							
512308 Physical Therapy/Therapist.	24,276	931	38,361	32.5	32.5	12.7	28.9
513818 Nursing Practice.	9,776	218	22,255	20.0	23.1	4.8	9.4
422801 Clinical Psychology.	8,491	336	39,612	32.7	40.9	15.2	27.6
511508 Mental Health Counseling/Counselor.	7,017	60	8,604	1.6	2.2	0.0	0.0
512306 Occupational Therapy/Therapist.	6,386	230	35,998	30.8	31.4	11.0	25.2
513804 Nurse Anesthetist.	3,959	194	49,045	35.5	28.5	20.4	45.2
420101 Psychology, General.	2,951	62	20,902	20.4	31.1	1.7	6.2
513801 Registered Nursing/Registered Nurse.	2,586	42	16,318	12.2	15.0	2.1	4.2
511505 Marriage And Family Therapy/Counseling.	1,982	22	11,352	6.2	8.0	1.1	1.5
513805 Family Practice Nurse/Nursing.	1,512	32	20,900	17.3	22.6	2.8	4.5
All Other Programs in Proposal	18,151	448	24,697	20.3	26.1	5.9	12.0

Notes: This table lists the ten largest programs (by number of unique title IV borrowers) added in the Department's proposed rule and in the non-Federal negotiators' proposed definition. It does not include the 10 programs listed in Section 668.2; these 10 programs are shown in Table 5.2.

Source: Department analysis using data from NSLDS for the 2023-24 award year.

In addition to examining the numbers and types of programs included in the alternative definitions of a *professional degree*, the Department also estimated the budget costs and increased in loan disbursements for each of the alternatives (Table 5.4 and Table 5.5, respectively). We again compare these impacts relative to a definition limited to only the 10 programs listed in Section 668.2.

The Department's proposed definition would increase outlays by \$112 million

over the 10-year budget window relative to restricting professional degrees to only the 10 programs listed in Section 668.2 (Table 5.4). Loan disbursements would increase by \$961 million between 2026–2035 under the Department's proposal, mostly due to the addition of programs in Clinical Psychology (Table 5.5). Conversely, the non-Federal negotiators' proposal would increase outlays by \$1.12 billion in the 2026–2035 budget window, relative to the cost

of limiting professional programs to only the 10 programs in section 668.2 (Table 5.4). Additionally, the non-Federal negotiator's proposal would increase loan disbursements by an estimated \$9.79 billion, relative to the same baseline (Table 5.5). Programs in physical therapy and nursing account for a large share of the projected increase in loan disbursements and budget costs relative to the Department's proposal and the baseline 10 programs.

Table 5.4 - Budget Cost Comparison of Professional Student Definition Alternatives (\$ in millions)

		1994-2025 Modifications	2026-2035
Baseline Plus	Budget Authority	\$0	\$74
Clinical Psychology Outlays		0	72
Department's	Budget Authority	0	118
Proposed Rule	Outlays	0	112
Negotiator's	Budget Authority	0	1,138
Proposal	Outlays	0	1,120

Note: Estimates are relative to a baseline under which only the 10 programs (at the 6-digit CIP level) listed in Section 668.2 that also meet the program length and licensure criteria are eligible under the professional student definition. Estimates are made according to the Federal Credit Reform Act and reflect the lifetime present value costs for loans issued each year.

Table 5.5 - Increase in Loan Disbursement for Professional Student Definition Alternatives For 2026-2035 (\$ in millions)

Baseline Plus	\$538
Clinical Psychology	
Department's	961
Proposed Rule	
Negotiator's	9,785
Proposal	

Note: Loan disbursement increase is relative to a baseline under which only the 10 programs (at the 6-digit CIP level) listed in Section 668.2 that also meet the program length and licensure criteria are eligible for the professional student definition.

Regulatory Flexibility Act

This section considers the effects that the proposed regulations may have on small entities in the Educational Sector as required by the Regulatory Flexibility Act (RFA, 5 U.S.C. *et seq.*, Public Law 96–354) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA). The purpose of the RFA is to establish as a principle of regulation that agencies should tailor regulatory and informational requirements to the size of entities, consistent with the objectives of a particular regulation and applicable statutes.

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act (APA) or any other statute unless the agency certifies that the rule will not have a “significant impact on a substantial number of small entities.”

This proposed rule amends the regulations for the Federal student loan programs authorized under the title IV, HEA programs to implement the statutory changes to the title IV, HEA programs included in the OBBB signed into law on July 4, 2025. These changes include establishing new loan limits for graduate students, professional students, and parents. The OBBB also simplifies the current broken and confusing myriad of Federal student loan repayment plans by phasing out

the existing Income-Contingent Repayment plans, creates a new tiered standard repayment plan option, and implements a new income-driven repayment plan known as the Repayment Assistance Plan.

As we describe below, the Department anticipates that this regulatory action will have a significant economic impact on a substantial number of small entities. We therefore present this Initial Regulatory Flexibility Analysis. Our analysis focuses on the loan limit components of the OBBB and the proposed regulation, as those would have the most economically significant implications for small entities.

Description of, and, Where Feasible, an Estimate of the Number of Small Entities to Which the Regulations Will Apply

The Small Business Administration (SBA) defines “small institution” using data on revenue, market dominance, tax filing status, governing body, and population. The majority of entities to which the Office of Postsecondary Education’s (OPE) regulations apply are postsecondary institutions, which do not report such data to the Department. As a result, for purposes of this NPRM, the Department proposes to continue defining “small entities” by reference to enrollment, to allow meaningful comparison of regulatory impact across all types of higher education institutions. We construct four different categories of small entities for the

purposes of classifying higher education institutions: (1) Extremely Small (1–249 FTE, full-time equivalent student enrollees); (2) Very Small (250–499 FTE); (3) Moderately Small (500–749 FTE); and (4) Small (750–999 FTE).

Table 5.6 summarizes the number of institutions affected by these proposed regulations. In total, 53 percent of institutions are classified as small institutions under the enrollment-based definition. Specifically, 33 percent are Extremely Small (1–249 FTE), 9 percent are Very Small (250–499 FTE), 6 percent are Moderately Small (500–749 FTE), and 5 percent are Small (750–999 FTE). The remaining 47 percent of institutions are not in one of these categories.

As seen in Table 5.7, small entities (all four categories combined) in the public sector generate \$3.5 billion in institutional revenues annually, small entities (all four categories combined) in the private non-profit sector generate \$12.3 billion in institutional revenues annually, and small entities (all four categories combined) in the for-profit sector generate \$4.2 billion in institutional revenues annually. An outsized share of these revenues come from institutions in the largest category of small entities (institutions with 750–999 FTE). These institutions make up just 9 percent of all institutions classified as a small entity (having fewer than 1,000 FTE) but comprise 38 percent of the annual revenues generated by these institutions.

Table 5.6 - Number of Small Institutions Under Enrollment-Based Definition

	Small Entities				Small Subtotal	All Colleges	Percent Small
	Extremely Small (1–249 FTE)	Very Small (250–499 FTE)	Moderately Small (500–749 FTE)	Small (750–999 FTE)			
	(1)	(2)	(3)	(4)	(5)	(6)	(7)
Public	181	73	74	91	419	1,780	23.54
2-Year	181	68	68	81	398	1,233	32.28
4-Year	0	5	6	10	21	547	3.84
Non-Profit	455	138	142	111	846	1,638	51.65
2-Year	159	34	21	8	222	251	88.45
4-Year	296	104	121	103	624	1,387	44.99
For-Profit	983	242	80	63	1,368	1,540	88.83
2-Year	954	227	70	57	1,308	1,438	90.96
4-Year	29	15	10	6	60	102	58.82
Total	1,619	453	296	265	2,633	4,958	53.11

Notes: Institutions are defined using OPEID6 identification codes.
Source: Department analysis using 2022–23 and 2023–24 IPEDS data.

Table 5.7 - Total Revenue at Small Institutions and All Institutions in 2023-24 (\$ in millions).

	Small Entities					All Colleges	Percent Small
	Extremely Small (1-249 FTE)	Very Small (250-499 FTE)	Moderately Small (500-749 FTE)	Small (750-999 FTE)	Small Subtotal		
	(1)	(2)	(3)	(4)	(5)	(6)	(7)
Public	203.5	431.4	956.9	1,939.7	3,531.6	433,146.1	0.82
2-Year	203.5	340.9	799.2	1,498.8	2,842.3	104,190.5	2.73
4-Year	0.0	90.5	157.8	441.0	689.3	328,955.6	0.21
Non-Profit	1,998.1	2,293.1	3,192.2	4,769.0	12,252.5	275,556.3	4.45
2-Year	294.6	213.0	241.9	106.2	855.8	12,257.1	6.98
4-Year	1,703.5	2,080.0	2,950.3	4,662.8	11,396.7	263,299.3	4.33
For-Profit	1,361.8	1,157.6	705.6	934.5	4,159.4	18,684.4	22.26
2-Year	1,299.2	1,042.8	555.9	754.6	3,652.5	9,581.4	38.12
4-Year	62.6	114.7	149.7	179.9	506.9	9,102.9	5.57
Total	3,563.4	3,882.1	4,854.7	7,643.3	19,943.5	727,386.8	2.74

Notes: Institutions are defined using OPEID6 identification codes.

Monetary values are measured in 2023 nominal dollars.

Source: Department analysis using 2022-23 and 2023-24 IPEDS data.

Table 5.8 shows the estimated change in annual loan disbursements from the Department to small entities as a result of the new loan limits established in the OBBB. As noted in the previous section, the OBBB includes new annual and aggregate loan limits for graduate and professional students as well as parents of dependent undergraduate students who use the Parent PLUS Program. The annual limits, as described in the previous section, are \$20,500 for graduate students, \$50,000 for professional students as defined in the proposed regulation, and \$20,000 for parents borrowing on behalf of their dependent undergraduate student.

Among all small entities (institutions with 1-999 FTE), the percentage of annual loan volume that exceeds the annual loan limits established under the Act approximately 13.9 percent on

average, though there is variation across institutional sectors. Among private non-profit small entities, the average share of annual loan volume above the limit is 21 percent, whereas the share of annual volume above the limit at public and for-profit small entities is between 4 percent-6 percent. These values represent an estimate of the share of annual Federal student loan disbursements to small entities that will no longer be issued due to the OBBB's loan limits for graduate students and parent borrowers.

Federal student loans can comprise a significant portion of institutions' revenue, including small institutions, if such funds are used to pay tuition and other costs billed directly by the institution. However, it is important to note that not all Federal loan disbursements contribute to

institutional revenues. Sometimes, Federal loan dollars are used to pay for other items, like housing, transportation, and food, which do not always go to the institution the student attends. Therefore, the new loan limits could result in a reduction in institutional revenue unless those direct costs are funded by other sources, such as grants, non-Federal loans, or personal savings. Due to data limitations, we are unable to estimate reliably the share of Federal loan disbursements to small entities that the institution receives and therefore are unable to reliably estimate the share of small entities' revenue affected by the loan limit reduction. Table 5.8 presents the maximum amount of revenue that could be affected, but the actual amount will be lower and may vary by institution.

Table 5.8 - Annual Federal Student Loan Volume to Small Entities and All Colleges in Excess of New Annual Loan Limits in OBBB in 2023-2024 (\$ in millions)

	Small Entities								
	Extremely Small (1-249 FTE)			Very Small (250-499 FTE)			Moderately Small (500-749 FTE)		
	Revenue	Loan Volume Exceeding Limit	Percent	Revenue	Loan Volume Exceeding Limit	Percent	Revenue	Loan Volume Exceeding Limit	Percent
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
Public	203.5	0.0	0.0%	431.4	3.8	0.9%	956.9	0.5	0.1%
Non-Profit	1,998.1	32.6	1.6%	2,293.1	76.9	3.4%	3,192.2	257.0	8.1%
For-Profit	1,361.8	10.5	0.8%	1,157.6	18.5	1.6%	705.6	31.0	4.4%
Total	3,563.4	43.1	1.2%	3,882.1	99.2	2.6%	4,854.7	288.5	5.9%

	Small (750-999 FTE)			Small Subtotal			All Colleges		
	Revenue	Loan Volume Exceeding Limit	Percent	Revenue	Loan Volume Exceeding Limit	Percent	Revenue	Loan Volume Exceeding Limit	Percent
	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
Public	1,939.7	8.3	0.4%	3,531.6	12.7	0.4%	433,146.1	3,948.3	0.9%
Non-Profit	4,769.0	177.3	3.7%	12,252.5	543.8	4.4%	275,556.3	8,641.6	3.1%
For-Profit	934.5	15.4	1.6%	4,159.4	75.3	1.8%	18,684.4	898.5	4.8%
Total	7,643.3	201.0	2.6%	19,943.5	631.8	3.2%	727,386.8	13,488.4	1.9%

Notes: Institutions are defined using OPEID6 identification codes.

Source: Department analysis using 2022-23 and 2023-24 IPEDS data and data from NSLDS for the 2023-24 award year.

Description of the Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Regulations, Including of the Classes of Small Entities That Will Be Subject to the Requirement and the Type of Professional Skills Necessary for Preparation of the Report or Record

The regulations are unlikely to result in additional reporting, recordkeeping, or additional compliance requirements for small entities beyond the paperwork burden as described in the *Paperwork Reduction Act* section.

Identification, to the Extent Practicable, of all Relevant Federal Regulations That May Duplicate, Overlap, or Conflict With the Regulations

The regulations are unlikely to conflict with or duplicate existing Federal regulations.

Alternatives Considered (Small Entities)

The Department examined whether the proposed rule could incorporate other options or changes to the rule intended to make compliance less burdensome for small institutions of higher education. Specifically, the Department considered whether small institutions of higher education could

be exempted from the changes to the statute in the proposed rule, or whether they could be granted a delayed start date to the changes, particularly those changes related to the reductions in student loan limits in the OBBB. The Department does not have discretion in the OBBB to exempt certain institutions of higher education from the OBBB requirements. The statute also establishes the effective date for the changes to the Federal student loan program and does not leave flexibility to the Department to consider granting a delay in compliance for small entities that may benefit from such a delay. Therefore, the Department determined that none of these options would be permissible under the statute. The agency invites comments on reasonable alternatives that are consistent with the stated objectives of the statute.

The Department acknowledges that this analysis defines small entities based on institutions' enrollment. The Department is interested in comments addressing this approach and other alternatives if they were to more fully capture the impact of the proposed rule on small entities. The Department welcomes comments and data from the public that may help it improve its

impact analyses for small entities with respect to the changes in this proposed rule.

Paperwork Reduction Act of 1995

As part of its continuing effort to reduce paperwork and respondent burden, the Department provides the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This helps make certain that: the public understands the Department's collection instructions, respondents can provide the requested data in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the Department can properly assess the impact of collection requirements on respondents.

This Notice of Proposed Rulemaking amends existing collections of information that contain reporting or recordkeeping burden. The Department, through this proposed regulation, seeks comment on revisions to the following existing information collections:

OMB Control #	Title
1845-0021	William D. Ford Federal Direct Loan Program (DL) Regulations

The proposed regulation will also modify other existing information collections. However, at this time it is unclear what changes will be made to these existing collections. In the below

table, we identify information collections that we anticipate will also be modified by these regulations. The Department will separately seek public comment on the proposed revisions to

these collections before changes go into effect.

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Additional Information Collections impacted by RISE

OMB Control #	Title	Current Burden
1845-0014	William D. Ford Federal Direct Loan Program Repayment Plan Selection Form	Responses: 660,000 Burden hours: 110,220
1845-0058	Loan Discharge Applications (DL/FFEL/Perkins)	Responses: 32,761 Burden hours: 21,376
1845-0059	Federal Direct Loan Program and Federal Family Education Loan Program Teacher Loan Forgiveness Forms	Responses: 8,700 Burden hours: 2,871
1845-0065	Direct Loan, FFEL, Perkins and TEACH Grant Total and Permanent Disability Discharge Application and Related Forms	Responses: 61,629 Burden hours: 30,814
1845-0103	William D. Ford Federal Direct Loan Program, Federal Direct PLUS Loan Request for Supplemental Information	Responses: 1,230,000 Burden hours: 615,000
1845-0110	Application and Employment Certification for Public Service Loan Forgiveness	Responses: 913,713 Burden hours: 456,857
1845-0120	Loan Rehabilitation: Reasonable and Affordable Payments	Responses: 139,000 Burden hours: 139,000
1845-0164	Public Service Loan Forgiveness Reconsideration Request	Responses: 36,000 Burden hours: 9,000
1845-0182	Joint Consolidation Loan Separation Application	Responses: 74,000 Burden hours: 24,050
1845-0102	Income-Driven Repayment Plan	Responses: 9,500,000

	Request for the William D. Ford Federal Direct Loans and Federal Family Education Loan Programs	Burden hours: 3,135,000
1845-0023	Federal Perkins Loan Program Regulations	Responses: 8,217,172 Burden hours: 149,369
1845-0019	Federal Perkins Loan Program and General Provisions Regulation	Responses: 11,616,710 Burden hours: 6,247,152
1845-0119	Federal Direct Loan Program Regulations for Forbearance and Loan Rehabilitation	Responses: 129,027 Burden hours: 35,094

BILLING CODE 4000-01-C

Below we identify the provisions in the proposed regulation that may have an impact on information collections.

§ 685.102 Definitions

Proposed § 685.102 would add the following new definitions: expected time to credential; graduate student; professional student; and program length. To comply, institutions will be required to update their internal systems and policies to bifurcate and update the definition of graduate or professional student in order to determine a student's annual and aggregate loan limits. We expect the associated burden on institutions will be minimal. Institutions already differentiate graduate students from baccalaureate students while packaging aid. The proposed regulation would not create a new burden for schools as they already have a process to differentiate students in their systems. We believe separating graduate and professional student would only slightly alter the burden already assigned to this type of activity within this regulation.

Proposed § 685.102, will require institutions to update their internal system definitions of expected time to credential and program length. We believe the burden to conform with these new definitions will be minimal as the proposed definitions serve to provide consistency and clarity of these terms rather than change them.

In sum, to conform to all definitions in proposed § 685.102, institutions would be required to review the new definitions, update internal policies and procedures, modify systems, perform

basic testing, and train staff. We believe there will be a small increase in burden of approximately 300 hours per institution in order to implement these regulations. This additional burden is assigned to this regulatory collection, 1845-0021.

§ 682.215 Income-Based Repayment

Proposed 682.215(b) would amend the terms and conditions of the IBR plan to remove any references to partial financial hardship to conform with changes from the OBBB Section 82001(f)(1)(B). This will decrease burden on borrowers as they will no longer be required to demonstrate a partial financial hardship to apply for an IDR plan, including the IBR plan. Updates to the IDR form and burden estimates on individual borrowers will be completed and made available for comment in a separate public comment notice issued under OMB Control #1845-0102 Income-Driven Repayment Plan Request for the William D. Ford Federal Direct Loans and Federal Family Education Loan Programs before being made available for use by the effective date of the regulations.

Likewise, loan servicers will no longer have to determine that the borrower meets the partial financial hardship requirement before placing a borrower in the income-based repayment plan, nor will they be required to make annual redeterminations of partial financial hardship status.

The proposed elimination of the partial financial hardship requirement will reduce burden on loan servicers.

When partial financial hardship was first implemented, the Department estimated there would be an increase of 90,286 burden hours on loan servicers. Because these partial financial hardship determinations will no longer be required under this proposed regulation, the Department would remove all 90,286 hours of burden from this regulatory collection, 1845-0021.

§ 685.201 Obtaining a Loan

Before July 1, 2026, for a graduate or professional student to apply for a Direct PLUS Loan, the borrower would complete a FAFSA and submit it in accordance with instructions in the application. The borrower would also complete the Direct PLUS Loan Request and the Direct PLUS Loan MPN.

Proposed 685.201 would align the regulations with the changes to section 81001(1)(C) of the OBBB, which amends section 455(a)(3)(C) of the HEA by terminating graduate and professional students' access to the Direct PLUS Loan program for any period of instruction beginning on or after July 1, 2026 (except for those current students who qualify for the interim exception).

By discontinuing the Graduate PLUS Loan program for new students and those who do not qualify for the interim exception for certain students, the Department proposes removing an entire category of loan processing requirements for servicers and institutions. This will reduce burden in any collection related to PLUS loans, including the 1845-0021 collection.

In the 2024-25 award year, there were 2,020 title IV eligible schools who

originated and disbursed at least one Graduate PLUS Loan. Of those, 124 proprietary schools made an average of 465 Graduate PLUS Loans; 1,341 private schools made an average of 279 Graduate PLUS Loans; and 555 public schools made an average of 413 Graduate PLUS Loans.

Title IV eligible schools may still participate in the Direct PLUS Loan program. Proposed § 685.201 would disqualify graduate and professional students from eligibility, but parents of dependent undergraduate students remain eligible to borrow Parent PLUS Loans. Therefore, this specific loan program will not be eliminated in its entirety. Because of this, we estimate there would be a 620-hour reduction in burden per title IV institution participating in the Direct PLUS Loan Program. This would remove approximately 1,252,400 hours of burden from the 1845–0021 William D. Ford Federal Direct Loan Program collection.

Additional reductions in burden on individual borrowers stemming from proposed § 685.201 will be assessed to OMB Control #1845–0103 William D. Ford Federal Direct Loan Program, Federal Direct PLUS Loan Request for Supplemental Information and OMB Control #1845–0129 PLUS Adverse Credit Reconsideration Loan Counseling. As previously mentioned, once regulations are finalized, these updates will be completed and made available for comment through a separate public comment notice before these requirements are in effect.

§ 685.220 Consolidation

Section 82001(e) of the OBBA made statutory changes to permit defaulted borrowers to consolidate their loans for the purposes of obtaining access to the IBR or Repayment Assistance Plan plans to fix the default. The Department proposes to amend § 685.220 to conform with these statutory changes. Before July 1, 2028, defaulted borrowers may consolidate to gain access to the IBR and/or ICR plans. On or after July 1, 2028, defaulted borrowers may consolidate to gain access to the IBR plan or the Repayment Assistance Plan.

Proposed § 685.220 would ensure defaulted borrowers are able to consolidate into the Direct Loan Program and defines which repayment plans they have access to, including the Repayment Assistance Plan. Increases in burden to individual borrowers will be assessed under OMB Control #1845–0007 William D. Ford Federal Direct Loan Program (Direct Loan Program) Promissory Notes and related form, which the Department will seek

comment on in a separate public comment notice.

Servicers are already in the practice of limiting repayment plans available to defaulted borrowers. We do not believe that the particular change in proposed § 685.220 will have an impact on the burden hours or number of respondents currently assessed to OMB Control #1845–0021.

§ 685.211 Miscellaneous, § 674.39 Loan Rehabilitation, and § 682.405 Loan Rehabilitation Agreement

Three of the proposed regulations would allow a borrower to rehabilitate and/or receive the benefit of a suspension of AWG for a second time: Sections 674.39, 682.405, and 685.211. This widens eligibility for loan rehabilitation and thus adds burden to servicers who process rehabilitations. The Department estimates that approximately 91,700 additional borrowers would successfully rehabilitate their loan for a second time. If a servicer spends 8 hours on each borrower's loan rehabilitation, this adds 733,600 burden hours for loan servicers under this regulatory collection, 1845–0021 William D. Ford Federal Direct Loan Program regulations.

Once regulations are final, updates to burden on individuals due to the increased number of respondents for loans eligible for rehabilitation and/or administrative wage garnishment will be assessed under form changes to OMB Control #1845–0120 Loan Rehabilitation: Reasonable and Affordable Payments. The Department will seek comment on this in a separate public comment notice.

§ 685.208 Fixed Repayment

The Department proposes to restructure § 685.208 to provide fixed repayment plans based on when the Direct Loan was made. Loans made before July 1, 2026, will contain the following fixed repayment plans: standard, graduated, and extended. Loans made on or after July 1, 2026, would only have the Tiered Standard repayment plan as a fixed repayment plan option. Updates would be made to the form and the burden assessed under OMB Control #1845–0014 William D. Ford Federal Direct Loan Program Repayment Plan Selection Form. These updates will be completed and made available for comment through a separate public comment notice before the requirements are in effect.

This will also require servicers to update their systems, including eligibility logic for the updated repayment plans, train staff, and make edits to communications materials.

Based upon experience with prior repayment plan changes, the Department estimates it will take a total of 1,500 hours for servicers to update their systems to comply with the changes in repayment plan options. This would result in 9,000 additional burden hours that would be assessed to OMB Control #1845–0021 William D. Ford Federal Direct Loan Program regulations.

§ 685.210 Choice of Repayment Plan

Proposed § 685.210 would change the eligible repayment plans available for loans made on or after July 1, 2026. Updates will be made to the form and the burden assessed under OMB Control #1845–0014 William D. Ford Federal Direct Loan Program Repayment Plan Selection Form. These updates will be completed and made available for comment through a separate public comment notice before requirements go into effect.

Additional burden on servicers due to changes to repayment plans in their systems was accounted for in § 685.208.

§ 685.200 Borrower Eligibility

Section 81001 of the OBBA amended Section 455(a)(3)(C) of the HEA by eliminating the graduate and professional Direct PLUS Loan Program for new loans made on or after July 1, 2026. This proposed regulation would decrease burden on institutions and individuals.

Section 685.200 requires Direct PLUS Loan applicants who have been denied a Direct PLUS Loan due to an adverse credit history determination to complete enhanced Direct PLUS Loan counseling and submit documentation of extenuating circumstances to the Secretary to request a review of their loan application. Proposed § 685.200 would result in a change in burden for institutions. Because graduate and professional students would no longer be eligible for PLUS loans there will be a reduction in the number of PLUS loans originated by institutions and therefore a reduction of respondents to form OMB Control #1845–0129 PLUS Adverse Credit Reconsideration Loan Counseling. The Department will seek approval for this modification through a separate public comment notice before the requirements are in effect.

§ 685.204 Deferment

Proposed § 685.204 would update the eligibility criteria for an economic hardship deferment based on loan disbursement date. Section 82002 of the OBBA amends section 455(f) of the HEA to remove the authority for unemployment and economic hardship

deferments for Direct Loans made on or after July 1, 2027. The proposed changes would decrease burden related to the deferment processes. Updates will need to be made to the current deferment forms under OMB Control #1845–0011 Federal Student Loan Program Deferment Request Forms and its associated burden. This form update will be completed and made available for comment through a separate public comment notice before requirements go into effect.

§ 685.205 Forbearance

Section 82002 of the OBBB amends Section 455(f) of the HEA to limit the use of forbearance for future borrowers with loans made on or after July 1, 2027. Proposed § 685.205 would decrease the burden related to the forbearance process due to the new limitations on the use of forbearance. Updates would need to be made to OMB Control #1845–0018 Federal Student Loan Program: Internship/Residency and Loan Debt Burden Forbearance Forms and its associated burden. The Department will seek comment on this form update in a separate public comment notice before requirements go into effect.

§ 685.221 Alternative Repayment

Section 82001(b) of the OBBB amended Section 455(d) of the HEA to define which repayment plans are available to borrowers with loans made on or after July 1, 2026, thereby limiting which loans may use the alternative repayment plan to borrowers with Direct Loans made before July 1, 2026. We do not believe this proposed regulation would require a change to burden estimates for loan servicers. The alternative repayment plan was promulgated into regulation for borrowers with extreme circumstances. There is no OMB control number assigned to this repayment plan because the annual number of respondents does not meet the minimum required by OMB. As a result, the Department does not anticipate there will be enough borrowers who meet the alternative repayment plan requirements each year to have an impact on burden for servicers.

§ 685.203 Loan Limits

To conform with changes from the OBBB, proposed § 685.203 would require updates to loan limits.

Additionally, due to the changes proposed in § 685.203, the Department proposes to waive the requirement in § 685.303(d)(5) that prevents Direct Loans from being disbursed in any amount other than substantially equal installments when a borrower is enrolled for less than full-time enrollment. These changes will create burden on institutions. A school may need to make significant changes to implement revised disbursement requirements including the ability to accommodate uneven disbursements between periods of enrollment.

Proposed § 685.203(m) addresses when a student is enrolled in an eligible program on a less than full-time basis that would require a school to calculate and reduce a borrower's loan disbursement amount based upon less than full-time enrollment status. Schools are already required to package title IV aid evaluating for half-time or greater enrollment and less than half-time enrollment and adjusting, as needed.

The Department estimates that changes proposed in § 685.203 will take 950 hours per institution or servicer to complete creating a total of 5,350,400 additional burden hours assigned to the 1845–0021 William D. Ford Federal Direct Loan Program collection.

§ 685.209 Income-Driven Repayment

Section 685.209 proposes several modifications to the administration of IDR plans. First, we propose a new repayment plan, the Repayment Assistance Plan, to be added to 685.209 of the Direct Loan regulations. This repayment plan would be available to all Direct Loan borrowers regardless of when the borrower received their loan except for excepted Direct Loans. The legacy plans of PAYE, IBR, and ICR would only be available to borrowers with Direct Loans made before July 1, 2026. This regulation may alter the current IDR form. Any adjustments to burden calculation and number of respondents due to revisions to income-driven repayment regulations will be captured under OMB Control #1845–0102 Income-Driven Repayment and the Department will seek public comment on this in a separate notice before requirements go into effect. Proposed 685.209 would also require loan servicers to update their systems and policies and procedures to comply with

the modified regulations. This includes changes related to repayment plan eligibility and monthly payment calculations.

We estimate it will take servicers 700 hours to complete systems programming and integration; 190 hours for testing; 50 hours for edits to letters or communication material; and 600 hours for project management for a total of 1,540 burden hours. Currently there are six loan servicers, which would create 9,240 additional burden hours assessed to this regulatory collection, 1845–0021 William D. Ford Federal Direct Loan Program regulations.

§ 685.219 Public Service Loan Forgiveness Program (PSLF)

The Department proposes to amend § 685.219 Public Service Loan Forgiveness in accordance with amendments made by 82004(b)(1) through (3) of the OBBB to specify the qualifying repayment plans for the purposes of PSLF. Proposed § 685.219 expands the definition of a qualifying repayment plan for PSLF by adding two new categories: (1) income-contingent repayment plans, but only for payments made on or before June 30, 2028, and (2) the new Repayment Assistance Plan under § 685.209. This will require updates to burden assessed to OMB Control #1845–0110 Application and Employment Certification for Public Service Loan Forgiveness. The Department will update this form through a separate public comment notice before requirements go into effect.

Collection of Information

We provide below our preliminary estimates for potential burden changes and potential costs associated with changes to information collections impacted by this proposed regulation. We note these estimates may change once the regulation is finalized. The Department will also update any burden and cost estimates in the public comment notices seeking changes to these collections. For institutions, we used the median hourly wage for Education Administrators, Postsecondary (11–9033) from the U.S. Bureau of Labor Statistics. In 2024 this was \$49.98.

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Regulation	Information Collection Requirement	Burden Hours	Costs
§ 685.211 Miscellaneous, § 674.39 Loan rehabilitation, § 682.405 Loan rehabilitation agreement	OMB Control #1845-0120 Loan Rehabilitation: Reasonable and Affordable Payments OMB Control #1845-0021 William D. Ford Federal Direct Loan Program (DL) Regulations: Borrowers would be permitted to seek loan rehabilitation for a second time, increasing burden on servicers.	The Department will assess the burden hours for proposed regulations with the form updates to 1845-0120. 8 burden hours X 91,700 = 733,600 additional burden hours.	\$49.98 X 733,600 burden hours = \$36,665,328 total cost.
§ 685.102 Definitions	OMB Control # 1845-0021: Institutions will be required to update internal systems and policies.	300 hours X 5,626 institutions = 1,687,800 burden hours.	\$49.98 X 1,687,800 burden hours = \$84,356,244 total cost.
§ 682.215 Income-Based Repayment	OMB Control #1845-0102 Income-Driven Repayment Plan Request for the William D. Ford: Federal Direct Loans and Federal Family Education Loan Programs. OMB Control #1845-0021: Partial Financial Hardship will no longer	The Department will assess the burden hours for proposed regulations with the form updates to 1845-0102.	\$49.98 X 90,286 = \$4,512,494 decrease in cost burden.

	be a requirement for IBR applicants removing burden from servicers.	Decrease of 90,286 burden hours from the regulatory collection 1845-0021 William D. Ford Federal Direct Loan Program regulation.	
§ 685.200 Borrower Eligibility	OMB Control #1845-0129 PLUS Adverse Credit Reconsideration Loan Counseling.	The Department will assess the burden hours for proposed regulations with the form updates to 1845-0129.	N/A
§ 685.201 Obtaining a Loan	OMB Control #1845-0103 William D. Ford Federal Direct Loan Program, Federal Direct PLUS Loan Request for Supplemental Information OMB Control #1845-0129 PLUS Adverse Credit Reconsideration Loan Counseling. OMB Control # 1845-0021: Graduate and professional students will not be able to borrow a Direct PLUS Loan therefore decreasing the number of PLUS Loans originated by institutions	Updates to burden for individuals will be assessed under 1845-0103. 2,020 institutions X 620 burden hours = 1,252,400 decrease in burden hours.	\$49.98 X 1,252,400 burden hours = \$62,594,952 total decrease in cost burden.
§ 685.203 Loan Limits	OMB Control # 1845-0021: Internal system changes for updates to loan limits would increase burden on institutions and servicers.	5,626 institutions + 6 Servicers = 5,632 respondents. 900 burden hours x 5,632 institutions = 5,350,400 total burden hours.	\$49.98 X 5,350,400 burden hours = \$267,412,992 total costs.
§ 685.204 Deferment	OMB Control #1845-0011 Federal Student Loan Program Deferment Request Forms.	The Department will assess the burden	N/A

		hours for individuals for proposed regulations with the form updates to 1845-0011.	
§ 685.205 Forbearance	OMB Control #1845-0018 Federal Student Loan Program: Internship/Residency and Loan Debt Burden Forbearance Forms.	The Department will assess the burden hours for individuals for proposed regulations with the form updates to 1845-0018.	N/A
§ 685.208 Fixed payment repayment plans.	OMB Control #1845-0014 William D. Ford Federal Direct Loan Program Repayment Plan Selection Form. OMB Control #1845-0021: servicers will be required to update their systems.	The Department will assess the burden hours for individuals under proposed regulations with the form updates to 1845-0014. Additional 1,500 burden hours X 6 servicers = 9,000 hours	\$49.98 X 9,000 hours = \$449,820 00 increase in costs.
§ 685.209 Income-driven repayment	OMB Control #1845-0102 Income-Driven Repayment Plan Request for the William D. Ford Federal Direct Loans and Federal Family Education Loan Programs. OMB Control #1845-0021: servicers will be required to update systems, policies, and procedures.	The Department will assess the burden hours for individuals for proposed regulations with the form updates to 1845-0102. 6,000 burden hours X 6 servicers = 36,000 additional burden hours.	\$49.98 X 36,000 = \$1,799,280 increase in costs.
§ 685.210 Choice of Repayment Plan	OMB Control #1845-0014 William D. Ford Federal Direct Loan Program Repayment Plan Selection Form.	The Department will assess the burden hours for individuals proposed	N/A

		regulations with the form updates to 1845-0314.	
§ 685.220 Consolidation	OMB Control #1845-0007 William D. Ford Federal Direct Loan Program Promissory Notes and related forms.	The Department will assess the burden hours for individuals for proposed regulations with the form updates to 1845-0307.	N/A
§ 685.210 Miscellaneous	OMB Control #1845-0007 William D. Ford Federal Direct Loan Program Promissory Notes and related forms.	The Department will assess the burden hours for individuals for proposed regulations with the form updates to 1845-0307.	N/A
§ 685.219 Public Service Loan Forgiveness	OMB Control #1845-0102 Income-Driven Repayment Plan Request for the William D. Ford Federal Direct Loans and Federal Family Education Loan programs. OMB Control #1845-0110 Application and Employment Certification for Public Service Loan Forgiveness. OMB Control #1845-0164 Public Service Loan Forgiveness Reconsideration Request.	The Department will assess the burden hours for individuals for proposed regulations with the form updates to 1845-0102, 0110, and 0164.	N/A
§ 685.220 Consolidation	OMB Control #1845-0007 William D. Ford Federal Direct Loan Program Promissory Notes and related forms.	The Department will assess the burden hours for individuals for proposed regulations with the form updates to 1845-0307.	N/A
§ 685.303 Processing Loan Proceeds	Schools must use a new calculation for	Burden for this proposed regulation	N/A
	students enrolling less than full-time.	was accounted for in 685.102.	
TOTAL		6,474,114	\$323,576,218

by approximately 1,342,686 hours. This results in a net increase of 6,474,114 burden hours assessed to 1845–0021 William D. Ford Federal Direct Loan Program Regulations.

A Federal agency may not conduct or sponsor a collection of information unless OMB approves the collection under the PRA and the corresponding information collection instrument displays a currently valid OMB control number. Notwithstanding any other provision of law, no person is required to comply with or is subject to penalty for failure to comply with, a collection of information if the collection instrument does not display a currently valid OMB control number.

In the final regulations we will display the control numbers assigned by OMB to any information collection requirements proposed in this NPRM and adopted in the final regulations.

Intergovernmental Review

This program is subject to E.O. 12372 and the regulations in 34 CFR part 79. One of the objectives of the E.O. is to foster an intergovernmental partnership and strengthen Federalism. The E.O. relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans and actions for this program.

Assessment of Education Impact

In accordance with section 411 of the General Education Provisions Act, 20 U.S.C. 1221e–4, the Secretary requests comments on whether these final regulations would require transmission of information that any other agency or authority of the United States gathers or makes available.

Federalism

E.O. 13132 requires us to provide meaningful and timely input by State and local elected officials in the development of regulatory policies that have Federalism implications. “Federalism implications” means substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. The proposed regulations do not have Federalism implications.

Accessible Format: On request to the program contact person(s) listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document in an accessible format. The Department will provide the

requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

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You may also access documents of the Department published in the **Federal Register** by using the article search feature at www.federalregister.gov. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

List of Subjects in 34 CFR Parts 674, 682, and 685

Administrative practice and procedure, Annual and aggregate loan limits, Colleges and universities, Federal Family Education Loan (FFEL) Program, Federal Perkins Loan Program, Less than full-time enrollment, Loan consolidation, Education, Reporting and recordkeeping requirements, Student aid, William D. Ford Direct Loan Program.

Nicholas Kent,

Under Secretary of Education.

For the reasons discussed in the preamble, the Secretary of Education proposes to amend parts 674, 682, and 685 of title 34 of the Code of Federal Regulations as follows:

PART 674—FEDERAL PERKINS LOAN PROGRAM

■ 1. The authority citation for part 674 is revised to read as follows:

Authority: 20 U.S.C. 1071–1087ii; 1087dd(h)(1)(D)

■ 2. Section 674.39 is amended by revising paragraph (e) (1) and adding paragraph (e)(2).

The revision reads as follows:

§ 674.39 Loan rehabilitation.

* * * * *

(e) (1) On or before June 30, 2027, the borrower may rehabilitate a defaulted loan only one time.

(2) On or after July 1, 2027, the borrower may rehabilitate a defaulted loan a maximum of two times.

PART 682—FEDERAL FAMILY EDUCATION LOAN (FFEL) PROGRAM

■ 3. The authority citation for part 682 is revised to read as follows:

Authority: 20 U.S.C. 1071–1087–2, 1078–6(a)(5)

■ 4. Section 682.215 is amended by revising paragraphs (a)(4), (b)(1), (b)(5)–(7), (d)(1), (e)(1)–(6), and (f)(1). The revision reads as follows:

§ 682.215 Income-based repayment plan.

(a) * *

(4) *Applicable amount* means, for the purposes of the IBR plan, 15 percent of the result obtained by calculating, on at least an annual basis, the amount by which the adjusted gross income of the borrower and the borrower’s spouse (if applicable) exceeds 150 percent of the poverty guideline.

* * * * *

(b) * * *

(1) For the Income-Based Repayment plan, a borrower may elect to have their aggregate monthly payment recalculated to not exceed the applicable amount. The borrower’s aggregate monthly loan payments are limited to no more than 15 percent of the amount by which the borrower’s AGI exceeds 150 percent of the poverty line income applicable to the borrower’s family size, divided by 12. The loan holder adjusts the calculated monthly payment if—

(i) Except for borrowers provided for in paragraph (b)(1)(ii) of this section, the total amount of the borrower’s eligible loans includes loans not held by the loan holder, in which case the loan holder determines the borrower’s adjusted monthly payment by multiplying the calculated payment by the percentage of the total outstanding principal amount of the borrower’s eligible loans that are held by the loan holder;

(ii) Both the borrower and the borrower’s spouse have eligible loans and filed a joint Federal tax return, in which case the loan holder determines—

(A) Each borrower’s percentage of the couple’s total eligible loan debt;

(B) The adjusted monthly payment for each borrower by multiplying the calculated payment by the percentage determined in paragraph (b)(1)(ii)(A) of this section; and

(C) If the borrower’s loans are held by multiple holders, the borrower’s adjusted monthly payment by multiplying the payment determined in paragraph (b)(1)(ii)(B) of this section by the percentage of the total outstanding principal amount of the borrower’s eligible loans that are held by the loan holder;

(iii) The calculated amount under paragraph (b)(1), (b)(1)(i), or (b)(1)(ii) of this section is less than \$5.00, in which case the borrower's monthly payment is \$0.00; or

(iv) The calculated amount under paragraph (b)(1), (b)(1)(i), or (b)(1)(ii) of this section is equal to or greater than \$5.00 but less than \$10.00, in which case the borrower's monthly payment is \$10.00.

* * * * *

(5) Except as provided in paragraph (b)(4) of this section, accrued interest is capitalized at the time the borrower chooses to leave the income-based repayment plan or when the applicable amount exceeds the maximum amount calculated under paragraph (d)(1)(i) of this section.

(6) If the borrower's monthly payment amount is not sufficient to pay any principal due, the payment of that principal is postponed until the borrower chooses to leave the income-based repayment plan or when the applicable amount exceeds the maximum amount calculated under paragraph (d)(1)(i) of this section.

(7) The special allowance payment to a lender during the period in which the borrower has their aggregate monthly payment recalculated to not exceed the applicable amount, under the income-based repayment plan, is calculated on the principal balance of the loan and any accrued interest unpaid by the borrower.

* * * * *

(d) * * *

(1) If a borrower's applicable amount exceeds the maximum amount calculated under paragraph (d)(1)(i) of this section, the borrower may continue to make payments under the income-based repayment plan, but the loan holder must recalculate the borrower's monthly payment. The loan holder also recalculates the monthly payment for a borrower who chooses to stop making income-based payments. In either case, as a result of the recalculation—

(i) The maximum monthly amount that the loan holder requires the borrower to repay is the amount the borrower would have paid under the FFEL standard repayment plan based on a 10-year repayment period using the amount of the borrower's eligible loans that was outstanding at the time the borrower began repayment on the loans with that holder under the income-based repayment plan; and

(ii) The borrower's repayment period based on the recalculated payment amount may exceed 10 years.

* * * * *

(e) * * *

(1) The loan holder recalculates the borrower's aggregate monthly payment to not exceed the applicable amount for the year the borrower elects the Income-Based Repayment plan and for each subsequent year that the borrower remains on the plan. To make this determination, the loan holder requires the borrower to—

(i) Provide documentation, acceptable to the loan holder, of the borrower's AGI;

(ii) If the borrower's AGI is not available, or the loan holder believes that the borrower's reported AGI does not reasonably reflect the borrower's current income, provide other documentation to verify income;

(iii) If the spouse of a married borrower who files a joint Federal tax return has eligible loans and the loan holder does not hold at least one of the spouse's eligible loans—

(A) Confirm that the borrower's spouse has provided consent for the loan holder to obtain information about the spouse's eligible loans from the National Student Loan Data System; or

(B) Provide other documentation, acceptable to the loan holder, of the spouse's eligible loan information; and

(iv) Annually certify the borrower's family size. If the borrower fails to certify family size, the loan holder must assume a family size of one for that year.

(2) After determining the borrower's aggregate monthly payment for the year the borrower initially elects the plan and for any subsequent year that the borrower remains on the Income-Based Repayment plan, the loan holder must send the borrower a written notification that provides the borrower with—

(i) The borrower's scheduled monthly payment amount, as calculated under paragraph (b)(1) of this section, and the time period during which this scheduled monthly payment amount will apply (annual payment period);

(ii) Information about the requirement for the borrower to annually provide the information described in paragraph (e)(1) of this section, if the borrower chooses to remain on the income-based repayment plan after the initial year on the plan, and an explanation that the borrower will be notified in advance of the date by which the loan holder must receive this information;

(iii) An explanation of the consequences, as described in paragraph (e)(1)(iv) and (e)(7) of this section, if the borrower does not provide the required information;

(iv) An explanation of the consequences if the borrower no longer wishes to repay under the income-based repayment plan; and

(v) Information about the borrower's option to request, at any time during the borrower's current annual payment period, that the loan holder recalculate the borrower's monthly payment amount if the borrower's financial circumstances have changed and the income amount that was used to calculate the borrower's current monthly payment no longer reflects the borrower's current income. If the loan holder recalculates the borrower's monthly payment amount based on the borrower's request, the loan holder must send the borrower a written notification that includes the information described in paragraph (e)(2)(i) through (e)(2)(v) of this section.

(3) For each subsequent year that a borrower remains on the income-based repayment plan, the loan holder must notify the borrower in writing of the requirements in paragraph (e)(1) of this section no later than 60 days and no earlier than 90 days prior to the date specified in paragraph (e)(3)(i) of this section. The notification must provide the borrower with—

(i) The date, no earlier than 35 days before the end of the borrower's annual payment period, by which the loan holder must receive all of the information described in paragraph (e)(1) of this section (annual deadline); and

(ii) The consequences if the loan holder does not receive the information within 10 days following the annual deadline specified in the notice, including the borrower's new monthly payment amount as determined under paragraph (d)(1) of this section, the effective date for the recalculated monthly payment amount, and the fact that unpaid accrued interest will be capitalized at the end of the borrower's current annual payment period in accordance with paragraph (b)(5) of this section.

(4) Each time a loan holder recalculates the borrower's monthly payment amount for a subsequent year that the borrower wishes to remain on the plan, the loan holder must send the borrower a written notification that provides the borrower with—

(i) The borrower's recalculated monthly payment amount, as determined in accordance with paragraph (d)(1) of this section;

(ii) An explanation that unpaid accrued interest will be capitalized in accordance with paragraph (b)(5) of this section; and

(iii) Information about the borrower's option to request, at any time, that the loan holder recalculate the monthly payment amount, if the borrower's financial circumstances have changed

and the income amount used does not reflect the borrower's current income, and an explanation that the borrower will be notified annually of this option. If the loan holder recalculates the borrower's monthly payment amount based on the borrower's request, the loan holder must send the borrower a written notification that includes the information described in paragraph (e)(2)(i) through (e)(2)(v) of this section.

(5) For each subsequent year that a borrower remains on the income-based repayment plan, the loan holder must send the borrower a written notification that includes the information described in paragraph (e)(4)(iii) of this section.

(6) If a borrower who is currently repaying under another repayment plan selects the income-based repayment plan but does not provide the documentation described in paragraphs (e)(1)(i) through (e)(1)(iii) of this section, the borrower remains on his or her current repayment plan.

* * * * *

(f) * * *

(1) To qualify for loan forgiveness after 25 years, the borrower must have participated in the income-based repayment plan and satisfied at least one of the following conditions during that period—

(i) Made reduced monthly payments as provided in paragraph (b)(1) of this section, including a monthly payment amount of \$0.00, as provided in paragraph (b)(1)(iii) of this section;

(ii) Made reduced monthly payments or stopped making income-based payments as provided in paragraph (d)(1) of this section;

(iii) Made monthly payments under any repayment plan, that were not less than the amount required under the FFEL standard repayment plan described in § 682.209(a)(6)(vi) with a 10-year repayment period for the amount of the borrower's loans that were outstanding at the time the loans initially entered repayment;

(iv) Made monthly payments under the FFEL standard repayment plan described in § 682.209(a)(6)(vi) based on a 10-year repayment period; or

(v) Received an economic hardship deferment on eligible FFEL loans.

* * * * *

■ 5. Amend § 682.405 by revising paragraphs (a)(3) and (4) to read as follows:

§ 682.405 Loan rehabilitation agreement.

(a) * * *

(3) * * *

(iii)(A) Through July 1, 2027, a borrower may only obtain the benefit of suspension of administrative wage

garnishment while also attempting to rehabilitate a defaulted loan once.

(B) On or after July 1, 2027, a borrower may only obtain the benefit of suspension of administrative wage garnishment one time per each attempt to rehabilitate a defaulted loan.

(4) (i) After the loan has been rehabilitated, the borrower regains all benefits of the program, including any remaining deferment eligibility under section 428(b)(1)(M) of the Act, from the date of the rehabilitation.

(ii) A loan may only be rehabilitated once between August 14, 2008, through June 30, 2027. On or after July 1, 2027, a loan may only be rehabilitated a maximum of two times over the loan's lifetime, regardless of when the loan was made.

* * * * *

**PART 685—WILLIAM D. FORD
FEDERAL DIRECT LOAN PROGRAM**

■ 6. The authority citation for part 685 is revised to read as follows:

Authority: 20 U.S.C. 1087a—1087j, Section 685.102 also issued under U.S.C. 1087e(a)

Section 685.200 also issued under U.S.C. 1087e(a)

Section 685.201 also issued under U.S.C. 1087e(a), 1091a

Section 685.203 also issued under U.S.C. 1087e(a)

Section 685.204 also issued under U.S.C. 1087e(f)

Section 685.205 also issued under U.S.C. 1087e(f)

Section 685.208 also issued under U.S.C. 1087e(d)

Section 685.209 also issued under U.S.C. 1078, 1078–3, 1087e(b), 1087e(d), 1092(d)(1), 1098e(a)(3), 1098h(a)(2)

Section 685.210 also issued under U.S.C. 1087e(d)

Section 685.211 also issued under U.S.C. 1087e

Section 685.219 also issued under U.S.C. 1087(m)(1)(A)

Section 685.220 also issued under U.S.C. 1087e(g)

Section 685.221 also issued under U.S.C. 1098e(a)(2)

Section 685.303 also issued under U.S.C. 1087a

■ 7. Section 685.102 is amended by adding new definitions in (b).

Add “*Expected time to credential:*”

after “*Estimated financial assistance:*”

and before “*Federal Direct Consolidation Loan Program (Direct Consolidation Loan Program):*”

Add “*Graduate student:*” after “*Grace period:*” and before “*Guaranty agency:*”

Add “*Professional student:*” after “*Period of enrollment:*” and add “*Program length:*” after “*Professional*

student:” and before “*Satisfactory repayment arrangement:*”

The revisions read as follows:

§ 685.102 Definitions.

* * * * *

(b) * * *

Expected time to credential: From July 1, 2026, the expected time for a student to complete a program that is equal to or the lesser of—

(1) three academic years, as defined in 34 CFR 668.3; or

(2) the period determined by calculating the difference between—

(i) the program length for the program of study in which the individual is enrolled; and

(ii) the period of such program of study that such individual has completed as of the date of the determination under paragraph (2) of this definition.

* * * * *

Graduate student: A student enrolled in a program of study that is above the baccalaureate level and awards a graduate credential (other than a professional degree) upon completion of the program.

* * * * *

Professional student: A student enrolled in a program of study that awards a professional degree upon completion of the program;

(1) A professional degree is a degree that:

(i) Signifies both completion of the academic requirements for beginning practice in a given profession, and a level of professional skill beyond that normally required for a bachelor's degree;

(ii) Is generally at the doctoral level, and that requires at least six academic years of postsecondary education coursework for completion, including at least two years of post-baccalaureate level coursework;

(iii) Generally requires professional licensure to begin practice; and

(iv) Includes a four-digit program CIP code, as assigned by the institution or determined by the Secretary, in the same intermediate group as the fields listed in paragraph (2)(i) of this definition.

(2) A professional degree may be awarded in the following fields:

(i) Pharmacy (Pharm.D.), Dentistry (D.D.S. or D.M.D.), Veterinary Medicine (D.V.M.), Chiropractic (DC or DCM.), Law (L.L.B. or J.D.), Medicine (M.D.), Optometry (O.D.), Osteopathic Medicine (D.O.), Podiatry (D.P.M., D.P., or Pod.D.), Theology (M.Div., or M.H.L.), and Clinical Psychology (Psy.D. or Ph.D.).

(3) A professional student under this definition:

(i) May not receive title IV aid as an undergraduate student for the same period of enrollment; and

(ii) Must be enrolled in a program leading to a professional degree under paragraph (2) of this definition.

Program length: The minimum amount of time in weeks, months, or years that is specified in the catalog, marketing materials, or other official publications of an institution for a full-time student to complete the requirements for a specific program of study.

* * * * *

■ 8. Section 685.200 is amended by revising paragraph (b)(1) to include a new introductory sentence, renumbering the subordinate remaining sentences to (i–iv) and adding new paragraphs (2) and (3).

The revisions read as follows:

§ 685.200 Borrower eligibility.

* * * * *

(b) Student PLUS borrower.

(1) A graduate student or professional student is eligible to receive a Direct PLUS Loan if the student meets the following requirements:

(i) The student is enrolled, or accepted for enrollment, on at least a half-time basis in a school that participates in the Direct Loan Program.

(ii) The student meets the requirements for an eligible student under 34 CFR part 668.

(iii) The student meets the requirements of paragraphs (a)(1)(iv) and (a)(1)(v) of this section, if applicable.

(iv) The student has received a determination of his or her annual loan maximum eligibility under the Direct Unsubsidized Loan Program and, for periods of enrollment beginning before July 1, 2012, the Direct Subsidized Loan Program; and

(v) The student meets the requirements that apply to a parent under paragraphs (c)(2)(viii)(A) through (G) of this section.

(2)(i) Beginning on July 1, 2026, a graduate student or professional student may not borrow a Direct PLUS Loan.

(ii) The limitation for making new Federal Direct PLUS Loan awards described in paragraph (b)(2)(i) of this section shall not be applicable to student borrowers during the period of the student's expected time to credential, if—

(A) the student is enrolled in a program of study at an institution as of June 30, 2026; and

(B) a Direct Loan was made for such program of study prior to July 1, 2026.

(3) If the student withdraws in accordance with § 668.22 or otherwise ceases to be enrolled in the program of study at any point after receiving the exception under paragraph (b)(2)(ii) of this section, the limitations under paragraph (b)(2)(i) shall apply.

* * * * *

■ 9. Section 685.201 is amended by revising (b)(2)(ii).

The revisions read as follows:

§ 685.201 Obtaining a Loan.

* * * * *

(b) * * *

(2) * * *

(i) Before July 1, 2026, for a graduate or professional student to apply for a Direct PLUS Loan, the student must complete a Free Application for Federal Student Aid and submit it in accordance with instructions in the application. The graduate or professional student must also complete the Direct PLUS Loan MPN.

(ii) On or after July 1, 2026, a graduate student or professional student may only apply for a Direct PLUS Loan if the student satisfies the conditions set forth in § 685.200(b)(2)(ii).

* * * * *

■ 10. Section 685.203 is amended by revising paragraphs (b)(2), (c)(2), (e), (f), (g), and (j); and adding new paragraphs (l) and (m).

The revisions read as follows:

§ 685.203 Loan Limits.

* * * * *

(b) * * *

(2) * * *

(iii) In the case of a graduate or professional student for a period of enrollment beginning on or after July 1, 2012, and ending on or before June 30, 2026, the total amount the student may borrow for any academic year of study under the Direct Unsubsidized Loan Program may not exceed \$8,500.

(iv) *Loan Limits for Graduate and Professional Students for Periods of Enrollment Beginning On or After July 1, 2026*

(A)(1) A graduate student, who is not a professional student, for a period of enrollment beginning on or after July 1, 2026, may borrow up to \$20,500 for any academic year under the Direct Unsubsidized Loan Program.

(2) A professional student, for a period of enrollment beginning on or after July 1, 2026, may borrow up to \$50,000 for any academic year under the Direct Unsubsidized Loan Program.

(B) The limitations in effect on July 1, 2026, for annual loan limits as described in paragraph (b)(2)(iv)(A) of this section shall not be applicable to student borrowers during the period of the

student's expected time to credential if—

(1) the student is enrolled in a program of study at an institution as of June 30, 2026; and

(2) a Direct Loan was made prior to July 1, 2026, for such a program of study.

(C) If the student withdraws in accordance with § 668.22 or otherwise ceases to be enrolled in the program of study at any point after receiving the exception under paragraph (b)(2)(iv)(B) of this section, the limitations under paragraph (b)(2)(iv)(A) shall apply.

* * * * *

(c) * * *

(2) * * *

(v) In the case of a graduate or professional student for a period of enrollment through June 30, 2026, \$12,000.

* * * * *

(e) * * *

(3) For a graduate or professional student for periods of enrollment beginning before July 1, 2026, \$138,500, including any loans for undergraduate study, minus any Direct Subsidized Loan, Subsidized Federal Stafford Loan, and Federal SLS Program loan amounts.

(4) For a graduate student for a period of enrollment beginning on or after July 1, 2026—

(i) who is not and has never been a professional student at an institution, \$100,000.

(ii) who is or has been a professional student at an institution, \$200,000, minus any amounts such student borrowed as a professional student.

(5) For a professional student for a period of enrollment beginning on or after July 1, 2026, \$200,000, minus any Direct Subsidized Loan, Subsidized Federal Stafford Loan, and Federal SLS Program loan amounts and any amounts such student borrowed as a graduate student, if applicable.

(6) The limitations for aggregate loan limits described in paragraphs (e)(4) and (e)(5) of this section shall not be applicable to student borrowers during the period of the student's expected time to credential, if—

(i) the student is enrolled in a program of study at an institution as of June 30, 2026; and

(ii) a Direct Loan was made for such program of study prior to July 1, 2026.

(7) If the student withdraws in accordance with § 668.22 or otherwise ceases to be enrolled in the program of study at any point after receiving the exception under paragraph (e)(6) of this section, the limitations under paragraphs (e)(4) or (e)(5) shall apply, as applicable.

* * * * *

(f) Direct PLUS Loans annual limit.

(1) *Annual Limits Before July 1, 2026.*

The total amount of all Direct PLUS Loans that a parent or parents may borrow on behalf of each dependent student, or that a graduate or professional student may borrow, for any academic year of study for a period of enrollment beginning before July 1, 2026, may not exceed the cost of attendance minus other estimated financial assistance for the student.

(2) *Direct PLUS Annual Limits for Parents of Dependents Undergraduates On or After July 1, 2026*

(i) For periods of enrollment beginning on or after July 1, 2026, the total amount of all Direct PLUS Loans that all parents may borrow on behalf of each dependent student for any academic year of study may not exceed \$20,000 minus other financial assistance (as defined in Section 480(i) of the Act) for the student.

(ii) The limitation for annual loan limits described in paragraph (f)(2)(i) of this section shall not be applicable to parent borrowers, who borrowed a loan on behalf of a dependent student, during the period of the student's expected time to credential, if—

(A) the student is enrolled in a program of study at an institution as of June 30, 2026; and

(B) a Direct Loan was made to the parent borrower for such program of study on behalf of the dependent student, or a Direct Loan was made to the dependent student for such program of study.

(iii) If the student withdraws in accordance with § 668.22 or otherwise ceases to be enrolled in the program of study at any point after receiving the exception under paragraph (f)(2)(ii) of this section, the limitations under paragraph (f)(2)(i) of this section shall apply to the parent borrower of that dependent student.

(iv) For the purposes of this subparagraph (f), a student who changes majors within the same degree or certificate shall be considered to be enrolled in the same program of study.

(3) *Direct PLUS Annual Limits for Graduate Students and Professional Students On or After July 1, 2026.* The Direct PLUS annual limits for graduate students and professional students for periods of enrollment beginning on or after July 1, 2026, can be found at § 685.200(b)(2) and (3).

* * * * *

(g) Direct PLUS Loans aggregate limit.

(1) *Aggregate Limits Before July 1, 2026.* The total amount of all Direct PLUS Loans that a parent or parents may borrow on behalf of each

dependent student, or that a graduate or professional student may borrow for a period of enrollment beginning before July 1, 2026, for enrollment in an eligible program of study may not exceed the student's cost of attendance minus other estimated financial assistance for that student for the entire period of enrollment.

(2) *Direct PLUS Aggregate Limits for Parents of Dependent Undergraduates On or After July 1, 2026.* For periods of enrollment beginning on or after July 1, 2026, the total amount of all Direct PLUS Loans that all parents may borrow on behalf of each dependent student may not exceed \$65,000, without regard to any amounts repaid, forgiven, canceled, or otherwise discharged on any such loan. Any amount of loan funds that have been returned by the institution, or the borrower will not count against the aggregate loan limit under this paragraph (g)(2).

(3) The limitation for aggregate loan limits described in paragraph (g)(2) of this section shall not be applicable to parent borrowers during the period of the student's expected time to credential, if—

(i) the student is enrolled in a program of study at an institution as of June 30, 2026; and

(ii) a Direct Loan was made to the parent for such program of study on behalf of the dependent student, or a Direct Loan was made to the dependent student for such program of study prior to July 1, 2026.

(4) If the student withdraws in accordance with § 668.22 or otherwise ceases to be enrolled in the program of study at any point after receiving the exception under paragraph (g)(3) of this section, the limitations under paragraph (g)(2) of this section shall apply.

(5) For the purposes of this paragraph (g), a student who changes majors within the same degree or certificate shall be considered to be enrolled in the same program of study.

(6) *Direct PLUS Aggregate Limits for Graduate Students and Professional Students On or After July 1, 2026.* The Direct PLUS aggregate limits for graduate students and professional students for periods of enrollment beginning on or after July 1, 2026, can be found at § 685.200(b)(2) and (3).

* * * * *

(j) Maximum loan amounts.

(1) In no case may a Direct Subsidized, Direct Unsubsidized, or Direct PLUS Loan amount exceed the student's estimated cost of attendance for the period of enrollment for which the loan is intended, less—

(i) The student's estimated financial assistance for that period; and

(ii) In the case of a Direct Subsidized Loan, the borrower's expected family contribution for that period.

(2) Effective July 1, 2026, the lifetime maximum aggregate amount of loans made, insured, or guaranteed under the Act that a student may borrow, excluding Federal PLUS loans or Federal Direct PLUS Loans, shall be \$257,500 without regard to any amounts repaid, forgiven, canceled, or otherwise discharged on such loans. Any amount of loan funds that have been returned by the institution, or the borrower, will not count against the lifetime maximum aggregate loan limit in this paragraph (j)(2).

(3) The limitation for lifetime maximum aggregate loan limits described in paragraph (j)(2) of this section shall not be applicable to student borrowers during the period of the student's expected time to credential, if—

(i) the student is enrolled in a program of study at an institution as of June 30, 2026; and

(ii) a Direct Loan was made for such program of study prior to July 1, 2026.

(4) If the student withdraws in accordance with § 668.22 or otherwise ceases to be enrolled in the program of study at any point after receiving the exception under paragraph (j)(3) of this section, the limitations under paragraph (j)(2) of this section shall apply.

* * * * *

(l) For the purposes of this section, if a student is enrolled in a program that awards both a graduate degree and professional degree, the student shall be considered a professional student if more than 50 percent of the credit hours in that program count toward the professional degree.

* * * * *

(m) Additional Rules for Loan Limits.

(1) *Less Than Full-Time Enrollment.* Notwithstanding any provision of 34 CFR parts 682 or 685, in any case in which a student is enrolled in an eligible program (except for a non-term program) at an institution on a less than a full-time basis during any academic year, the amount of any Direct Loan that student may borrow for an academic year or its equivalent shall be reduced in direct proportion to the degree to which that student is not so enrolled on a full-time basis, as of the date the institution determined the student's eligibility for the disbursement in accordance with 34 CFR 668.164(b)(3), rounded to the nearest whole percentage point, as follows:

$$\left(\frac{\text{number of credit hours enrolled for academic year}}{\text{number of credit hours considered full time for that academic year for the program of study}} \right) \times 100$$

= reduced annual loan limit percentage

(i) *Periods of Enrollment that are Less than a Full Academic Year.* For a period of enrollment of less than an academic year as defined under § 668.3, the institution must calculate the Direct Loan eligibility that student may borrow for the term in which the borrower is enrolled, or its equivalent, in direct

proportion to the degree to which that student is not so enrolled on a full-time basis for that term.

(A) The institution shall first determine the amount of the academic year loan limit under this section that the term represents.

(B) The institution shall then determine the borrower's eligibility for

a disbursement of a Direct Loan for the term, in accordance with 34 CFR 668.164(b)(3).

(C) The institution shall then reduce the borrower's Direct Loan amount based on less than full-time enrollment for that term at that institution, as follows:

$$\left(\frac{\text{number of credit hours enrolled for the term}}{\text{number of credit hours considered full time for that term for the program of study}} \right) \times 100$$

= reduced annual loan limit percentage

(2) Institutionally Determined Loan Limits

(i) Beginning on July 1, 2026, an institution may limit the total amount of Direct Subsidized, Unsubsidized, and PLUS loans that a student, or a parent on behalf of such student, may borrow for a program of study for an academic year, as long as any such limit is applied consistently to all students enrolled in that program of study.

(ii) An institution that limits the total amount of Direct Loans for an eligible program under paragraph (m)(2)(i) of this section must document its decision and follow the record retention and examination requirements in 34 CFR 668.24.

(iii) An institution must provide clear and conspicuous information describing any program of study that is subject to the loan limitation and explain the need for such limitation to current and prospective students, including, but not limited to: publication in the institution's course catalog, publication on institution's website(s), and award notifications.

(iv) Prior to taking such action under paragraph (m)(2)(i) of this section, an institution must notify the student who plans to enroll or is enrolled in the program subject to this limitation.

(v) For purposes of this paragraph (m)(2), program of study means eligible program.

* * * * *

■ 11. Section 685.204 is amended by revising paragraphs (f) and (g) to read as follows:

§ 685.204 Deferment.

* * * * *

(f) *Unemployment deferment.*

(1) (i) For loans disbursed before July 1, 2027, a Direct Loan borrower is eligible for a deferment during periods that, collectively, do not exceed three years in which the borrower is seeking and unable to find full-time employment.

(ii) For loans disbursed on or after July 1, 2027, a borrower may not receive an unemployment deferment.

* * * * *

(3) For the purposes of obtaining an unemployment deferment under paragraph (f)(2)(ii) of this section, the following rules apply:

(i) * * *

* * * * *

(g) *Economic hardship deferment.*

(1)(i) For loans disbursed before July 1, 2027, a Direct Loan borrower who has experienced or will experience an economic hardship in accordance with paragraph (g)(2) of this section, is eligible for a deferment during periods that, collectively, do not exceed three years.

(ii) For loans disbursed on or after July 1, 2027, a borrower may not receive an economic hardship deferment under paragraph (g) of this section.

(iii) An economic hardship deferment is granted for periods of up to one year at a time, except that a borrower who receives a deferment under paragraph (g)(2)(iv) of this section may receive an economic hardship deferment for the lesser of the borrower's full term of service in the Peace Corps or the borrower's remaining period of economic hardship deferment eligibility under the 3-year maximum.

* * * * *

■ 12. Section 685.205 is amended by revising paragraph (c)(1) The revisions read as follows:

§ 685.205 Forbearance.

* * * * *

(c) *Period of forbearance.*

(1) (i) The Secretary grants forbearance for a period of up to one year.

(ii) For loans disbursed on or after July 1, 2027, and notwithstanding paragraph (c)(1)(i) of this section, the Secretary grants forbearance for a period that does not exceed nine months within a 24-month period for forbearances under paragraph (a)(1) of this section. The forbearance under this paragraph (c)(1)(ii) begins on the first month for which the forbearance is granted.

* * * * *

■ 13. Section 685.208 is amended by revising and republishing the section in its entirety.

The revisions read as follows:

§ 685.208 Fixed payment repayment plans.

(a) *General.*

Under a fixed payment repayment plan, the borrower's required monthly payment amount is determined based on the amount of the borrower's Direct Loans, the interest rates on the loans, and the repayment plan's maximum repayment period.

(b) *Fixed Repayment Plans for Direct Loans Made Before July 1, 2026.*

(1) Standard repayment plan for all Direct Subsidized Loan, Direct Unsubsidized Loan, and Direct PLUS Loan borrowers, who have not received a Direct Loan on or after July 1, 2026, and for Direct Consolidation Loan borrowers who entered repayment before July 1, 2006, and have not received a Direct Loan on or after July 1, 2026.

(i) Under this repayment plan, a borrower must repay a loan in full within ten years from the date the loan entered repayment by making fixed monthly payments.

(ii) A borrower's payments under this repayment plan are at least \$50 per month, except that a borrower's final payment may be less than \$50.

(iii) The number of payments or the fixed monthly repayment amount may be adjusted to reflect changes in the variable interest rate identified in § 685.202(a).

(iv) The repayment period for the repayment plan described in this paragraph (b)(1) does not include periods of authorized deferment or forbearance.

(2) Standard repayment plan for Direct Consolidation Loan borrowers entering repayment on or after July 1, 2006, and who have not received a Direct Loan on or after July 1, 2026.

(i) Under this repayment plan, a borrower must repay a loan in full by making fixed monthly payments over a repayment period that varies with the total amount of the borrower's student loans, as described in paragraph (b)(2)(iii) of this section.

(ii) A borrower's payments under this repayment plan are at least \$50 per month, except that a borrower's final payment may be less than \$50.

(iii) *Repayment period under this paragraph (b)(2).* If the total amount of the Direct Consolidation Loan and the borrower's other student loans, as defined in § 685.220(i), is—

(A) Less than \$7,500, the borrower must repay the Consolidation Loan within 10 years of entering repayment;

(B) Equal to or greater than \$7,500 but less than \$10,000, the borrower must repay the Consolidation Loan within 12 years of entering repayment;

(C) Equal to or greater than \$10,000 but less than \$20,000, the borrower must repay the Consolidation Loan within 15 years of entering repayment;

(D) Equal to or greater than \$20,000 but less than \$40,000, the borrower must repay the Consolidation Loan within 20 years of entering repayment;

(E) Equal to or greater than \$40,000 but less than \$60,000, the borrower must repay the Consolidation Loan within 25 years of entering repayment; and

(F) Equal to or greater than \$60,000, the borrower must repay the Consolidation Loan within 30 years of entering repayment.

(iv) The repayment period for the repayment plan described in this paragraph (b)(2) does not include periods of authorized deferment or forbearance.

(3) Extended repayment plan for all Direct Loan borrowers who entered repayment before July 1, 2006, and who have not received a Direct Loan on or after July 1, 2026.

(i) Under this repayment plan, a borrower must repay a loan in full by making fixed monthly payments within an extended period of time that varies with the total amount of the borrower's loans, as described in paragraph (b)(4)(iv) of this section.

(ii) A borrower makes fixed monthly payments of at least \$50, except that a borrower's final payment may be less than \$50.

(iii) The number of payments or the fixed monthly repayment amount may be adjusted to reflect changes in the variable interest rate identified in § 685.202(a).

(iv) *Repayment period under this paragraph (b)(3).* If the total amount of the borrower's Direct Loans is—

(A) Less than \$10,000, the borrower must repay the loans within 12 years of entering repayment;

(B) Greater than or equal to \$10,000 but less than \$20,000, the borrower must repay the loans within 15 years of entering repayment;

(C) Greater than or equal to \$20,000 but less than \$40,000, the borrower must repay the loans within 20 years of entering repayment;

(D) Greater than or equal to \$40,000 but less than \$60,000, the borrower must repay the loans within 25 years of entering repayment; and

(E) Greater than or equal to \$60,000, the borrower must repay the loans within 30 years of entering repayment.

(v) The repayment period for the repayment plan described in this paragraph (b)(3) does not include periods of authorized deferment or forbearance.

(4) Extended repayment plan for all Direct Loan borrowers entering repayment on or after July 1, 2006, and who have not received a Direct Loan on or after July 1, 2026.

(i) Under this repayment plan, a new borrower with more than \$30,000 in outstanding Direct Loans accumulated on or after October 7, 1998, must repay either a fixed annual or graduated repayment amount over a period not to exceed 25 years from the date the loan entered repayment. For this repayment plan, a new borrower is defined as an individual who has no outstanding principal or interest balance on a Direct Loan as of October 7, 1998, or on the date the borrower obtains a Direct Loan on or after October 7, 1998.

(ii) A borrower's payments under this plan are at least \$50 per month and will

be more if necessary to repay the loan within the required time period.

(iii) The number of payments or the monthly repayment amount may be adjusted to reflect changes in the variable interest rate identified in § 685.202(a).

(iv) *Repayment period under this paragraph (b)(4).* If the total amount of the borrower's Direct Loans is—

(A) Less than \$10,000, the borrower must repay the loans within 12 years of entering repayment;

(B) Greater than or equal to \$10,000 but less than \$20,000, the borrower must repay the loans within 15 years of entering repayment;

(C) Greater than or equal to \$20,000 but less than \$40,000, the borrower must repay the loans within 20 years of entering repayment;

(D) Greater than or equal to \$40,000 but less than \$60,000, the borrower must repay the loans within 25 years of entering repayment; and

(E) Greater than or equal to \$60,000, the borrower must repay the loans within 30 years of entering repayment.

(v) The repayment period for the repayment plan described in this paragraph (b)(4) does not include periods of authorized deferment or forbearance.

(5) Graduated repayment plan for all Direct Loan borrowers who entered repayment before July 1, 2006, and who have not received a Direct Loan on or after July 1, 2026.

(i) Under this repayment plan, a borrower must repay a loan in full by making payments at two or more levels within a period of time that varies with the total amount of the borrower's loans, as described in paragraph (b)(5)(iv) of this section.

(ii) The number of payments or the monthly repayment amount may be adjusted to reflect changes in the variable interest rate identified in § 685.202(a).

(iii) No scheduled payment under this repayment plan may be less than the amount of interest accrued on the loan between monthly payments, less than 50 percent of the payment amount that would be required under the standard repayment plan described in paragraph (b)(1) of this section, or more than 150 percent of the payment amount that would be required under the standard repayment plan described in paragraph (b)(1) of this section.

(iv) *Repayment period under this paragraph (b)(5).* If the total amount of the borrower's Direct Loans is—

(A) Less than \$10,000, the borrower must repay the loans within 12 years of entering repayment;

(B) Greater than or equal to \$10,000 but less than \$20,000, the borrower must repay the loans within 15 years of entering repayment;

(C) Greater than or equal to \$20,000 but less than \$40,000, the borrower must repay the loans within 20 years of entering repayment;

(D) Greater than or equal to \$40,000 but less than \$60,000, the borrower must repay the loans within 25 years of entering repayment; and

(E) Greater than or equal to \$60,000, the borrower must repay the loans within 30 years of entering repayment.

(v) The repayment period for the repayment plan described in this paragraph (b)(5) does not include periods of authorized deferment or forbearance.

(6) Graduated repayment plan for Direct Subsidized Loan, Direct Unsubsidized Loan, and Direct PLUS Loan borrowers entering repayment on or after July 1, 2006, and who have not received a Direct Loan on or after July 1, 2026.

(i) Under this repayment plan, a borrower must repay a loan in full by making payments at two or more levels over a period of time not to exceed ten years from the date the loan entered repayment.

(ii) The number of payments or the monthly repayment amount may be adjusted to reflect changes in the variable interest rate identified in § 685.202(a).

(iii) A borrower's payments under this repayment plan may be less than \$50 per month. No single payment under this plan will be more than three times greater than any other payment.

(iv) The repayment period for the repayment plan described in this paragraph (b)(6) does not include periods of authorized deferment or forbearance.

(7) Graduated repayment plan for Direct Consolidation Loan borrowers entering repayment on or after July 1, 2006, and who have not received a Direct Loan on or after July 1, 2026.

(i) Under this repayment plan, a borrower must repay a loan in full by making monthly payments that gradually increase in stages over the course of a repayment period that varies with the total amount of the borrower's student loans, as described in paragraph (j)(b)(7)(iii) of this section.

(ii) A borrower's payments under this repayment plan may be less than \$50 per month. No single payment under this plan will be more than three times greater than any other payment.

(iii) *Repayment period under this paragraph (b)(7).* If the total amount of the Direct Consolidation Loan and the

borrower's other student loans, as defined in § 685.220(i), is—

(A) Less than \$7,500, the borrower must repay the Consolidation Loan within 10 years of entering repayment;

(B) Equal to or greater than \$7,500 but less than \$10,000, the borrower must repay the Consolidation Loan within 12 years of entering repayment;

(C) Equal to or greater than \$10,000 but less than \$20,000, the borrower must repay the Consolidation Loan within 15 years of entering repayment;

(D) Equal to or greater than \$20,000 but less than \$40,000, the borrower must repay the Consolidation Loan within 20 years of entering repayment;

(E) Equal to or greater than \$40,000 but less than \$60,000, the borrower must repay the Consolidation Loan within 25 years of entering repayment; and

(F) Equal to or greater than \$60,000, the borrower must repay the Consolidation Loan within 30 years of entering repayment.

(iv) The repayment period for the repayment plan described in this paragraph (b)(7) does not include periods of authorized deferment or forbearance.

(8) Tiered Standard repayment plan for Direct Loan borrowers who received a Direct Loan before July 1, 2026, and also received a Direct Loan that was made on or after July 1, 2026.

(i) Under this repayment plan, a borrower must repay a loan in full by making fixed monthly payments over a repayment period that varies with the total amount of the borrower's Direct Loans, as described in paragraph (b)(8)(ii) of this section.

(ii) A borrower's payments under this repayment plan are at least \$50 per month, except that when a borrower's balance is less than \$50, the minimum payment will be equal to the outstanding amount due.

(iii) *Repayment period.* Under this repayment plan, if the total amount of Direct Loans at the time the borrower is entering repayment, is—

(A) Less than \$25,000, the borrower must repay the Direct Loan within 10 years of entering repayment;

(B) Equal to or greater than \$25,000 but less than \$50,000, the borrower must repay the Direct Loan within 15 years of entering repayment;

(C) Equal to or greater than \$50,000 but less than \$100,000, the borrower must repay the Direct Loan within 20 years of entering repayment; and

(D) Equal to or greater than \$100,000, the borrower must repay the Direct Loan within 25 years of entering repayment.

(c) *Fixed Repayment Plans for Direct Loans Made On or After July 1, 2026.*

The fixed repayment plans under this paragraph (c) shall only apply to Direct Loans made on or after July 1, 2026.

(1) Tiered Standard repayment plan for Direct Loan borrowers who received a Direct Loan on or after July 1, 2026.

(i) Under this repayment plan, a borrower must repay a loan in full by making fixed monthly payments over a repayment period that varies with the total amount of the borrower's Direct Loans, as described in paragraph (c)(1)(ii) of this section.

(ii) A borrower's payments under this repayment plan are at least \$50 per month, except that when a borrower's balance is less than \$50, the minimum payment will be equal to the outstanding amount due.

(iii) *Repayment period.* Under this repayment plan, if the total amount of Direct Loans at the time the borrower is entering repayment, is—

(A) Less than \$25,000, the borrower must repay the Direct Loan within 10 years of entering repayment;

(B) Equal to or greater than \$25,000 but less than \$50,000, the borrower must repay the Direct Loan within 15 years of entering repayment;

(C) Equal to or greater than \$50,000 but less than \$100,000, the borrower must repay the Direct Loan within 20 years of entering repayment; and

(D) Equal to or greater than \$100,000, the borrower must repay the Direct Loan within 25 years of entering repayment.

■ 14. Section 685.209 is amended by revising and republishing the section in its entirety to read as follows:

§ 685.209 Income-driven repayment plans.

(a) General.

Income-driven repayment (IDR) plans are repayment plans that base the borrower's monthly payment amount on the borrower's income and family size. The five IDR plans are—

(1) The Revised Pay As You Earn (REPAYE) plan, which may also be referred to as the Saving on a Valuable Education (SAVE) plan;

(2) The Income-Based Repayment (IBR) plan;

(3) The Pay As You Earn (PAYE) Repayment plan; and

(4) The Income-Contingent Repayment (ICR) plan; and

(5) The Repayment Assistance Plan.

(b) For the purposes of this section, the following terms apply:

(1) *Applicable amount* means—

(i) For a borrower who is not a new borrower under the IBR plan, 15 percent of the result obtained by calculating on at least an annual basis, the amount of the borrower's adjusted gross income, and the borrower's spouse's adjusted gross income if married filing jointly,

that exceeds 150 percent of the poverty guideline;

(ii) For a new borrower under the IBR plan, 10 percent of the result obtained by calculating on at least an annual basis, the amount of the borrower's adjusted gross income, and the borrower's spouse's adjusted gross income if married filing jointly, that exceeds 150 percent of the poverty guideline; or

(iii) For any borrower under the PAYE plan, 10 percent of the result obtained by calculating on at least an annual basis, the amount of the borrower's adjusted gross income, and the borrower's spouse's adjusted gross income if married filing jointly, that exceeds 150 percent of the poverty guideline.

(2) *Base payment*, under the Repayment Assistance Plan, means the amount of the applicable base payment for a borrower with an adjusted gross income—

(i) not more than \$10,000, is \$120;

(ii) more than \$10,000 and not more than \$20,000, is 1 percent of such adjusted gross income;

(iii) more than \$20,000 and not more than \$30,000, is 2 percent of such adjusted gross income;

(iv) more than \$30,000 and not more than \$40,000, is 3 percent of such adjusted gross income;

(v) more than \$40,000 and not more than \$50,000, is 4 percent of such adjusted gross income;

(vi) more than \$50,000 and not more than \$60,000, is 5 percent of such adjusted gross income;

(vii) more than \$60,000 and not more than \$70,000, is 6 percent of such adjusted gross income;

(viii) more than \$70,000 and not more than \$80,000, is 7 percent of such adjusted gross income;

(ix) more than \$80,000 and not more than \$90,000, is 8 percent of such adjusted gross income;

(x) more than \$90,000 and not more than \$100,000, is 9 percent of such adjusted gross income; and

(xi) more than \$100,000, is 10 percent of such adjusted gross income.

(3) *Dependent*, for the purposes of the Repayment Assistance Plan, means an individual who qualifies as a dependent under section 152 of the Internal Revenue Code of 1986, as amended, and who were claimed on the borrower's Federal income tax return. For a borrower who filed a Federal tax return as married filing separately, "dependent" shall only include the dependents claimed on the borrower's return.

(4) *Discretionary income* means the greater of \$0 or the difference between

the borrower's income as determined under paragraph (e)(1) of this section and—

(i) For the REPAYE plan, 225 percent of the applicable Federal poverty guideline;

(ii) For the IBR and PAYE plans, 150 percent of the applicable Federal poverty guideline; and

(iii) For the ICR plan, 100 percent of the applicable Federal poverty guideline.

(5) *Eligible loan*, for purposes of determining the applicable amount and for adjusting the monthly payment amount in accordance with paragraph (g) of this section means—

(i) Any outstanding loan made to a borrower under the Direct Loan Program, except for a Direct PLUS Loan made to a parent borrower, or an excepted consolidation loan; and

(ii) Any outstanding loan made to a borrower under the FFEL Program, except for a Federal PLUS Loan made to a parent borrower, or an excepted consolidation loan.

(6) *Excepted consolidation loan*, means—

(i)

(A) A FFEL or Direct Consolidation Loan if such consolidation loan repaid a FFEL or Direct PLUS Loan made to a parent borrower on behalf of a dependent student; or

(B) A FFEL or Direct Consolidation Loan that repaid a FFEL or Direct Consolidation loan described under paragraph (b)(6)(i)(A) of this definition that repaid a FFEL or Direct PLUS Loan made to a parent borrower on behalf of a dependent student; and

(ii) Excludes a loan described under paragraphs (b)(6)(i)(A) or (B) of this definition that was being repaid under the ICR, PAYE, or IBR plans on any date on or after July 4, 2025, through and including June 30, 2028. For purposes of paragraph (b)(6)(ii) of this definition, being repaid means at least one payment was made under the ICR, PAYE, or IBR repayment plans.

(7) *Excepted loan* means any outstanding loan that is—

(i) a Federal Direct PLUS Loan made to a parent borrower on behalf of a dependent student; or

(ii) a Federal Direct Consolidation Loan, if it repaid an excepted PLUS loan (as defined in this section) or an excepted consolidation loan (as defined in this section).

(8) *Excepted PLUS loan* means any outstanding loan that is a FFEL or Direct PLUS Loan made to a parent borrower on behalf of a dependent student.

(9) *Family size* means, for all IDR plans except the Repayment Assistance Plan, the number of individuals that is determined by adding together—

(i)

(A) The borrower;

(B) The borrower's spouse, for a married borrower filing a joint Federal income tax return;

(C) The borrower's children, including unborn children who will be born during the year the borrower certifies family size, if the children receive more than half their support from the borrower and are not included in the family size for any other borrower except the borrower's spouse who filed jointly with the borrower; and

(D) Other individuals if, at the time the borrower certifies family size, the other individuals live with the borrower and receive more than half their support from the borrower and will continue to receive this support from the borrower for the year for which the borrower certifies family size.

(ii) The Department may calculate family size based on FTI reported to the Internal Revenue Service.

(10) *Income* means either—

(i) The borrower's and, if applicable, the spouse's, Adjusted Gross Income (AGI) as reported to the Internal Revenue Service; or

(ii) The amount calculated based on alternative documentation of all forms of taxable income received by the borrower and provided to the Secretary.

(11) *Income-driven repayment plan* means a repayment plan in which the monthly payment amount is primarily determined by the borrower's income.

(12) *Monthly payment or the equivalent* under the PAYE, ICR, and IBR plans means—

(i) A required monthly payment as determined in accordance with paragraphs (k)(4)(i) through (iii) of this section;

(ii) A month in which a borrower receives a deferment or forbearance of repayment under one of the deferment or forbearance conditions listed in paragraph (k)(4)(iv) of this section; or

(iii) A month in which a borrower makes a payment in accordance with procedures in paragraph (k)(6) of this section.

(13) *New borrower* means—

(i) For the purpose of the PAYE plan, an individual who—

(A) Has no outstanding balance on a Direct Loan Program loan or a FFEL program loan as of October 1, 2007, or who has no outstanding balance on such a loan on the date the borrower receives a new loan after October 1, 2007; and

(B) Receives a disbursement of a Direct Subsidized Loan, a Direct Unsubsidized Loan, a Direct PLUS Loan made to a graduate or professional student, or a Direct Consolidation Loan on or after October 1, 2011, except that

a borrower is not considered a new borrower if the Direct Consolidation Loan repaid a loan that would otherwise make the borrower ineligible under paragraph (13)(i)(A) of this definition.

(ii) For the purposes of the IBR plan, an individual who has no outstanding balance on a Direct Loan or FFEL program loan before July 1, 2014 and obtains no new loan on or after July 1, 2026, or who has no outstanding balance on such a loan on the date the borrower obtains a loan after July 1, 2014 but before July 1, 2026.

(14) *Poverty guideline* refers to the income categorized by State and family size in the Federal poverty guidelines published annually by the United States Department of Health and Human Services pursuant to 42 U.S.C. 9902(2). If a borrower is not a resident of a State identified in the Federal poverty guidelines, the Federal poverty guideline to be used for the borrower is the Federal poverty guideline (for the relevant family size) used for the 48 contiguous States.

(15) *Support* includes money, gifts, loans, housing, food, clothes, car, medical and dental care, and payment of college costs.

(c) Borrower eligibility for IDR plans.

(1) Except as provided in paragraphs (d)(2) and (d)(4) of this section, defaulted loans may not be repaid under an IDR plan.

(2) Through June 30, 2028, a Direct Loan borrower who has not received a Direct Loan on or after July 1, 2026, may repay under the REPAYE plan if the borrower has loans eligible for repayment under the plan;

(3)

(i) Except as provided in paragraph (c)(3)(ii) of this section, any Direct Loan borrower may repay under the IBR plan if the borrower has loans eligible for repayment under the plan and elects to have their aggregate monthly payment amount recalculated to not exceed the applicable amount when the borrower initially enters the plan.

(ii) A borrower who has made 60 or more qualifying repayments under the REPAYE plan on or after July 1, 2024, may not enroll in the IBR plan.

(4) Through June 30, 2028, a borrower may repay under the PAYE plan only if the borrower—

(i) Has loans eligible for repayment under the plan;

(ii) Is a new borrower;

(iii) Elects to have their aggregate monthly payment amount recalculated to not exceed the applicable amount when the borrower initially enters the plan;

(iv) Was repaying a loan under the PAYE plan on July 1, 2024. A borrower

who was repaying under the PAYE plan on or after July 1, 2024, and changes to a different repayment plan in accordance with § 685.210(b) may not re-enroll in the PAYE plan; and

(v) Has not received a Direct Loan on or after July 1, 2026.

(5)

(i) Except as provided in (c)(5)(ii) or (c)(5)(iii) of this section, and through June 30, 2028, a borrower may enroll under the ICR plan only if the borrower—

(A) Has loans eligible for repayment under the plan;

(B) Was repaying a loan under the ICR plan on July 1, 2024. A borrower who was repaying under the ICR plan on or after July 1, 2024, and changes to a different repayment plan in accordance with § 685.210(b) may not re-enroll in the ICR plan unless they meet the criteria in paragraphs (c)(5)(ii) or (c)(5)(iii); and

(C) Has not received a Direct Loan on or after July 1, 2026.

(ii) (A) Through June 30, 2028, a borrower may choose the ICR plan to repay a Direct Consolidation Loan disbursed on or after July 1, 2006, and that repaid a parent Direct PLUS Loan or a parent Federal PLUS Loan.

(B) Paragraph (c)(5)(ii)(A) of this section shall not apply if that borrower received a Direct Loan on or after July 1, 2026.

(iii) (A) Through June 30, 2028, a borrower who has a Direct Consolidation Loan disbursed on or after July 1, 2025, which repaid a Direct Parent PLUS Loan, a FFEL Parent PLUS Loan, or a Direct Consolidation Loan that repaid a consolidation loan that included a Direct Parent PLUS or FFEL Parent PLUS Loan may not choose any IDR plan except the ICR plan.

(B) Paragraph (c)(5)(iii)(A) of this section shall not apply if that borrower received a Direct Loan on or after July 1, 2026.

(6) Any Direct Loan borrower may repay under the Repayment Assistance Plan if the borrower has loans eligible for repayment under the plan.

(7) Transition from Income-Contingent Repayment Plans

(i) Before July 1, 2028, a borrower repaying Direct Loans under the PAYE, and ICR plan, respectively, under paragraphs (a)(1), (a)(3), or (a)(4) of this section, or who is in an administrative forbearance (as defined under § 685.205(b)) associated with PAYE, or ICR, must elect to repay those Direct Loans under one of the following repayment plans for which they are otherwise eligible before July 1, 2028:

(A) the Repayment Assistance Plan under paragraph (a)(5) of this section;

(B) the IBR plan under paragraph (a)(2) of this section;

(C) the standard repayment plans under § 685.208(b)(1) or (b)(2);

(D) the graduated repayment plans under § 685.208(b)(5), (b)(6), or (g)(7);

(E) the extended repayment plans under § 685.208(b)(3) or (b)(4); or

(F) through June 30, 2028, the PAYE and ICR plans, respectively, under paragraphs (a)(3) and (a)(4) of this section.

(ii) A borrower who elects to repay their loans under paragraph (c)(7)(i) of this section shall begin repaying under the terms of their elected repayment plan on July 1, 2028. Notwithstanding the foregoing, the borrower may elect to repay their loans earlier than July 1, 2028.

(iii) (A) In the case of a borrower who does not select a repayment plan under paragraph (c)(7)(i) of this section by July 1, 2028, the Secretary shall require the loans to be repaid under the following repayment plans:

(1) the Repayment Assistance Plan under paragraph (a)(5) of this section, for the Direct Loans eligible to be repaid under such repayment plan; or

(2) the IBR plan under paragraph (a)(2), for the Direct Loans that are ineligible to be repaid under the Repayment Assistance Plan.

(B) The Secretary will require the borrower to repay their Direct Loans that are in a repayment status in PAYE, or ICR or an administrative forbearance associated with PAYE, or ICR repayment plan under the terms of the applicable plan under paragraphs (c)(7)(iii)(A)(1) or (2) of this section on July 1, 2028.

(d) Loans eligible to be repaid under an IDR plan.

(1) Through June 30, 2028, the following loans are eligible to be repaid under the REPAYE and PAYE plans: Direct Subsidized Loans, Direct Unsubsidized Loans, Direct PLUS Loans made to graduate or professional students, and Direct Consolidation Loans that are not excepted consolidation loans;

(2) The following loans, including defaulted loans, are eligible to be repaid under the IBR plan: Direct Subsidized Loans, Direct Unsubsidized Loans, Direct PLUS Loans made to graduate or professional students, and Direct Consolidation Loans that are not excepted consolidation loans.

(3) Through June 30, 2028, the following loans are eligible to be repaid under the ICR plan: Direct Subsidized Loans, Direct Unsubsidized Loans, Direct PLUS Loans made to graduate or professional students, and all Direct Consolidation Loans (including

excepted consolidation loans), except for Direct PLUS Consolidation Loans made before July 1, 2006.

(4) The following loans, including defaulted loans, are eligible to be repaid under the Repayment Assistance Plan: Direct Subsidized Loans, Direct Unsubsidized Loans, Direct PLUS Loans made to graduate or professional students, and Direct Consolidation Loans that are not excepted consolidation loans.

(5) Notwithstanding the conditions under paragraphs (d)(1) through (d)(3) of this section, only Direct Loans made before July 1, 2026, may be repaid under the PAYE, IBR, and ICR plans.

(e) Treatment of income and loan debt—

(1) Income.

(i) For purposes of calculating the borrower's monthly payment amount under the Repayment Assistance Plan, REPAYE, IBR, and PAYE plans—

(A) For an unmarried borrower, a married borrower filing a separate Federal income tax return, or a married borrower filing a joint Federal tax return who certifies that the borrower is currently separated from the borrower's spouse or is currently unable to reasonably access the spouse's income, only the borrower's income is used in the calculation.

(B) For a married borrower filing a joint Federal income tax return, except as provided in paragraph (e)(1)(i)(A) of this section, the combined income of the borrower and spouse is used in the calculation.

(ii) For purposes of calculating the monthly payment amount under the ICR plan—

(A) For an unmarried borrower, a married borrower filing a separate Federal income tax return, or a married borrower filing a joint Federal tax return who certifies that the borrower is currently separated from the borrower's spouse or is currently unable to reasonably access the spouse's income, only the borrower's income is used in the calculation.

(B) For married borrowers (regardless of tax filing status) who elect to repay their Direct Loans jointly under the ICR Plan or (except as provided in paragraph (e)(1)(ii)(A) of this section) for a married borrower filing a joint Federal income tax return, the combined income of the borrower and spouse is used in the calculation.

(2) Loan debt.

(i) For the REPAYE, IBR, PAYE plans and the Repayment Assistance Plan, the spouse's eligible loan debt is included for the purposes of adjusting the borrower's monthly payment amount as described in paragraph (g) of this

section if the spouse's income is included in the calculation of the borrower's monthly payment amount in accordance with paragraph (e)(1) of this section.

(ii) For the ICR plan, the spouse's loans that are eligible for repayment under the ICR plan in accordance with paragraph (d)(3) of this section are included in the calculation of the borrower's monthly payment amount only if the borrower and the borrower's spouse elect to repay their eligible Direct Loans jointly under the ICR plan.

(f) Monthly payment amounts.

(1) For the REPAYE plan, the borrower's monthly payments are—

(i) \$0 for the portion of the borrower's income, as determined under paragraph (e)(1) of this section, that is less than or equal to 225 percent of the applicable Federal poverty guideline; plus

(ii) 5 percent of the portion of income as determined under paragraph (e)(1) of this section that is greater than 225 percent of the applicable poverty guideline, prorated by the percentage that is the result of dividing the borrower's original total loan balance attributable to eligible loans received for the borrower's undergraduate study by the original total loan balance attributable to all eligible loans, divided by 12; plus

(iii) For loans not subject to paragraph (f)(1)(ii) of this section, 10 percent of the portion of income as determined under paragraph (e)(1) of this section that is greater than 225 percent of the applicable Federal poverty guidelines, prorated by the percentage that is the result of dividing the borrower's original total loan balance minus the original total loan balance of loans subject to paragraph (f)(1)(ii) of this section by the borrower's original total loan balance attributable to all eligible loans, divided by 12.

(2) For new borrowers under the IBR plan and for all borrowers on the PAYE plan, the borrower's monthly payments are the lesser of—

(i) 10 percent of the borrower's discretionary income, divided by 12; or

(ii) What the borrower would have paid on a 10-year standard repayment plan based on the eligible loan balances and interest rates on the loans at the time the borrower began paying under the IBR or PAYE plans, except that the borrower may repay such loans in excess of 10 years.

(3) For those who are not new borrowers under the IBR plan, the borrower's monthly payments are the lesser of—

(i) 15 percent of the borrower's discretionary income, divided by 12; or

(ii) What the borrower would have paid on a 10-year standard repayment plan based on the eligible loan balances and interest rates on the loans at the time the borrower began paying under the IBR plan, except that the borrower may repay such loans in excess of 10 years.

(4)

(i) For the ICR plan, the borrower's monthly payments are the lesser of—

(A) What the borrower would have paid under a repayment plan with fixed monthly payments over a 12-year repayment period, based on the amount that the borrower owed when the borrower began repaying under the ICR plan, multiplied by a percentage based on the borrower's income as established by the Secretary in a **Federal Register** notice published annually to account for inflation; or

(B) 20 percent of the borrower's discretionary income, divided by 12.

(ii)

(A) Married borrowers may repay their loans jointly under the ICR plan. The outstanding balances on the loans of each borrower are added together to determine the borrowers' combined monthly payment amount under paragraph (f)(4)(i) of this section;

(B) The amount of the payment applied to each borrower's debt is the proportion of the payments that equals the same proportion as that borrower's debt to the total outstanding balance, except that the payment is credited toward outstanding interest on any loan before any payment is credited toward principal.

(5) For the Repayment Assistance Plan, the borrower's applicable monthly payment is an amount equal to—

(i) the borrower's applicable base payment, divided by 12; minus

(ii) \$50 for each dependent of the borrower.

(g) Adjustments to monthly payment amounts.

(1) Monthly payment amounts calculated under paragraphs (f)(1) through (3) of this section will be adjusted in the following circumstances:

(i) In cases where the spouse's loan debt is included in accordance with paragraph (e)(2)(i) of this section, the borrower's payment is adjusted by—

(A) Dividing the outstanding principal and interest balance of the borrower's eligible loans by the couple's combined outstanding principal and interest balance on eligible loans; and

(B) Multiplying the borrower's payment amount as calculated in accordance with paragraphs (f)(1) through (3) of this section by the percentage determined under paragraph (g)(1)(i) of this section.

(ii) In cases where the borrower has outstanding eligible loans made under the FFEL Program, the borrower's calculated monthly payment amount, as determined in accordance with paragraphs (f)(1) through (3), of this section or, if applicable, the borrower's adjusted payment as determined in accordance with paragraph (g)(1) of this section is adjusted by—

(A) Dividing the outstanding principal and interest balance of the borrower's eligible loans that are Direct Loans by the borrower's total outstanding principal and interest balance on eligible loans; and

(B) Multiplying the borrower's payment amount as calculated in accordance with paragraphs (f)(1) through (3) of this section or the borrower's adjusted payment amount as determined in accordance with paragraph (g)(1) of this section by the percentage determined under paragraph (g)(2)(i) of this section.

(iii) In cases where the borrower's monthly payment amount calculated under paragraphs (f)(1) through (3) of this section or the borrower's adjusted monthly payment as calculated under paragraphs (g)(1)(i) or (g)(1)(ii) of this section is—

(A) Less than \$5, the monthly payment is \$0; or

(B) Equal to or greater than \$5 but less than \$10, the monthly payment is \$10.

(2) Monthly payment amounts calculated under paragraph (f)(4) of this section will be adjusted to \$5 in circumstances where the borrower's calculated payment amount is greater than \$0 but less than or equal to \$5.

(3) Monthly payment amounts calculated under paragraph (f)(5) of this section will be adjusted in cases when the borrower's spouse's loan debt is included in accordance with paragraph (e)(2)(i) of this section:

(i) The borrower's payment is adjusted by—

(A) Dividing the outstanding principal and interest balance of the borrower's eligible loans by the couple's combined outstanding principal and interest balance on eligible loans; and

(B) Multiplying the borrower's payment amount as calculated in accordance with paragraph (f)(5) of this section by the percentage determined under paragraph (g)(3)(i) of this section.

(ii) If a borrower's adjusted monthly payment, as calculated under paragraph (g)(3)(i), is less than \$10, the monthly payment is \$10.

(h) *Interest.* If a borrower's calculated monthly payment under an IDR plan is insufficient to pay the accrued interest on the borrower's loans, the Secretary charges the remaining accrued interest

to the borrower in accordance with paragraphs (h)(1) through (4) of this section.

(1) Under the REPAYE plan, during all periods of repayment on all loans being repaid under the REPAYE plan, the Secretary does not charge the borrower's account any accrued interest that is not covered by the borrower's payment;

(2)

(i) Under the IBR and PAYE plans, the Secretary does not charge the borrower's account with an amount equal to the amount of accrued interest on the borrower's Direct Subsidized Loans and Direct Subsidized Consolidation Loans that is not covered by the borrower's payment for the first three consecutive years of repayment under the plan, except as provided for the IBR and PAYE plans in paragraph (h)(2)(ii) of this section;

(ii) Under the IBR and PAYE plans, the 3-year period described in paragraph (h)(2)(i) of this section excludes any period during which the borrower receives an economic hardship deferment under § 685.204(g); and

(3) Under the ICR plan, the Secretary charges all accrued interest to the borrower.

(4) (i) Under the Repayment Assistance Plan, during all periods of repayment on all loans being repaid under the Repayment Assistance Plan, the Secretary does not charge the borrower's account for any accrued interest that is not covered by the borrower's on-time payment of the amount due for that month.

(ii) If a borrower's payment is credited to a future monthly payment, and the payment equals or exceeds the on-time monthly payment amount made under the Repayment Assistance Plan under (f)(5)(i) of this section, the Secretary charges the borrower's account any accrued interest that is not covered by the borrower's on-time payment of the amount due for that month, in accordance with paragraph (h)(4)(i) of this section.

(i) *Changing repayment plans.* A borrower who is repaying under an IDR plan may change at any time to any other repayment plan for which the borrower is eligible, except as otherwise provided in § 685.210(b).

(j) *Interest capitalization.*

(1) Under the Repayment Assistance Plan, REPAYE, PAYE, and ICR plans, the Secretary capitalizes unpaid accrued interest in accordance with § 685.202(b).

(2) Under the IBR plan, the Secretary capitalizes unpaid accrued interest—

(i) In accordance with § 685.202(b);

(ii) When a borrower's payment is the amount described in paragraphs (f)(2)(ii) and (f)(3)(ii) of this section; and

(iii) When a borrower leaves the IBR plan.

(k) *Forgiveness timeline.*

(1) In the case of a borrower repaying under the REPAYE plan who is repaying at least one loan received for graduate or professional study, or a Direct Consolidation Loan that repaid one or more loans received for graduate or professional study, a borrower repaying under the IBR-plan who is not a new borrower, or a borrower repaying under the ICR plan, the borrower receives forgiveness of the remaining balance of the borrower's loan after the borrower has satisfied 300 monthly payments or the equivalent in accordance with paragraph (k)(4) of this section over a period of at least 25 years;

(2) In the case of a borrower repaying under the REPAYE plan who is repaying only loans received for undergraduate study, or a Direct Consolidation Loan that repaid only loans received for undergraduate study, a borrower repaying under the IBR plan who is a new borrower, or a borrower repaying under the PAYE plan, the borrower receives forgiveness of the remaining balance of the borrower's loans after the borrower has satisfied 240 monthly payments or the equivalent in accordance with paragraph (k)(4) of this section over a period of at least 20 years;

(3) Notwithstanding paragraphs (k)(1) and (k)(2) of this section, a borrower receives forgiveness if the borrower's total original principal balance on all loans that are being paid under the REPAYE plan was less than or equal to \$12,000, after the borrower has satisfied 120 monthly payments or the equivalent, plus an additional 12 monthly payments or the equivalent over a period of at least 1 year for every \$1,000 if the total original principal balance is above \$12,000.

(4) For the PAYE, ICR, and IBR plans, a borrower receives a month of credit toward forgiveness by—

(i) (A) Notwithstanding paragraph (k)(4)(i)(B) of this section, making a payment under an IDR plan or having a monthly payment obligation of \$0;

(B) For the IBR plan only, making a payment on or before June 30, 2028, under the PAYE, or ICR plan or having a monthly payment obligation of \$0;

(ii) Making a payment under the 10-year standard repayment plan under § 685.208(b)(1);

(iii) Making a payment under a repayment plan with payments that are as least as much as they would have been under the 10-year standard repayment plan under § 685.208(b)(1),

except that no more than 12 payments made under paragraph (l)(9)(iii) of this section may count toward forgiveness under the REPAYE plan;

(iv) Deferring or forbearing monthly payments under the following provisions:

(A) A cancer treatment deferment under section 455(f)(3) of the Act;

(B) A rehabilitation training program deferment under § 685.204(e);

(C) An unemployment deferment under § 685.204(f);

(D) An economic hardship deferment under § 685.204(g), which includes volunteer service in the Peace Corps as an economic hardship condition;

(E) A military service deferment under § 685.204(h);

(F) A post active-duty student deferment under § 685.204(i);

(G) A national service forbearance under § 685.205(a)(4) on or after July 1, 2024;

(H) A national guard duty forbearance under § 685.205(a)(7) on or after July 1, 2024;

(I) A Department of Defense Student Loan Repayment forbearance under § 685.205(a)(9) on or after July 1, 2024;

(J) An administrative forbearance under § 685.205(b)(8) or (9) on or after July 1, 2024; or

(K) A bankruptcy forbearance under § 685.205(b)(6)(viii) on or after July 1, 2024, if the borrower made the required payments on a confirmed bankruptcy plan.

(v) Making a qualifying payment as described under § 685.219(c)(2),

(vi)

(A) Counting payments a borrower of a Direct Consolidation Loan made on the Direct Loans or FFEL program loans repaid by the Direct Consolidation Loan if the payments met the criteria in paragraph (k)(4) of this section, the criteria in § 682.209(a)(6)(vi) that were based on a 10-year repayment period, or the criteria in § 682.215.

(B) For a borrower whose Direct Consolidation Loan repaid loans with more than one period of qualifying payments, the borrower receives credit for the number of months equal to the weighted average of qualifying payments made rounded up to the nearest whole month.

(C) For borrowers whose Joint Direct Consolidation Loan is separated into individual Direct Consolidation loans, each borrower receives credit for the number of months equal to the number of months that was credited prior to the separation; or,

(vii) Making payments under paragraph (k)(6) of this section.

(5) For the IBR plan only, a monthly repayment obligation for the purposes of forgiveness includes—

(i) A payment made pursuant to paragraph (k)(4)(i) or (k)(4)(ii) of this section on a loan in default;

(ii) An amount collected through administrative wage garnishment or Federal Offset that is equivalent to the amount a borrower would owe under paragraph (k)(4)(i) of this section, except that the number of monthly payment obligations satisfied by the borrower cannot exceed the number of months from the Secretary's receipt of the collected amount until the borrower's next annual repayment plan recertification date under IBR; or

(iii) An amount collected through administrative wage garnishment or Federal Offset that is equivalent to the amount a borrower would owe on the 10-year standard plan.

(6)

(i) A borrower may obtain credit toward forgiveness as defined in paragraph (k) of this section for any months in which a borrower was in a deferment or forbearance not listed in paragraph (k)(4)(iv) of this section, other than periods in an in-school deferment, by making an additional payment equal to or greater than their current IDR payment, including a payment of \$0, for a deferment or forbearance that ended within 3 years of the additional repayment date and occurred after July 1, 2024.

(ii) Upon request, the Secretary informs the borrower of the months for which the borrower can make payments under paragraph (k)(6)(i) of this section.

(7) In the case of a borrower repaying under the Repayment Assistance Plan, the borrower receives forgiveness of the remaining balance of the borrower's loans after the borrower has satisfied 360 monthly payments or the equivalent in accordance with paragraph (k)(8) of this section over a period of at least 30 years.

(8) For a borrower repaying at least one loan under the Repayment Assistance Plan—

(i) To qualify for loan forgiveness, a borrower must have—

(A) participated in the Repayment Assistance Plan during any period;

(B) made their final payment under such Repayment Assistance Plan prior to loan cancellation; and

(C) Made 360 qualifying monthly payments, which includes any of the following:

(1) An on-time monthly payment made by the date the payment is due for that month in accordance with paragraph (f)(5) of this section;

(2) An on-time monthly payment made by the date the payment is due for that month under the Tiered Standard

repayment plan in accordance with § 685.208(c)(1);

(3) A monthly payment under any other repayment plan (excluding the Repayment Assistance Plan), of not less than the monthly payment that would have been required under a standard repayment plan amortized over a 10-year period;

(4) A monthly payment under the IBR plan in accordance with this section of not less than the monthly payment required under the plan, including the minimum payment permitted under that plan;

(5) Prior to July 1, 2028, a monthly payment under an income-contingent repayment plan under this section, of not less than the monthly payment required under the applicable plan, including the minimum payment permitted under such plan;

(6) Prior to July 1, 2028, a monthly payment under an alternative repayment plan in accordance with § 685.221, of not less than the monthly payment required under the plan, including the minimum payment permitted under that plan;

(7) A month when the borrower received an unemployment deferment (as provided under § 685.204(f)) or economic hardship deferment (as provided under § 685.204(g)); or

(8) A month that ended before July 1, 2026, when the borrower did not make a payment because they were in a period of deferment or forbearance as follows:

(a) A cancer treatment deferment under section 455(f)(3) of the Act;

(b) A rehabilitation training program deferment under § 685.204(e);

(c) An unemployment deferment under § 685.204(f);

(d) An economic hardship deferment under § 685.204(g), which includes volunteer service in the Peace Corps as an economic hardship condition;

(e) A military service deferment under § 685.204(h);

(f) A post active-duty student deferment under § 685.204(i);

(g) A national service forbearance under § 685.205(a)(4) on or after July 1, 2024;

(h) A national guard duty forbearance under § 685.205(a)(7) on or after July 1, 2024;

(i) A Department of Defense Student Loan Repayment forbearance under § 685.205(a)(9) on or after July 1, 2024;

(j) An administrative forbearance under § 685.205(b)(8) or (9) on or after July 1, 2024; or

(k) A bankruptcy forbearance under § 685.205(b)(6)(viii) on or after July 1, 2024, if the borrower made the required payments on a confirmed bankruptcy plan.

(l) Application and annual recertification procedures.

(1) To initially enter or recertify their intent to repay under an IDR plan, a borrower (and their spouse, if applicable) provides approval for the disclosure of applicable tax information to the Secretary either as part of the process of completing a Direct Loan Master Promissory Note or a Direct Consolidation Loan Application and Promissory Note in accordance with sections 493C(c)(2) and 494(a)(2) of the Act or on application form approved by the Secretary.

(2) If a borrower (and their spouse, if applicable) does not provide approval for the disclosure of applicable tax information under sections 493C(c)(2) and 494(a)(2) of the Act when completing the promissory note or on the application form for an IDR plan, the borrower must provide documentation to the Secretary—

(i) for the Income-Based Repayment plan, of the borrower's income and family size; or

(ii) for the Repayment Assistance Plan, the borrower's income and the number of dependents of the borrower.

(3) If the Secretary has received approval for disclosure of applicable tax information, but cannot obtain the borrower's tax information from the Internal Revenue Service, the borrower (and their spouse, if applicable) must provide documentation to the Secretary—

(i) for the Income-Based Repayment plan, the borrower's income and family size; or

(ii) for the Repayment Assistance Plan, the borrower's income and the number of dependents.

(4) After the Secretary obtains sufficient information to calculate the borrower's monthly payment amount, the Secretary calculates the borrower's payment and establishes the 12-month period during which the borrower will be obligated to make a payment in that amount.

(5) The Secretary sends to the borrower a repayment disclosure that—

(i) Specifies the borrower's calculated monthly payment amount;

(ii) Explains how the payment was calculated;

(iii) Informs the borrower of the terms and conditions of the borrower's selected repayment plan;

(iv) Informs the borrower of how to contact the Secretary if the calculated payment amount is not reflective of the borrower's current income and family size, or income and the number of dependents for the Repayment Assistance Plan;

(v) Informs the borrower of the right of the Secretary to follow the procedures in paragraph (l)(3) of this section and in accordance with section 493C(c)(2) of the Act on an annual basis to automatically recertify their eligibility for an IDR plan; and

(vi) Informs the borrower of their right to opt out, at any time, of the disclosure of applicable tax information under section 493C(c)(2) of the Act and describes the process for affirmatively opting out.

(6) If the borrower believes that the payment amount is not reflective of the borrower's current income and family size, or income and the number of dependents for the Repayment Assistance Plan, the borrower may request that the Secretary recalculate the payment amount. To support the request, the borrower must also submit alternative documentation of income and family size, or income and the number of dependents for the Repayment Assistance Plan to account for circumstances such as a decrease in income since the borrower last filed a tax return, the borrower's separation from a spouse with whom the borrower had previously filed a joint tax return, the birth or impending birth of a child, or other comparable circumstances.

(7) If the borrower provides alternative documentation under paragraph (l)(6) of this section or if the Secretary obtains documentation from the borrower or spouse under paragraph (l)(3) of this section, the Secretary grants forbearance under § 685.205(b)(9) to provide time for the Secretary to recalculate the borrower's monthly payment amount based on the documentation obtained from the borrower or spouse.

(8) Once the borrower has 3 monthly payments remaining under the 12-month period specified in paragraph (l)(4) of this section, the Secretary follows the procedures in paragraphs (l)(3) through (l)(7) of this section.

(9) If the Secretary requires information from the borrower under paragraph (l)(3) of this section to recalculate the borrower's monthly repayment amount under paragraph (l)(8) of this section, and the borrower does not provide the necessary documentation to the Secretary by the time the last payment is due under the 12-month period specified under paragraph (l)(4) of this section—

(i) For the IBR and PAYE plans, the borrower's monthly payment amount is the amount determined under paragraphs (f)(2)(ii) or (f)(3)(ii) of this section;

(ii) For the ICR plan, the borrower's monthly payment amount is the amount

the borrower would have paid under a 10-year standard repayment plan based on the total balance of the loans being repaid under the ICR Plan when the borrower initially entered the ICR Plan;

(iii) For the REPAYE plan, the Secretary removes the borrower from the REPAYE plan and places the borrower on an alternative repayment plan under which the borrower's required monthly payment is the amount the borrower would have paid on a 10-year standard repayment plan based on the current loan balances and interest rates on the loans at the time the borrower is removed from the REPAYE plan; and (iv) For the Repayment Assistance Plan, the borrower's required monthly payment is the amount the borrower would have paid on a 10-year standard repayment plan based on the total balance of the loans when such loans entered repayment.

(10) At any point during the 12-month period specified under paragraph (l)(4) of this section, the borrower may request that the Secretary recalculate the borrower's payment earlier than would have otherwise been the case to account for a change in the borrower's circumstances, such as a loss of income or employment or divorce. In such cases, the 12-month period specified under paragraph (l)(4) of this section is reset based on the borrower's new information.

(11) The Secretary tracks a borrower's progress toward eligibility for forgiveness under paragraph (k) of this section and forgives loans that meet the criteria under paragraph (k) of this section without the need for an application or documentation from the borrower.

(m) Automatic enrollment in an IDR plan.

The Secretary places a borrower on the IDR plan under this section that results in the lowest monthly payment based on the borrower's income and family size if—

(1) The borrower is otherwise eligible for the plan;

(2) The borrower has approved the disclosure of tax information under paragraph (l)(1) of this section;

(3) The borrower has not made a scheduled payment on the loan for at least 75 days or is in default on the loan and is not subject to a Federal offset, administrative wage garnishment under section 488A of the Act, or to a judgment secured through litigation; and

(4) The Secretary determines that the borrower's payment under the IDR plan would be lower than or equal to the payment on the plan in which the borrower is enrolled.

(n) Removal from default.

The Secretary will no longer consider a borrower in default on a loan if—

(1) The borrower provides information necessary to calculate a payment under paragraph (f) of this section;

(2) The payment calculated pursuant to paragraph (f) of this section is \$0; and

(3) The income information used to calculate the payment under paragraph (f) of this section includes the point at which the loan defaulted.

(o) Other Provisions.

(1) For the PAYE plan, Repayment Assistance Plan, and REPAYE plan, if the borrower's monthly payment amount or the monthly payment reduced under paragraph (g)(3)(i) of this section is not sufficient to pay any of the principal due, the payment of that principal is postponed.

(2)(i) *Matching Principal Payment under the Repayment Assistance Plan.* When the borrower is not in a period of deferment under § 685.204 or forbearance under § 685.205, for each month the borrower makes an on-time monthly payment as applied in paragraph (f)(5)(i) of this section and the outstanding principal balance is reduced by less than \$50, the Secretary reduces such total outstanding principal of the borrower by an amount that is equal to—

(A) the lesser of—

(1) \$50; or

(2) the monthly payment made; minus

(B) the amount of the monthly payment that is applied to such total outstanding principal balance.

(ii) If a borrower's payment is credited to a future monthly payment, and the payment equals or exceeds the monthly repayment amount made under (f)(5)(i) of this section, the Secretary does not provide the borrower a matching principal payment in accordance with paragraph (o)(2)(i) of this section.

(3) For purposes of the Repayment Assistance Plan under this section, a borrower's monthly payment under (f)(5) of this section is considered on-time if the payment is received on or before the due date for the current month, but after the due date for the previous month.

(i) When the borrower elects to make a payment in excess of the amount due, the Secretary allows the borrower to opt-out of advancing the due date which is provided for in 34 CFR 685.211. In the case where the borrower makes an electronic payment, the Secretary allows the borrower to select when submitting the payment whether the excess payment will advance the due date (and eliminate the possibility of a Repayment Assistance Plan subsidy until the next

month in which a payment becomes due), or to not advance the due date. No matter the method of payment, the borrower may contact their servicer by phone to elect not to advance the due date. The Secretary shall disclose to the borrower the potential consequences of electing to advance the due date or not.

(ii) If a borrower elects to make a payment in excess of the amount due and does not opt-out of advancing the due date through the process described in subparagraph (o)(3)(i), for the month the payment was made, as well as for each month the borrower would have been required to make a payment if the due date had not been advanced, the borrower will be considered to have made:

(A) a qualifying monthly payment under subparagraph (k)(8)(C) of this section;

(B) a monthly payment for the purposes of the Public Service Loan Forgiveness Program under section § 685.219(c)(2).

■ 15. Section 685.210 is amended by revising and republishing the section in its entirety.

The revisions read as follows:

§ 685.210 Choice of repayment plan.

(a) Initial selection of a repayment plan.

(1) (i) Before a Direct Loan enters into repayment, the Secretary provides a borrower with a description of the available repayment plans and requests that the borrower select one. A borrower may select a repayment plan before the loan enters repayment by notifying the Secretary of the borrower's selection in writing.

(ii) Borrowers with Direct Loans made on or after July 1, 2026, may select—

(A) The Tiered Standard repayment plan in accordance with § 685.208 if those Direct Loans are otherwise eligible to be repaid under the plan; or

(B) The Repayment Assistance Plan in accordance with § 685.209 if those Direct Loans are otherwise eligible to be repaid under the plan.

(2) (i) For Direct Loans made before July 1, 2026, if a borrower does not select a repayment plan, the Secretary designates the standard repayment plan described in § 685.208(b)(1) or (b)(2) for the borrower, as applicable.

(ii) For Direct Loans made on or after July 1, 2026, if a borrower does not select a repayment plan, the Secretary designates the Tiered Standard repayment plan described in § 685.208(c)(1) for the borrower.

(3) All Direct Loans obtained by one borrower must be repaid together under the same repayment plan, except that—

(i) A borrower of a Direct PLUS Loan or a Direct Consolidation Loan that is

not eligible for repayment under an IDR plan may repay the Direct PLUS Loan or Direct Consolidation Loan separately from other Direct Loans obtained by the borrower;

(ii) A borrower of a Direct PLUS Consolidation Loan that entered repayment before July 1, 2006, may repay the Direct PLUS Consolidation Loan separately from other Direct Loans obtained by that borrower; and

(iii)(A) A borrower of a Direct PLUS Loan or an excepted consolidation loan defined under § 685.209 that is not eligible for repayment under the Repayment Assistance Plan must repay the Direct PLUS Loan or excepted consolidation loan separately from other Direct Loans obtained by the borrower that are being repaid under the Repayment Assistance Plan.

(B) A borrower who has received an excepted loan as defined under § 685.209 made on or after July 1, 2026, must repay the excepted loan under the Tiered Standard repayment plan under § 685.208(c)(1) and may repay the other Direct Loans separately from such excepted loan.

(b) Changing repayment plans.

(1) For Direct Loans made before July 1, 2026, a borrower who has entered repayment may change to any other repayment plan for which the borrower is eligible at any time by notifying the Secretary. However, a borrower who is repaying a defaulted loan under the IBR plan or who is repaying a Direct Consolidation Loan under an IDR plan in accordance with

§ 685.220(d)(1)(i)(A)(3) may not change to another repayment plan unless—

(i) The borrower was required to and did make a payment under the IBR plan or other IDR plan in each of the prior three months; or

(ii) The borrower was not required to make payments but made three reasonable and affordable payments in each of the prior 3 months; and

(iii) The borrower makes, and the Secretary approves, a request to change plans.

(2)

(i) For Direct Loans made before July 1, 2026, a borrower may not change to a repayment plan that would cause the borrower to have a remaining repayment period that is less than zero months, except that an eligible borrower may change to an IDR plan under § 685.209 at any time.

(ii) For the purposes of paragraph (b)(2)(i) of this section, the remaining repayment period is—

(A) For a fixed repayment plan under § 685.208 or an alternative repayment plan under § 685.221, the maximum repayment period for the repayment

plan, the borrower is seeking to enter, less the period of time since the loan has entered repayment, plus any periods of deferment and forbearance; and

(B) For an IDR plan under § 685.209, as determined under § 685.209(k).

(3) For Direct Loans made before July 1, 2026, a borrower who made payments under the IBR plan and successfully completed rehabilitation of a defaulted loan may choose the REPAYE plan when the loan is returned to current repayment if the borrower is otherwise eligible for the REPAYE plan and if the monthly payment under the REPAYE plan is equal to or less than their payment on IBR.

(4)

(i) For Direct Loans made before July 1, 2026, if a borrower no longer wishes to pay under the IBR plan, the borrower must pay under the standard repayment plan or the Repayment Assistance Plan. For the standard repayment plan, the Secretary recalculates the borrower's monthly payment based on—

(A) For a Direct Subsidized Loan, a Direct Unsubsidized Loan, or a Direct PLUS Loan, the time remaining under the maximum ten-year repayment period for the amount of the borrower's loans that were outstanding at the time the borrower discontinued paying under the IBR plan; or

(B) For a Direct Consolidation Loan, the time remaining under the applicable repayment period as initially determined under § 685.208(b)(7)(iii) and the amount of that loan that was outstanding at the time the borrower discontinued paying under the IBR plan.

(ii) For Direct Loans made before July 1, 2026, a borrower who no longer wishes to repay under the IBR plan and who is required to repay under the Direct Loan standard repayment plan in accordance with paragraph (b)(4)(i) of this section may request a change to a different repayment plan after making one monthly payment under the Direct Loan standard repayment plan. For this purpose, a monthly payment may include one payment made under a forbearance that provides for accepting smaller payments than previously scheduled, in accordance with § 685.205(a).

(5) For Direct Loans made on or after July 1, 2026, a borrower may change repayment plans in accordance with this paragraph (b)(5) at any time after the loan has entered repayment by notifying the Secretary.

(i) A borrower who is enrolled in the Tiered Standard repayment plan under § 685.208(c)(1) or is placed in the Tiered Standard repayment plan in accordance with the provisions under paragraph

(a)(2)(ii) of this section may change to the Repayment Assistance Plan under § 685.209.

(ii) A borrower who is enrolled in the Repayment Assistance Plan under § 685.209 may change to the Tiered Standard repayment plan under § 685.208(c)(1).

■ 16. Section 685.211 is amended by revising paragraphs (a), (d), and (f).

The revisions read as follows:

§ 685.211 Miscellaneous payment provisions.

(a) * * *

(1) * * *

(i) Except as provided for the Income-Based Repayment plan or Repayment Assistance Plan in paragraph (a)(1)(ii) of this section, the Secretary applies any payment in the following order:

(A) Accrued charges and collection costs.

(B) Outstanding interest.

(C) Outstanding principal.

(ii) The Secretary applies any payment made under the Income-Based Repayment plan or the Repayment Assistance Plan in the following order:

(A) Accrued interest.

(B) Collection costs and late charges.

(C) Loan principal.

* * * * *

(d) * * *

(3) * * *

(ii) If a borrower defaults on a Direct Subsidized Loan, a Direct Unsubsidized Loan, a Direct Consolidation Loan that is not an excepted consolidation loan as defined in § 685.209, or a student Direct PLUS Loan, the Secretary may designate the Repayment Assistance Plan or the income-based repayment plan for the borrower.

* * * * *

(f) * * *

(1) * * *

(i) *Minimum Payment Amounts.*

(A) Before July 1, 2027, the Secretary initially considers the borrower's reasonable and affordable payment amount to be an amount equal to the minimum payment required under the IBR plan, except that if this amount is less than \$5, the borrower's monthly payment is \$5.

(B) Beginning on and after July 1, 2027, the Secretary initially considers the borrower's reasonable and affordable payment amount to be an amount equal to the minimum payment required under the IBR plan, except that if this amount is less than \$10, the borrower's monthly payment is \$10.

* * * * *

(11) * * *

(iii)(A) Before July 1, 2027, a borrower may only obtain the benefit of a

suspension of administrative wage garnishment while also attempting to rehabilitate a defaulted loan once.

(B) On or after July 1, 2027, a borrower may only obtain the benefit of a suspension of administrative wage garnishment while also attempting to rehabilitate a defaulted loan a maximum of twice per loan.

(12)(i) Effective for any defaulted Direct Loan that is rehabilitated on or after August 14, 2008, and before July 1, 2027, the borrower cannot rehabilitate the loan again if the loan returns to default status following the rehabilitation.

(ii) Effective for any defaulted Direct Loan on or after July 1, 2027, the borrower may not rehabilitate the loan again if the loan returns to default status following the second rehabilitation.

■ 7. Section 685.219 is amended by revising paragraphs (b) Definitions, Qualifying Repayment Plan (iv) and (v), (c)(2)(iv), and (c)(2)(v), and (g)(6).

The revisions read as follows:

§ 685.219 Public Service Loan Forgiveness Program (PSLF).

* * * * *

(b) * * *

Qualifying repayment plan means:

* * * * *

(iv) An income-contingent repayment plan under § 685.209 for which a payment was received on or before June 30, 2028; or

(v) The Repayment Assistance Plan as defined under § 685.209.

* * * * *

(c) * * *

(2) * * *

(iv) For a borrower on the 10-year standard repayment plan under § 685.208(b)(1) or the consolidation loan standard repayment plan with a 10-year repayment term under § 685.208(b)(2), paying a lump sum or monthly payment amount that is equal to or greater than the full scheduled amount in advance of the borrower's scheduled payment due date for a period of months not to exceed the period from the Secretary's receipt of the payment until the lesser of 12 months from that date or the date upon which the Secretary receives the borrower's next submission under subsection (e).

(v) Except during periods when a borrower is enrolled in the Repayment Assistance Plan under § 685.209, receiving one of the following deferments or forbearances for the month:

(A) Cancer treatment deferment under section 455(f)(3) of the Act;

(B) Economic hardship deferment under § 685.204(g);

(C) Military service deferment under § 685.204(h);

(D) Post-active-duty student deferment under § 685.204(i);

(E) AmeriCorps forbearance under § 685.205(a)(4);

(F) National Guard Duty forbearance under § 685.205(a)(7);

(G) U.S. Department of Defense Student Loan Repayment Program forbearance under § 685.205(a)(9);

(H) Administrative forbearance or mandatory administrative forbearance under § 685.205(b)(8) or (9); and

(vi) Being employed full-time with a qualifying employer, as defined in this section, at any point during the month for which the payment is credited.

* * * * *

(g) *Reconsideration process.*

(6) Except for repayment periods when a borrower is repaying under the Repayment Assistance Plan under § 685.209, for any months in which a borrower postponed monthly payments under a deferment or forbearance and was employed full-time at a qualifying employer as defined in this section but was in a deferment or forbearance status besides those listed in paragraph (c)(2)(v) of this section, the borrower may obtain credit toward forgiveness for those months, as defined in paragraph (d) of this section, for any months in which the borrower—

(i) Makes an additional payment equal to or greater than the amount they would have paid at that time on a qualifying repayment plan or

(ii) Otherwise qualified for a \$0 payment on an income-driven repayment plan under § 685.209.

* * * * *

■ 18. Section 685.220 is amended by revising paragraphs (d)(2), (h), and (i).

The revisions read as follows:

§ 685.220 Consolidation.

* * * * *

(d) * * *

(2) * * *

(i)

(A) Before July 1, 2028, the borrower has a Federal Consolidation Loan that is in default or has been submitted to the guaranty agency by the lender for

default aversion, and the borrower wants to consolidate the Federal Consolidation Loan into the Direct Loan Program for the purpose of obtaining an income-contingent repayment plan or an income-based repayment plan; or

(B) On or after July 1, 2028, the borrower has a Federal Consolidation Loan that is in default or has been submitted to the guaranty agency by the lender for default aversion, and the borrower wants to consolidate the Federal Consolidation Loan into the Direct Loan Program for the purpose of obtaining the Repayment Assistance Plan; or

* * * * *

(h) * * *

(1) For a Direct Consolidation Loan made before July 1, 2026, a borrower may choose a repayment plan, in accordance with §§ 685.208, 685.209, and 685.221, and may change repayment plans in accordance with § 685.210(b).

(2) For a Direct Consolidation Loan made on or after July 1, 2026, a borrower may choose the Tiered Standard repayment plan, or the Repayment Assistance Plan, in accordance with §§ 685.208, 685.209 and may change repayment plans in accordance with § 685.210(b).

(i) * * *

(2)

(i) Borrowers who entered repayment before July 1, 2006. The Secretary determines the repayment period under § 685.208 (b)(3)(iv) or (5)(iv) on the basis of the outstanding balances on all of the borrower's loans that are eligible for consolidation and the balances on other education loans except as provided in paragraphs (i)(3)(i), (ii), and (iii) of this section.

(ii) Borrowers entering repayment on or after July 1, 2006. The Secretary determines the repayment period under § 685.208 (b)(2)(iii) or (7)(iii) on the basis of the outstanding balances on all of the borrower's loans that are eligible for consolidation and the balances on other education loans except as provided in paragraphs (i)(3)(i) through (iii) of this section.

(3)

(i) The total amount of outstanding balances on the other education loans used to determine the repayment period under § 685.208(b)(2)(iii), (3)(iv), (5)(iv), and (7)(iii) may not exceed the amount of the Direct Consolidation Loan.

(ii) The borrower may not be in default on the other education loan unless the borrower has made satisfactory repayment arrangements with the holder of the loan.

(iii) The lender of the other educational loan may not be an individual.

* * * * *

■ 19. Section 685.221 is amended by revising paragraph (a) and adding paragraph (e).

The revisions read as follows:

§ 685.221 Alternative repayment plan.

(a) The Secretary may provide an alternative repayment plan to a borrower who has not received a Direct Loan on or after July 1, 2026 and who demonstrates to the Secretary's satisfaction that the terms and conditions of the repayment plans specified in §§ 685.208 and 685.209 are not adequate to accommodate the borrower's exceptional circumstances.

* * * * *

(e) The repayment plan under this section shall only apply to Direct Loans made before July 1, 2026.

■ 20. Section 685.303 is amended by revising paragraph (d)(5).

The revisions read as follows:

§ 685.303 Processing loan proceeds.

* * * * *

(d) * * *

(5) The school must disburse loan proceeds in substantially equal installments, and no installment may exceed one-half of the loan, except when borrowers are subject to the award year loan limit for less than full-time enrollment, as described in 34 CFR 685.203(m), the institution will disburse in accordance with such schedule of reductions.

* * * * *

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Part IV

Department of Labor

Employee Benefits Security Administration

29 CFR Part 2550

Improving Transparency into Pharmacy Benefit Manager Fee Disclosure;
Proposed Rule

DEPARTMENT OF LABOR

Employee Benefits Security
Administration

29 CFR Part 2550

RIN 1210-AB37

Improving Transparency Into
Pharmacy Benefit Manager Fee
Disclosure**AGENCY:** Employee Benefits Security
Administration, Department of Labor.**ACTION:** Proposed rule.

SUMMARY: The Department is proposing a regulation that would require providers of pharmacy benefit management services and affiliated providers of brokerage and consulting services to disclose information about their compensation to fiduciaries of self-insured group health plans subject to the Employee Retirement Income Security Act (ERISA). These disclosures are needed so that fiduciaries can assess the reasonableness of the contracts or arrangements with these service providers, including the reasonableness of the service providers' compensation. These disclosure requirements would apply for purposes of ERISA's statutory prohibited transaction exemption for services arrangements. This proposal implements section 12 of President Trump's Executive Order 14273, *Lowering Drug Prices by Once Again Putting Americans First*, which instructs the Department to propose regulations to improve employer health plan transparency into the direct and indirect compensation received by pharmacy benefit managers. If finalized, this regulation would affect sponsors and other fiduciaries of self-insured group health plans and certain service providers to such plans.

DATES: Comments are due on or before March 31, 2026.

ADDRESSES: You may submit comments, identified by RIN 1210-AB37, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Mail or personal delivery:* Office of Regulations and Interpretations, Employee Benefits Security Administration, Room N-5655, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210.

Instructions: All submissions received must include the agency name and Regulation Identifier Number (RIN) for this rulemaking. Comments received, including any personal information provided, will be posted without change

to <http://www.regulations.gov> and <http://www.dol.gov/ebsa>, and made available for public inspection at the Public Disclosure Room, N-1513, Employee Benefits Security Administration, 200 Constitution Avenue NW, Washington, DC 20210. Persons submitting comments electronically are encouraged not to submit paper copies.

We encourage commenters to include supporting facts, research, and evidence in their comments. When doing so, commenters are encouraged to provide citations to the published materials referenced, including active hyperlinks. Likewise, commenters who reference materials which have not been published are encouraged to upload relevant data collection instruments, data sets, and detailed findings as a part of their comment. Providing such citations and documentation will assist us in analyzing the comments.

Warning: Do not include any personally identifiable or confidential business information that you do not want publicly disclosed. Comments are public records posted on the internet as received and can be retrieved by most internet search engines.

Docket: Go to the Federal eRulemaking Portal at <https://www.regulations.gov> for access to the rulemaking docket, including the plain-language summary of the proposed rule of not more than 100 words in length required by the Providing Accountability Through Transparency Act of 2023.

FOR FURTHER INFORMATION CONTACT: Stephen Sklenar or Saliha Moore, Office of Regulations and Interpretations, Employee Benefits Security Administration, Department of Labor, at 202-693-8513. This is not a toll-free number.

Customer service information: Individuals interested in obtaining general information from the Department of Labor concerning Title I of ERISA may call the EBSA Toll-Free Hotline at 1-866-444-EBSA (3272) or visit the Department's website (www.dol.gov/agencies/ebsa).

SUPPLEMENTARY INFORMATION:**A. Executive Summary**

In Executive Order 14273, *Lowering Drug Prices by Once Again Putting Americans First*, President Trump instructed the Department to propose regulations to improve employer health plan transparency into the direct and indirect compensation received by pharmacy benefit managers.¹ Businesses that provide pharmacy benefit

management services (hereinafter "PBMs" unless otherwise specified) to ERISA-covered self-insured group health plans have acquired significant influence over prescription drug costs in recent years. By addressing the influence of PBMs and promoting transparent pricing, President Trump's Executive Order aims to create a fairer and more competitive prescription drug market that lowers costs and ensures accountability across the health-care system.² This proposed rule responding to those directives is only one component of the Trump Administration's larger initiative to address rising health-care costs for Americans.³

PBMs are described as the "middlemen" in the pharmaceutical supply chain.⁴ For ERISA-covered self-insured group health plans, PBMs perform a wide range of services including, but not limited to, organizing pharmacy networks, negotiating pharmacy reimbursement amounts and drug rebates, establishing drug formularies,⁵ and processing claims. In connection with these services, PBMs receive compensation from self-insured group health plans as well as other sources in the pharmaceutical supply chain. Self-insured group health plan sponsors and other fiduciaries who are responsible for prudently selecting and monitoring service providers (referred to herein as "responsible plan fiduciaries") also commonly rely on brokers or consultants to help them with advice, recommendations, and referrals regarding pharmacy benefit management services.⁶ The brokers or

² See Fact Sheet: President Donald J. Trump Announces Actions to Lower Prescription Drug Prices (April 15, 2025) ("The [Executive] Order builds off [the Administration's] critical work and reevaluates the role of middlemen by: Improving disclosure of fees that pharmaceutical benefit managers (PBMs) pay to brokers for steering employers to utilize their services . . ."), <https://www.whitehouse.gov/fact-sheets/2025/04/fact-sheet-president-donald-j-trump-announces-actions-to-lower-prescription-drug-prices/>.

³ See e.g., Department of Labor News Release, *Departments of Labor, Health and Human Services, Treasury Announce Move to Strengthen Healthcare Price Transparency*, <https://www.dol.gov/newsroom/releases/ebsa/ebsa20250522>.

⁴ See e.g., Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* (July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

⁵ A formulary is a list of drugs covered by the plan.

⁶ It is well established that plan sponsors as defined in ERISA section 3(16)(B)(i) often wear two hats—an employer or settlor hat and a fiduciary hat. Yet it is equally well established that "ERISA does require, however, that the fiduciary with two hats wear only one at a time, and wear the fiduciary hat when making fiduciary decisions." *Pegram v.*

consultants may, in some cases, be affiliated with a PBM, and they also may receive compensation from sources other than self-insured group health plans.

Concerns have existed for many years that PBMs, including in their capacities as brokers and consultants with respect to pharmacy benefit management services, are not fully disclosing their compensation to the responsible plan fiduciaries. These concerns prompted the ERISA Advisory Council to recommend that the Department consider extending its service provider disclosure regulation to require specific disclosures by PBMs.⁷ In addition, in 2020, Congress amended ERISA's statutory service provider exemption to add a provision addressing disclosure by brokers and consultants to group health plans' responsible plan fiduciaries.⁸

The Department's proposed regulation is intended to provide much needed transparency into contracts and arrangements with PBMs and affiliated brokers and consultants so that the responsible plan fiduciaries of ERISA-covered self-insured group health plans can better fulfill their statutorily mandated role to determine that the service contracts or arrangements are reasonable. Under the Department's proposed regulation, these service providers would be required to provide robust disclosures to responsible plan fiduciaries of self-insured group health plans regarding their compensation for such services, including the advance disclosure of compensation they reasonably expect to receive. The proposed regulation also includes audit provisions designed to ensure that the responsible plan fiduciaries of self-insured group health plans can verify the accuracy of the disclosures. The responsible plan fiduciaries would be able to use the disclosures in their process of selecting a provider of pharmacy benefit management services,

Herdich, 530 U.S. 211, 225 (2000). Under this principle, a contract or arrangement with a covered service provider necessary for the establishment or operation of the self-insured group health plan does not evade the requirements of this proposed regulation merely because it is signed by a plan sponsor.

⁷ See Advisory Council on Employee Welfare and Pension Benefit Plans (ERISA Advisory Council), *PBM Compensation and Fee Disclosure* at 20 (November 2014) ("Plan sponsors uniformly testified about the difficulties in obtaining the disclosure of PBM compensation, and how this interfered with their efforts to negotiate and monitor PBM contracts."), https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf.

⁸ ERISA section 408(b)(2)(B), added by section 202 of Title II of Division BB of the Consolidated Appropriations Act, 2021.

engaging an affiliated broker or consultant, monitoring these service providers' operations and compliance with contractual obligations, and also in analyzing the drivers of prescription drug costs.

B. Background

1. Group Health Plan Prescription Drug Coverage

Approximately 136 million Americans receive health coverage through their employers (or their family members' employers) in group health plans covered by ERISA.⁹ Group health plans provide healthcare benefits such as hospitalization, sickness, prescription drugs, vision, and dental. Group health plans provide these benefits by purchasing insurance or by self-funding benefits from the employer's general assets or using a funded trust.

Retail prescription drug spending in the U.S. is expected to have amounted to nearly \$495 billion in 2024 and is projected to grow 7 percent in 2025, but grow more slowly from 2026 to 2033.¹⁰ In employer-sponsored group health plans, the cost of prescription drugs is usually shared between the group health plan and the individual participant, where the participant pays a fixed amount (copayment) or a percentage of the drug's cost (coinsurance). The group health plan's drug formulary identifies the drugs that are covered and organizes the drugs into tiers with different cost-sharing requirements imposed on participants. The tiers often distinguish between generic drugs and brand-name drugs, and may have a separate tier for "specialty drugs."¹¹

⁹ U.S. Department of Labor, *Health Insurance Coverage Bulletin: Abstract of Auxiliary Data for the March 2023 Annual Social and Economic Supplement to the Current Population Survey* at 6 (August 30, 2024), <https://www.dol.gov/sites/dolgov/files/EBSA/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2023.pdf>.

¹⁰ Centers for Medicare & Medicaid Services, *National Health Expenditure Projections 2024–2033*, <https://www.cms.gov/files/document/nhe-projections-forecast-summary.pdf>. "From 2025–27, average growth is projected to slow to 5.6 percent due to decreasing Marketplace enrollment and slower anti-obesity medication uptake. For 2028–33, growth is projected to average 4.7 percent." Centers for Medicare & Medicaid Services, *National Health Expenditure Projections 2024–2033*, <https://www.cms.gov/files/document/nhe-projections-forecast-summary.pdf>.

¹¹ Generic drugs are "medication[s] created to be the same as an already marketed brand-name drug in dosage form, safety, strength, route of administration, quantity, performance characteristics, and intended use." U.S. Food & Drug Administration *Generic Drugs: Questions & Answers*, <https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers#q1>. Specialty drugs do not have a standard definition, but some characteristics that may identify specialty drugs are special handling

Managing a group health plan's prescription drug coverage is exceedingly complex for a number of reasons, including, but not limited to, the vast number of drugs available on the market and the large number of drug manufacturers and pharmacies. Further, the pharmaceutical supply chain involves multiple entities—including drug manufacturers, drug wholesalers, pharmacies, PBMs, payors (e.g., group health plans), and participants—that interact with each other in arrangements that can be quite opaque.¹²

Due to the complexity of the pharmaceutical supply chain and the multitude of players involved, responsible plan fiduciaries of group health plans often outsource pharmacy benefit management services among other types of services. When group health plan benefits are obtained through insurance, pharmacy benefit management services are often integrated with the insurance contract. When group health plans are self-insured, however, the responsible plan fiduciaries may engage a PBM directly or they may obtain pharmacy benefit management services through a third-party administrator (TPA) or other entity.

2. Pharmacy Benefit Managers' Services Provided to Self-Insured Group Health Plans

PBMs perform numerous services related to self-insured group health plans' prescription drug coverage, including identifying the prescription drugs that will be covered by a plan and negotiating prices with various entities in the pharmaceutical supply chain.¹³

requirements or high costs. Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 17–18 (July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

¹² See Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 1 (July 2024) ("PBM business practices and their effects remain extraordinarily opaque."), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf; United States Senate Finance Committee, *Staff Report, Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* at 65, [https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20\(FINAL%201\).pdf](https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf). Many sources that discuss the pharmaceutical supply chain find it useful to include a chart to map out the parties involved. See e.g., U.S. Government Accountability Office, *Prescription Drugs: Selected States' Regulation of Pharmacy Benefit Managers* at 9 (GAO–24–106898, March 2024), <https://www.gao.gov/assets/gao-24-106898.pdf>.

¹³ See National Association of Insurance Commissioners, *A Guide to Understanding*

Continued

2.1. Formulary Development and Design

PBMs develop a self-insured group health plan's prescription drug formulary,¹⁴ which is a list of drugs that

Pharmacy Benefit Manager and Associated Stakeholder Regulation (2025), <https://content.naic.org/sites/default/files/pmbwhitepap.pdf>; U.S. Government Accountability Office, *Prescription Drugs: Selected States' Regulation of Pharmacy Benefit Managers* (GAO-24-106898, March 2024), <https://www.gao.gov/assets/gao-24-106898.pdf>; Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* (July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf; Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* (April 2025), <https://compass-lexecon.files.svdcn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921>; United States Senate Finance Committee, *Staff Report, Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* (2021), [https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20\(FINAL%201\).pdf](https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf); Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* (November 2014), https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf.

¹⁴ Some formularies are open—covering virtually all drugs while others are more restrictive. There has been a growing trend over the last decade, however, in usage of more restrictive formularies, excluding more drugs. United States Senate Finance Committee, *Staff Report, Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug*, at 71, [https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20\(FINAL%201\).pdf](https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf); Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* 66–67 (July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

¹⁵ Tasmina Hyderi & Vimal Reddy, *A Primer on Formulary Structures and Strategies*, *Journal of Managed Care & Specialty Pharmacy* (February 3, 2024), <https://www.jmcp.org/doi/10.18553/jmcp.2024.30.2.206>.

¹⁶ Tasmina Hyderi & Vimal Reddy, *A Primer on Formulary Structures and Strategies*, *Journal of Managed Care & Specialty Pharmacy* (February 3, 2024), <https://www.jmcp.org/doi/10.18553/jmcp.2024.30.2.206>.

¹⁷ National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 18 (2025), <https://content.naic.org/sites/default/files/pmbwhitepap.pdf>.

¹⁸ United States Senate Finance Committee, *Staff Report, Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* at 35 (2021), [https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20\(FINAL%201\).pdf](https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf).

¹⁹ United States Senate Finance Committee, *Staff Report, Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* at 36 (2021), [https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20\(FINAL%201\).pdf](https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf).

²⁰ United States Senate Finance Committee, *Staff Report, Insulin: Examining the Factors Driving the*

the self-insured group health plan will cover, typically sorted into tiers of cost-sharing requirements.¹⁵ Formularies generally balance access to prescription drugs with managing costs, and their development is similar across PBMs in that they follow a multi-step process involving several distinct committees.¹⁶ For example, the Pharmacy and Therapeutics (P&T) committee is often an external body of experts who “evaluate clinical and medical literature to select the most appropriate medications for individual disease states and conditions.”¹⁷ These committees are staffed with health-care providers including physicians, pharmacists, and patient representatives. Following their analyses, the P&T Committee makes recommendations for the PBM's template formulary or for an individual client's custom formulary.¹⁸ Notably, this is only one of several PBM committees with influence over formulary design.¹⁹ There are also formulary review and value assessment committees which review P&T Committee recommendations to make formulary placement decisions and trade relations groups which negotiate and approve rebate agreements with drug manufacturers.²⁰

In connection with formulary development, PBMs and their affiliates negotiate with drug manufacturers for rebates and fees on prescription drugs and other remuneration, in return for preferred formulary placement.²¹ PBMs reportedly use the large number of participants across multiple self-insured group health plans to negotiate with drug manufacturers based on “covered lives,” primarily where there are competing therapeutic alternatives.²²

Rising Cost of a Century Old Drug at 36, 38 (2021), [https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20\(FINAL%201\).pdf](https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf).

²¹ Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 10–11 (July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf; U.S. Government Accountability Office, *Prescription Drugs: Selected States' Regulation of Pharmacy Benefit Managers* at 8 (GAO-24-106898, March 2024), <https://www.gao.gov/assets/gao-24-106898.pdf>; National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 19 (2025), <https://content.naic.org/sites/default/files/pmbwhitepap.pdf>.

²² Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* at 8 (April 2025), <https://compass-lexecon.files.svdcn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921>;

Rebates are paid to the PBM periodically after the prescriptions are filled and are passed through to the self-insured group health plan to the extent required by the services contract.²³

More recently, PBM-affiliated group purchasing organizations (GPOs), also known as rebate aggregators, have taken over much of the rebate negotiation function for commercial health plans in return for incremental fees, or for a portion of the rebate that is then shared with the PBM and the self-insured group health plan, again pursuant to contractual terms.²⁴ Each of the three largest PBMs is part of a vertically integrated entity which owns and controls such GPO subsidiaries. These GPOs are affiliates of their respective PBMs and perform the roles of rebate aggregators, two of which are headquartered outside of the United States.²⁵

2.2. Drug Utilization Management

PBMs also provide drug utilization management services, which help optimize medication use, improve clinical outcomes, and control drug costs.²⁶ For example, PBMs perform utilization management services by

United States Senate Finance Committee, *Staff Report, Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* at 29 (2021), [https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20\(FINAL%201\).pdf](https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf).

²³ National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 19 (2025), <https://content.naic.org/sites/default/files/pmbwhitepap.pdf>; United States Senate Finance Committee, *Staff Report, Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* at 39 (2021), [https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20\(FINAL%201\).pdf](https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf).

²⁴ Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 21 (July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf; United States Senate Finance Committee, *Staff Report, Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* at 83 (2021), [https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20\(FINAL%201\).pdf](https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf).

²⁵ Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 24 (July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

²⁶ Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 12 (July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf; U.S. Government Accountability Office, *Prescription Drugs: Selected States' Regulation of Pharmacy Benefit Managers* at 8 (GAO-24-106898, March 2024), <https://www.gao.gov/assets/gao-24-106898.pdf>.

which they determine specific drugs that require prior authorization, under which prescribers must receive pre-approval from the PBM before a particular drug can be prescribed to the patient. Another utilization management technique is step therapy, under which a PBM determines that patients must first try and fail a particular drug or drugs, typically a lower cost or preferred drug, before moving to a different drug. Another is quantity limits on the doses provided to patients in a year. Other drug utilization management services PBMs provide include:

- Non-medical switching to move a patient from one drug to another for a non-clinical reason, such as lowering cost;²⁷
- Patient compliance analysis, also known as medication adherence analysis, in which a PBM reviews various data elements related to a participant's prescription drug benefit claims to determine whether (or to the extent which) a participant is indicated as conforming to the usage of a drug as prescribed;²⁸
- Therapeutic intervention, or therapeutic interchange intervention, is the substitution of a prescribed drug for another drug that is essentially equivalent in terms of efficacy, safety, and outcomes;²⁹ and,
- Generic substitution, which is the practice of substituting a prescribed brand name drug for a therapeutically equivalent generic alternative to reduce cost.³⁰

2.3. Pharmacy Networks

PBMs also develop pharmacy networks for self-insured group health plans which can be divided into three categories: retail, mail-order, and

specialty.³¹ Retail pharmacies, which may be part of a pharmacy chain or independent, purchase prescription drugs from drug manufacturers and drug wholesalers and make them available to self-insured group health plan participants.³² Mail order pharmacies dispense and deliver prescriptions directly to participants and are often utilized for prescription drugs that are taken regularly.³³ Specialty drugs that meet certain characteristics such as special handling needs or high cost may be provided through a separate pharmacy.³⁴ As noted by the Federal Trade Commission (FTC), Congress, and others, the largest PBMs are vertically integrated with retail, specialty, and mail-order pharmacies.³⁵

In developing a pharmacy network, PBMs negotiate dispensing fees and reimburse pharmacies for the cost of a prescription drug.³⁶ PBMs will establish maximum allowable cost (MAC) lists

that state the greatest amount that a self-insured group health plan will pay for generics and, in some cases, brand name drugs with generic equivalents.³⁷ As in their negotiations with drug manufacturers, PBMs negotiate with pharmacies based on volume expected from the participants of multiple plan sponsors.³⁸

2.4. Claims Administration and Other Services

Finally, PBMs also perform prescription drug claims administration services, which like the others, is key to a self-insured group health plan's pharmacy benefit program. Claims processing may involve the determination of "(1) whether an individual was an eligible participant; (2) whether the prescribed drug was covered by the plan; (3) whether the participant met his or her deductible; and (4) what the participant's co-payment would be if required by the plan."³⁹ PBMs have developed systems to transmit prescription information between themselves and pharmacies, permitting the rapid processing of claims as prescriptions are being filled.⁴⁰ Other services include adjudicating appeals, plan recordkeeping and regulatory compliance.⁴¹

³¹ Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 11 (July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf; U.S. Government Accountability Office, *Prescription Drugs: Selected States' Regulation of Pharmacy Benefit Managers* at 8 (GAO-24-106898, March 2024), <https://www.gao.gov/assets/gao-24-106898.pdf>.

³² Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 17 (July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

³³ Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 17 (July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

³⁴ Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 17-18 (July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

³⁵ Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 15-18 (July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf; United States Senate Finance Committee, *Staff Report, Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* at 31 (2021), [https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20\(FINAL%201\).pdf](https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf).

³⁶ Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 11 (July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf; Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* at 26 (April 2025), <https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921>.

³⁷ U.S. Government Accountability Office, *Prescription Drugs: Selected States' Regulation of Pharmacy Benefit Managers* at 13 (GAO-24-106898, March 2024), <https://www.gao.gov/assets/gao-24-106898.pdf>.

³⁸ Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* at 8 (April 2025), <https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921>.

³⁹ Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 9 (November 2014), https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf.

⁴⁰ Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 13 (July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf; Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* at 11 (April 2025), <https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921>.

⁴¹ U.S. Government Accountability Office, *Prescription Drugs: Selected States' Regulation of Pharmacy Benefit Managers* at 8 (GAO-24-106898, March 2024), <https://www.gao.gov/assets/gao-24-106898.pdf>; Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 6 (November 2014) https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf.

²⁷ National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 19 (2025), <https://content.naic.org/sites/default/files/pmbwhitepap.pdf>.

²⁸ Taiwo Opeyemi Aremu, Oluwatosin Esther Oluwale, Kehinde Oluwatosin Adeyinka, & Jon C Schommer, *Medication Adherence and Compliance: Recipe for Improving Patient Outcomes*, MDPI (August 28, 2022), <https://pubmed.ncbi.nlm.nih.gov/36136839/>.

²⁹ Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* at 17 (April 2025), <https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921>.

³⁰ William H Shrank, Michael E. Porter, Sachin H. Jain, & Nitesh K. Choudhry, *A Blueprint for Pharmacy Benefit Managers to Increase Value*, Am J Manag Care (February 2009), <https://pmc.ncbi.nlm.nih.gov/articles/PMC2737824/>.

3. PBM Contracts and Arrangements With Self-Insured Group Health Plans

When engaging in a request for proposal process, responsible plan fiduciaries of self-insured group health plans receive bids to contract directly with a PBM for services, or they may contract for services with a third-party administrator (TPA) or other entity (examples discussed herein) that agrees to provide pharmacy benefit management services to the self-insured group health plan.⁴² Some responsible plan fiduciaries also join coalitions or cooperatives that negotiate with PBMs on behalf of a group of employer-sponsored self-insured group health plans.⁴³

Negotiating a pharmacy benefit contract is a complex process that requires specialized expertise. Responsible plan fiduciaries, especially those without internal expertise and practices to manage drug benefits, often work with a separate consultant or broker to select and negotiate a direct contractual agreement with the PBM. Services can include requests for proposals (RFPs), PBM oversight, and PBM audit services.⁴⁴ In some cases, the consultants and brokers receive indirect compensation (e.g., compensation from the PBMs or other sources other than the self-insured group health plan) that may create a conflict of interest with respect to their self-insured group health plan customers.⁴⁵ Consulting firms and brokerages reportedly may receive payments on a per prescription or per covered employee basis, or they may share in rebates earned by PBMs.⁴⁶

⁴² See Matthew Fiedler, Loren Adler, & Richard G. Frank, *A Brief Look at Current Debates about Pharmacy Benefit Managers*, The Brookings Institution (2023) <https://www.brookings.edu/articles/a-brief-look-at-current-debates-about-pharmacy-benefit-managers/>.

⁴³ Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* at 19–20, 59 (April 2025), <https://compass-lexecon.files.svdcn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921>.

⁴⁴ Milliman, *Pharmacy Benefits Consulting*, <https://www.milliman.com/en/services/pharmacy-benefits-consulting>.

⁴⁵ Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 3 (November 2014), https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf; AJ Ally, Patrick Cambel, Mark Gruenhaupt, & Kristin Niakan, *Report of Pharmacy Benefit Manager Practices* at 34 (2025), <https://portal.ct.gov/-/media/ohs-reports/ohs-report-of-pharmacy-benefit-manager-practices-pa-23-171-s7.pdf?rev=01a4809a4795421e890970d8cd52fcl>.

⁴⁶ Bob Herman, ‘It’s beyond unethical’: Opaque conflicts of interest permeate prescription drug benefits (June 2023), <https://www.statnews.com/2023/06/20/pbms-consulting-firms-investigation/>.

Consultants may have preferred relationships with certain PBMs which may impact their recommendations.⁴⁷

In addition to the complexity of the negotiations, responsible plan fiduciaries often lack a clear understanding of the contractual terms, or knowledge of how PBMs operate and how they receive compensation.⁴⁸ For example, PBM contracts may be for one year or multiple years, and may be amended at any point during the contract period if the formulary changes. The contracts may also allow for interim “market checks.”⁴⁹ As described by one source, this involves “a comparison of the aggregate program pricing terms with the market access product types/distribution channels, administrative fees, allowances, other financial guarantees, and rebates to determine if the plan sponsor is receiving competitive market rates.”⁵⁰ The contracts also address the ability of the responsible plan fiduciary to audit the PBM’s compliance with the contract.⁵¹ PBMs often limit a self-

⁴⁷ Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 21 (November 2014), https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf.

⁴⁸ While Congress has prohibited plans and issuers from entering into contracts with health care providers, networks or association of providers, third-party administrators, or other service providers offering access to a network of providers that would prohibit them from electronically accessing de-identified claims and encounter information or data, including financial information, such as the allowed amount, or any other claim-related financial obligations included in the provider contract, such provisions do not affirmatively provide disclosure to responsible plan fiduciaries. See ERISA section 724; Code section 9824(a)(1)(B); PHS Act section 2799A–9.

⁴⁹ Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* at 60 (April 2025), <https://compass-lexecon.files.svdcn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921>. Alex Johnson & Brian N. Anderson, *PBM Best Practices Series, RFP Process*; Milliman White Paper (September 2016), <https://edge.sitecorecloud.io/millimaninc5660-milliman6442-prod27d5-0001/media/Milliman/PDFs/Articles/Best-practices-PBM-RFP-process.pdf>.

⁵⁰ Alex Johnson & Brian N. Anderson, *PBM Best Practices Series, RFP Process*; Milliman White Paper (September 2016), <https://edge.sitecorecloud.io/millimaninc5660-milliman6442-prod27d5-0001/media/Milliman/PDFs/Articles/Best-practices-PBM-RFP-process.pdf>.

⁵¹ Scott McEachern & Patrick Cambel, *PBM Contracts: Understand then Optimize*; Milliman White Paper (August 2020) (“PBMs normally define all audit rights and limitations in the PBM contract and plan sponsors must initiate the audit.”), <https://us.milliman.com/en/insight/pbm-contracts-understand-then-optimize>; Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 24 (November 2014), https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf.

insured group health plan’s audit rights, however, providing only a sample of records relating to contractual performance, requiring that the auditor be approved by the PBM, or that the audit be conducted on-site at a facility chosen by the PBM.

3.1. Administrative Fees and Spread Pricing

PBM compensation arrangements with self-insured group health plans may have multiple components, but the compensation models are sometimes described as falling into two general categories: pass through pricing and spread pricing.⁵²

In a pass-through pricing model, self-insured group health plans may, for example, pay the PBM the average wholesale price (AWP) for a drug minus a negotiated discount (also referred to as the negotiated rate) plus an administrative fee, which may be structured on a per claim basis, per participant basis, flat rate, or other mechanism.⁵³ In a spread pricing model, self-insured group health plans may pay AWP or AWP minus a smaller negotiated discount than in a pass-through model, but will either not pay or pay a reduced administrative fee.⁵⁴ The PBM will instead retain the spread between the price reimbursed to the pharmacy, which might be based on

⁵² National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 13 (2025), <https://content.naic.org/sites/default/files/pmbwhitepap.pdf>; House Committee on Oversight and Accountability Staff, *The Role of Pharmacy Benefit Managers in Prescription Drug Markets* at 7 (2024), <https://oversight.house.gov/wp-content/uploads/2024/07/PBM-Report-FINAL-with-Redactions.pdf>; Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* at 2 (April 2025), <https://compass-lexecon.files.svdcn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921>.

⁵³ National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 13 (2025), <https://content.naic.org/sites/default/files/pmbwhitepap.pdf>; Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* at 142–43 (October 2024), <https://compass-lexecon.files.svdcn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921>.

⁵⁴ Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* at 119 (April 2025), <https://compass-lexecon.files.svdcn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921>.

maximum allowable costs (MAC) or a different formula, and the negotiated rate with self-insured group health plans.⁵⁵

The spread pricing model presents challenges for responsible plan fiduciaries in evaluating costs because there is no agreed upon AWP for a given drug. Accessing AWP data may be costly, and AWP providers use proprietary, hard-to-verify data sources and methodologies.⁵⁶ Additionally, PBMs typically do not disclose to the responsible plan fiduciaries either the reimbursement amount paid to pharmacies or the pharmacies' acquisition costs.⁵⁷ Even where a price guarantee is included in a PBM contract, this guarantee may apply on an aggregate basis where PBMs may use periodic true-ups to show compliance with the price guarantee, rather than ensuring each individual prescription is billed at or below the guaranteed price.⁵⁸ One testimony to the ERISA

Advisory Council indicated that PBMs may also use complex pricing algorithms in aggregate calculations, which can involve including or excluding certain claims in ways that affect the calculations used to measure the fulfillment of price guarantees.⁵⁹

Some responsible plan fiduciaries may view the spread pricing model as providing potential benefits such as smoothing fluctuations in drug costs, which could reduce unpredictability, compared to models where the full drug costs are passed through to the self-insured group health plan, without applying a price smoothing mechanism.⁶⁰ However, the spread pricing model may be less transparent to responsible plan fiduciaries if there are no disclosures of the differences between the amounts the PBM paid to pharmacies and the amounts charged to the self-insured group health plan, or if pricing guarantees are verified only in the aggregate. Comparatively, in the pass-through model, PBMs charge the plan the same amount they reimburse pharmacies, and compensation is more plainly identified, which some responsible plan fiduciaries characterize as a more "transparent" arrangement.⁶¹ Some PBMs that offer pass-through pricing also have business models that provide customers with frequent audit

opportunities and minimal limitations on access to PBM data.⁶²

Additionally, as discussed in greater detail later in the Regulatory Impact Analysis, the largest PBMs have become vertically integrated with health insurance companies, pharmacies, drug manufacturers, and other entities.⁶³ PBMs sometimes operate affiliated pharmacies and require plan participants to use these affiliated pharmacies for certain prescriptions such as mail-order and/or specialty drugs.⁶⁴ In some ways, the vertically integrated structure can be efficient and cost-effective, but some believe it may affect price competition when participants are required to use a PBM-affiliated pharmacy for certain prescriptions.⁶⁵ With respect to specialty drugs, which are an increasing source of drug spending, the FTC found in a recent study that the three largest PBMs "reimbursed their affiliated pharmacies at a higher rate than unaffiliated pharmacies on nearly every specialty generic drug examined."⁶⁶

3.2. Payments From Drug Manufacturers

Payments from drug manufacturers are another component of PBM compensation. These types of payments include, but are not limited to, rebates, administrative fees, and price protection

⁵⁵ National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 13 (2025), <https://content.naic.org/sites/default/files/pmbwhitepap.pdf>; U.S. Government Accountability Office, *Prescription Drugs: Selected States' Regulation of Pharmacy Benefit Managers* at 7–8 (GAO–24–106898, March 2024), <https://www.gao.gov/assets/gao-24-106898.pdf>.

⁵⁶ AWP is described as "an estimate of the price wholesalers charge for drugs." National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 12 (2025), <https://content.naic.org/sites/default/files/pmbwhitepap.pdf>. AWP prices are available from third-party vendors. Andrew W. Mulcahy & Vishnupriya Karedy, *Prescription Drug Supply Chains: An Overview of Stakeholder Relationships*, RAND Corporation at 30 (2021), <https://aspe.hhs.gov/sites/default/files/documents/0a464f25f02e987170f0a1d7ec21448/RR4328-1-Rxsupplychain.pdf>. The Department reviewed the publicly available information on the websites of AWP providers and found no methodology documents, quality control practices, or sample price lists or analysis that could validate the accuracy of the AWP.

⁵⁷ National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 21 (2025) ("Pharmacy pricing is complex, and the process is not transparent. Plan sponsors are often unaware of the difference between the amount they are billed and the pharmacy reimbursement."), <https://content.naic.org/sites/default/files/pmbwhitepap.pdf>; Eastern Research Group, *An Examination of Pharmaceutical Supply Chain Intermediary Margins in the U.S. Retail Chain* at ii (September 2024), https://aspe.hhs.gov/sites/default/files/documents/db1ad86053b1fda8ae9efd01c10ddc8/Pharma%20Supply%20Chains%20Margins%20Report_Final_2024.09.27_Clean_508.pdf.

⁵⁸ Scott McEachern & Patrick Cambel, *PBM Contracts: Understand then Optimize*; Milliman White Paper (August 2020) ("Contracts with PBMs typically involve guarantees in a number of pricing areas. The PBM may guarantee individual pricing by dispensing channel (retail, mail order, and

specialty) as well as by drug type (brand or generic). The PBM might commit to these pricing metrics such that overall, at the end of the year, the aggregate pricing within each channel and drug type will be at least as good as the guarantees outlined in the contract. In the case that a PBM has not met a guarantee, the PBM would issue a true-up payment to the plan sponsor to make up for any deficiencies. However, some contracting language may allow the PBM to cover its underperformance by using any overperformance from other channels."); <https://us.milliman.com/en/insight/pbm-contracts-understand-then-optimize>.

⁵⁹ Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 22 (November 2014), https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf.

⁶⁰ Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* at 34 (April 2025), <https://compass-lexecon.files.svdcn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921>.

⁶¹ House Committee on Oversight and Accountability Staff, *The Role of Pharmacy Benefit Managers in Prescription Drug Markets* at 26 (2024), <https://oversight.house.gov/wp-content/uploads/2024/07/PBM-Report-FINAL-with-Redactions.pdf>; Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* at 142 (April 2025), <https://compass-lexecon.files.svdcn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921>.

⁶² House Committee on Oversight and Accountability Staff, *The Role of Pharmacy Benefit Managers in Prescription Drug Markets* at 26 (2024), <https://oversight.house.gov/wp-content/uploads/2024/07/PBM-Report-FINAL-with-Redactions.pdf>.

⁶³ Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 1–2 (July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

⁶⁴ Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 12 (July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf. Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 11 (November 2014), https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf.

⁶⁵ National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 23 (2025), <https://content.naic.org/sites/default/files/pmbwhitepap.pdf>; Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* at 18 (April 2025), <https://compass-lexecon.files.svdcn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921>.

⁶⁶ Federal Trade Commission, *Second Interim Staff Report, Specialty Generic Drugs: A Growing Profit Center for Vertically Integrated Pharmacy Benefit Managers* at 2 (January 2025), https://www.ftc.gov/system/files/ftc_gov/pdf/PBM-6b-Second-Interim-Staff-Report.pdf.

fees. These payments are often defined by reference to list price, which commenters allege incentivizes PBMs to choose high-list price, high-rebate drugs when creating a self-insured group health plan's formulary.

Rebates are discounts on drugs offered by the pharmaceutical manufacturer in return for preferred placement on a self-insured group health plan's formulary; and the extent to which rebates are retained by the PBM or passed through to the self-insured group health plan is negotiated by the parties.⁶⁷ PBMs also earn administrative fees from drug manufacturers when prescriptions are filled based on the utilization of the drugs and plan design decisions made by plan sponsors, including formulary and utilization strategies.⁶⁸ Price protection fees are an additional rebate that a manufacturer pays the PBM if list prices rise faster than inflation or another agreed upon amount.⁶⁹

To the extent rebates, fees, and other sources of remuneration are passed through to the self-insured group health plan, this can help defray the cost of the health-care benefits being provided.⁷⁰

However, some sources indicate that responsible plan fiduciaries may benefit from more transparent disclosures to ensure that rebates, fees, and other sources of remuneration are passed through as agreed to under the contract with the PBM, in part due to evolving terminology used in the contracts.⁷¹ Some have indicated that the role of rebate aggregators adds complexity to drug pricing and transparency for disclosure of rebates owed to group health plans.⁷²

The rebate payment structure would also benefit from more transparent disclosure for other reasons. One commonly cited concern is that PBMs may have an incentive to select certain drugs with high-list prices over others for group health plan formularies due to the size of the rebate payments from drug manufacturers.⁷³ In addition to providing PBMs with an incentive to select higher priced drugs for the formularies, some sources indicate that rebates may be offered by drug

manufacturers to PBMs to exclude competing products from the formulary.⁷⁴ Disclosure of rebates and other payments from drug manufacturers will allow self-insured group health plan responsible plan fiduciaries to evaluate the impact of these payments on the plan's formulary.

Sources also indicate that rebates and related PBM formulary practices may be related to increases in the manufacturers' drug list prices.⁷⁵ Drug manufacturers may raise list prices to accommodate rebate demands to secure preferred formulary placement to protect its market share, profits, or to recoup the costs for research and development.⁷⁶ Increases in list prices do not directly impact self-insured group health plans, as they generally pay a lower price due to rebates and other discounts negotiated by the PBMs.⁷⁷ However, increases in list

⁶⁷ National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 19 (2025), <https://content.naic.org/sites/default/files/pmbwhitepap.pdf>.

⁶⁸ United States Senate Finance Committee, *Staff Report, Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* at 8 (2021), [https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20\(FINAL%201\).pdf](https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf); Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* at 13 (April 2025), <https://compasslexecon.files.svdcn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921>.

⁶⁹ United States Senate Finance Committee, *Staff Report, Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* at 9 (2021), [https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20\(FINAL%201\).pdf](https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf); Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* at 13 (April 2025), <https://compasslexecon.files.svdcn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921>.

⁷⁰ For example, rebates passed through to a trust established to fund a self-insured group health plan would be required to be used for the exclusive purposes of providing benefits to the plan's participants and beneficiaries and defraying reasonable expenses of administering the plan. See ERISA section 403(c)(1). See also, AJ Ally, Patrick Cambel, Mark Gruenhaupt, & Kristin Niakan, *Report of Pharmacy Benefit Manager Practices* at 40 (2025) ("From the plan sponsor's perspective, rebates are a valuable tool in keeping plan premiums low as most plans use rebate value to directly offset plan liability and do not share rebate value with members at the point of sale."), <https://portal.ct.gov/-/media/ohs/reports/ohs-report-of-pharmacy-benefit-manager-practices-pa-23-171-s7.pdf?rev=01a4809a4795421e890970d8cd5f2fc1>.

⁷¹ Joanna Shepherd, *Pharmacy Benefit Managers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs*, Yale Law & Policy Review at 382 (2020) ("PBMs rarely disclose the rebates they receive from manufacturers, and in situations in which they've agreed to share rebate information, the PBMs may recategorize rebates as fees to circumvent disclosure obligations."), <https://openyls.law.yale.edu/server/api/core/bitstreams/fc20e184-b2d6-4b02-a0f6-a495e3fb5cd2/content>; Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 22 (November 2014), https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf.

⁷² Percher, *Trends in Profitability and Compensation of PBMs & PBM Contracting Entities*, at 2 (Sep. 18, 2023).

⁷³ National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 20 (2025) ("The existence of rebates alone is not a problem. However, the PBM's ability to retain a percentage of the rebate creates a concern, as they are also commonly in charge of formulary design. These two factors give PBMs a financial incentive to prioritize drugs in the formulary based on the highest rebate instead of the lowest total cost to the plan sponsor or consumer."), <https://content.naic.org/sites/default/files/pmbwhitepap.pdf>; <https://content.naic.org/sites/default/files/pmbwhitepap.pdf>; House Committee on Oversight and Accountability Staff, *The Role of Pharmacy Benefit Managers in Prescription Drug Markets* at 7 (2024), <https://oversight.house.gov/wp-content/uploads/2024/07/PBM-Report-FINAL-with-Redactions.pdf>; Shepherd, *Pharmacy Benefit Managers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs*, Yale Law & Policy Review at 360 (2020), <https://openyls.law.yale.edu/server/api/core/bitstreams/fc20e184-b2d6-4b02-a0f6-a495e3fb5cd2/content>; T. Joseph Mattingly 2nd, David A Hyman, Ge Bai, *Pharmacy Benefit Managers: History, Business Practices, Economics, and Policy*, <https://pubmed.ncbi.nlm.nih.gov/37921745/>; <https://pubmed.ncbi.nlm.nih.gov/37921745/>.

⁷⁴ Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 4 (July 2024) ("We share evidence that PBMs and brand pharmaceutical manufacturers sometimes enter agreements to exclude generic drugs and biosimilars from certain formularies in exchange for higher rebates from the manufacturer."), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf; United States Senate Finance Committee, *Staff Report, Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* at 8 (2021), [https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20\(FINAL%201\).pdf](https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf).

⁷⁵ Neeraj Sood, Rocio Ribero, Martha Ryan, & Karen Van Nuys, *The Association Between Drug Rebates and List Prices* at 3, U.S.C. Schaeffer (February 2020) https://schaeffer.usc.edu/wp-content/uploads/2024/10/SchaefferCenter-RebatesListPrices_WhitePaper-1.pdf ("Our finding that increased rebates are positively associated with increased list prices supports the notion that PBMs' demand for rebates is at least partly responsible for increasing list prices."); United States Senate Finance Committee, *Staff Report, Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* at 80 (2021), [https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20\(FINAL%201\).pdf](https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf).

⁷⁶ See Joanna Shepherd, *Pharmacy Benefit Managers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs*, Yale Law & Policy Review at 362 (2020), <https://openyls.law.yale.edu/server/api/core/bitstreams/fc20e184-b2d6-4b02-a0f6-a495e3fb5cd2/content>.

⁷⁷ U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, *Report to Congress: Prescription Drug Spending, Pricing Trends, and Premiums in Private Health Insurance Plans* at 4 (November 2024) ("For many drugs, however, list prices are not the prices ultimately paid to manufacturers; payers or pharmacy benefit managers (PBMs) negotiate with manufacturers over formulary placement in exchange for discounts in the form or rebates off the list price;" noting that "[a]s used throughout this report, the term 'rebates' includes rebates, fees, and other remuneration transferred to PBMs from drug manufacturers and pharmacies."), <https://www.dol.gov/sites/dolgov/files/ebsa/laws-and-regulations/laws/no-surprises-act/2024-report-to-congress-prescription-drug-spending.pdf>.

prices may be a factor for a responsible plan fiduciary assessing the overall reasonableness of the contract or arrangement. Participants in self-insured group health plans that include a deductible not only often pay the full cost of the drug up to the amount of the annual deductible, but also a portion of prescription drug costs after the deductible is satisfied, typically in the form of a copayment or coinsurance. In many self-insured group health plans, cost sharing is often based off list price, resulting in higher out-of-pocket costs for participants.⁷⁸

While participants can obtain assistance with the cost of prescription drugs from drug manufacturers in the form of copay cards and coupons, which can lower cost sharing for participants, some argue this effectively bypasses formulary designs, hindering generic drug substitution and increasing overall out-of-pocket costs to participants. Some self-insured group health plans have reacted to the use of copay cards and coupons by adopting programs that address how drug manufacturer assistance will interact with the self-insured group health plan's cost sharing structure, sometimes referred to as "copay maximizer," "copay accumulator," or "alternative funding programs." For example, a PBM or their affiliated entity might develop a list of specialty medications as part of an alternative funding program for exclusion from coverage under a self-insured group health plan. This has the effect of allowing the plan sponsor to drop drug coverage for participants and beneficiaries in order to access assistance intended for uninsured patients. If a participant needs the medication, he or she is then redirected to another funding source, such as a patient assistance program, outside of the self-insured group health plan.

⁷⁸ Neeraj Sood, Rocio Ribero, Martha Ryan, & Karen Van Nuys, *The Association Between Drug Rebates and List Prices* at 5, U.S.C. Schaeffer (February 2020) ("We find that rebates and list prices are positively related, with an increase in rebates associated with a roughly dollar-for-dollar increase in list price. This suggests that reducing or eliminating rebates could result in lower list prices, thereby decreasing out-of-pocket costs for uninsured patients and for insured patients with deductibles or coinsurance."), https://schaeffer.usc.edu/wp-content/uploads/2024/10/SchaefferCenter_RebatesListPrices_WhitePaper-1.pdf; Joanna Shepherd, *Pharmacy Benefit Managers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs*, Yale Law & Policy Review at 362–63 (2020), <https://openyls.law.yale.edu/server/api/core/bitstreams/fc20e184-b2d6-4b02-a0f6-a495e3fb5cd2/content>; T. Joseph Mattingly 2nd, David A Hyman, & Ge Bai, *Pharmacy Benefit Managers: History, Business Practices, Economics, and Policy*, <https://pubmed.ncbi.nlm.nih.gov/37921745/>; <https://pubmed.ncbi.nlm.nih.gov/37921745/>.

These programs reportedly may be administered by PBMs and appear to be a source of additional PBM compensation.⁷⁹

3.3. Payments From Pharmacies

PBMs receive payments from pharmacies in a number of different circumstances. If a participant's copay is higher than the total reimbursement owed to the pharmacy, a PBM may "claw-back" the overpayment amount.⁸⁰ For example, if a participant's copayment for a generic drug is \$15 dollars, but the PBM has agreed to pay the pharmacy \$5, the PBM will "claw-back" the excess \$10. In such cases, it is not clear whether such overpayments are generally or ever reimbursed to the self-insured group health plan (or participant).⁸¹

PBMs also reportedly recoup amounts paid to pharmacies for other reasons, including "network participation fees, fees for non-compliance or lower performance with quality measures, and reimbursement reconciliation."⁸² A relatively new PBM practice is "effective rate reconciliation," in which the contractual reimbursement rate paid by a PBM to a pharmacy for dispensing a drug is determined by an aggregate

⁷⁹ Michelle Long, Meghan Salaga, & Kaye Pestaina, *Copay Adjustment Programs: What Are They and What Do They Mean for Consumers* (October 24, 2024), <https://www.kff.org/report-section/copay-adjustment-programs-what-are-they-and-what-do-they-mean-for-consumers-issue-brief/>; David Choi, Autumn D. Zuckerman, Svetlana Gerzenshtein, Katherine V. Katsivalis, Patrick J. Nichols, Marci C. Saknini, Megan P. Schneider, Paige Taylor, & Stacie B. Dusetzina, *A Primer on Copay Accumulators, Copay Maximizers, and Alternative Funding Programs* (August 1, 2024), <https://www.jmcp.org/doi/10.18553/jmcp.2024.30.8.883>.

⁸⁰ National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 21 (2025), <https://content.naic.org/sites/default/files/pmbwhitepap.pdf>. Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 23 (November 2014), https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf.

⁸¹ Some self-funded plans have benefit design edits that make copayments the "lesser of" the copayment amount and the acquisition cost to prevent overpayment and therefore claw-backs.

⁸² AJ Ally, Patrick Cambel, Mark Gruenhaupt, & Kristin Niakan, *Report of Pharmacy Benefit Manager Practices* at 17 (2025) ("Brokers earn revenues in several ways that may not be apparent to the plan sponsor, such as commissions, bonuses, fees, TPA fees paid by PBMs, per prescription fees, etc."), <https://portal.ct.gov/-/media/ohs/reports/ohs-report-of-pharmacy-benefit-manager-practices-pa-23-171-s7.pdf?rev=01a4809a4795421e890970d8cd5f2fc1>. Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 11 (July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

effective rate, typically expressed as a percentage discount from AWP.⁸³ The PBM periodically reconciles the payments made to pharmacies at the point of sale with the specified effective rate and will adjust future reimbursement to the pharmacy to account for the difference between the amount paid at the point of sale and the effective rate following the reconciliation.⁸⁴ In addition to generic effective rate and brand effective rate, the PBM may also include a "dispensing fee effective rate" for the administrative cost charged by a pharmacy to dispense a drug.⁸⁵

C. Service Provider Arrangements Under ERISA

1. Prohibited Transaction Framework

Responsible plan fiduciaries of self-insured group health plans must determine that service provider relationships involving the self-insured group health plan meet certain conditions to avoid constituting a prohibited transaction under ERISA. Specifically, unless an exemption applies, the furnishing of goods, services, or facilities between a self-insured group health plan and a party in interest to the plan is a prohibited transaction under ERISA section 406(a)(1)(C). A person providing services to the self-insured group health plan is defined by ERISA to be a "party in interest" to the self-insured group health plan.

ERISA section 408(b)(2) exempts certain arrangements between ERISA-covered plans (including self-insured group health plans) and service providers that otherwise would be prohibited transactions under ERISA section 406. Section 408(b)(2) provides relief from ERISA's prohibited transaction rules for service contracts or arrangements between a plan and a party in interest if the contract or

⁸³ Andrew W. Mulcahy & Vishnupriya Karedy, *Prescription Drug Supply Chains: An Overview of Stakeholder Relationships*, RAND Corporation at 19 (2021), <https://aspe.hhs.gov/sites/default/files/documents/0a464f25f02e987170f0a1d7ec21448/RR4328-1-Rxsupplychain.pdf>.

⁸⁴ U.S. Senate Committee on Finance, *Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers*, Written testimony of Jonathan Levitt (2023), https://www.finance.senate.gov/imo/media/doc/Jonathan%20Levitt%20Testimony%20US%20Senate%20Committee%20on%20Finance%20-%20Frier%20Levitt%20-%20March%202023_Redacted1.pdf.

⁸⁵ Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers, U.S. Senate Committee on Finance, 118th Cong. (2023) (Written testimony of Jonathan Levitt); Elevate Provider Network, What are GERS/BERs/DFERs?, <https://www.alliantrx.com/wp-content/uploads/2020/05/GER-Explainer-Documents.pdf> (June 24, 2025).

arrangement is reasonable, the services are necessary for the establishment or operation of the plan, and no more than reasonable compensation is paid for the services.

The Department's regulation under ERISA section 408(b)(2) clarifies the exemption's "necessary service," "reasonable contract or arrangement" and "reasonable compensation" conditions.⁸⁶ The regulation also clarifies that the exemption in ERISA section 408(b)(2) does not extend to acts described in ERISA section 406(b) relating to fiduciary conflicts of interest and provides examples illustrating this principle.⁸⁷

In 2012, the Department amended its regulation under ERISA section 408(b)(2) to require parties who are "covered service providers" with respect to pension plans to disclose specified information to a responsible plan fiduciary, in order for certain services contracts or arrangements to be reasonable.⁸⁸ The amended regulation generally requires covered service providers to provide initial disclosure of: the services to be provided; the status of the covered service provider, an affiliate, or subcontractor as a fiduciary, if applicable; the direct and indirect compensation reasonably expected to be received by the covered service provider, their affiliates and their subcontractors; as well as allocations of compensation reasonably expected to be made among the covered service providers and its affiliates and subcontractors. The amended regulation also establishes ongoing disclosure obligations in the event of a change in the information required to be provided in the initial disclosures and disclosures to be provided upon the written request of the responsible plan fiduciary as needed for the plan to comply with the reporting and disclosure requirements of title 1 of ERISA. The amended regulation also carries over a provision from the initial regulation regarding termination of the contract or arrangement.⁸⁹

The amended regulation defines a responsible plan fiduciary as a fiduciary with authority to cause the plan to enter into, or extend or renew, a contract or arrangement for the provision of services to the plan.⁹⁰ The Department's amended regulation is accompanied by an administrative class exemption for responsible plan fiduciaries, codified at paragraph (c)(1)(ix), which provides prohibited transaction relief for responsible plan fiduciaries in the event a covered service provider fails to disclose information as required under the regulation. In the absence of an exemption providing otherwise, the service provider's failure to comply with the regulation will result in a prohibited transaction by the responsible plan fiduciary.⁹¹

In the final rule amending its regulation, the Department reserved paragraph (c)(2) for future guidance on disclosure with respect to welfare plans (including self-insured group health plans). The Department concluded that there were significant differences between service and compensation arrangements for welfare plans and those involving pension plans, and that those differences supported the development of specifically tailored disclosure requirements for welfare plans.⁹²

In 2014, the ERISA Advisory Council studied PBM fee disclosures and recommended that the Department should "consider making Section 408(b)(2) Regulations applicable to welfare plan arrangements with PBMs, and thereby deem such arrangements reasonable only where PBMs disclose direct and indirect compensation, including compensation paid among related parties such as subcontractors,

arrangement which reasonably compensates the service provider or lessor for loss upon early termination of the contract, arrangement, or lease is not a penalty. For example, a minimal fee in a service contract which is charged to allow recoupment of reasonable start-up costs is not a penalty. Similarly, a provision in a lease for a termination fee that covers reasonably foreseeable expenses related to the vacancy and reletting of the office space upon early termination of the lease is not a penalty. Such a provision does not reasonably compensate for loss if it provides for payment in excess of actual loss or if it fails to require mitigation of damages."

⁹⁰ 29 CFR 2550.408b-2(c)(1)(viii)(E).

⁹¹ See ERISA section 406(a)(1) ("Except as provided in [section 408] . . . [a] fiduciary with respect to a plan shall not cause the plan to engage in a transaction, if he knows or should know that such transaction constitutes a direct or indirect . . . furnishing of goods, services, or facilities between the plan and a party in interest.")

⁹² 77 FR at 5649. The Department held a public hearing on December 7, 2010, to explore operational, disclosure, and fee transparency issues concerning welfare benefit plans. See <https://www.dol.gov/agencies/ebsa/laws-and-regulations/rules-and-regulations/public-comments/1210-AB37>.

in a manner consistent with current Section 408(b)(2) Regulations."⁹³

The report included several findings related to this recommendation, including:

- "Plan sponsors of group health plans who testified at the Council hearings were unanimous in their view that they face many challenges managing pharmacy benefits on a cost-effective basis. However, plan sponsors uniformly testified that PBM services are a valuable part of this effort."

- "Testimony submitted to the Council revealed that drug pricing methodologies and PBM compensation are complex and evolving, including rebates, price spreads, discounts, and other payments from retail pharmacy chains and manufacturers. Substantial evidence was submitted to the Council from ERISA plan sponsors and others that many PBMs do not fully disclose compensation in a manner which is readily understandable to even the most sophisticated plan sponsors and consultants."

- "Testimony before the Council indicated that some forms of PBM compensation have the potential for creating conflicts of interest. Sponsors of ERISA health plans may or may not be aware of these potential conflicts."

- "ERISA group health plans that contract directly with PBMs frequently use consultants to assist in negotiations with the PBM. Testimony was submitted to the Council that it is common for consultants to receive indirect compensation. The payment of indirect compensation to consultants who are advising plan sponsors in negotiations with the PBM may create the potential for conflicts of interest that may be adverse to the plan sponsor. Sponsors of ERISA health plans may or may not be informed of such indirect compensation."

- "Plan sponsors testified that disclosure of PBM compensation would better enable them to comply with their obligations to determine reasonable compensation under Section 408(b)(2). Nondisclosure creates the potential for impediments to plan sponsors' ability to comply with 408(b)(2)."

The second recommendation of the ERISA Advisory Council related to audits of a PBM's compliance with its contract with the welfare plan.⁹⁴ Specifically, the Council recommended

⁹³ Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 3–4 (November 2014), https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf.

⁹⁴ The council noted this audit should not be confused with the requirement under ERISA section 103(3)(A).

⁸⁶ 29 CFR 2550.408b-2(b), (c), (d).

⁸⁷ 29 CFR 2550.408b-2(e).

⁸⁸ Reasonable Contract or Arrangement Under Section 408(b)(2)—Fee Disclosure; Final Rule, 77 FR 5632 (Feb. 3, 2012).

⁸⁹ 29 CFR 2550.408b-2(c)(3) ("No contract or arrangement is reasonable within the meaning of section 408(b)(2) of the Act and paragraph (a)(2) of this section if it does not permit termination by the plan without penalty to the plan on reasonably short notice under the circumstances to prevent the plan from becoming locked into an arrangement that has become disadvantageous. A long-term lease which may be terminated prior to its expiration (without penalty to the plan) on reasonably short notice under the circumstances is not generally an unreasonable arrangement merely because of its long term. A provision in a contract or other

that the Department should “consider issuing guidance to assist plan sponsors in determining whether to and how to conduct a PBM audit of direct and indirect compensation.”⁹⁵

Findings related to this recommendation included identification of the following problem areas, among others:

- “The exclusion of auditors who the PBM believes hold hostile views.”
- “On-site audits are required at PBM headquarters.”
- “PBMs limit the auditor to transcribing notes of documents.”
- “Confidentiality agreements can be overly broad and put unnecessary burdens on the parties when they prohibit disclosure of information by an auditor to its client plan.”
- “PBMs will not disclose documents requested by some auditors such as PBM contracts with retail pharmacies and drug manufacturers.”
- “Access to claims data is restricted.”
- “Audit rights restricted to limited periods (such as 2 years).”
- “Some necessary data sources such as AWP pricing are not public and access is expensive . . . and disclosure is limited.”

2. Consolidated Appropriations Act, 2021 408(b)(2) Amendment

In the Consolidated Appropriations Act (CAA), 2021, Congress amended the ERISA section 408(b)(2) statutory exemption to add a new paragraph (B) applicable to certain services arrangements with group health plans, effective December 27, 2021.⁹⁶ As part of the amendment, Congress designated the pre-existing text as ERISA section 408(b)(2)(A).⁹⁷ The requirements in ERISA section 408(b)(2)(B) apply to a group of covered service providers, defined as persons or entities who provide “brokerage services” or “consulting” to group health plans with respect to a list of sub-services including pharmacy benefit management services.⁹⁸

⁹⁵ Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 5 (November 2014), https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf.

⁹⁶ Section 202 of Title II of Division BB of the Consolidated Appropriations Act, 2021.

⁹⁷ ERISA section 408(b)(2)(A) now provides an exemption for “[c]ontracting or making reasonable arrangements with a party in interest for office space, or legal, accounting, or other services necessary for the establishment or operation of the plan, if no more than reasonable compensation is paid therefor.”

⁹⁸ Specifically, see ERISA section 408(b)(2)(B)(i)(I)(bb)(AA) (defining a covered service provider as one who provides *brokerage services* “provided to a covered plan with respect

The new ERISA section 408(b)(2)(B) closely tracks the Department’s regulation for pension plan arrangements. It requires disclosure of: the services to be provided; the status of the covered service provider, an affiliate, or subcontractor as a fiduciary, if applicable; the direct and indirect compensation reasonably expected to be received by the covered service provider, their affiliates and their subcontractors; as well as allocations of compensation reasonably expected to be made among the covered service providers and its affiliates and subcontractors. The new provision also establishes ongoing disclosure obligations in the event of a change in the information required to be provided in the initial disclosures and disclosures to be provided upon the written request of the responsible plan fiduciary as needed for the plan to comply with the reporting and disclosure requirements of title I of ERISA.

In December 2021, the Department provided a guidance and temporary enforcement policy addressing questions about ERISA section 408(b)(2)(B).⁹⁹ In general, the policy provided that, pending future guidance or rulemaking, covered service providers and responsible plan fiduciaries would be expected to implement the ERISA section 408(b)(2)(B) requirements using a good faith, reasonable interpretation of the law.

With respect to the terms “brokerage services” and “consulting” as used in ERISA section 408(b)(2)(B) to define a covered service provider, the Department noted that neither term was defined and the categories may overlap

to selection of insurance products (including vision and dental), recordkeeping services, medical management vendor, benefits administration (including vision and dental), stop-loss insurance, pharmacy benefit management services, wellness services, transparency tools and vendors, group purchasing organization preferred vendor panels, disease management vendors and products, compliance services, employee assistance programs, or third party administration services”) and ERISA sections 408(b)(2)(B)(i)(I)(bb)(BB) defining a covered service provider as one who provides *consulting services* “related to the development or implementation of plan design, insurance or insurance product selection (including vision and dental), recordkeeping, medical management, benefits administration selection (including vision and dental), stop-loss insurance, pharmacy benefit management services, wellness design and management services, transparency tools, group purchasing organization agreements and services, participation in and services from preferred vendor panels, disease management, compliance services, employee assistance programs, or third party administration services.”

⁹⁹ Field Assistance Bulletin No. 2021–03, <https://www.dol.gov/agencies/ebsa/employers-and-advisers/guidance/field-assistance-bulletins/2021-03>.

in some circumstances, but that the fact that a service provider did not call itself a broker or consultant would not be dispositive. Instead, the Department’s enforcement policy would apply to parties who reasonably and in good faith determined their status as a covered service provider. The Department expressed that “service providers who reasonably expect to receive indirect compensation from third parties in connection with *advice, recommendations, or referrals* regarding any of the listed sub-services . . . should be prepared, if the Department is auditing their 408(b)(2)(B) compliance, to be able to explain how a conclusion that they are not covered service providers is consistent with a reasonable good faith interpretation of the statute.”¹⁰⁰

D. Description of the Proposed Regulation

1. Scope of the Proposed Regulation

1.1. General—Proposed Paragraph (a)

As discussed above in section C of this preamble, ERISA section 408(b)(2) provides an exemption for services contracts and arrangements with ERISA-covered plans, provided the contracts or arrangements are reasonable, the services are necessary for the establishment or operation of the plan, and that no more than reasonable compensation is paid. Paragraph (a) of the proposed regulation provides that for purposes of the statutory exemption under ERISA section 408(b)(2), no contract or arrangement for services between a “covered plan” and a “covered service provider,” nor any extension or renewal, is reasonable unless the requirements of the regulation are satisfied.¹⁰¹

¹⁰⁰ *Id.* (emphasis added). In addition to the new ERISA section 408(b)(2)(B), in 2019, Congress added a distinct statutory exemption in ERISA section 408(h) for the provision of pharmacy benefit services, although in a limited context. The exemption is available to “an entity described in [ERISA section 3(37)(G)(vi)]” or any related organization or subsidiary, provides pharmacy benefit services to a group health plan sponsored by the entity or any other group health plan sponsored by a regional council, local union, or other labor organization affiliated with such entity, see Section 1302 of Division P of the Further Consolidated Appropriations Act, 2020. The Department is aware that the United Brotherhood of Carpenters and Joiners of America takes the position that it is a 501(c)(5) organization, tax exempt under Section 501(a) of the Code, and was established in Chicago, Illinois, on August 12, 1881, as referenced in ERISA section 3(37)(G)(vi), see Exemption from Certain Prohibited Transaction Restrictions Involving the United Brotherhood of Carpenters and Joiners of America, 90 FR 2748, n. 3 (January 13, 2025).

¹⁰¹ Title I of ERISA sets forth various requirements for covered plans, which, subject to

1.2. Covered Plan—Proposed Paragraph (b)

Paragraph (b) of the proposed regulation provides that, for purposes of the regulation, a covered plan means a group health plan as defined in ERISA section 733(a), other than a group health plan in which all of the benefits are provided exclusively through a contract or policy of insurance issued by a health insurance issuer as defined in § 2590.701–2.¹⁰² ERISA section 733(a) defines a “group health plan” as “an employee welfare benefit plan to the extent that the plan provides medical care . . . to employees or their dependents . . . directly or through insurance, reimbursement, or otherwise.” The term “group health plan” includes both insured and self-insured group health plans, and includes grandfathered health plans, as defined in section 1251(e) of the Patient Protection and Affordable Care Act. Excepted benefits, such as limited scope dental and vision plans, are also group health plans for purposes of the definition of a covered plan in this proposal.¹⁰³ However, ERISA section 733(a)(1) expressly excludes qualified small employer health reimbursement arrangements from the definition of group health plan, and therefore such arrangements would not be covered plans under the regulation.

The definition of “covered plan” in the proposal excludes fully insured group health plans, and disclosure obligations with respect to these plans are reserved for future action. Accordingly, the requirements in the

proposed regulation would apply only to contracts and arrangements involving self-insured group health plans. For clarity, this preamble description of the proposed regulation uses the term “self-insured group health plan” instead of the term “covered plan.”

The Department has reserved obligations with respect to fully insured group health plans for future action based on the preliminary view that responsible plan fiduciaries may focus on different considerations when contracting with an insurance company for health insurance coverage that integrates prescription drug coverage, as opposed to self-funding medical care and contracting for pharmacy benefit management services. Specifically, the Department questions whether responsible plan fiduciaries responsible for procuring fully insured health insurance policy would find the specific disclosures proposed in the regulation sufficiently useful when they are negotiating more comprehensive health insurance coverage as to justify the costs associated with the disclosures (both to the covered service provider providing the disclosures and the responsible plan fiduciary reviewing and analyzing the disclosures). It is also the Department’s understanding that, in some instances, other relevant reporting and disclosure requirements may apply under State law to the health insurance issuer, either independently under the applicable insurance code, or as part of the issuer’s routine form filing review.

However, the reservation of these disclosure obligations should not be interpreted as alleviating responsible plan fiduciaries of group health plans of any other obligations under ERISA. Responsible plan fiduciaries must continue to satisfy their general fiduciary obligations under ERISA with respect to the selection and monitoring of all service providers. Further, service contracts or arrangements with these service providers must be “reasonable” and otherwise satisfy the requirements of ERISA section 408(b)(2). For covered service providers as described in ERISA section 408(b)(2)(B), this includes providing the disclosures specified in that statutory provision.

The Department seeks comments on the relevance of the disclosures in this proposed regulation to responsible plan fiduciaries of fully insured group health plans. As indicated, the proposal would not apply to fully insured group health plans, in which the prescription drug coverage is integrated as a component of the insurance coverage and the insurance coverage is subject to State law. In these circumstances, in which services are fully bundled with

insurance, the proposal assumes the responsible plan fiduciary discharges its obligation to ensure that the contract or arrangement is reasonable by focusing on premiums, covered benefits, coverage limits, exclusions, and cost-sharing requirements. The proposal further assumes that responsible plan fiduciaries would not, in these circumstances, benefit from the specific disclosures required under the proposal because when the pharmacy benefit management services are fully bundled with insurance, the responsible plan fiduciary has a clearer understanding of the total compensation paid for the services.

The proposal could have required a disclosure from the insurance company in which each premium dollar is apportioned to the various elements comprising the insurance product, including insurance and services components. Moreover, the disclosure could have further required the prescription drug coverage portion to be divided between the insurance component and the services components, with an itemization of compensation received and expected to be received with respect to each of the service components. The Department has no basis, however, to determine whether the responsible plan fiduciaries of fully insured group health plans would benefit from these or similar disclosures. The Department welcomes comments on this conclusion in general, on the two specific disclosure regimes laid out above, and on whether (and, if so, how) the responsible plan fiduciary would benefit from such disclosures.

1.3. Covered Service Providers—Proposed Paragraph (c)

Paragraph (c) of the proposed regulation defines the entities that would be covered service providers under the regulation and therefore would have disclosure and related audit obligations. The proposal identifies two types of covered service providers: (i) providers of pharmacy benefit management services (as defined in paragraph (d) of the proposal) and (ii) providers of advice, recommendations, or referrals regarding pharmacy benefit management services who are themselves providers of pharmacy benefit management services or their affiliates.¹⁰⁴ In each case, to be a covered service provider, the entity must reasonably expect to receive \$1,000¹⁰⁵ or more in compensation,

certain specific exceptions, “apply to any employee benefit plan if it is established or maintained . . . by any employer . . . or . . . by any employee organization . . . or . . . by both.” ERISA section 4(a); 29 U.S.C. 1003(a). However, Title I of ERISA specifically does “not apply to any employee benefit plan if . . . such plan is a governmental plan.” ERISA section 4(b); 29 U.S.C. 1003(b). “Governmental plan” is defined for purposes of this exclusion as “a plan established or maintained for its employees by the Government of the United States, by the government of any State or political subdivision thereof, or by any agency or instrumentality of any of the foregoing.” ERISA section 3(32); 29 U.S.C. 1002(32).

¹⁰² 29 U.S.C. 1191b.

¹⁰³ See Field Assistance Bulletin No. 2021–03, Q&A 3 (“ERISA section 733(c)(2) provides that certain benefits are not subject to certain requirements of Part 7 of ERISA if offered separately, including limited scope dental or vision benefits The view of the Department is that limited scope dental and vision plans, although excepted from certain requirements in Part 7 of ERISA, are “covered plans” subject to the requirements of ERISA section 408(b)(2)(B). The definition of a “covered plan” in ERISA section 408(b)(2)(B) refers to ERISA section 733(a), without any indication that the definition is further limited by ERISA section 733(c)(2).”), <https://www.dol.gov/agencies/ebsa/employers-and-advisers/guidance/field-assistance-bulletins/2021-03>.

¹⁰⁴ Non-affiliated brokers and consultants remain subject to the ERISA section 408(b)(2)(B) disclosures.

¹⁰⁵ This \$1,000 threshold is consistent with the thresholds in the statute (29 U.S.C.

direct or indirect, in connection with providing the services.¹⁰⁶

The proposal's focus on providers of pharmacy benefit management services is consistent with President Trump's Executive Order 14273, *Lowering Drug Prices by Once Again Putting Americans First*, which instructs the Department to propose regulations to improve employer health plan transparency into the direct and indirect compensation received by pharmacy benefit managers. However, the Department recognizes that self-funded group health plans have other service providers that are not covered by this proposal and that may not be considered providers of "brokerage services" or "consulting" for purposes of ERISA section 408(b)(2)(B). These service providers include TPAs, health insurers, and others involved in the administration of self-insured group health plans' medical claims, such as for hospital stays, surgeries, and chronic treatment. Stakeholders have indicated that group health plan fiduciaries may not have access to all claims data, payments to providers, and fee and pricing data that could enable negotiation for cost savings to group health plans and participants.¹⁰⁷ The Department seeks comment on whether, and the extent to which it could and should expand the disclosures in this proposal to cover additional service providers and if so, which service providers should be covered. Additionally, the Department seeks comment on whether the disclosures proposed herein would be sufficient to bring transparency into arrangements with those additional service providers or whether additional disclosures would be needed, such as claims data, payments to providers, and other fee and pricing data.

1.4. Providers of Pharmacy Benefit Management Services—Proposed Paragraph (c)(1)(i)

Paragraph (c)(1)(i) of the proposal defines, as covered service providers, service providers that enter into a

contract or arrangement with a self-insured group health plan to provide pharmacy benefit management services. The proposal clarifies that this would be the case regardless of whether the services will be performed by the covered service provider, an affiliate, an agent, or a subcontractor.¹⁰⁸ Thus, the proposed definition recognizes that the pharmacy benefit management services may be performed by the covered service provider, or they may be performed by an affiliate, agent, or subcontractor of the covered service provider. Likewise, the proposed definition recognizes that compensation in connection with the services may be received by the covered service provider or it may be received by an affiliate, agent, or subcontractor of the covered service provider.

Under this framework, paragraph (c)(1)(i) of the proposed rule focuses on the entity that has a contract or arrangement with the self-insured group health plan to provide any pharmacy benefit management services to that self-insured group health plan—that counterparty is the covered service provider. The Department believes that the service provider directly responsible to the self-insured group health plan for the provision of pharmacy benefit management services is the appropriate party to ensure that the required disclosures under the regulation are made. This approach is consistent with the Department's service provider regulation applicable to pension plans (29 CFR 2550.408b–2(c)(1)) as well as in the new statutory provision in ERISA section 408(b)(2)(B).¹⁰⁹

In this regard, the Department understands that responsible plan fiduciaries to self-insured group health plans may take a number of different approaches in identifying and selecting a provider of pharmacy benefit management services. The self-insured group health plan may ultimately contract directly with the entity that will perform the services, or it may enter into a contract with a different

entity that agrees to provide the services to the self-insured group health plan through an affiliate, agent, or subcontractor. It is common, for example, for responsible plan fiduciaries to work with a consultant or broker to conduct a request for proposal and to assist in negotiations with the providers of pharmacy benefit management services. In that case, the self-insured group health plan will enter into a contract directly with the PBM.

On the other hand, the Department understands that TPAs may contract directly with self-insured group health plans to provide a range of health-care related services, such as creating networks of health-care providers, negotiating payments rates, and processing and paying health claims. One component of these services may be pharmacy benefit management services. If the TPA contracts with the self-insured group health plan to provide pharmacy benefit management services, the TPA would be a covered service provider under this regulation, even if it intends to rely on another provider to perform those services. In that event, the TPA would be responsible for making the disclosures to the responsible plan fiduciary required under the proposed rule and therefore must be able to obtain information from the provider performing the pharmacy benefit management services necessary for those disclosures.

Self-insured group health plans may access pharmacy benefit management services through other similar types of arrangements, where the provider may or may not refer to itself as a TPA. For example, it is common for group health plans to enter into level-funded arrangements that have excessive stop loss policies to emulate characteristics of fully insured arrangements, such as predictable spending, but that are actually self-funded arrangements. These arrangements commonly include pharmacy benefit services and the entity that contracts with the self-insured group health plan to provide those services would be the covered service provider. As in the TPA example, if the entity contracting or arranging with the self-insured group health plan is not providing the services itself, it would be responsible for making the disclosures to the responsible plan fiduciary required under the proposal, and therefore must be able to obtain information from the provider performing the pharmacy benefit management services necessary for those disclosures.

Questions may arise regarding which party is the covered service provider and which party is the responsible plan

408(b)(2)(B)(ii)(I)(bb)) and the Department's service provider disclosure regulation for pension plans (29 CFR 2550.408b–2(c)(1)(iii)).

¹⁰⁶ Under proposed paragraph (m)(3), compensation is defined as "anything of monetary value but does not include any item or service valued at \$250 or less, in the aggregate, during the term of the service contract or arrangement." The \$250 threshold in this context is consistent with the definitions in the statutory provision (29 U.S.C. 408(b)(2)(B)(ii)(I)(dd)(AA)) and the Department's service provider disclosure regulation for pension plans (29 CFR 2550.408b–2(c)(1)(viii)(B)).

¹⁰⁷ See letter to The Honorable Donald J. Trump from Cynthia A. Fisher, *PatientRightsAdvocate.org* (November 25, 2025), <https://www.patientrightsadvocate.org/lettertopresidentonaffordabilityandhealthcare>.

¹⁰⁸ The definition of pharmacy benefit management services is in paragraph (d) of the proposal, discussed in the next subsection of this preamble. The terms affiliate, agent, and subcontractor are defined in paragraph (m) of the proposal and are discussed in the following subsection of this preamble.

¹⁰⁹ Reasonable Contract or Arrangement Under Section 408(b)(2)—Fee Disclosure; Interim Final Rule, 75 FR 41600, 41606 (July 16, 2010) ("In the view of the Department, the service provider directly responsible to the plan for the provision of services is the appropriate party to ensure that the required disclosures under the regulation are made."); ERISA section 408(b)(2)(B)(ii)(I)(bb) ("The term 'covered service provider' means a service provider that enters into a contract or arrangement with the covered plan . . .").

fiduciary in the context of a multiple employer welfare arrangement (MEWA).¹¹⁰ For MEWAs that are considered single ERISA plans, the responsible plan fiduciary for the self-insured group health plan would receive the disclosures from the party that contracts with the self-insured group health plan to provide pharmacy benefit management services. In the case of a MEWA that is not considered a single ERISA plan, but rather involves a number of self-insured group health plans each sponsored by an employer individually, the party operating the MEWA is likely to be the covered service provider that contracts with the individual self-insured group health plans to provide pharmacy benefit management services. In that case, the MEWA operator would have the responsibility to make the disclosures required by the proposed rule to the responsible plan fiduciaries (*i.e.*, the employers or other fiduciary responsible for entering into the contract or arrangement to provide such services),¹¹¹ and therefore must obtain the necessary information from the provider (*e.g.*, as a subcontractor) performing the pharmacy benefit management services.

Self-insured group health plans alternatively may access pharmacy benefit management services through employer consortiums or other types of employer groups. The analysis of who the covered service provider is in those arrangements would depend on the details of the arrangement and specifically, which entity contracts with the self-insured group health plan to provide the pharmacy benefit management services. If the consortium or other group assists in negotiating with the provider of pharmacy benefit management services but the self-insured group health plan contracts directly with the provider—which the Department believes is the predominant approach—the provider of pharmacy benefit management services would be the covered service provider.¹¹²

¹¹⁰ For more information on MEWAs, see *MEWAs Multiple Employer Welfare Arrangements under the Employee Retirement Income Security Act (ERISA): A Guide to Federal and State Regulation*, https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/mewa-under-erisa-a-guide-to-federal-and-state-regulation.pdf.

¹¹¹ See proposed paragraph (m)(4) defining “responsible plan fiduciary.”

¹¹² Although the Department assumes these consortiums and employer groups are not affiliates of providers of pharmacy benefit management services (and therefore would not be affiliates providing advice, recommendations and referrals for purposes of paragraph (c)(2) of the proposal), depending on the facts, the consortium or other group may be considered to be a provider of

However, if the consortium or other employer group were to contract to provide the services to the self-insured group health plan, the consortium or other group would be the covered service provider.

Finally, a single self-insured group health plan may directly contract with more than one entity for pharmacy benefit management services as such services are defined in paragraph (d) of the proposal. In such circumstances, the self-insured group health plan would thus have more than one PBM, each of which would be a covered service provider and responsible for making its own disclosures with respect to services under its contract or arrangement with the self-insured group health plan.

1.4.1. Definition of Pharmacy Benefit Management Services—Proposed Paragraph (d)

Paragraph (d) of the proposed regulation defines pharmacy benefit management services as services necessary for the management or administration of a self-insured group health plan’s prescription drug benefits (including the self-insured group health plan’s provision of prescription drugs through the plan’s medical benefit), regardless of whether the person, business, or entity performing the service identifies itself as a ‘pharmacy benefit manager.’ The proposed definition includes a list of examples of such services, as follows:

- acting as a negotiator or aggregator of rebates, fees, discounts and other price concessions for prescription drugs;
- establishing or maintaining prescription drug formularies;
- establishing or maintaining pharmacy networks, through contract or otherwise, including a mail order pharmacy, a specialty pharmacy, a retail pharmacy, a nursing home pharmacy, a long-term care pharmacy, and an infusion or other outpatient pharmacy, to provide prescription drugs;
- processing and payment of claims for prescription drugs;
- performing utilization review and management, including the processing of prior authorization requests for drugs, step therapy protocols, patient compliance analyses, conducting therapeutic intervention, and administering generic substitution programs;
- adjudicating appeals or grievances related to the self-insured group health plan’s prescription drug benefits;

“brokerage services” or “consulting” under ERISA section 408(b)(2)(B).

- recordkeeping related to the self-insured group health plan’s prescription drug benefits; and
- in conjunction with any of these other services, performing regulatory compliance with respect to the self-insured group health plan’s prescription drug benefits under the contract or arrangement.

As discussed above, pharmacy benefit management encompasses a number of services related to: developing drug formularies; negotiating with drug manufacturers for rebates and other discounts; negotiating with pharmacies; and processing claims and other functions for self-insured group health plans. The examples provided in the proposed definition are intended to describe the services expansively to ensure comprehensive disclosures are made. Consequently, the proposed definition specifies that whether the person providing the services identifies itself as a PBM is not dispositive of the requirement to disclose. Additionally, a person will be a covered service provider by virtue of performing any of the services identified in the definition; covered service provider status does not depend on comprehensively providing all the services set forth in the proposed definition.

The Department requests comments on its proposed definition of pharmacy benefit management services, including whether the description of any of the services should be altered and whether any services should be expressly added as examples.

1.4.2. Affiliates, Agents and Subcontractors—Proposed Paragraph (m)

The proposed terms “affiliate,” “agent,” and “subcontractor,” identify parties other than the covered service provider that may perform pharmacy benefit management services and also may receive compensation in connection with pharmacy benefit management services, and would be required to be disclosed under the regulation. As noted above, the regulation places the obligation on the covered service provider to make the disclosures and to seek any required information from these parties as needed for the disclosure. Proposed paragraph (c)(2) would clarify that affiliates, agents, and subcontractors of covered service providers do not, themselves, become covered service providers as a result of providing services pursuant to the contract or arrangement.¹¹³

¹¹³ This clarifying provision is also in the Department’s service provider disclosure regulation

Under paragraph (m)(1) of the proposal, an affiliate is an entity that “directly or indirectly (through one or more intermediaries) controls, is controlled by, or is under common control with such person or entity; or is an officer, director, or employee of, or partner in, such person or entity.” The proposed definition states that unless otherwise specified, an “affiliate” in the regulation refers to an affiliate of the covered service provider. In other contexts, the Department has said “control” refers to the power to exercise a controlling influence over the management or policies of a person other than an individual.¹¹⁴

Paragraph (m)(5) defines a subcontractor as a “person or entity (or an affiliate of such person or entity) that is not an affiliate of the covered service provider and that, pursuant to a contract or arrangement with the covered service provider or an affiliate, reasonably expects to receive \$1,000 or more in compensation for performing one or more services described pursuant to paragraph (d) of this section provided for by the contract or arrangement” with the self-insured group health plan. Accordingly, under the proposed definition, an affiliate of a subcontractor would also be considered a subcontractor for purposes of the regulation, including the disclosure requirements.

The proposed definitions of the terms “affiliate” and “subcontractor” are consistent with the definitions of these terms in the Department’s service provider disclosure regulation for pension plans (29 CFR 2550.408b–2(c)) as well as the new service provider disclosure obligations in ERISA section 408(b)(2)(B), and the Department believes they are well understood by stakeholders.¹¹⁵

The proposal also includes, in addition to “affiliates” and “subcontractors,” the term “agent,” defined in paragraph (m)(2) as “any person or entity authorized (whether that authorization is expressed or implied) to represent or act on behalf of another person or entity.” Unless otherwise specified, an “agent” for purposes of the regulation refers to an agent of the covered service provider. This additional proposed term is included based on the concern that, in the context of pharmacy benefit management services, entities that receive undisclosed compensation in

connection with pharmacy benefit management services may not technically fall within the definition of an “affiliate” or a “subcontractor.” As one example, the Department is aware that some providers of pharmacy benefit management services have formed rebate aggregators or GPOs outside of the laws of the United States.¹¹⁶ The Department intends that any compensation received by these entities in connection with pharmacy benefit management services to a self-insured group health plan would be disclosed under the regulation.

The Department requests comments on the proposed definitions of affiliate, agent, and subcontractor, including whether parties such as rebate aggregators or GPOs (or any other parties that fall within the proposed definition of agent) are likely to be covered by either of the other proposed definitions (*i.e.*, affiliate or subcontractor).

1.5. Affiliated Providers of Brokerage or Consulting Services—Proposed Paragraph (c)(1)(ii)

Concerns have been raised that brokers and consultants may receive payments from parties they are recommending, which may be undisclosed to their self-insured group health plan clients.¹¹⁷ These arrangements have a high potential for conflicts of interest that warrant disclosure, as evidenced by Congress’s amendment to ERISA section 408(b)(2) requiring disclosure of, among other things, indirect compensation reasonably expected to be received by providers of “brokerage services” and “consulting” with respect to pharmacy benefit management services.

To the extent that PBMs as described in paragraph (c)(1)(i) of the proposal, or their affiliates, also provide “brokerage services” or “consulting” to self-insured group health plans regarding pharmacy benefit management services, the Department has determined that special

provisions under the proposal are needed. Paragraph (c)(1)(ii) of the proposed regulation therefore identifies as covered service providers those parties described in paragraph (c)(1)(i) of the proposal or their affiliates, that enter into a contract or arrangement with a self-insured group health plan to provide advice, recommendations, or referrals of pharmacy benefit management services. These covered service providers would have the obligation proposed in the regulation to disclose their compensation and to allow for an audit, as discussed below.

Although the terms “brokerage services” and “consulting” in ERISA section 408(b)(2)(B) are not defined, entities that would be covered service providers under paragraph (c)(1)(ii) of the regulation are also likely to be covered service providers under ERISA section 408(b)(2)(B). In the Department’s view, the obligations under the proposal may be more specific than the statutory disclosure requirements but are not inconsistent with them. Moreover, because this proposed regulation provides specific descriptions of compensation streams and arrangements in the pharmaceutical supply chain that must be disclosed, the Department envisions that compliance with the requirements of the regulation, if adopted, would also satisfy the requirements of section 408(b)(2)(B) with respect to provision of brokerage services or consulting with respect to pharmacy benefit management services.

The Department believes that these brokers and consultants should be described as covered service providers under this regulation, rather than only under ERISA section 408(b)(2)(B), because of their affiliation with providers of pharmacy benefit management services. The conflicts associated with that affiliation should be disclosed to the self-insured group health plans’ responsible plan fiduciaries. Further, if this regulation is adopted, it may be difficult as a practical matter for affiliated brokers and consultants to determine the extent of their obligations under the statutory provision given the lack of a definition of “brokerage services” and “consulting”, and ambiguity surrounding the “indirect compensation” that must be disclosed. Additionally, the Department has tailored the requirements of this proposal to the practices of pharmacy benefit management service providers and therefore to the extent that their broker and consultant affiliates receive compensation that is specifically described in the regulation, responsible plan fiduciaries may receive higher

for pension plans (29 CFR 2550.408b–2(c)(1)(iii)(D) and is in ERISA section 408(b)(2)(B)(ii)(III).

¹¹⁴ See *e.g.*, 29 CFR 2550.404c–1(e)(3).

¹¹⁵ See 29 CFR 2550.408b–2(c)(1)(viii)(A) and (F); ERISA section 408(b)(2)(B)(ii)(D)(cc) and (ff).

¹¹⁶ See *e.g.*, Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* (July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

¹¹⁷ Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 3 (November 2014) (“Testimony was submitted to the Council that it is common for consultants to receive indirect compensation. The payment of indirect compensation to consultants who are advising plan sponsors in negotiations with the PBM may create the potential for conflicts of interest that may be adverse to the plan sponsor. Sponsors of ERISA health plans may or may not be informed of such indirect compensation.”), <https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/about-us/erisa-advisory-council/2014-pbm-compensation-and-fee-disclosure.pdf>.

quality disclosures from these brokers and consultants than they would receive absent such tailoring. Brokers and consultants may benefit from greater confidence in satisfying their disclosure requirements under the prohibited transaction exemption. Therefore, including these entities in the regulation would serve a compliance assistance function. On the other hand, to the extent brokers and consultants that are covered service providers have very simple compensation arrangements—*e.g.*, they only receive direct payments from the self-insured group health plan—the obligations under the regulation would be relatively minor.

The Department intends that brokers and consultants that provide advice, recommendations, or referrals regarding pharmacy benefit management services, but are not affiliates of these providers, would be able to determine their disclosure obligations under ERISA section 408(b)(2)(B), which is self-effecting.¹¹⁸ With respect to these entities, the Department does not envision that its enforcement policies announced in Field Assistance Bulletin 2021–03 would change in connection with this proposal. Thus, entities that are not affiliated with providers of pharmacy benefit management services would continue to use a good faith, reasonable interpretation of ERISA section 408(b)(2)(B), including with respect to determining their status as covered services providers. The Department continues to believe that “service providers who reasonably expect to receive indirect compensation from third parties in connection with *advice, recommendations, or referrals* regarding any of the listed sub-services . . . should be prepared, if the Department is auditing their 408(b)(2)(B) compliance, to be able to explain how a conclusion that they are not covered service providers is consistent with a reasonable good faith interpretation of the statute.”¹¹⁹

2. Overview of Covered Service Provider Obligations Under This Proposed Regulation

Under this proposed regulation, covered service providers would be required to provide specified disclosures to a responsible plan fiduciary of the self-insured group health plan, and also to permit the responsible plan fiduciary to conduct an audit for accuracy of the disclosures. The disclosures would focus on the services provided, the compensation received, and the arrangements with other parties in the pharmaceutical supply chain.¹²⁰ The disclosures generally would be provided on an initial basis prior to the self-insured group health plan entering into the service contract or arrangement and then on a semiannual basis thereafter.

As discussed in greater detail below, the disclosure obligations of providers of pharmacy benefit management services (covered service providers under paragraph (c)(1)(i)) would ensure that both the service provider and the responsible plan fiduciary are clear as to the services to be provided. The disclosures would also ensure that responsible plan fiduciaries are aware of all compensation that the provider of pharmacy benefit management services (and its affiliates, agents, and subcontractors) will receive from other parties in the pharmaceutical supply chain in connection with their services to the plan as well as the arrangements (such as formulary incentives) and practices (such as claw-backs) that may impact the performance of the services or the reasonableness of the compensation received.

With respect to brokers and consultants that are affiliated with providers of pharmacy benefit management services and recommend those services (covered service providers under paragraph (c)(1)(ii)), the required disclosures under the regulation would ensure that the responsible plan fiduciaries that may hire these brokers or consultants for their advice, recommendations, and referrals, are aware of the other sources of compensation that the brokers and consultants may be receiving, also so as to evaluate the potential impact on their services to the plan and the reasonableness of their compensation. The other compensation sources received by the brokers and consultants

may be specifically described in the proposed regulation (*e.g.*, payments from drug manufacturers), but if not, they would be disclosed under the catch-all provisions in paragraphs (e)(8) (initial disclosure) and (g)(6) (semiannual disclosure).

Throughout the proposed regulatory text, the disclosure requirement is phrased in terms of compensation “in connection with services under the service contract or arrangement.” The Department intends that the proposed language “in connection with” would be construed broadly. This is consistent with the approach taken in the Department’s service provider disclosure regulation for pension plans (29 CFR 2550.408b–2(c)(1)), where the Department stated in the preamble that: “[t]o the extent a covered service provider reasonably expects that compensation will be received, which is based in whole or in part on its service contract or arrangement with the covered plan, the compensation will be considered ‘in connection with’ such contract or arrangement.”¹²¹ Therefore, for example, the required disclosures under the proposal of payments from drug manufacturers would extend to payments based on a structure of incentives not solely related to the contract or arrangement with the self-insured group health plan.¹²² The Department seeks comment on whether the final rule should specify that such disclosures would be made on a pro-rata basis.

Paragraph (k) of the proposed regulation provides information about the manner of disclosure, including a requirement that disclosures must be “clear and concise, free of misrepresentation, and contain sufficient specificity to permit evaluation of the reasonableness of the contract or arrangement.” For required descriptions of compensation amounts, paragraph (k) provides that these descriptions must be expressed as a monetary amount, may be estimated to the extent that the actual amount is not reasonably ascertainable, but in any event shall contain sufficient information and specificity to permit evaluation of the reasonableness of the compensation received by the covered service provider, affiliate, agent or subcontractor.

¹²¹ Reasonable Contract or Arrangement Under Section 408(b)(2)—Fee Disclosure 77 FR 5632, 5637 (February 3, 2012).

¹²² See also ERISA section 408(b)(2)(B)(iii)(IV) (requiring a description of all indirect compensation “including compensation from a vendor to a brokerage firm based on a structure of incentives not solely related to the contract with the covered plan”).

¹¹⁸ See Field Assistance Bulletin No. 2021–03, (“The CAA does not require the Department to issue regulations under ERISA section 408(b)(2)(B) . . .”), <https://www.dol.gov/agencies/ebsa/employers-and-advisers/guidance/field-assistance-bulletins/2021-03>. Likewise, to the extent that PBMs were to provide “brokerage services” or “consulting” to group health plans with respect to any of the listed sub-services in ERISA section 408(b)(2)(B)(ii)(I)(bb) other than regarding the provision of pharmacy benefit management services as defined in paragraph (d) of the proposed regulation, such PBMs, in that capacity, would be subject to the disclosure requirements in ERISA section 408(b)(2)(B) and not the disclosure requirements in this proposed regulation.

¹¹⁹ *Id.* (emphasis added).

¹²⁰ The term “compensation” is defined in paragraph (m)(3) of the proposed regulation as anything of monetary value but does not include any item or service valued at \$250 or less, in the aggregate, during the term of the contract or arrangement.

The specific elements of the disclosure and audit provisions are discussed in greater detail below. Paragraph (e) of the proposed regulation would establish initial disclosure requirements. Paragraph (f) is reserved for initial disclosure requirements for fully insured group health plans. Paragraph (g) would establish semiannual disclosure obligations. Paragraph (h) is reserved for semiannual disclosure obligations for fully insured group health plans. Paragraph (i) would establish a requirement for the covered service provider to provide certain information upon request of the responsible plan fiduciary of the self-insured group health plan. Paragraph (j) would establish the audit rights that must be provided to the self-insured group health plan under the service contract or arrangement. Paragraph (k) would address the manner of disclosure and paragraph (l) would address disclosure errors. Paragraph (m) provides definitions for certain terms used in the regulation.

Overall, the disclosures are intended to provide responsible plan fiduciaries with a fuller picture of the terms under which the services will be provided, so they can assess both the reasonableness of the compensation in light of the services being provided and the potential for or existence of conflicts of interest that may impact the quality of services provided. The Department believes that these disclosures will provide necessary information to responsible plan fiduciaries who are required to determine that the services contract or arrangement meets the standards for an exemption under ERISA section 408(b)(2).

3. Initial Disclosure Requirements—Proposed Paragraph (e)

Paragraph (e) of the proposal sets forth the initial disclosure requirements. These disclosures would be required to be provided to the responsible plan fiduciary, in writing, no later than the date that is reasonably in advance of the date on which the contract or arrangement is entered, extended, or renewed. For extensions and renewals, the proposal specifies that 30 calendar days in advance is deemed to be a reasonable period of time absent an agreement by the parties to a longer timeframe. This timeframe is similar to other disclosure requirements in the Title XXVII of the Public Health Service (PHS) Act, Chapter 100 of the Internal Revenue Code, and Part 7 of ERISA that require 30-day timelines for disclosures, including the summary of benefits and coverage (SBC) requirements under PHS Act section 2715, as added by the

Affordable Care Act, and incorporated into ERISA section 715 and Code section 9815, for renewals, reissuances and reenrollments.¹²³ The Department is of the view that aligning the timing requirements with other disclosures that group health plans and issuers already comply with may provide clarity and minimize compliance burdens by streamlining the collection of similar data and disclosure for multiple purposes during the same cadence. The Department seeks comment on the proposed timing requirements for the initial disclosure including whether additional specificity is needed for the timing of the disclosure outside of the context of contract extensions and renewals. If commenters believe that additional specificity is needed, the Department requests that commenters identify the appropriate timing.

The required disclosures in some instances would require disclosure of amounts reasonably expected to be paid to the covered service provider or an affiliate, agent, or subcontractor. As noted above, paragraph (k) of the proposal would require descriptions of compensation to be expressed as a monetary amount, for example, \$1,000. The amounts could be estimated to the extent that the actual amount is not reasonably ascertainable, but they must contain sufficient information and specificity to permit evaluation of the reasonableness of the compensation to be received by the covered service provider, an affiliate, agent, or subcontractor.

In proposing paragraph (k), the Department intends that disclosures of a monetary amount (even if estimated) in this context would further the transparency goals of this rulemaking which are intended to make possible a responsible plan fiduciary's assessment of reasonableness of compensation and potential for or existence of conflicts of interest. This would also foster a fairer prescription drug market that lowers costs. Accordingly, on this point, the proposal offers less flexibility than the Department's service provider disclosure regulation for pension plans (29 CFR 2550.408b–2) and the statutory provision at ERISA section 408(b)(2)(B), each of which permit compensation disclosure to be expressed as an alternative to a monetary amount, such as a “formula,” “per capita charge” for each participant, or, if the compensation cannot reasonably be expressed in such terms, “by any other reasonable method.”¹²⁴ However, consistent with

this proposal, the Department's service provider disclosure regulation for pension plans (29 CFR 2550.408b–2) and the statutory provision at ERISA section 408(b)(2)(B) also require that any description contain “sufficient information to permit evaluation of the reasonableness of the compensation or cost.”¹²⁵

3.1. Description of Services

Under proposed paragraph (e)(1), the initial disclosure must include a description of each pharmacy benefit management service or of the advice, recommendations, or referrals regarding the provision of pharmacy benefit management services to be provided to the self-insured group health plan pursuant to the contract or arrangement. Full disclosure of the services is essential so that the responsible plan fiduciary can satisfy its duties under ERISA at the outset of the contract or arrangement and its ongoing duty to monitor. Full disclosure helps ensure that both parties have a common understanding of the services to be performed as part of the contract or arrangement. Absent full disclosure of services, questions may arise as to whether a responsible plan fiduciary has effectively approved otherwise discretionary behavior by the covered service provider.

Full disclosures are also important for covered service providers. Depending on the particular pharmacy benefit services being provided, if they are not performed in accordance with parameters established with the plan, the provider may have assumed discretionary authority or control over the administration of the plan. Providers who exercise such discretionary authority or control fall within the definition of a fiduciary under ERISA section 3(21)(A) and are subject to ERISA's fiduciary duties in section 403 and 404, and the prohibited transaction provisions in ERISA section 406. Therefore, it is crucial that disclosures be complete and accurate and carefully written in a manner that conforms with the plain language requirements in paragraph (k) of the proposal. When disclosures meet these standards, both parties to the contract or arrangement are more likely to have a common understanding of their roles and limitations under the contract or arrangement and the law.

the covered plan's assets); ERISA section 408(b)(2)(B)(ii)(II).

¹²³ 29 CFR 2590.715–2715.

¹²⁴ 29 CFR 2550.408b–2(c)(1)(viii)(B)(3) (also permitting disclosure expressed as a percentage of

¹²⁵ 29 CFR 2550.408b–2(c)(1)(viii)(B)(3); ERISA section 408(b)(2)(B)(ii)(II).

3.2. Direct Compensation

Under proposed paragraph (e)(2), the initial disclosure must include a description of direct compensation the covered service provider, an affiliate, agent, or subcontractor reasonably expects to receive in connection with the pharmacy benefit management services under the contract or arrangement. Specifically, the proposal requires a description of the amount of all direct compensation, both in the aggregate and by service, that the covered service provider, an affiliate, agent, or subcontractor reasonably expects to receive on a quarterly basis in connection with pharmacy benefit management services under the contract or arrangement. An example is an administrative fee calculated on a per-participant, per-month basis.

For purposes of paragraph (e)(2) of the proposal, the term “direct compensation” means compensation received directly from the self-insured group health plan, or from the plan sponsor on behalf of the self-insured group health plan regardless of whether such compensation is paid from plan assets. It is important to ensure that all direct compensation is disclosed, regardless of the source of the payment, to avoid frustrating the purposes of this proposal, because service providers to self-insured group health plans sometimes are paid, in whole or in part, directly from the general assets of the employer sponsoring the self-insured group health plan as opposed to a plan asset trust. Consequently, responsible plan fiduciaries may find it challenging to assess the overall reasonableness of the covered service provider’s compensation if this source of revenue is excluded from disclosure. An example of compensation covered by paragraph (e)(2) of the proposal is an administrative fee calculated on a per-participant, per-month basis, paid directly by the self-insured group health plan.

The Department requests comments as to whether the requirements under the proposed rule for disclosure of direct compensation as defined in paragraph (e)(2) ensure sufficient disclosure of information for bundled services. If not, should the description of direct compensation under paragraph (e)(2) for a bundled services option include additional information, such as the bundled discounted value along with a description of services provided in the bundle?

3.3. Payments From Drug Manufacturers

Under proposed paragraph (e)(3), the initial disclosure must include the

amount, in dollars, of payments from drug manufacturers (or rebate aggregators) reasonably expected to be received by the covered service provider, affiliate, agent, or subcontractor in connection with the contract or arrangement. The disclosure must cover the amount of any payment, both in the aggregate and for each drug on the formulary, and it must be expressed as an amount reasonably expected to be paid on a quarterly basis. It also must specify both the amount that will be passed on to the self-insured group health plan and, if applicable, the plan sponsor, and the amount that will be retained by the covered service provider, affiliate(s), agent(s), or subcontractor(s).

Under proposed paragraph (e)(6), the initial disclosure must include a description of any inflation protection or price protection agreements that the covered service provider, an affiliate, agent, or subcontractor has entered with any drug manufacturer or other party regarding each prescription drug dispensed under the service contract or arrangement. The disclosure must specify the quarterly amount reasonably expected to be retained by the covered service provider, affiliate, agent, or subcontractor in connection with each prescription drug product and under each such contract or arrangement and the price protection amount that will be passed on to the self-insured group health plan and, if applicable, plan sponsor. The Department separated the disclosure required under this proposed paragraph (e)(6) from the disclosure required under proposed paragraph (e)(3) because of the contingent nature of inflation and price protection.

The disclosure required by these provisions would be intended to apply broadly to payments, including but not limited to rebates, fees, and other remuneration reasonably expected to be received from drug manufacturers by the covered service provider, affiliate, agent, or subcontractor in connection with their services to the self-insured group health plan, regardless of how they are characterized. The disclosure also would extend to payments received from rebate aggregators or other entities that negotiate rebates with drug manufacturers.

Disclosure of aggregate payments reasonably expected from drug manufacturers and rebate aggregators is important for responsible plan fiduciaries in their evaluation of the reasonableness of the compensation that the covered service provider, affiliate, agent, and subcontractor will receive. Additionally, disclosure of payments for each drug on the formulary may assist

responsible plan fiduciaries in evaluating the covered service provider’s incentives to select particular prescription drugs for the formulary.

The Department seeks comments on the proposed disclosure of payments from drug manufacturers and rebate aggregators. Do the provisions in proposed paragraph (e)(3) and proposed paragraph (e)(6) adequately describe the type of payments that may be received in this respect? Given the varied payment structures and definitional terms, is broad term “payments” sufficient to define the disclosure obligation or is more specificity needed to ensure full disclosure?

3.4. Spread Compensation

Under proposed paragraph (e)(4), the initial disclosure must include the dollar amount of spread compensation both in the aggregate and for each drug on the formulary, and for each pharmacy channel (*i.e.*, retail pharmacy, mail order pharmacy, and specialty pharmacy) available under the contract or arrangement. Spread compensation is defined under the proposal as the difference between the negotiated rate reasonably expected to be paid by the self-insured group health plan to the covered service provider, an affiliate, agent, or subcontractor and the negotiated rate reasonably expected to be paid by such entity to the pharmacy for dispensing drugs.

As discussed in greater detail elsewhere in this preamble, spread pricing is one of the primary sources of compensation in some PBM contracts or arrangements. Proposed paragraph (e)(4) would require a covered service provider to disclose two distinct amounts of spread compensation reasonably expected to be received each quarter. The covered service provider must disclose the amount of reasonably expected spread compensation for each drug on the formulary and in the aggregate (*i.e.*, the total spread on all drugs). These disclosures must be made for each pharmacy channel available under the contract or arrangement. Disclosure of spread compensation in these distinct amounts would serve multiple purposes in assisting a responsible plan fiduciary in evaluating the reasonableness of the contract or arrangement with the covered service provider.

Disclosure of the expected aggregate spread compensation, per pharmacy channel, would provide a high-level view of how much revenue the PBM earns from spread pricing across the entire self-insured group health plan. This would allow a responsible plan fiduciary to evaluate the reasonableness

of compensation, including whether any amounts of spread compensation appear to be excessive under the circumstances, and to compare the initial disclosures of expected aggregate compensation to semi-annual disclosures made pursuant to proposed paragraph (g)(3) of actual aggregate compensation received by the covered service provider.

Disclosure of spread at the level of each drug on the formulary would further transparency goals by affording a responsible plan fiduciary access to profit variations across specific drugs such as branded versus generic or biologics versus biosimilars, which can be used to evaluate whether selection of a particular drug by the covered service provider is driven by spread compensation rather than cost-effectiveness or clinical effectiveness.

Finally, disclosure of spread at the pharmacy channel level, separately for retail, mail order, and specialty pharmacies, would reveal whether the covered service provider earns disproportionate compensation based on which dispensing pharmacy is used.

The Department is seeking comments on the requirements under the proposed rule for disclosure of spread compensation as defined in proposed section (e)(4). Does the proposed provision require disclosure of information that is sufficient to assess reasonableness? Are arrangements with retail, mail order, and specialty pharmacies sufficiently similar to one another that dividing disclosures into these three channels is efficient? Would greater transparency incentivize the use of a pass-through pricing or a flat-fee compensation model? What challenges would arise from a covered service provider providing or a responsible plan fiduciary reviewing this level of disclosure?

3.5. Copay Claw-Backs

Under proposed paragraph (e)(5), the initial disclosure must include a description of amounts of copay claw-back compensation reasonably expected to be recouped from a pharmacy by a covered service provider, an affiliate, agent, or subcontractor in connection with prescription drugs dispensed under the contract or arrangement. The disclosure must be expressed as amounts per quarter and must specify the total number of transactions.

The proposed regulatory text specifies that a copay claw-back means the dollar amount of the difference between a copayment or coinsurance amount paid to the pharmacy by a self-insured group health plan participant or beneficiary and the reimbursement to the pharmacy by the covered service provider. There

would be no claw-back compensation to disclose, however, if the pharmacy reimbursement amount exceeded the copayment amount.

Where a covered service provider, affiliate, agent, or subcontractor claws back any portion of a payment to a pharmacy made at point-of-sale and does not pass along the full amount recouped to the self-insured group health plan, information as to the value of any such amount recouped may not be otherwise available to a responsible plan fiduciary assessing the reasonableness of compensation under the contract or arrangement. For example, where the pharmacy's reimbursement price for dispensing a drug is less than the copayment made to the dispensing pharmacy by a participant or beneficiary and the self-insured group health plan's cost share for the drug is zero dollars, the responsible plan fiduciary may be unaware of the difference between the cost of the drug and the copayment that results in compensation to the covered service provider, affiliate, agent, or subcontractor recouping such difference. The Department believes that additional disclosure of the total number of transactions reasonably expected to occur in the quarter would provide the responsible plan fiduciary key information needed to assess the pervasiveness of this practice and whether adjustments to the plan's cost sharing structure may be appropriate.

The Department seeks comments on the requirements under the proposed rule for the disclosure of copay claw-back compensation as defined in proposed paragraph (e)(5). Is the proposed provision's scope of required disclosure of information for copay claw-back payments sufficient to assess reasonableness in this respect or should other types of recouped payments be included? If commenters believe the provision should require disclosure of information for recouped payments other than copay claw-backs, commenters are requested to describe the type(s) of recouped payments recommended to be included and how disclosure of this information is necessary to assess the reasonableness of the compensation under the contract or arrangement.

3.6. Compensation for Termination of Contract or Arrangement

Under proposed paragraph (e)(7), the initial disclosure must include a description of any compensation that the covered service provider, an affiliate, agent, or a subcontractor reasonably expects to receive in connection with termination of the

contract or arrangement, and how any prepaid amounts will be calculated and refunded upon such termination. A determination of reasonableness necessitates that a responsible plan fiduciary be aware of any termination costs or potential costs to a self-insured group health plan upfront. Without this information, a responsible plan fiduciary cannot sufficiently evaluate the economic consequences of such termination to the self-insured group health plan. Proposed paragraph (e)(7), for example, will enable the responsible plan fiduciary to understand and ensure proper treatment of any rebates owed at the time of the termination. While covered service providers may recoup reasonable amounts for actual losses upon early termination of the contract or arrangement, no contract or arrangement is reasonable if it does not permit termination by the self-insured group health plan without penalty on reasonably short notice under the circumstances to prevent the self-insured group health plan from becoming locked into a contract or arrangement that has become disadvantageous.¹²⁶

3.7. Other Compensation

Proposed paragraph (e)(8) provides a catch-all provision for any compensation not disclosed under proposed paragraphs (e)(1)–(7). The disclosure must include a description of all compensation that the covered service provider, affiliate(s), agent(s), or subcontractor(s) reasonably expects to receive on a quarterly basis in connection with the contract or arrangement along with an identification of the payer of such compensation, an identification of the services for which such compensation will be received, and a description of the arrangement between the payer and the covered service provider, affiliate, agent, or subcontractor, as applicable, pursuant to which such compensation is paid.

This category of “other” compensation may be particularly relevant to covered service providers defined in proposed paragraph (c)(1)(ii) of the regulation (*i.e.*, affiliates of providers of pharmacy benefit management services that provide advice, recommendations and referrals regarding the pharmacy benefit management services). The compensation of these covered service providers may come from the providers of pharmacy benefit management services themselves, as opposed to the compensation described in the other

¹²⁶ 29 CFR 2550.408b–2(c)(3).

subparagraphs in paragraph (e). The Department requests comments on whether the final regulation should specify payments that these covered service providers may receive.

In connection with this category of “other” compensation, the Department also seeks comments on whether it should specify any other type of compensation that may be received by covered service providers, instead of having those items disclosed under paragraph (e)(8). For example, should there be specific disclosure requirements related to compensation received by entities providing pharmacy benefit management services in connection with copay maximizer, copay accumulator, or alternative funding programs? More generally, the Department seeks comments on the role of entities earning compensation in connection with these programs, including the mechanics of these programs and payment amounts related to these programs. The Department is also seeking comments on the extent to which self-insured group health plans use each of these types of programs.

3.8. Formulary Placement Incentives

Proposed paragraph (e)(9) would require the initial disclosures to include specified information regarding formulary placement incentives. The purpose of proposed paragraph (e)(9) would be to assist responsible plan fiduciaries in evaluating the covered service provider’s formulary selections and how the selections might be influenced by incentives, arrangements, and payments. While proposed paragraph (e)(3) would require covered service providers to provide a description of the *amounts of payments* reasonably expected to be paid by drug manufacturers or rebate aggregators in connection with the contract or arrangement, proposed paragraph (e)(9) would require *description of the arrangements* so that the responsible plan fiduciary would gain additional insight as to their impact. The proposed disclosures are set forth in three subparagraphs, described below, each of which addresses a different aspect of formulary design and maintenance.

3.8.1. Proposed Paragraph (e)(9)(i)

Under proposed paragraph (e)(9)(i), the initial disclosure would include a description of any formulary placement incentives and arrangements that the covered service provider, an affiliate, an agent, or a subcontractor has entered with any drug manufacturer in connection with the contract or arrangement. The disclosure would also include an explanation of how the

incentives and arrangements affect services to and are aligned with the interests of the self-insured group health plan and/or its participants and beneficiaries, such as by controlling prescription drug costs, providing clinically superior drugs, or both.

Formulary incentives or arrangements widely reported on in industry literature include concessions made by a drug manufacturer to include its drugs in a formulary, for tiering of drugs within a formulary, for excluding or tiering of other manufacturers’ drugs within a formulary, and for a drug to be treated differently than therapeutically equivalent drugs under a utilization management protocol. In addition, adding to a formulary a drug that is manufactured or co-manufactured by the PBM or an affiliate, in the view of the Department, would be a formulary placement incentive that triggers the disclosure required under proposed paragraph (e)(9)(i).

Under proposed paragraph (e)(9)(i), the covered service provider is required to provide an explanation of how the formulary placement incentives and arrangements affect services to and align with the interests of the self-insured group health plan and/or its participants and beneficiaries. The concept of alignment is inherently factual and depends on the specific facts and circumstances of the incentive or arrangement in question. However, examples of incentives or arrangements that are aligned with the interests of the self-insured group health plan and/or its participants and beneficiaries, include incentives or arrangements to control prescription drug costs, provide clinically superior drugs, or both. In this regard, the Department notes that a particular formulary placement incentive or arrangement can be aligned with the interests of the self-insured group health plan and/or its participants and beneficiaries based on a combination of the clinical value and cost-effectiveness of the associated drug, even though the drug is not necessarily clinically superior to all alternatives.

The Department anticipates that, in connection with developing these disclosures, covered service providers will carefully review the incentives and arrangements to determine how the incentives and arrangements would impact services to the self-insured group health plan. Likewise, covered service providers would be required to determine that they could accurately disclose how the incentives and arrangements are aligned with the interests of the self-insured group health plan and/or its participants and beneficiaries, whether by contributing to

controlling prescription drug costs, by providing clinically superior drugs, or both.

The Department requests comments on the proposed requirement to explain how formulary incentives and arrangements affect services to and are aligned with the interests of the self-insured group health plan and/or its participants and beneficiaries. Do commenters believe this requirement will contribute to the elimination of incentives and arrangements that are not aligned with the interests of the self-insured group health plan and/or its participants and beneficiaries? To ensure that the regulation appropriately protects the interests of the participants in self-insured group health plans, should any assertions of clinical superiority provided in the disclosure be required to be accompanied by evidence? Are there other examples of incentives or arrangements that align with the interests of the self-insured group health plan and/or its participants and beneficiaries (other than by controlling prescription drug costs, providing clinically superior drugs, or both) that should be specified in the regulatory text?

3.8.2. Proposed Paragraph (e)(9)(ii)

Under proposed paragraph (e)(9)(ii), the initial disclosure also must include an identification of reasonably available therapeutically equivalent alternatives for any drug on the formulary with respect to which the covered service provider, an affiliate, agent, or subcontractor reasonably expects to receive any payment by the manufacturer or rebate aggregator (and not passed through to the self-insured group health plan). This provision also requires the covered service provider to explain the reason for omitting such alternatives from the plan’s formulary.

The purpose of this provision is to provide the responsible plan fiduciary with information on the constitution of the formulary and the extent to which its overall composition was influenced by lower cost and/or clinical efficacy, as discussed above, as opposed to financial incentives. For instance, when the formulary contains a drug for which the PBM will receive a payment from the drug manufacturer (and not pass the payment through to the self-insured group health plan), proposed paragraph (e)(9)(ii) requires the subject disclosure to identify reasonably available therapeutically equivalent alternatives that do not similarly compensate the PBM. This disclosure, thus, enables responsible plan fiduciaries to evaluate the way the PBM has designed the formulary and the extent to which its

composition might be overly influenced by conflicts of interests that impact the quality or performance of services and that require mitigation. Because the mere fact that alternatives without manufacturers' payments may exist in the marketplace is not dispositive of an unreasonable contract or arrangement, proposed paragraph (e)(9)(ii) requires the disclosure to explain the reason for their omission from the formulary, such as the alternatives having lower clinical efficacy, higher pricing, or inadequate supply.

Paragraph (e)(9)(ii) of the proposal does not define what is meant by "identification" with respect to the reasonably available alternatives. At a minimum, however, this identification must include enough information about the alternatives that the responsible plan fiduciary is able to consult a publicly available directory to complete a prudent analysis.¹²⁷ Typically, this will include the manufacturer's name, the generic or trade name of the drug, and dosage form. The disclosure is required to include only a reasonable number of alternatives, not every alternative on the market. The Department requests comments on whether the final rule should contain an explicit standard on this topic versus allowing the contracting parties the leeway to establish parameters on their own.

3.8.3. Proposed Paragraph (e)(9)(iii)

Under proposed paragraph (e)(9)(iii), if the covered service provider, an affiliate, an agent, or a subcontractor retains authority to modify the formulary during the term of the contract or arrangement—such as by adding or removing drugs or changing their tiering—the initial disclosure must include an explanation of the reasons for retaining such authority and the expected frequency of such changes. Further, the disclosure must provide that the responsible plan fiduciary will be notified reasonably in advance of any modifications that, individually or in the aggregate, are reasonably expected to have a material impact on the reasonableness of compensation under the contract or arrangement. The disclosure also must notify the responsible plan fiduciary of the self-insured group health plan's right to terminate the contract or arrangement

on reasonably short notice under the circumstances.

The purpose of the advance disclosure requirement is to notify the responsible plan fiduciary sufficiently in advance of the upcoming modification so that the responsible plan fiduciary can either consent or raise an objection. Modifying the formulary is an act of plan administration, with important consequences to the self-insured group health plan and its participants. The responsible plan fiduciary could not properly carry out its administrative responsibilities under ERISA without this advance notice, and likewise the covered service provider might be exercising discretionary authority or responsibility in the administration of the self-insured group health plan if it unilaterally effected the modifications without the responsible plan fiduciary's consent.

With respect to this advance notice requirement, the proposed regulation does not specify a number of days "in advance" for the notice to be provided. Ideally, the notice would be given sufficiently in advance so that responsible plan fiduciary has a reasonable period to consider the modification and consent or raise an objection. Comments are requested on whether the final regulation should provide more specificity regarding the timing of this advance notice. In this regard, for example, the Department currently is considering whether to require the notice to be furnished at least 75 days in advance of the change, to allow the self-insured group health plan to provide notice to plan participants at least 60 days prior to the date the upcoming material modification becomes effective, if required.¹²⁸

This advance notice requirement would be triggered only with respect to formulary modifications that, individually or in the aggregate, are reasonably expected to have a material impact on the reasonableness of compensation under the contract or arrangement. In this way, the trigger is carefully tied to matters of compensation—the chief topic of section 408(b)(2) of ERISA.

For this purpose, proposed paragraph (e)(9)(iii) provides that the term "material" means an amount that is 5 percent or more, or such lower percentage or dollar amount that may be agreed to by the responsible plan fiduciary and set forth in writing in the contract or arrangement, of the aggregate compensation (on a quarterly basis)

disclosed pursuant to paragraph (e)(3) of the proposed regulation, adjusted for any increases previously disclosed under paragraph (e)(9). Thus, the base amount on which the materiality of the modification is judged would initially be the amount disclosed pursuant to paragraph (e)(3), but it would increase by the amount of any modifications disclosed under proposed paragraph (e)(9)(iii).

The following example illustrates how the base amount paragraph (e)(9)(iii) adjusts as material modifications are made to the formulary. Assume that in advance of entering a contract with a self-insured group health plan, a covered service provider discloses pursuant to paragraph (e)(3) reasonably expected payments on a quarterly basis of 100 dollars. After entering the contract, the drug formulary is not modified in the first quarter. In the second quarter, a contemplated modification would result in an increase in compensation above the initially-disclosed amount (100 dollars) by two percent. Advance disclosure of this modification would not be required by proposed paragraph (e)(9)(iii), unless the parties had agreed to a two percent threshold. No changes are made in the third quarter. Then, a contemplated modification in the fourth quarter would result in an increase in compensation above the initially-disclosed amount (100 dollars) by four percent. Because the aggregate of the fourth quarter modification (four percent increase to initially-disclosed amount) and the second quarter modification (two percent increase to initially-disclosed amount) collectively are expected to exceed five percent, advance notice of the fourth quarter modification would be required under proposed paragraph (e)(9)(iii). The disclosure would need to describe the aggregate (six percent) increase to the initially-disclosed amount. Going forward, the five percent threshold in proposed paragraph (e)(9)(iii) would apply to the initially disclosed amount (100 dollars) plus the amount disclosed under paragraph (e)(9) (six dollars, or six percent of 100 dollars).

The Department is proposing a materiality standard as a trigger to balance the amount of disclosure provided to responsible plan fiduciaries. Without a materiality standard, the Department is concerned that responsible plan fiduciaries might be inundated with advance notices of formulary modifications. This concern is based on the understanding that PBMs make frequent changes to formularies.

¹²⁷ See, e.g., U.S. Food and Drug Administration's National Drug Code Directory available at <https://dps.fda.gov/ndc> (last accessed July 31, 2025); U.S. Food and Drug Administration's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* available at <https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm> (last accessed July 31, 2025).

¹²⁸ See 29 CFR 2590.715–2715(b).

The proposed materiality standard has two components: it would include a ceiling of a five percent impact over the base amount, and it would also allow for the covered service provider and responsible plan fiduciary to negotiate a lower threshold (dollar or percentage).¹²⁹ The Department understands that in other contexts, materiality is determined based on the significance to the impacted parties.¹³⁰ However, the Department also believes that covered service providers and responsible plan fiduciaries may appreciate a bright line rule as an alternative. In another context, the Department has used a five percent standard to define materiality.¹³¹

The Department seeks comments on the approach in proposed paragraph (e)(9)(iii), including whether it is common for providers of pharmacy benefit management services to retain authority to modify the formulary during the term of the contract or arrangement—such as by adding or removing drugs, changing their tiering, or changing utilization management strategies. If it is common, how frequently do PBMs make formulary changes, and is advance notice of such modifications given to self-insured group health plans? Further, the Department seeks comments on the proposed definition of materiality. Do commenters believe the approach taken in the proposal is workable and identifies an appropriate test for materiality? For example, should the test for materiality in the proposal—which is based on a 5 percent increase over the estimated amount of expected rebates from manufacturers or aggregators—be broadened to include other compensation, such as spread? Are there alternative tests for materiality, such as the annual increase in the average cost of health care, that would be more appropriate? Alternatively, would it be better to trigger advance disclosure on “any non-trivial changes in the formulary that could affect the covered service provider’s own compensation?”

¹²⁹ The parties may agree to other changes to the formulary that would trigger advance notification to the responsible plan fiduciary. It is a best practice to memorialize in writing any such negotiated advance notice thresholds or triggers.

¹³⁰ See *e.g.*, *Basic Inc. v. Levinson*, 485 U.S. 224, 240 (1988).

¹³¹ See 29 CFR 2520.101–5(g)(3) (in the annual funding notice for defined benefit pension plans, providing that events having a material effect on liabilities or assets would be defined, in part, as events resulting in or projected to result in an increase or decrease of five percent or more in the value of assets or liabilities from the valuation date of the notice year); see also Annual Funding Notice for Defined Benefit Plans, 80 FR 5626 (February 2, 2015).

The Department also seeks comments on the proposed requirements in paragraph (e)(9) as a whole. Is the information required for disclosure under paragraph (e)(9) useful to a responsible plan fiduciary in assessing the reasonableness of compensation under the terms of the contract or arrangement, or potential conflicts on the part of the provider of services? Are there additional factors or considerations related to the use of formulary placement incentives that the Department should consider? What challenges are likely to arise in requiring a covered service provider to disclose this information? What challenges will a responsible plan fiduciary encounter in using the information disclosed to assess the reasonableness of compensation?

3.9. Drug Pricing Methodology

Under proposed paragraph (e)(10), the initial disclosure must include a description of the net cost to the self-insured group health plan of each drug on the formulary, for each pharmacy channel, expressed as a monetary amount. If a monetary amount is not ascertainable, the covered service provider must disclose the methodology used by the covered service provider, an affiliate, an agent, or a subcontractor, under the contract or arrangement, to determine the cost the self-insured group health plan will pay for each drug on the formulary, for each pharmacy channel, along with an objective means to verify the accuracy.

The proposed regulation would require the covered service provider to disclose the net cost to the self-insured group health plan of each drug on the formulary by pharmacy channel, including mail order pharmacy, retail pharmacy, and specialty pharmacy. The net cost refers to the total cost to the self-insured group health plan after all discounts, rebates, or other adjustments are applied by the covered service provider pursuant to the contract or arrangement. The covered service provider would disclose to the responsible plan fiduciary the cost of each drug as a monetary amount when such figures can be ascertained by available information.

In instances where a monetary amount cannot be ascertained by the covered service provider, the (e)(10) disclosure requirement may be satisfied if the covered service provider instead discloses the methodology that will be used to determine the cost to the self-insured group health plan and an objective means to verify the accuracy of that methodology. An example of this methodology would be a price

determined by reference to AWP, and a direction to the plan as to where the AWP that will be used may be located. Depending on the specific pricing methodology being used, other examples of information that may be provided by the covered service provider, enabling the responsible plan fiduciary to verify the accuracy of the disclosed drug pricing methodology, could include pricing indices, rate schedules, benchmark formulas, or similar objective data sources.

The Department has no single specific list or benchmark in mind to satisfy this verification requirement. The self-insured group health plan and PBM are best situated, on a case-by-case basis, to establish solutions that meet their individual needs. The intent of this provision is to address the reported opacity in the pharmaceutical supply chain and to remedy the imbalance in bargaining power between self-insured group health plans and large PBMs.

The (e)(10) disclosure requirements serve to establish price transparency to ensure a responsible plan fiduciary can effectively evaluate whether the contract or arrangement with the covered service provider is reasonable. The responsible plan fiduciary gains clear and upfront awareness of drug costs and can assess the fairness and predictability of such prices, preventing arbitrarily inflated net costs, and enabling the selection of pricing models most aligned with the interests of the self-insured group health plan. Additionally, the (e)(10) provision limits opportunities for covered service providers to use non-transparent discretionary pricing formulas that could obscure the true costs of drugs on the formulary.

The Department requests comment on whether the language in paragraph (e)(10) provides sufficient clarity to covered service providers regarding their disclosure obligations or whether adjustments should be made. For example, should the provision specify how the term “drug” will be defined? If so, the Department requests that commenters please provide suggested language.

3.10. Statement of Fiduciary Status

Under proposed paragraph (e)(11), the initial disclosure must include, if applicable, a statement that the covered service provider, an affiliate, an agent, or a subcontractor will provide, or reasonably expects to provide, services pursuant to the contract or arrangement directly to the self-insured group health plan as an ERISA fiduciary.

Along with this statement, such entity must disclose any activity or policy that may create a conflict of interest,

including, for example, if such entity will benefit financially from drug substitution, from incentivizing use of affiliated pharmacies when other network pharmacies offer lower costs, or from step therapy or “fail first” protocols that require participants and beneficiaries to use drugs that generate greater manufacturer rebates than other therapeutically equivalent drugs on the formulary.

As relevant to this proposal, ERISA provides that a person is generally a fiduciary with respect to a self-insured group health plan to the extent he exercises any discretionary authority or discretionary control respecting management of such plan or exercises any authority or control respecting management or disposition of its assets, or do so, or has any discretionary authority or discretionary responsibility in the administration of such plan.¹³² In complying with proposed paragraph (e)(11), therefore, the covered service provider would carefully consider whether it, or an affiliate, agent, or subcontractor, will meet this definition in its services to the self-insured group health plan.

The Department has previously explained in this respect that a person who performs “purely ministerial functions . . . within a framework of policies, interpretations, rules, practices and procedures made by other persons” is not a fiduciary under this test.¹³³ Thus, to avoid fiduciary status, a covered service provider would ensure that its services to the self-insured group health plan, and the services of its affiliates, agents, and subcontractors, are not discretionary, but instead operate within policies and procedures disclosed to and approved by the responsible plan fiduciary.¹³⁴

3.11. Statement of Audit Right

Under proposed paragraph (e)(12), the initial disclosure must provide a statement of the self-insured group health plan’s right to the audit described in paragraph (j) of this the proposed regulation and the procedures for requesting such an audit. Among other things, proposed paragraph (j) would

ensure that the contract or arrangement does not contain terms that would impede the self-insured group health plan’s ability to conduct an audit. As discussed in preamble section D.6., the right to audit the completeness and accuracy of the required disclosures is an essential part of the proposal’s framework for establishing transparency in the marketplace for pharmacy benefit management services. Proposed paragraph (e)(12) would ensure that the responsible plan fiduciary is aware of the audit rights that are preserved in the regulation.

3.12. Initial Disclosure Requirements for Fully Insured Group Health Plans Reserved—Proposed Paragraph (f)

As discussed above, the initial disclosure requirements for fully insured group health plans are reserved.

4. Semiannual Disclosure Requirements—Proposed Paragraph (g)

Paragraph (g) of the proposed regulation would require semiannual disclosures of the actual compensation received by the covered service provider and its affiliates, agents, and subcontractors in connection with the contract or arrangement. This disclosure would serve an important purpose for the responsible plan fiduciary’s monitoring obligations with respect to services to the self-insured group health plan. While selection of these covered service providers will be made based on the initial disclosures—which require disclosure of compensation “reasonably expected” to be received—the responsible plan fiduciary’s ability to evaluate compensation actually received is critical for ongoing oversight of the service arrangement.¹³⁵ The semiannual disclosures would be required to be provided no later than 30 calendar days after the end of each six-month period beginning on the date the contract or arrangement is entered, with respect to the preceding six-month period.

The content of semiannual disclosures would generally track the specific categories of compensation that were estimated in the initial disclosures. Thus, semiannual disclosures would address categorically direct compensation, manufacturer payments, spread compensation, copay claw-backs, and price protection agreements. Like the initial disclosures, the semiannual disclosures also would contain a catch-all category for any “other compensation” not covered by the specific compensation categories, and

would include a disclosure of the audit rights. Unlike the initial disclosures, the semiannual disclosures would contain amounts of compensation actually received (rather than estimates) for each of these categories.¹³⁶

Semiannual disclosures would contain an overage explanation, if applicable. Consistent with the purpose of the proposed semiannual disclosure to assist responsible plan fiduciaries in their ongoing monitoring of the contract or arrangement, proposed paragraph (g)(7) would require a disclosure if any category of compensation described in paragraph (g), in the aggregate, materially exceeds the corresponding estimate described in paragraph (e). Thus, for example, if the actual amount of spread compensation disclosed in the semiannual disclosure materially exceeded the amount identified in the initial disclosure, this overage explanation requirement would be triggered.

The proposed overage explanation provision would require an identification of the amount of the overage (in the aggregate) and the reason for the overage. For this purpose, the term “materially” would mean 5 percent or more, or such lower percentage or dollar amount as may be agreed to by the responsible plan fiduciary and set forth in writing in the contract or arrangement. This proposed definition of materiality generally parallels the approach taken in proposed paragraph (e)(9)(iii) (relating to the advance notification requirement for modifications to a formulary).

The overage explanation will help responsible plan fiduciaries by emphasizing areas where categories of compensation materially exceeded the parties’ expectations at the outset of the contract or arrangements. A responsible plan fiduciary will be able to take the explanation into account when deciding on the continuing reasonableness of the contract and whether to continue the service relationship with the covered service provider.

The Department notes that the semiannual disclosure obligation in the proposal differs in some respects from the approach in the Department’s service provider regulation for pension plans (29 CFR 2550.408b–2(c)(1)) and in ERISA section 408(b)(2)(B). While neither of these sources has a specific semiannual disclosure obligation, they each require disclosure of changes to the information provided in the initial

¹³² ERISA section 3(21)(A)(i) and (iii); 29 U.S.C. 1002(3)(21)(A)(i) and (iii). ERISA section 3(21)(a)(ii) (29 U.S.C. 1002(3)(21)(A)(ii)) is not described in the text as it pertains to the provision of investment advice for a fee.

¹³³ Interpretive Bulletin 75–8, 29 CFR 2509.75–8 (Q&A D–2).

¹³⁴ The test for fiduciary status under section 3(21) of ERISA is a functional test. While effective policies and procedures enable service providers to act ministerially and thereby avoid discretionary acts described in section 3(21) of ERISA, express disclaimers of fiduciary status, standing by themselves, have no such effect.

¹³⁵ As discussed above, the semiannual disclosure requirements for fully insured group health plans are reserved.

¹³⁶ The Department intends these disclosures to be based on amounts actually received. Comments are solicited as to whether they, or any other disclosures required by this section, should reflect amounts earned even if not actually received.

disclosures.¹³⁷ With respect to the compensation disclosures, changes to this information must be disclosed as soon as practicable, but generally no later than 60 calendar days from the date on which the covered service provider is informed of such change.¹³⁸ The Department believes that in the pharmacy benefit management context, it may be more efficient to have a semiannual disclosure that would provide all the compensation received in the prior 6 month period, rather than a requirement to disclose changes on an ongoing basis.

As indicated above, the primary purpose of proposed paragraph (g) is to ensure that responsible plan fiduciaries have more than just the estimates provided in the initial disclosure (before the contract or arrangement was even entered) under paragraph (e) of the proposal when conducting their statutory duty to monitor the ongoing reasonableness of the self-insured group health plan's service relationship with the covered service provider. In this way, the proposal responds to those instances of reported opacity in the pharmacy benefits management industry.

The Department has carefully attempted to mitigate regulatory burdens and welcomes ideas on ways to further simplify or streamline the semiannual disclosure without compromising the stated purpose of proposed paragraph (g). For example, the Department considered and rejected the idea of proposing annual disclosures of compensation actually received, rather than semiannual disclosures. The Department determined instead to propose a semiannual disclosure based on the understanding that pharmacy benefits management service contracts often are only one year in duration. Consequently, in such cases, a disclosure of actual compensation

received after the expiration of the contract would seem to be of significantly less value to the responsible plan fiduciary than if it had been received during the term of contract, when the ongoing duty to monitor the reasonableness of the relationship is most acute. The Department welcomes comments on proposed paragraph (g) generally and on its specific features, including the overage explanation and its related materiality trigger.

5. Reporting and Disclosure Information Upon Request—Proposed Paragraph (i)

Under proposed paragraph (i), certain information must be provided upon written request of the self-insured group health plan's responsible plan fiduciary. The required information is any other information relating to the contract or arrangement that is required for the self-insured group health plan to comply with the reporting and disclosure requirements of Title I of ERISA and the regulations, forms and schedules issued thereunder. The information must be provided reasonably in advance of the date upon which such responsible plan fiduciary states that it must comply with the applicable reporting or disclosure requirement, unless such disclosure is precluded due to extraordinary circumstances beyond the covered service provider's control, in which case the information must be disclosed as soon as practicable.

The information that might be requested by a responsible plan fiduciary may include information needed to complete the self-insured group health plan's Form 5500 filing.¹³⁹ In 2010, the Department issued supplemental FAQs stating that certain fees received by PBMs for services to an ERISA plan that are paid with plan assets are reportable direct compensation on Schedule C of the Form 5500.¹⁴⁰ Further, the Department stated that discount and rebate revenue would be reportable indirect compensation to the extent the plan and the PBM agree that these payments will be used to compensate the PBM for services to the plan.¹⁴¹ While information to support these Schedule C items would likely be provided as part of the semiannual disclosure in proposed paragraph (g), paragraph (i) would underscore the covered service provider's obligation to provide any

information that is needed to complete the Form 5500 report.

The CAA also added annual reporting requirements (Prescription Drug Data Collection) about prescription drug and health care expenditures under Code section 9825(a), ERISA section 725(a), and PHS Act section 2799A–10(a).¹⁴² To comply with the reporting requirement, a responsible plan fiduciary may also request information needed to comply with reporting obligations under ERISA section 725, which was added by the CAA, 2021. The information required under ERISA section 725, and parallel provisions under the Code and PHS Act, includes the 50 most frequently dispensed brand prescription drugs, the 50 most costly prescription drugs by total annual spending, and the 50 prescription drugs with the greatest increase in plan expenditures over the preceding plan year. Further, the group health plan is required to report information on rebates, fees, and any other remuneration paid by drug manufacturers to the self-insured group health plan or its administrators or service providers overall, with respect to each therapeutic class of drugs, and for each of the 25 drugs that yielded the highest amount of rebates and other remuneration from drug manufacturers during the plan year. As part of these requirements, group health plans are also required to report spread amounts retained by its PBM(s).

6. Right to Audit—Proposed Paragraph (j)

Paragraph (j) establishes a right for self-insured group health plans to audit their covered service providers at least once per year. The proposal leaves it to the parties to define "year" for this purpose, e.g., contract year, calendar year, or plan year. Comments are invited on whether the final rule should be more prescriptive on this point.

The purpose of the audit is to enable the responsible plan fiduciary to verify the accuracy of the disclosures that would be required in the proposal, if adopted as a final regulation. In describing the scope of the audit provision, paragraph (j)(1) of the proposal narrowly reflects this purpose. Paragraph (j)(1), however, could be broader, e.g., the scope of the audit could be extended more globally to ensure the covered service provider complied with the contract or arrangement, with all applicable law, or its scope could be left to the discretion of the responsible plan fiduciary.

¹³⁷ 29 CFR 2550.408b–2(c)(1)(v)(B)(1) ("A covered service provider must disclose a change to the information required by paragraph (c)(1)(iv)(A) through (D), and (G) of this section as soon as practicable, but not later than 60 days from the date on which the covered service provider is informed of such change, unless such disclosure is precluded due to extraordinary circumstances beyond the covered service provider's control, in which case the information must be disclosed as soon as practicable."); ERISA section 408(b)(2)(B)(v)(II) ("A covered service provider shall disclose any change to the information required under clause (iii) and (iv) as soon as practicable, but not later than 60 days from the date on which the covered service provider is informed of such change, unless such disclosure is precluded due to extraordinary circumstances beyond the covered service provider's control, in which case the information shall be disclosed as soon as practicable.")

¹³⁸ See *id.*, noting that if a disclosure is precluded due to extraordinary circumstances beyond the covered service provider's control, the information shall be disclosed as soon as practicable.

¹³⁹ 29 CFR 2520.103–1.

¹⁴⁰ Supplemental Frequently Asked Questions about the 2009 Schedule C, Q26, <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/reporting-schedule-c-faq.pdf>.

¹⁴¹ *Id.*, at Q27.

¹⁴² See <https://www.cms.gov/marketplace/about/oversight/other-insurance-protections/prescription-drug-data-collection-rxdc>.

Comments are invited on the scope of the audit provision considering the purpose of the proposal.

The parties would split the audit costs under the proposed regulation. The self-insured group health plan would be responsible for compensating the auditor. The covered service provider would bear the costs of providing the auditor with the information, data, and other materials needed to perform the audit. The Department believes this shared cost approach is fair, balanced, adequately protective of self-insured group health plans, and not unduly financially burdensome to covered service providers. The Department requests comment on this approach and whether there are any circumstances in which the covered service provider should bear the entire cost of the audit, such as if the audit reveals a certain level of inaccurate disclosures. If so, how should the regulation identify a level of disclosure inaccuracy that would trigger the obligation for the covered service provider to bear the audit cost?

Under the proposal, the self-insured group health plans have the sole authority to select the auditor, and the covered service providers are prohibited from imposing limitations on the selection process. Likewise, the proposal broadly prohibits covered service providers from imposing restrictive conditions on the auditor, such as the location of the audit or the number of records to be provided, including contracts with retail pharmacies and drug manufacturers. The proposal, however, would allow the scope of the audit to be limited to the period covered by the disclosures under the regulation.

The Department considers these conditions necessary to ensure a proper and meaningful audit so that the accuracy of the disclosures can be verified. A right to audit the veracity of any and all disclosures made by the covered service provider to a responsible plan fiduciary under the terms of the contract or arrangement as required by this regulation, including the responsibility of the covered service provider to deliver all necessary information to conduct such an audit, is an essential part of the proposal's framework for establishing transparency in the marketplace for pharmacy benefit management services. As a general matter, the Department believes that covered service providers will be mindful of the regulation's audit rights when developing their disclosures, and the audit rights therefore are deliberately intended to result in disclosures that are more carefully

constructed, robust, and transparent. Further, to the extent that an audit reveals information that was not previously disclosed or flaws in the disclosure, the responsible plan fiduciary can evaluate the additional information in assessing the reasonableness of the compensation and determining whether additional payments should have been passed through to the self-insured group health plan or whether to exercise other rights.

In this regard, responsible plan fiduciaries must periodically monitor compliance by covered service providers with the terms of their agreements and the reasonableness of their compensation under the agreements in order to ensure continuation of the agreement meets the requirements of ERISA section 408(b)(2) as well as the general fiduciary obligations under ERISA section 404. In satisfying its monitoring obligations, however, the responsible plan fiduciary retains discretion as to when, if at all, to request an audit of disclosures issued by the covered service provider and is determined by a responsible plan fiduciary's assessment of the circumstances attendant to the terms of the contract or arrangement, information provided in the disclosures, and other factors related to the prudence and reasonableness of requesting such audit. The right to conduct an audit does not necessitate that it is exercised. For example, the responsible plan fiduciary of a small plan may reasonably determine that the expense incurred by the plan to audit the covered service provider under this section outweighs the likely benefit to the plan resulting from such audit where additional circumstances suggesting the covered service provider is noncompliant with the terms of the contract or arrangement or the requirements of the regulation are absent.

7. Manner of Disclosure—Proposed Paragraph (k)

Proposed paragraph (k) includes four separate provisions regarding the manner of disclosures under the regulation. Each is discussed below.

7.1. Plain Language

Paragraph (k)(1) specifies that all disclosures must be clear and concise, free of misrepresentations, and contain sufficient specificity to permit evaluation of the reasonableness of the contract or arrangement. The paragraph further specifies that, for example, the Department will consider the use of generic industry terms, jargon, or legalese, without definition, to lack the sufficient specificity required under the

preceding sentence unless the language in question specifically refers to objectively determinable definitions, standards, or other similar guidelines, that are publicly available or will be provided by the covered service provider to the responsible plan fiduciary free of charge and within a reasonable period of time following the request.

7.2. Description of Compensation

With respect to descriptions of compensation required under the regulation, proposed paragraph (k)(2) requires that they must be expressed as a monetary amount (for example, \$1,000) and may be estimated to the extent that the actual amount is not reasonably ascertainable. However, the disclosure must contain sufficient information and specificity to permit evaluation of the reasonableness of the compensation received by the covered service provider, an affiliate, an agent, or a subcontractor. As discussed above in section D.2. of the preamble, this aspect of the proposal offers less flexibility than the Department's service provider disclosure regulation for pension plans (29 CFR 2550.408b–2(c)(1)) and the statutory provision at ERISA section 408(b)(2)(B), each of which permit compensation disclosure to be expressed—as an alternative to a monetary amount—as a “formula,” “per capita charge” for each participant, or, if the compensation cannot reasonably be expressed in such terms, “by any other reasonable method.” This difference in approach is based on the Department's tentative conclusion that disclosures of a monetary amount (even if estimated) in this context would further the transparency goals of this rulemaking which are intended to further a responsible plan fiduciary's assessment of reasonableness of compensation potential for conflicts of interest, and would also foster a fairer prescription drug market that lowers costs. The Department seeks comments on its tentative conclusion in support of this paragraph of the proposal.

7.3. Machine-Readability Format

Proposed paragraph (k)(3) provides that upon request of a responsible plan fiduciary of a self-insured group health plan, descriptions of compensation must also be provided, within a reasonable time after such request, in a machine-readable file. For this purpose, the proposal provides that “machine-readable file” means a digital representation of data or information in a file that can be imported or read by a computer system for further processing without human intervention, while

ensuring no semantic meaning is lost. This requirement of the proposal is designed to ensure that a responsible plan fiduciary can obtain information in this format if the responsible plan fiduciary determines that this will aid in its evaluation of the reasonableness of the contract or arrangement.

7.4. Confidentiality Agreements

Proposed paragraph (k)(4) addresses confidentiality agreements. The paragraph provides that, except as provided in paragraph (j)(3), the covered service provider and its affiliates, agents, and subcontractors may not impose restrictions on the self-insured group health plan's use of disclosures required under this section, or the contract or arrangement described in paragraph (c)(1) of this section, except that the covered contract or arrangement may require the responsible plan fiduciary to require third parties to whom it rediscloses such information to execute reasonable confidentiality agreements preventing redisclosure by such parties.

The primary purpose of paragraph (k)(4) of the proposal is to ensure that covered service providers are not able to undermine responsible plan fiduciaries' efforts to evaluate their compensation by limiting the self-insured group health plan's ability to meaningfully use information in the disclosures, for example, by restricting responsible plan fiduciaries from sharing the information with other plan service providers, such as healthcare consultants or attorneys, for quality control and other purposes. At the same time, however, paragraph (k)(4) would also protect covered service providers by allowing them to make sure self-insured group health plans take steps to ensure that third parties to whom self-insured group health plans disclose the information do not themselves redisclose the information to fourth parties. The Department seeks comment on whether the proposal strikes the correct balance regarding the use of confidentiality agreements and the potential for re-disclosure of information disclosed under the regulation.

8. Disclosure Errors—Proposed Paragraph (l)

Proposed paragraph (l) provides a rule for disclosure errors. Under the proposed rule, no contract or arrangement will fail to be reasonable under the regulation solely because the covered service provider, acting in good faith and with reasonable diligence, makes an error or omission in disclosing the information required pursuant to paragraphs (e), (g), or (j), so long as the

covered service provider discloses the correct information to the responsible plan fiduciary as soon as practicable, but not later than 30 calendar days from the date on which the covered service provider knows of such error or omission.

9. Consequences of Non-Compliance and Proposed Administrative Class Exemption for Responsible Plan Fiduciary—Proposed Paragraph (n)

As directed by President Trump's Executive Order 14273, *Lowering Drug Prices by Once Again Putting Americans First*, this proposed regulation aims to promote transparent pricing and create a fairer and more competitive prescription drug market that lowers costs and ensures accountability across the healthcare system. Responsible plan fiduciaries of self-insured group health plans would be able to use the disclosures in their process of selecting a provider of pharmacy benefit management services, engaging an affiliated broker or consultant, monitoring these service providers' operations and compliance with contractual obligations, and also in analyzing the drivers of prescription drug costs.

In this regard, responsible plan fiduciaries of self-insured group health plans must determine that service provider relationships involving the self-insured group health plan meet certain conditions in an exemption to avoid constituting a prohibited transaction under ERISA. Specifically, unless an exemption applies, the furnishing of goods, services, or facilities between a self-insured group health plan and a party in interest to the plan is a prohibited transaction under ERISA section 406(a)(1)(C). A person providing services to the self-insured group health plan is defined by ERISA to be a "party in interest" to the self-insured group health plan.

ERISA section 408(b)(2) exempts certain arrangements between ERISA-covered plans (including self-insured group health plans) and service providers that otherwise would be prohibited transactions under ERISA section 406. Section 408(b)(2) provides relief from ERISA's prohibited transaction rules for service contracts or arrangements between a plan and a party in interest if the contract or arrangement is reasonable, the services are necessary for the establishment or operation of the plan, and no more than reasonable compensation is paid for the services.

If the terms of an exemption are not satisfied, responsible plan fiduciaries entering into service arrangements with

parties in interest to self-insured group health plans, and the parties in interest themselves, may be subject to enforcement action by the Department and imposition of a civil penalty.¹⁴³ The Department's enforcement will be aided by the requirement in the proposed administrative class exemption that plan fiduciaries report to the Department a service provider's non-compliance with the disclosure or audit provisions.

The Department recognizes that there may be circumstances when a responsible plan fiduciary enters into (or extends or renews) a contract or arrangement that appears to meet the requirements of the regulation under ERISA section 408(b)(2), but the covered service provider fails to comply with its obligations, including by not disclosing the required information or failing to comply with the audit request. Without an exemption, the covered service provider's failure would result in a prohibited transaction by both the service provider and the responsible plan fiduciary. The Department is proposing an administrative class exemption in paragraph (n) to provide relief for responsible plan fiduciaries in the event covered service providers fail to comply with the regulation, consistent with the relief available in the Department's service provider regulation for pension plans (29 CFR 2550.408b–2(c)(1)(ix)) and ERISA section 408(b)(2)(B)(viii), which provide exemptions for responsible plan fiduciaries who do not receive necessary disclosures from covered service providers to their ERISA-covered plans or are impeded in their right to access information related to the contract or arrangement as required under the regulation.

Paragraph (n) of the proposed rule would provide a responsible plan fiduciary with relief from the restrictions of ERISA section 406(a)(1)(C) and (D) if, among other things, the responsible plan fiduciary did not know that the covered service provider failed to comply with the regulation and "reasonably believed" that the regulatory requirements were satisfied. Upon discovery of a failure to comply, the responsible plan fiduciary must take certain specified steps within designated timeframes, as described in

¹⁴³ ERISA section 502(a)(5) provides that the Secretary may bring a civil action to enjoin any act or practice which violates any provision of ERISA . . . or to obtain other appropriate equitable relief (i) to redress such violation or (ii) to enforce any provisions of this title or the terms of the plan. ERISA section 502(i) authorizes the Secretary to assess a civil penalty on a party in interest in the case of a transaction prohibited by ERISA section 406.

proposed paragraphs (n)(1) and (2), including notifying the Department of any failures that are not corrected within the designated timeframes. In this way, the proposed administrative class exemption would facilitate oversight by the Department of those covered service providers that fail to comply with the regulation. Proposed paragraphs (n)(3) and (4) set forth the timing, content and other requirements applicable to the notice required to be filed with the Department by the responsible plan fiduciary. The Department notes that parties seeking to avail themselves of the relief provided by the exemption would need to be able to demonstrate compliance with the conditions of the exemption.

Proposed paragraph (n)(5) addresses the potential that the responsible plan fiduciary would terminate the contract or arrangement in connection with the covered service provider's failure to comply with its obligations under the regulation. It provides that if the covered service provider fails to comply with the written request to correct the failure within 90 calendar days of such request, the responsible plan fiduciary shall determine whether to terminate or continue the contract or arrangement consistent with its duty of prudence under ERISA section 404.

This provision is based on a similar provision in the Department's service provider regulation for pension plans and ERISA section 408(b)(2)(B)(viii)(IV), but it does not include language from these sources that suggests that a responsible plan fiduciary must always terminate a contract or arrangement with a noncompliant covered service provider if the failure to disclose relates to future services. Although the provisions in the Department's service provider regulation for pension plans and ERISA section 408(b)(2)(B)(viii)(IV) provide that the contract or arrangement must be terminated as "expeditiously as possible, consistent with the duty of prudence," the Department is wary of imposing an absolute requirement to terminate a contract as a condition of obtaining the prohibited transaction relief under paragraph (n) because it could cause concerns about the responsible plan fiduciary's ability to prudently provide for plan benefits. Such a requirement to terminate could be read as precluding a responsible plan fiduciary from continuing a contract or arrangement for some period even if, taking into account surrounding facts and circumstances, it reasonably determines that it would be prudent and in the best interest of participants and beneficiaries to do so. Comments are solicited on whether an approach that

gives flexibility for a responsible plan fiduciary to continue a contract or arrangement is appropriate despite failure to comply with an obligation under the regulation with respect to future services, or whether paragraph (n)(5) should instead mirror the Department's service provider regulation for pension plans and ERISA section 408(b)(2)(B)(viii)(IV) and require termination of a contract or arrangement in such circumstances.

The Department is proposing paragraph (n) pursuant to its authority under ERISA section 408(a) and in accordance with the procedures set forth in 29 CFR part 2570, subpart B (89 FR 4662 (January 24, 2024)). The attention of interested persons is directed to the following: (1) the fact that a transaction is the subject of an exemption under ERISA section 408(a) does not relieve a fiduciary, or other party in interest with respect to a self-insured group health plan, from certain other provisions of ERISA, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of ERISA section 404 which require, among other things, that a fiduciary act prudently and discharge his or her duties respecting the plan solely in the interests of the participants and beneficiaries of the plan; (2) before the proposed administrative class exemption may be granted under ERISA section 408(a), the Department must find that it is administratively feasible, in the interests of self-insured group health plans and their participants and beneficiaries and protective of the rights of participants and beneficiaries of the self-insured group health plans; (3) if granted, the proposed administrative class exemption is applicable only to transactions that satisfy the conditions specified in the exemption; and (4) the proposed administrative class exemption, if granted, is supplemental to, and not in derogation of, any other provisions of ERISA, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction.

10. Authority for and Placement of Proposed Regulation

10.1. Authority

Section 408(b)(2)(A) of ERISA exempts from the prohibitions of ERISA section 406(a) "reasonable" contracts or arrangements with a party in interest, including a fiduciary, for office space, or

legal, accounting, or other services necessary for the establishment or operation of the plan, if no more than reasonable compensation is paid. Section 408(b)(2)(B)(i) of ERISA, in turn, clarifies that in the case of persons who provide "brokerage services" or "consulting," no such contract or arrangement is "reasonable" unless the disclosure requirements in subparagraph (ii) of section ERISA 408(b)(2)(B) are satisfied.

While section 408(b)(2)(A) of ERISA comprehensively covers the full range of plans and service providers covered by ERISA, section 408(b)(2)(B) of ERISA deals only with a select type of plan (group health plans) and subset of service providers (brokers and consultants) to such plans. The existence of section 408(b)(2)(B) does not foreclose the Department from regulating arrangements not described in section 408(b)(2)(B) of ERISA but otherwise within the reach of section 408(b)(2)(A). Put differently, while Congress directly addressed brokers and consultants under ERISA section 408(b)(2)(B), this does not relieve other service providers of their obligations under ERISA section 408(b)(2)(A) to disclose information that would assist fiduciaries in determining the reasonableness of a contract or arrangement.

This proposed rule is under the authority of section 505 of ERISA, as well as both section 408(b)(2)(A) and section 408(b)(2)(B) of ERISA, as follows. The Department proposes to regulate entities providing pharmacy benefit management services, identified in paragraph (c)(1)(i) of the proposal, pursuant to the authority in sections 505 and 408(b)(2)(A) of ERISA. However, the Department notes that the terms "brokerage services" and "consulting" are undefined, and in connection with the list of sub-services in ERISA section 408(b)(2)(B)—these terms could be construed to describe services provided by PBMs. For example, pharmacy benefit management services related to establishment and maintenance of formularies could be considered to involve consulting related to the development and implementation of plan design.¹⁴⁴

The Department is regulating entities providing advice, recommendations, or referrals regarding the provision of pharmacy benefit management services, identified in paragraph (c)(1)(ii) of the proposal and who are affiliated with entities described in paragraph (c)(1)(i) of the proposal, pursuant to the authority in sections 505, 408(b)(2)(A),

¹⁴⁴ See ERISA section 408(b)(2)(B)(ii)(I)(bb)(BB).

and 408(b)(2)(B) of ERISA. Paragraphs (c)(1)(i) and (c)(1)(ii) of the proposal admit that certain businesses are likely to perform services in both categories. Thus, the Department could structure the final regulation under either or both section 408(b)(2)(A) and section 408(b)(2)(B) along with section 505 of ERISA.

10.2. Placement

This proposed regulation, establishing disclosure requirements for covered service providers to group health plans, would appear at 29 CFR 2550.408b–22. In connection with this proposed regulation, the Department is also proposing to revise its existing service provider regulation (29 CFR 2550.408b–2(c)(2)) in the Code of Federal Regulations to cross-reference the proposed regulation.

11. Proposed Effective and Applicability Dates—Proposed Paragraph (p)

Proposed paragraph (p) provides both an effective date and an applicability date for the proposed rule. Under paragraph (p)(1), the proposed rule would be effective sixty calendar days after the date of the publication of the final rule. Once effective, however, paragraph (p)(2) of the proposal provides that the rule would be applicable to plan years beginning on or after July 1, 2026. This approach is intended to balance the need for prompt action to increase transparency into contracts and arrangements with PBMs and affiliated brokers and consultants with due concern being given to the cost and burden associated with transitioning current and future contracts or arrangements to satisfy the requirements of the final rule.

E. Regulatory Impact Analysis

Summary

The Department has examined the impacts of this proposed rule as required by Executive Order 12866,¹⁴⁵ Executive Order 13563,¹⁴⁶ Executive Order 14192,¹⁴⁷ the Paperwork Reduction Act of 1995,¹⁴⁸ the Regulatory Flexibility Act,¹⁴⁹ section 202 of the Unfunded Mandates Reform Act of 1995,¹⁵⁰ and Executive Order 13132.¹⁵¹

1. Executive Orders 12866 and 13563

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

Under Executive Order 12866, “significant” regulatory actions are subject to review by the Office of Management and Budget (OMB). Section 3(f) of the Executive order defines a “significant regulatory action” as any regulatory action that is likely to result in a rule that may:

(1) Have an annual effect on the economy of \$100 million or more; or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities (also referred to as “economically significant”);

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in this Executive order.

This proposal seeks to build upon the existing provisions of ERISA section 408(b)(2), as amended, including the 2012 final regulation and relevant provisions of the CAA 2021. Based on the Department’s estimates, OMB’s OIRA has determined this rulemaking is economically significant per Executive Order 12866 section 3(f)(1) as it is likely to have an impact of \$100 million or more in any one year. The Department has provided an assessment of the potential costs, benefits, and transfers, associated with this proposed rule, and OMB has reviewed this proposed rule.

Executive Order 14192, titled “Unleashing Prosperity Through Deregulation,” was issued on January 31, 2025. Section 3(a) of Executive Order 14192 requires an agency, unless prohibited by law, to identify at least ten existing regulations to be repealed when the agency issues a new regulation. In furtherance of this requirement, section 3(c) of Executive Order 14192 requires that the new

incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with prior regulations. A significant regulatory action (as defined in section 3(f) of Executive Order 12866) that would impose total costs greater than zero is considered an Executive Order 14192 regulatory action. This proposed rule, if finalized as proposed, is, therefore, expected to be an Executive Order 14192 regulatory action. When analyzing the rule for the purpose of Executive Order 14192, the Department considers the burden caused by the proposal alone. The proposed rule would require covered service providers, including PBMs, to provide fee and compensation structure disclosures to responsible plan fiduciaries of self-insured group health plans. As such, this proposal is considered regulatory and is expected to contribute to the Department’s regulatory burden under Executive Order 14192.

2. Introduction and Need for Regulation

The rising cost of pharmaceutical drugs has been an increasing concern for the U.S. health-care system in recent years. Between January 2022 and January 2023, nearly 5,900 prescription drug products in the National Drug Code Directory reported a price change. More than 70 percent (4,300) of these products experienced an increase in their manufacturer list price, and 46 percent (2,000) of those price increases exceeded the rate of inflation. While the annual average rate of price increases was 20.1 percent for 2017 to 2018 compared to 15.2 percent for 2022 to 2023, the average increase was only \$160 per prescription drug for 2017 to 2018 compared to \$590 per prescription drug for 2022 to 2023. In other words, the average per prescription drug price increase between 2022 and 2023 was more than 3.5 times the average annual increase between 2017 and 2018. This suggests that recent price increases were concentrated in higher-cost prescription drug products.¹⁵²

Despite this growth, the share of total health spending on prescription drugs has remained relatively stable over time (increasing from seven percent in 1970 to nine percent in 2022). However, an increasing share of these costs appears to have shifted from individuals directly

¹⁴⁵ Regulatory Planning and Review, 58 FR 51735 (Oct. 4, 1993).

¹⁴⁶ Improving Regulation and Regulatory Review, 76 FR 3821 (Jan. 18, 2011).

¹⁴⁷ 90 FR 9065 (January 31, 2025).

¹⁴⁸ 44 U.S.C. 3506(c)(2)(A) (1995).

¹⁴⁹ 5 U.S.C. 601 *et seq.* (1980).

¹⁵⁰ 2 U.S.C. 1501 *et seq.* (1995).

¹⁵¹ Federalism, 64 FR 153 (Aug. 4, 1999).

¹⁵² Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, *Changes in the List Prices of Prescription Drugs, 2017–2023*, (2023), <https://aspe.hhs.gov/sites/default/files/documents/0cdd88059165eeef3bed1fc587a0fd68a/aspe-drug-price-tracking-brief.pdf>.

to insurance. According to the National Health Expenditure Accounts (NHEA) data, public and private health insurance accounted for only 16 percent of national prescription drug spending in 1970, increasing to 68 percent in 2000 and 86 percent in 2023, with out-of-pocket and other third-party payers and programs making up the balance.¹⁵³ Moreover, a survey of large employers reported that pharmacy costs are consuming an increasing share of their health-care budgets, with the median share rising from 21 percent in 2021 to 27 percent in 2023.¹⁵⁴

Due to the complexity of the pharmaceutical supply chain and the multitude of players involved, responsible plan fiduciaries of self-insured group health plans often outsource pharmacy benefit management services to intermediaries, such as PBMs. PBMs manage and administer prescription drug benefits between the self-insured group health plans, pharmacies, pharmaceutical companies, and other intermediaries. In this capacity, PBMs develop prescription drug formularies and benefit designs for self-insured group health plans, negotiate rebates with drug manufacturers for placement on those formularies, establish preferred pharmacy networks, and process prescription drug claims. As a result, PBMs influence multiple aspects of self-insured group health plans' prescription drug benefit design, affecting costs and fees, while responsible plan fiduciaries are charged with monitoring the PBMs' actions to ensure the service contract or arrangement is reasonable.

2.1. Fiduciary Challenges of Monitoring PBMs

Under ERISA, the persons responsible for hiring the self-insured group health plan's service providers are plan fiduciaries. In the PBM context, these "responsible plan fiduciaries" may be the self-insured group health plans' sponsor or another fiduciary such as a committee made up of plan sponsor employees. Responsible plan fiduciaries are required to act solely in the interests of plan participants and their beneficiaries when administering plan benefits and ensure that plan assets are

used exclusively to provide benefits and pay plan expenses. While they may engage service providers to provide benefits for the plan, responsible plan fiduciaries are responsible for prudently negotiating terms when entering into a contract, so that only reasonable and necessary costs are paid, and conflicts of interest are disclosed and mitigated. They are also required to monitor service providers' performance. Moreover, for these responsible plan fiduciaries to avoid a prohibited transaction by relying on ERISA section 408(b)(2), they must determine, among other things, that the contract or arrangement is reasonable.

In the prescription drug space, these responsibilities can be particularly challenging as responsible plan fiduciaries often contract with a PBM to administer the self-insured group health prescription drug coverage, create the self-insured group health plan's formulary with varying cost-sharing amounts, and manage participant claims and appeals. In doing so, PBMs may separately enter into agreements with pharmacies to dispense drugs and with manufacturers for rebates to guarantee preferred placement on the self-insured group health plan's formulary among other entities. As a result of those independent relationships, PBMs may have numerous conflicts of interest related to providing prescription drug services as well as several different payment streams that responsible plan fiduciaries are required to monitor in accordance with their fiduciary duties to ensure that the fees related to these benefits are reasonable.

Failure to adequately fulfill their responsibility risks legal action for responsible plan fiduciaries. In recent years, multiple cases have been brought by plan participants claiming that their plan fiduciaries did not fulfill their fiduciary responsibilities regarding PBM services by incurring excessive fees, failing to negotiate better pricing terms for prescription drugs, and not behaving prudently when selecting the plan's PBM.¹⁵⁵ These cases highlight the plaintiffs' expectation that responsible plan fiduciaries scrutinize the agreements they enter into with PBMs, including by analyzing compensation disclosures, rooting out conflicts of interest, and auditing PBM's performance to ensure that prescription drug benefits are managed transparently, in accordance with the

health plan documents and ERISA, and in the best interest of plan participants.

Often, though, the underlying agreements that PBMs negotiate on behalf of self-insured group health plans with drug manufacturers and pharmacies for these services are not shared with the self-insured group health plans themselves, nor are the relationships between PBMs and their affiliates. Contracts between PBMs and self-insured group health plans often include savings guarantees based on list prices rather than net prices, the latter of which are not disclosed. These contracts may fail to disclose the size of rebates or rebate terms, and limit the self-insured group health plan's right to audit.¹⁵⁶ Such an arrangement, which prevents self-insured group health plans' responsible plan fiduciaries from evaluating drug utilization and spending, the cost effectiveness of the formulary, and the gross profit of the PBM, "deprives employers of the ability to completely understand the drug benefit design, evaluate the efficiency of their drug utilization, and assess the PBM's performance."¹⁵⁷ According to the 2024 KFF Employer Health Benefits Survey, of employers with 500 or more workers that offer health benefits, 37 percent did not know how much was received in rebates negotiated by their PBM or health plan,¹⁵⁸ suggesting that many plans and their sponsors have little insight into PBM rebate practices.¹⁵⁹

Even when pharmacy benefit consultants are used to select PBMs and assess their contract proposals, responsible plan fiduciaries can struggle to evaluate the arrangements, as drug classifications are inconsistent across PBMs, making it difficult to compare competing PBM bids or secure favorable contract terms.¹⁶⁰ Exacerbating matters

¹⁵⁶ Robin Feldman, *Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers Testimony*, (2023), at the U.S. Senate, Finance Committee, <https://www.finance.senate.gov/imo/media/doc/Feldman%20Written%20Testimony%20.pdf>.

¹⁵⁷ Ge Bai, Mariana P. Socal, & Gerard F. Anderson, *Policy Options to Help Self-Insured Employers Improve PBM Contracting Efficiency*, Health Affairs Blog (May 29, 2019), <https://www.healthaffairs.org/content/forefront/policy-options-help-self-insured-employers-improve-pbm-contracting-efficiency>.

¹⁵⁸ KFF, *2024 Employer Health Benefits Survey*, (Oct. 9, 2024), <https://www.kff.org/report-section/ehbs-2024-section-13-employer-practices-provider-networks-coverage-for-glp-1s-abortion-and-family-building-benefits/>.

¹⁵⁹ Arthur Allen, *Employers Haven't a Clue How Their Drug Benefits Are Managed*, KFF Health News, (October 9, 2024), <https://kffhealthnews.org/news/article/employer-drug-benefits-pbms-survey-kff/>.

¹⁶⁰ Patricia M. Danzon, *Pharmacy Benefit Management: Are Reporting Requirements Pro or*

¹⁵³ Centers for Medicare & Medicaid Services (CMS), *National Health Expenditure Accounts*, National Health Expenditures by Type of Service and Source of Funds, 1960–2023, (2023), <https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/historical>.

¹⁵⁴ Business Group on Health, *Executive Summary: 2025 Employer Health Care Strategy Survey*, (August 20, 2024), <https://www.businessgrouphealth.org/resources/2025-employer-health-care-strategy-survey-executive-summary>.

¹⁵⁵ See *Knudsen v. MetLife Group* (117 F.4th 570), *Navarro v. Well Fargo & Co* (24–cv–3043–LMP–DTS), and *Lewandowski v. Johnson and Johnson* (2025 WL 288230).

further, many pharmacy benefit consultants receive undisclosed compensation from the same PBMs that they are tasked with evaluating, including bonuses, shares of rebates, and per-prescription fees. For example, it has been reported that consultants can receive anywhere from \$1 to \$5 per prescription from the largest PBMs.¹⁶¹

This creates conflicts of interest, where consultants may be incentivized to recommend PBMs offering the highest payouts to them, rather than those that deliver the best value for self-insured group health plans and their participants, which makes the fiduciary task of selecting and monitoring PBMs to protect the interests of the self-insured group health plan and its participants, even more challenging. The transparency created by this proposed rule would help plan fiduciaries be aware of this conflict and consider its impact on decisions being made.

2.2. PBM Revenue-Generating Practices and the Impact on Self-Insured Group Health Plan Costs

PBMs utilize several practices to generate revenue when providing services to self-insured group health plans, including but not limited to rebates, price protection, spread pricing, copay claw-backs, specialty drugs administration, steering patients toward PBM-owned mail-order and specialty pharmacies, and high markups on generic drugs. Responsible plan fiduciaries, in order to fulfill their obligations regarding the selection and monitoring of service providers, need to know and understand the financial interests of PBMs and their relationships with other actors when providing these services. Additionally, when relying on ERISA section 408(b)(2) to avoid a prohibited transaction, they need to determine that the contract or arrangement is reasonable. The following sections discuss common PBM practices in greater detail, the lack of transparency surrounding these practices, and how they can impact the costs and services provided to self-insured group health plans.

Anti-Competitive? International Journal of the Economics of Business, (2015) <https://www.tandfonline.com/doi/full/10.1080/13571516.2015.1045741>.

¹⁶¹ United States District Court for the District of New Jersey, *Lewandowski v. Johnson & Johnson*, No. 1:24-cv-00671 (D.N.J. Feb. 5, 2024), https://litigationtracker.law.georgetown.edu/wp-content/uploads/2024/02/lewandowski-v-johnson-and-johnson_2.5.24_Complaint.pdf.

2.2.1. Rebates

PBMs generate a significant portion of their revenues through their negotiated share of rebates, which are payments made by the drug manufacturers to issuers or PBMs in order to receive preferential placement on the formulary, the list of drugs covered by the self-insured group health plan.¹⁶² Many contracts do not require PBMs to disclose the rebates that they receive and so self-insured group health plans often are unaware if monies are being refunded;¹⁶³ however, a frequently cited industry estimate is that “PBMs achieve rebates of 30 percent off list price, accounting for all discounts and fees.”¹⁶⁴ With respect to Medicare Part D, while Part D plan sponsors and their PBMs are required to disclose rebates retained by PBMs to the Centers for Medicare & Medicaid Services,¹⁶⁵ PBM contracts with issuers and self-insured group health plans often do not directly disclose the magnitude of rebates.¹⁶⁶ This in turn allows PBMs to retain rebates received from manufacturers, unless their service contracts explicitly require sharing of any rebates.¹⁶⁷ Smaller self-insured group health plans, in particular, are less likely to receive any share of rebates due to weaker negotiating power compared to large self-insured group health plans.¹⁶⁸

Further obscuring the actual rebate amount, the three largest PBMs, which

¹⁶² Nicole Rapfogel, *5 Things to Know About Pharmacy Benefit Managers*, (202), Center for American Progress, <https://www.americanprogress.org/article/5-things-to-know-about-pharmacy-benefit-managers/#:~:text=Rebate:%20A%20price%20concession%20paid,in%20part%20or%20in%20full.>

¹⁶³ Patricia M. Danzon, *Pharmacy Benefit Management: Are Reporting Requirements Pro or Anti-Competitive?* International Journal of the Economics of Business, (2015) <https://www.tandfonline.com/doi/full/10.1080/13571516.2015.1045741>.

¹⁶⁴ Health Affairs, *Health Policy Brief: Pharmacy Benefit Managers*, (2017), https://www.healthaffairs.org/doi/10.1377/hpb20171409.000178/full/healthpolicybrief_178.pdf.

¹⁶⁵ Social Security Act section 1150A.

¹⁶⁶ Patricia M. Danzon, *Pharmacy Benefit Management: Are Reporting Requirements Pro or Anti-Competitive?* International Journal of the Economics of Business, (2015) <https://www.tandfonline.com/doi/full/10.1080/13571516.2015.1045741>.

¹⁶⁷ Frier Levitt, *Pharmacy Benefit Manager Expose: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, and Employers, and Taxpayers*, The Community Oncology Alliance, (2022) https://communityoncology.org/wp-content/uploads/2022/02/COA_FL_PBM_Expose_2-2022.pdf.

¹⁶⁸ Patricia M. Danzon, *Pharmacy Benefit Management: Are Reporting Requirements Pro or Anti-Competitive?* International Journal of the Economics of Business, (2015) <https://www.tandfonline.com/doi/full/10.1080/13571516.2015.1045741>, <https://www.tandfonline.com/doi/full/10.1080/13571516.2015.1045741>.

account for roughly 80 percent of the prescription drug market, have created affiliated entities known as rebate aggregators, which serve as intermediaries between PBMs and drug manufacturers to negotiate and collect rebates. While PBMs argue that these entities provide greater bargaining power and savings, because rebate aggregators retain a share of the rebate themselves, depending on the terms of the contract between the self-insured group health plan and the PBM, they effectively reduce any rebate the PBM might be required to share with an issuer or self-insured group health plan, while, as an affiliated entity, still maximizing the PBM's profits. Additionally, according to a 2024 Federal Trade Commission (FTC) report, two of the three largest PBMs' rebate aggregators were found to be offshore entities, further limiting oversight and transparency.¹⁶⁹

The lack of transparency surrounding net prices has harmful effects on costs. For self-insured group health plans that rely on benefit consultants in their selection process, PBM proposals are often presented comparing the rebate guarantees, which encourages selection of the PBM with the highest rebate revenue. These guarantees are presented in aggregate across all impacted prescriptions regardless of which drugs are dispensed. As argued by the National Formulary Council, this “obscures” group health plan sponsors' visibility into the actual net prices of drugs on their formularies as well as the size of the rebates and other revenue (e.g., administrative fees, formulary placement fees, inflation penalties) PBMs receive from manufacturers.”¹⁷⁰ This can incentivize PBMs to prioritize drugs with higher rebates, such as brand-name prescription drugs, over lower-cost but equally effective alternatives. As a result, this can increase overall pharmacy costs. Moreover, while responsible plan fiduciaries generally receive notice of formulary changes, the disclosures typically do not include data to inform a responsible plan fiduciary of the impact of the change financially or its effect on the self-insured group health

¹⁶⁹ Federal Trade Commission, *Interim Staff Report: Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies*, (2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

¹⁷⁰ Rochelle Henderson & Julie Patterson, *Prescription Rebate Guarantees: Employer Insights*, The American Journal of Managed Care, Vol 30 (11), (November 2024), <https://www.ajmc.com/view/prescription-rebate-guarantees-employer-insights>.

plan participants.¹⁷¹ This lack of transparency limits self-insured group health plans' ability to assess the reasonableness of the changes, which can result in unintended consequences for plan participants.

Rebates received by self-insured group health plans can offset premiums and other health-care costs. Without transparent disclosures providing detailed descriptions of rebates, their impact on the formulary and how that will affect self-insured group health plan costs, responsible plan fiduciaries are unable to assess whether the underlying fees for PBM services are reasonable, particularly given the potential harm to self-insured group health plan participants and beneficiaries.

2.2.2. Price Protection

PBMs can further negotiate with drug manufacturers to receive additional rebates to protect them from price increases, known as price or inflation protection. In such instances, the manufacturer agrees to a maximum price paid for the drug so that if the wholesale acquisition cost (WAC) exceeds the agreed upon threshold, the PBM receives an additional rebate from the manufacturer, beyond the existing rebates and discounts.¹⁷² This practice is similar to the inflationary rebate provisions included in the Inflation Reduction Act (IRA) of 2022, which require manufacturers to pay rebates to Medicare if they increase prices beyond the rate of inflation.¹⁷³

Rather than discouraging price hikes, price protections can incentivize manufacturers to raise list prices more strategically. The Senate Finance Committee found that manufacturers timed their WAC price increases to avoid paying additional rebates under the price protection terms in the PBM contracts.¹⁷⁴ As such, while both PBMs

and self-insured group health plans could potentially benefit from price protection rebates, rebate practices also add an additional layer of complexity to contracts which can make it hard to determine if the arrangements are reasonable.

2.2.3. Spread Pricing

Under a spread pricing model, payments for individual prescription claims received by the PBM from self-insured group health plans or issuers often exceeds the reimbursement amount it pays to the pharmacy, allowing the PBM to retain the difference, or "spread" without disclosing this additional revenue to self-insured group health plans.¹⁷⁵ One source found that spread pricing accounted for an estimated 10 to 15 percent of a PBM's revenue.¹⁷⁶

PBMs' failure to disclose the actual spread makes it difficult, if not impossible, for self-insured group health plans to know whether they are unwittingly paying unreasonable costs for medications and treatment. Consequently, this practice has led to an increased number of State lawsuits that stem from allegations of deceptive practices resulting in financial losses.¹⁷⁷ For example, in 2018, the Ohio Office of Attorney General reported that Centene Corporation, which oversaw Ohio's Department of Medicaid prescription drug program, had engaged in spread pricing which cost the State program nearly \$225 million in excess payments.¹⁷⁸ Ohio brought a lawsuit against Centene, who ultimately agreed to pay \$88.3 million to the State¹⁷⁹ and also switched to a pass-through pricing contract, which increased payments to pharmacists by 5.74 percent, though this was significantly less than the "spread" of 31.4 percent on generic drug claims

from April 2017 to March 2019.¹⁸⁰ These findings suggest that overall group health plan costs may have declined as a result of eliminating spread pricing.¹⁸¹

2.2.4. Copay Claw-Backs

PBMs also generate profits through copay claw-backs, which can occur when the copayment an insured individual pays at a pharmacy exceeds the total cost of the drugs purchased. This practice results in patients paying more for prescriptions by using their insurance rather than purchasing them directly from the pharmacy, with the excess amount going to the PBMs. Self-insured group health plans' responsible plan fiduciaries are generally unaware of this practice and the resulting revenue, however, since the net drug prices that PBMs negotiate with pharmacies are often not disclosed to self-insured group health plan responsible plan fiduciaries.

A 2018 study using pharmacy claims data and National Average Retail Price (NARP) data, which contained drug prices paid by issuers as reported by pharmacists, found that commercially insured patients' copayments for generic prescriptions exceeded the total cost of the medicine 23 percent of the time.¹⁸² This means that nearly a quarter of the time, patients would find it cheaper to pay the out-of-pocket cost rather than rely on their insurance. In one particularly egregious example, a patient paid a \$285 copay in 2016 for a prescription whose cash cost was only \$40, resulting in the PBM retaining a profit of \$245.¹⁸³

The practice had been exacerbated by prohibitions on pharmacies from disclosing lower cash prices to patients due to "gag clauses" in their contracts with issuers and PBMs.¹⁸⁴ Congress

¹⁷¹ Linda Nilsen, *Written Testimony for the ERISA Advisory Council Hearing on PBM Compensation and Fee Disclosure*, (August 20, 2014), <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/about-us/erisa-advisory-council/2014-pbm-compensation-and-fee-disclosure-nilsen-08-20.pdf>.

¹⁷² U.S. Senate Committee on Finance, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug*, (2021), <https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf>.

¹⁷³ Center for Medicare and Medicaid Services, *Fact Sheet: Medicare Prescription Drug Inflation Rebate Program Policies in the Calendar Year 2025 Physician Fee Schedule Final Rule*, (2024), <https://www.cms.gov/files/document/medicare-prescription-drug-inflation-rebate-program-final-fact-sheet.pdf>.

¹⁷⁴ U.S. Senate Committee on Finance, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug*, (2021), <https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf>.

www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.

¹⁷⁵ KFF, *Medicaid Pharmacy Benefits State Fact Sheets*, (2020), <https://www.kff.org/statedata/medicaid-pharmacy-benefits-state-fact-sheets/>.

¹⁷⁶ Colorado Health Institute, *Pharmacy Benefit Managers: As Drug Prices Soar, Policymakers Take Aim*, (2018), https://www.coloradohealthinstitute.org/sites/default/files/file_attachments/Pharmacy%20Benefit%20Managers.pdf.

¹⁷⁷ None of the discussed lawsuits have occurred in states that have banned spread pricing.

¹⁷⁸ Ohio's Office of Attorney General, *Ohio's Medicaid Managed Care Pharmacy Services*, (2018), Auditor of State Report, https://audits.ohioauditor.gov/Reports/AuditReports/2018/Medicaid_Pharmacy_Services_2018_Franklin.pdf.

¹⁷⁹ Ohio's Office of Attorney General, *Centene Agrees to Pay a Record \$88.3 Million to Settle Ohio PBM Case Brought by AG Yost*, (2021), [https://www.ohioattorneygeneral.gov/Media/News-Releases/June-2021/Centene-Agrees-to-Pay-a-Record-\\$88-3-Million-to-Settle-Ohio-PBM-Case-Brought-by-AG-Yost](https://www.ohioattorneygeneral.gov/Media/News-Releases/June-2021/Centene-Agrees-to-Pay-a-Record-$88-3-Million-to-Settle-Ohio-PBM-Case-Brought-by-AG-Yost), [https://www.ohioattorneygeneral.gov/Media/News-Releases/June-2021/Centene-Agrees-to-Pay-a-Record-\\$88-3-Million-to-Settle-Ohio-PBM-Case-Brought-by-AG-Yost](https://www.ohioattorneygeneral.gov/Media/News-Releases/June-2021/Centene-Agrees-to-Pay-a-Record-$88-3-Million-to-Settle-Ohio-PBM-Case-Brought-by-AG-Yost), [https://www.ohioattorneygeneral.gov/Media/News-Releases/June-2021/Centene-Agrees-to-Pay-a-Record-\\$88-3-Million-to-Settle-Ohio-PBM-Case-Brought-by-AG-Yost](https://www.ohioattorneygeneral.gov/Media/News-Releases/June-2021/Centene-Agrees-to-Pay-a-Record-$88-3-Million-to-Settle-Ohio-PBM-Case-Brought-by-AG-Yost), [https://www.ohioattorneygeneral.gov/Media/News-Releases/June-2021/Centene-Agrees-to-Pay-a-Record-\\$88-3-Million-to-Settle-Ohio-PBM-Case-Brought-by-AG-Yost](https://www.ohioattorneygeneral.gov/Media/News-Releases/June-2021/Centene-Agrees-to-Pay-a-Record-$88-3-Million-to-Settle-Ohio-PBM-Case-Brought-by-AG-Yost), [https://www.ohioattorneygeneral.gov/Media/News-Releases/June-2021/Centene-Agrees-to-Pay-a-Record-\\$88-3-Million-to-Settle-Ohio-PBM-Case-Brought-by-AG-Yost](https://www.ohioattorneygeneral.gov/Media/News-Releases/June-2021/Centene-Agrees-to-Pay-a-Record-$88-3-Million-to-Settle-Ohio-PBM-Case-Brought-by-AG-Yost), 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outlawed such gag clauses through the *Patient Right to Know Drug Prices Act* in 2018, though the Federal law did not resolve all transparency issues in drug pricing.¹⁸⁵ While the legislative changes may have curtailed the practice, NARP data collection was discontinued after six months, which has made it difficult to continue monitoring the issue to assess whether it is still pervasive.

2.2.5. Specialty Drugs

PBMs have also utilized their management and distribution of specialty drugs to increase their profits. Specialty drugs are typically defined by (1) their complex handling, administration, or formulation requirements; (2) the severity or rarity of the condition being treated; and (3) their high cost.¹⁸⁶ However, there is no standard definition of a specialty drug. These drugs are often used to manage complex, chronic conditions, such as HIV, cancer, hepatitis, and cystic fibrosis. Not surprisingly, specialty drugs are among the most expensive. Although fewer than two percent of the population uses specialty drugs, those prescriptions account for 51 percent of total pharmacy spending.¹⁸⁷

The high prices associated with specialty drugs can translate into larger manufacturer rebates, which may incentivize PBMs to design formularies that classify more prescription drugs as specialty drugs. A 2016 study found that, between 2003 and 2014, the share of specialty prescriptions filled by commercially insured patients increased from 3.0 to 11.8 percent.¹⁸⁸ Moreover, once a drug is added to a PBM's specialty drug list, it can trigger exclusivity provisions in contracts that require the use of the PBM's affiliated specialty pharmacy.¹⁸⁹

Drugs: The Copay Clawback, (2018), <https://schaeffer.usc.edu/research/overpaying-for-prescription-drugs/>.

¹⁸⁵ 132 Stat. 3672—Public Law 115–263.

¹⁸⁶ Huseyin Naci & Aaron Kesselheim, *Specialty Drugs—A Distinctly American Phenomenon*, *The New England Journal of Medicine*, (2020), <https://eprints.lse.ac.uk/105102/4/nejmp1909513.pdf>.

¹⁸⁷ NAIC, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation*, (2023), https://content.naic.org/sites/default/files/inline-files/PBM%20White%20Paper%20Draft%20Adopted%20B%20Committee%2011-2-23_0.pdf.

¹⁸⁸ Stacie Dusetzina, *Share of Specialty Drugs in Commercial Plans Nearly Quadrupled, 2003–2014*, *Health Affairs* (2016), https://www.healthaffairs.org/doi/10.1377/hlthaff.2015.1657?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=c_pub%20%200pubmed.

¹⁸⁹ Federal Trade Commission, *Interim Staff Report: Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies*, (2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

Since PBMs often benefit financially from the placement of specialty drugs on formularies, this may create a conflict of interest in formulary design. Such a conflict could lead to the exclusion of lower-cost, equally effective alternatives, which would further limit access to prescription drugs.¹⁹⁰

2.2.6. High Markups on Generic Drugs

Compared to branded or specialty drugs, generic manufacturers rarely negotiate rebates with PBMs. Instead, PBMs can generate profits by basing reimbursement amounts to pharmacies on their own proprietary price lists for generic drugs, in a process known as maximum allowable costs (MAC) pricing. While pharmacies purchase prescription drug products from various wholesalers directly, they are reimbursed by PBMs at the MAC price, which may be below the average wholesale price. Moreover, MAC prices are updated frequently—often on a weekly basis—and so pharmacies do not know the reimbursement amount until they submit a claim.¹⁹¹

Pharmacy reimbursement rates are often compared to the National Average Drug Acquisition Cost (NADAC), which is a commonly used benchmark for pharmacy acquisition costs based on data reported by pharmacies to the Centers for Medicare & Medicaid Services (CMS).¹⁹² While PBMs offer lower cost-sharing on generics, PBMs can still steer patients toward affiliated pharmacies and give those pharmacies preferential reimbursement rates. This practice allows PBM-affiliated pharmacies to earn revenues for generics that significantly exceed their estimated drug acquisition costs. A 2024 FTC report examining reimbursement rates for two generic cancer drugs found that PBMs reimbursed affiliated pharmacies at rates 20 to 40 times higher than the NADAC. For example, in 2022, commercial health plans reimbursed affiliated pharmacies for one generic prostate cancer drug over \$5,800

¹⁹⁰ Trevor J. Royce, Caroline Schenkel, Kelsey Kirkwood, Laura Levit, Kathryn Levit, & Sheetal Kircher, *Impact of Pharmacy Benefit Managers on Oncology Practices and Patients*, *JCO Oncology Practice*, (2020), <https://pmc.ncbi.nlm.nih.gov/articles/PMC7351331/>.

¹⁹¹ Federal Trade Commission, *Interim Staff Report: Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies*, (2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

¹⁹² Casey B. Mulligan, *Restrict the Middleman? Quantitative Models of PBM Regulations and Their Consequences*, (2023), No. w30998. National Bureau of Economic Research, https://www.nber.org/system/files/working_papers/w30998/w30998.pdf.

per month, approximately 25 times the \$229 NADAC. This pattern was observed across both commercial and Medicare Part D payer groups, leading to nearly \$1.6 billion in excess dispensing revenue for affiliated pharmacies.¹⁹³

2.3. Summary

The previous sections illustrate the various practices that PBMs use to generate revenue and how these practices can impact access and costs of prescription drugs for self-insured group health plans, participants and beneficiaries. Moreover, these practices are often designed to mask how revenue is generated, making it difficult for self-insured group health responsible plan fiduciaries to make informed decisions when selecting a PBM, as well as monitor its activities once they have entered into an agreement. These practices underscore the importance of greater transparency and accountability in the operations of PBMs. Transparent disclosures to self-insured group health responsible plan fiduciaries regarding payments, compensation, arrangements between the PBM and affiliates, agents, and subcontractors, and the right to audit and access information are needed to enable responsible plan fiduciaries to make prudent decisions when selecting and monitoring PBMs and to ensure that the contract or arrangement, and the fees charged to self-insured group health plans, are reasonable. These decisions are crucial in ensuring patients have access to timely and affordable prescription drugs.¹⁹⁴

3. Regulatory State

3.1. History of 408(b)(2) Regulations

In December 2007, the Department issued a proposed regulation requiring service providers to disclose specified information before a contract was entered into that would allow responsible plan fiduciaries to assess whether a contract or arrangement was “reasonable” under Section 408(b)(2) of ERISA. The required disclosures included information on all compensation to be received and any conflicts of interest that may adversely affect the service provider's performance of the contract or

¹⁹³ Federal Trade Commission, *Interim Staff Report: Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies*, (2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

¹⁹⁴ U.S. House Committee on Oversight and Accountability, *The Role of Pharmacy Benefit Managers in Prescription Drug Markets*, (2024), <https://oversight.house.gov/wp-content/uploads/2024/07/PBM-Report-FINAL-with-Redactions.pdf>.

arrangement. The Department proposed that this information was necessary in order for responsible plan fiduciaries to make informed assessments and decisions about the services, costs, and the providers, in accordance with their responsible plan fiduciary obligations.¹⁹⁵

Under that proposed regulation, all employee benefit plans subject to Title I of ERISA were subject to the regulation's disclosure requirements, including both pension and welfare plans. However, the Department received a number of comments arguing against the inclusion of welfare plans, asserting that the disclosures contemplated were already made available to responsible plan fiduciaries through State regulatory processes. Additionally, the Department received comments suggesting that the inclusion of PBMs under the rule was contrary to the rationale for the rule itself. In particular, commenters argued that PBMs should be excluded from the rule because the FTC, at the time, had determined that market forces provide sufficient information to responsible plan fiduciaries, that excessive mandatory disclosure could weaken competition, and that this would negatively affect the delivery of prescription drugs to group health plan participants and beneficiaries.¹⁹⁶

While the view of the Department was that fiduciaries and service providers to welfare benefit plans would similarly benefit from regulatory guidance in this area, it acknowledged that there are significant differences between service and compensation arrangements of welfare plans and those involving pension plans. As such, the Department expressed its intention to develop separate, and more specifically tailored, disclosure requirements for welfare benefit plans, and excluded them from the final rule.¹⁹⁷

The 408(b)(2) disclosures required by the 2012 final regulation provided responsible plan fiduciaries of retirement plans with necessary information about the compensation arrangements of their service providers, enabling them to better assess whether those compensation arrangements were reasonable.¹⁹⁸ As a result, these disclosures helped responsible plan fiduciaries make more cost-effective investment choices, such as opting for cheaper share classes. Flows into the cheapest share classes of open-end mutual funds that indicated they

distributed to retirement channels more than doubled from 2011 to 2013, indicating a substantial increase after the final rule took effect.¹⁹⁹ However, the fees charged to plan participants had been declining both before and after the final rule took effect, making it difficult to isolate the specific benefits that resulted from this regulation.²⁰⁰

Building on this regulatory framework, Congress expanded similar requirements to a portion of the group health plan market. In the CAA, 2021, Congress amended the ERISA section 408(b)(2) statutory exemption to add a new paragraph (B) applicable to certain services arrangements with group health plans, effective December 27, 2021.²⁰¹ As part of the amendment, Congress designated the pre-existing text as ERISA section 408(b)(2)(A).²⁰² The requirements in ERISA section 408(b)(2)(B) apply to a group of covered service providers, defined as persons or entities who provide “brokerage services” or “consulting” to group health plans with respect to a list of sub-services including pharmacy benefit management services.²⁰³

The new ERISA section 408(b)(2)(B) closely tracks the Department's regulation for pension plan

arrangements. It requires disclosure of: the services to be provided; the status of the covered service provider, an affiliate, or subcontractor as a fiduciary, if applicable; the direct and indirect compensation reasonably expected to be received by the covered service provider, their affiliates and their subcontractors; as well as allocations of compensation reasonably expected to be made among the covered service providers and its affiliates and subcontractors. The new provision also establishes ongoing disclosure obligations in the event of a change in the information required to be provided in the initial disclosures, and disclosures to be provided upon the written request of the responsible plan fiduciary as needed for the plan to comply with the reporting and disclosure requirements of title I of ERISA.

Following the CAA, 2021, Executive Order 14273 directed the Department to propose regulations to improve employer health plan fiduciary transparency into the direct and indirect compensation received by PBMs.²⁰⁴

3.2. Current Regulatory Action

Like the Department's 2012 final pension disclosure regulation, the proposed rule is intended to ensure transparency by requiring covered service providers to make adequate disclosures to the responsible plan fiduciary so that they can perform their duties under ERISA in assessing the reasonableness of the arrangement with the service provider. The specific disclosure requirements are explained in detail in section D of this preamble.

Overall, the disclosures are intended to provide responsible plan fiduciaries with a fuller picture of the terms under which the services will be provided, so they can assess both the reasonableness of the compensation in light of the services being provided, and the potential for or existence of conflicts of interest that may impact the quality of services provided. The Department believes that these disclosures will provide necessary information to responsible plan fiduciaries who are required to determine that the services contract or arrangement meets the standards for an exemption under ERISA section 408(b)(2).

4. Baseline

The baseline for this analysis reflects the current legal and regulatory framework, including the existing provisions of ERISA section 408(b)(2),

¹⁹⁵ 72 FR 70988 (Dec. 13, 2007).

¹⁹⁶ 75 FR 41600 (July 16, 2010).

¹⁹⁷ 75 FR 41600 (July 16, 2010).

¹⁹⁸ 77 FR 5632 (Feb. 3, 2012).

¹⁹⁹ Based on internal analysis performed by EBSA.

²⁰⁰ Investment Company Institute, *The Economics of Providing 401(k) Plans: Services, Fees, and Expenses*, (2024), page 11, <https://www.ici.org/system/files/2024-07/per30-06.pdf>.

²⁰¹ Section 202 of Title II of Division BB of the Consolidated Appropriations Act, 2021.

²⁰² ERISA section 408(b)(2)(A) now provides an exemption for “[c]ontracting or making reasonable arrangements with a party in interest for office space, or legal, accounting, or other services necessary for the establishment or operation of the plan, if no more than reasonable compensation is paid therefor.”

²⁰³ Specifically, see ERISA section 408(b)(2)(B)(ii)(I)(bb)(AA) (defining a covered service provider as one who provides *brokerage services* “provided to a covered plan with respect to selection of insurance products (including vision and dental), recordkeeping services, medical management vendor, benefits administration (including vision and dental), stop-loss insurance, pharmacy benefit management services, wellness services, transparency tools and vendors, group purchasing organization preferred vendor panels, disease management vendors and products, compliance services, employee assistance programs, or third party administration services”) and ERISA sections 408(b)(2)(B)(ii)(I)(bb)(BB) defining a covered service provider as one who provides *consulting services* “related to the development or implementation of plan design, insurance or insurance product selection (including vision and dental), recordkeeping, medical management, benefits administration selection (including vision and dental), stop-loss insurance, pharmacy benefit management services, wellness design and management services, transparency tools, group purchasing organization agreements and services, participation in and services from preferred vendor panels, disease management, compliance services, employee assistance programs, or third party administration services.”

²⁰⁴ Lowering Drug Prices by Once Again Putting Americans First, 90 FR 16441 (April 15, 2025).

as amended, and applicable provisions of the CAA, 2021. However, while the CAA, 2021 did effectively extend the disclosure requirements from the 2012 regulation to include “brokerage services” or “consulting” to group health plans with respect to a list of sub-services including pharmacy benefit management services, the CAA, 2021 provisions do not explicitly apply to all pharmacy benefit management services. As a result, the baseline includes the disclosure requirements already in effect for covered service providers that provide brokerage or consulting services to group health plans, as required under the CAA, 2021. Benefits, costs, and transfers associated with the proposed rule are measured as changes relative to this baseline.

Accordingly, this regulatory impact analysis (RIA) does not account for the benefits or costs associated with the general requirements for service providers that provide brokerage or consulting services to group health plans to disclose direct and indirect compensation to fiduciaries, as these are already required by the provisions of the CAA, 2021 and are therefore included in

the baseline. However, this analysis does take into account the expected impacts of the proposed rule, the new disclosure requirements for PBMs, as well as the additional granularity and frequency of disclosures required of covered service providers. These requirements are expected to impose costs for PBMs and may potentially impose new costs to other service providers already in compliance with the CAA, 2021, while providing meaningful benefits to self-insured group health plans, participants, and beneficiaries.

5. Summary of Impacts

Accordingly, the proposed rule is expected to increase transparency in PBM compensation arrangements, helping self-insured group health plans responsible plan fiduciaries and other stakeholders to better understand PBM practices. This transparency would increase competition in the market for PBM services, enable responsible plan fiduciaries to compare offerings across PBMs, empower responsible plan fiduciaries to negotiate more favorable contract terms, reduce impacts on the

self-insured group health plan and participants resulting from PBMs’ conflicts of interest, and encourage PBMs to accurately classify prescription drugs, resulting in lower costs to both self-insured group health plans and participants.

Self-insured group health plans, third-party administrators (TPAs), and PBMs will incur costs to review this rule and comply with the additional disclosure requirements in the proposed rule. However, the Department has determined that the benefits of the proposed rule justify the costs. In accordance with OMB Circular A–4, Table 1 depicts an accounting statement summarizing the Department’s assessment of the benefits, costs, and transfers associated with these regulatory actions. The Department is unable to quantify all benefits, costs, and transfers of the proposed rule, but have sought, where possible, to describe these non-quantified impacts. The effects in Table 1 reflect non-quantified impacts and estimated direct monetary costs resulting from the provisions of the proposed rule.

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TABLE 1. Accounting Statement

Benefits:	Estimate (QALY Approach)	Estimate (Direct WTP Approach)	Year Dollar	Discount Rate	Period Covered
Annualized Monetized (\$million/year)	\$74.5 to \$746.2	\$39.0 to \$389.6	2025	7 percent	2026-2034
	\$74.6 to \$747.7	\$39.0 to \$389.6	2025	3 percent	2026-2034
Quantified Benefits using Quality Adjusted Life Years:					
- Improved health outcomes for patients due to increased treatment adherence from better access to lower cost prescription drugs (analysis limited to a subset of therapeutic classes) will result in undiscounted benefits of \$71.7 to \$717.1 million annually. - Reduced healthcare utilization arising from improved health outcomes (analysis limited to a subset of therapeutic classes) will result in undiscounted benefits of \$3.2 million to \$31.9 million annually.					
Alternative Method of Quantified Benefits directly using Consumer Willingness-to-Pay:					
- Increase in consumer surplus associated with increased consumption of prescribed medication resulting from lower prescription drug prices will generate undiscounted benefits of \$39.0 to \$389.6 million annually. - Annualized estimates are between \$39.0 million and \$389.6 million with a 7 percent discount rate and between \$39.0 million and \$389.6 million with a 3 percent discount rate.					
Non-Quantified Benefits and/or Mechanisms Yielding Quantified Benefits:					
- Improved understanding of PBMs by self-insured group health responsible plan fiduciaries. - Reduced administrative burden on self-insured group health plans due to lower search and preparation costs for PBM selection and contract negotiations. - Greater ability for self-insured group health responsible plan fiduciaries to compare offerings across PBMs, fostering competition, and improving drug pricing. - More favorably negotiated contracts for self-insured group health responsible plan fiduciaries with PBMs, resulting in lower costs and more appropriate coverage. - Reduced conflicts of interest that currently influence PBMs’ key decisions regarding rebates, formulary design, and prescription drug pricing. - Non-quantified only in the QALY approach: - Improved health outcomes for patients due to increased treatment adherence from better access to lower cost prescription drugs (for those conditions not included in quantified analysis above). - Reduced healthcare utilization and future medical expenditures arising from improved health outcomes. - Reduced costs to self-insured group health plans and employers, allowing them to shift resources to other benefits or priorities.					
Costs:	Estimate	Year Dollar		Discount	Period Covered
Annualized Monetized (\$million/year)	\$117.7	2025		7 percent	2026-2034
	\$116.3	2025		3 percent	2026-2034
Quantified Costs:					
- For familiarization with the proposed rule, ERISA covered self-insured group health plans, TPAs, and PBMs will incur approximately \$17.8 million in the first year. - For developing and maintaining the IT infrastructure systems, PBMs will incur \$73.0 million in the first year and \$14.6 million in subsequent years.					

- For preparing the required disclosures, PBMs and ERISA covered self-insured group health plans will annually incur approximately \$90.6 million.
- For preparing the audit request, ERISA-covered self-insured group health plans will incur approximately \$2.3 million.

Transfers:

	Estimate	Year Dollar	Discount	Period Covered
Annualized Monetized (\$million/year)	\$108.8 to \$1,088.3	2025	7 percent	2026-2034
	\$108.8 to \$1,088.3	2025	3 percent	2026-2034

Quantified Transfers:

- Reduced prescription prices for self-insured group health plans and participants will result in undiscounted transfers to participants of between \$108.8 million and \$1.1 billion annually.

Non-Quantified:

- Potential transfers from traditional PBMs to transparent PBMs like fully pass-through PBMs as self-insured group health responsible plan fiduciaries are better able to evaluate compensation structures.
- Potential transfers from affiliated to unaffiliated pharmacies, as PBMs remove preferential treatment of affiliated pharmacies, resulting in increased use of unaffiliated pharmacies.

Perpetual Time Horizon Costs:

- Annualized Cost (in 2024 dollars) (E.O. 14192 accounting): \$109.1 million.

BILLING CODE 4510-29-C**6. Request for Comments**

The Department invites comments addressing its estimates and underlying assumptions of the benefits, costs, and transfers associated with the proposed rulemaking, as well as any quantifiable data that would support or contradict any aspect of its analysis. Throughout the document, the Department has requested comments on specific assumptions in its analysis. In particular, the Department requests comments on the following questions:

1. How frequently are PBM contracts extended or renewed? Is this done once over the life of the contract or every year of the contract? Would initial disclosures only be required the first year of the contract or every year before an option is exercised?
2. Are there differences in how fully pass-through PBMs collect and disclose information and what are the impacts in prices associated with these differences?
3. What share of the PBM market is served by fully pass-through PBMs? Do these PBMs focus on specific segments of the market?
4. How many full-service PBMs provide services for the self-insured group health plans affected by this rulemaking?

5. Are there differences in extracting pricing, cost, rebate and utilization data for level-funded versus other self-insured group health plans? Are current disclosures for level-funded group health plans provided at the plan level? If not, how much additional effort would be required to provide this information at the plan level?

6. Do the existence of intermediaries like TPAs, coalition groups, rebate aggregators, etc. significantly impact the burden of collecting the information required in the disclosure? If so, to what degree?

7. How much of the information requested in the proposed rule for the initial disclosure is already included in responses to Requests for Proposals by self-insured group health plans seeking PBM services?

8. How much of the process of sending disclosures can be automated? What are the associated up-front costs to create templates and automate the disclosure process?

9. How much time does it take to prepare a disclosure for each self-insured group health plan? Are initial disclosures more time-consuming than semi-annual disclosures? What types of occupations are involved in preparing the actual disclosures?

10. How often and what share of self-insured group health plans request audit data? Do these requests vary by plan size? How often do insurers, serving as TPAs for self-insured plans, request this data?

11. If obtaining this data becomes easier, would plan sponsors be more likely to conduct audits? What are the main sources of costs for plans to conduct audits? Would this increase under the proposed regulation?

12. Quality Adjusted Life Years and Willingness-to-Pay are two possible ways to estimate the benefits of the proposed rule. Which approach is more appropriate for this analysis and the available data? How can the analysis presented be improved and are there other sources available for the needed data to perform the analysis?

7. Affected Entities

Table 2 summarizes the number of self-insured group health plans, TPAs, pharmacies, manufacturers, wholesalers, and PBMs that would be affected by the proposed rule. These estimates and their sources are discussed in greater detail later in Section 7 of the RIA.

TABLE 2. Affected Entities

	Total
Level-funded Group Health Plans	1,031,098
Large, self-insured Group Health Plans with 100 to 999 employees	104,123
Large, self-insured Group Health Plans with 1,000 or more employees	15,362
PBMs	73
Issuers	373
Issuers/State combinations in group market	809
TPAs	205
Pharmacies	43,879
Pharmaceutical Manufacturers	1,431
Pharmaceutical Wholesalers	1,427

7.1. Self-Insured and Level-funded Group Health Plans

The proposed rule applies only to a subset of ERISA-covered group health plans, which are self-insured and level-funded group health plans. Fully insured ERISA plans are not subject to these requirements and are therefore excluded from the estimates.

According to the 2024 KFF Employer Health Benefits Survey, 42 percent of small firms offering health benefits provide a level-funded plan, which are self-insured group health plans packaged with extensive stoploss coverage that significantly reduces the risk retained by the plan sponsor.²⁰⁵ Applying this percentage to the 2,454,996 small, ERISA-covered group health plans,²⁰⁶ the Department estimates there are approximately 1,031,098 level-funded group health plans.²⁰⁷ The Department also estimates that there are 104,123 self-insured group health plans with 100 to 999 employees and 15,362 self-insured group health plans with 1,000 or more employees.²⁰⁸

²⁰⁵ KFF, *2024 Employer Health Benefits Survey*, (Oct. 9, 2024), <https://www.kff.org/report-section/ehbs-2024-section-10-plan-funding/#figure106>.

²⁰⁶ The Department estimates that there 2,454,996 ERISA-covered group health plans with less than 100 employees using the 2023 Medical Expenditure Panel Survey Insurance Component (MEPS-IC) and the 2021 County Business Patterns from the Census Bureau.

²⁰⁷ Additionally, the Department estimates there are 1,031,098 small, level-funded ERISA-covered group health plans based on the 2024 KFF Employer Health Benefits Survey, the 2023 Medical Expenditure Panel Survey Insurance Component (MEPS-IC) and the 2021 County Business Patterns from the Census Bureau. Large is defined as having 100 or more participants and beneficiaries in the plan.

²⁰⁸ The Department estimates that there are 104,123 self-insured ERISA-covered group health plans with 100 to 999 employees and 15,362 self-insured ERISA-covered group health plans with 1,000 or more employees using the 2023 Medical

While all 1,150,583 of these plans are considered self-insured group health plans, the Department uses this distinction to categorize self-insured group health plans by size and other unique features. The 2024 KFF Employer Health Benefits Survey also found that nearly all covered workers (99 percent) are at firms that provide prescription drug benefits to enrollees in their group health plans.²⁰⁹ As such, the Department assumes that all self-insured and level-funded group health plans will be affected by the proposed rule.

7.2. TPAs and Issuers

The Department also estimates that the proposed rule will affect 205 TPAs and 373 issuers (*i.e.*, health insurance companies) in the group market with 809 issuers/State combinations²¹¹ that provide services such as plan management to level-funded and self-insured group health plans. The Department assumes that these TPAs and issuers will provide their services to level-funded group health plans and self-insured group health plans with fewer than 1,000 employees. TPAs and issuers are typically hired by self-insured group health plans to perform

Expenditure Panel Survey Insurance Component (MEPS-IC) and the 2021 County Business Patterns from the Census Bureau.

²⁰⁹ KFF reported this estimate for large firms only, as small firm respondents had a high percentage of “don’t know” responses to these questions.

²¹⁰ KFF, *2024 Employer Health Benefits Survey*, (Oct. 9, 2024), <https://www.kff.org/report-section/ehbs-2024-section-9-prescription-drug-benefits/>.

²¹¹ An “issuer/state combination” refers to a health insurance issuer and the state in which it offers coverage, such that the same issuer operating in multiple states is treated as separate issuer/state combinations. Data source: Centers for Medicare and Medicaid Services, *2023 Medical Loss Ratio Data*, <https://www.cms.gov/marketplace/resources/data/medical-loss-ratio-data-systems-resources>.

key administrative and compliance functions, including claims processing, formulary design, and oversight of pharmacy benefits. These service providers will offer economies of scale in regulatory compliance by leveraging their expertise and infrastructure to implement the proposed rule’s requirements on behalf of multiple self-insured group health plans. While responsible plan fiduciaries remain ultimately responsible for ensuring compliance, they rely on TPAs and issuers to manage the day-to-day operations of the self-insured group health plan and fulfill the requirements of the proposed rule. Plans may contract with the TPAs or issuers, who in-turn sub-contract with PBMs. In that case, the TPAs or issuers would be covered service providers. The TPAs or issuers would be responsible for making the disclosures to the self-insured group health plan required under the proposed rule and therefore must be able to obtain information from the provider performing the pharmacy benefit management services necessary for those disclosures.

7.3. Participants and Beneficiaries

There are approximately 89.4 million participants and beneficiaries in ERISA-covered self-insured and level-funded group health plans.²¹² According to the 2022 Center for Disease Control’s (CDC) National Center for Health Statistics, United States, 64.1 percent of individuals under the age of 65 with

²¹² Employee Benefits Security Administration, *Health Insurance Coverage Bulletin and Abstract of Auxiliary Data for the March 2023 Annual Social and Economic Supplement to the Current Population Survey*, (August 30, 2024), <https://www.dol.gov/sites/dolgov/files/EBSA/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2023.pdf>.

private health insurance used a prescription medication in the past year or 57.3 million participants.²¹³

7.4. PBMs

According to the Pharmaceutical Care Management Association (PCMA),²¹⁴ there were 70 full-service PBMs in 2021. Between 2021 and 2023, six new full-service PBMs entered the marketplace. During this same time, eight PBMs were acquired by other PBMs, primarily through mergers between small or mid-size companies. Furthermore, five PBMs that were previously not classified as “full-service” have expanded their services. As a result, the net number of full-service PBMs in the marketplace was 73 in 2023.²¹⁵ The Department requests comments on this assumption, including whether all PBMs service the self-insured group health plans affected by this rulemaking.

7.5. Brokers and Consultants

To the extent PBMs or their affiliates also act as brokers or consultants to level-funded and self-insured group health plans with respect to pharmacy benefit management services, they are covered service providers under the proposed regulation. The Department seeks comments on the number of brokers and consultants that are PBMs or affiliates of PBMs, and on their arrangements with level-funded and self-insured group health plans and PBMs, and costs, if any, that they will incur in complying with the requirements of the proposed regulation.

7.6. Drug Manufacturers, Wholesalers and Pharmacies

According to the U.S. Census Bureau, there were 1,436 drug manufacturers in 2023²¹⁶ and 1,427 pharmaceutical drug

wholesaler distributors in 2021.²¹⁷ Additionally, the U.S. Census Bureau reported there were 41,792 pharmacies and prescription drug stores in 2023, though a number had closed in the preceding years which makes estimating the current number challenging.²¹⁸

A 2024 study found that while the number of U.S. retail pharmacies increased from 2010 to 2017, there was a sharp decline beginning in 2018, resulting in the total number of retail pharmacies declining by 29 percent between 2010 and 2021. Moreover, independent pharmacies were more than twice as likely to close as chain stores, though the overall decline was driven largely by chain pharmacy closures due to their share of the market. These trends correspond with reported increases in planned closures, mergers, and acquisitions, and the integration of PBMs with large pharmacy chains. The study noted that the closures might have been driven by lower reimbursement rates for unaffiliated pharmacies rather than PBM affiliated counterparts and the increased exclusion of independent pharmacies from pharmacy networks.²¹⁹

8. Research Examining the Impact of PBMs on Prescription Drug Costs

Research shows mixed impact of PBMs on prescription drug costs. Some studies suggest that PBMs can lower costs by negotiating rebates and managing drug utilization, and that the absence of PBMs leads to greater inefficiencies and higher prescription drug prices. In contrast, other studies find that PBMs can inflate costs through spread pricing, formulary design, and requiring the use of mail-order or specialty pharmacies. These studies are discussed in greater detail below.

8.1. Research Finding That PBMs Generate Cost Savings and Their Absence Increases Prescription Drug Costs

PBMs argue that they generate cost savings for employers, health plans, participants, and taxpayers. For example, a 2025 study funded by the three largest PBMs—Caremark, Express Scripts, and OptumRx—found that PBMs reduce prescription drug costs for plan sponsors and their members. The authors estimate that PBM operating margins account for less than five percent of overall prescription drug costs and that approximately 98 percent of manufacturer rebates in recent years have been passed through to plan sponsors.²²⁰

It is important to note that this paper does not account for significant variability across plan types and PBM contracts. For example, another 2025 paper suggests that larger employers were more likely to receive manufacturer rebates than small employers, with only 15 percent of small employers²²¹ reporting capturing rebates, compared to 49 percent of large employers in 2024.²²² Evidence from a 2015 paper also finds that the average retail spread retained by PBMs is below two percent, though the Department notes that even a two percent spread represents a substantial amount when applied to prescription drug spending in the billions of dollars. The study further shows that net prices for branded drugs with rebates have grown more slowly than those without rebates. According to the authors, plan sponsors rely on PBMs because they can negotiate larger discounts with manufacturers and pharmacies, develop formularies that encourage the use of lower-cost drugs, and manage pharmacy networks more efficiently than plan sponsors could on their own. The study concludes that PBMs create significant value by managing prescription drug spending, which can help reduce premiums and out-of-pocket costs for patients.²²³

²¹³ Centers for Disease Control and Prevention, National Center for Health Statistics, *Prescription Medication Use Among Adults*, United States (2023), <https://nchsdata.cdc.gov/DQS/?topic=prescription-medication-use-among-adults&subtopic=&group=health-insurance-coverage-younger-than-65-years&subgroup=private&range=2019-to-2023>.

²¹⁴ The PCMA is a national trade association representing the PBM industry. (Source: PCMA, *About PCMA*, (2025), <https://www.pcmnet.org/about/>).

²¹⁵ The PCMA article estimated the total number of PBMs in 2023 in the following manner: 70 full-service PBMs + 6 new full-service PBMs—8 acquired PBMs + 5 PBMs that expanded services = 73 full-service PBMs. (Source: PCMA, *The PBM Marketplace is More Competitive, Not Less*, (May 8, 2023), <https://www.pcmnet.org/rx-research-corner/the-pbm-marketplace-is-more-competitive-not-less/05/08/2023/>).

²¹⁶ U.S. Census Bureau, *2023 Economic Surveys Business Patterns*, 325412: *Pharmaceutical Preparation Manufacturing*, (2023), https://data.census.gov/profile/325412_-_Pharmaceutical

Preparation Manufacturing?n=325412&g=010XX00US.

²¹⁷ 87 FR 6708 (Feb. 4, 2022), <https://www.federalregister.gov/documents/2022/02/04/2022-01929/national-standards-for-the-licensure-of-wholesale-drug-distributors-and-third-party-logistics>.

²¹⁸ U.S. Census Bureau, *All Sectors: County Business Patterns, including ZIP Code Business Patterns, by Legal Form of Organization and Employment Size Class for the U.S., States, and Selected Geographies: 2023, Economic Surveys, ECNSVY Business Patterns County Business Patterns*, Table CB2300CBP (2025), <https://data.census.gov/table/CBP2023.CB2300CBP?q=44611:+Pharmacies+and+drug+stores>.

²¹⁹ Jenny S. Guadamuz, G. Caleb Alexander, Genevieve P. Kanter, & Dima Mazen Qato, *More US Pharmacies Closed Than Opened In 2018–21; Independent Pharmacies, Those in Black, Latinx Communities Most at Risk: Study Examines US Pharmacy Closures at the County Level, 2018–21*, Health Affairs, (2024), <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2024.00192>.

²²⁰ Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* (April 2025), <https://compass-lexecon.files.svdcn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921>.

²²¹ The paper defines a small employer as an employer with fewer than with than 5,000 employees.

²²² Pharmaceutical Group Companies, *2025 Trends in Specialty Drug Benefits Report*, (2025), <https://www.psgconsults.com/blog/untapped-potential-medical-drug-rebate-strategies-for-payers/>.

²²³ Patricia M. Danzon, *Pharmacy Benefit Management: Are Reporting Requirements Pro or*

Furthermore, a 2016 study, commissioned by a PBM trade association, PCMA, highlights the methods PBMs use to generate savings including negotiating rebates and discounts, encouraging the use of generics and alternatives, managing high-cost specialty medications, and expanding access via mail-service and specialty pharmacy channels. The study estimated that PBMs could generate \$350 billion in savings for commercial plans and their members from 2016 to 2025 while promoting proper utilization and adherence to treatment. However, this analysis assumes that PBMs fully utilize their cost-saving tools: selective formularies with four or more tiers, pre-approval for step-therapy, strong incentives to use mail service, preferred pharmacy options with high performance networks, and high usage of specialty pharmacies.²²⁴ It is also important to note that the study bases its estimates on several assumptions about prescription drug trends, including price inflation and specialty drug growth. The authors also do not control for any inflationary pressure that PBMs themselves may have on the list price of prescription drugs. Additionally, this study does not account for the varying efficacy of utilization management and adherence programs across heterogeneous patient populations, which poses limitations in accurately estimating cost savings. Finally, it is worth noting that the study does not discuss the impact of transparency on the ability of PBMs to continue to provide these services and generate savings.

A 2022 study, also funded by PCMA, estimates the societal value of PBM services using a quantitative model that reflects the structure of the U.S. prescription drug market. The paper compares current PBM operations with three hypothetical scenarios: the absence of PBM services, the use of government-enforced price controls, and in-house management of PBM functions by individual health plans.²²⁵

In the first scenario, PBM services are estimated to annually contribute an additional \$145 billion more in societal

value than would be experienced without PBM services, though more than one-third of the calculated value is attributed to manufacturer rebates. This estimate is based on \$168 billion in quantified benefits, which include negotiated rebates, increased use of generic drugs, improved adherence, and reduced tax distortion, minus \$22 billion in resource costs associated with providing PBM services.²²⁶

In the second scenario, PBM services are estimated to provide an additional \$192 billion in societal value each year, compared to a healthcare system operating under government-enforced price controls. This estimate reflects the model's assumption that government-enforced price controls could lower drug utilization, weaken market-based price mechanisms, and significantly diminish incentives for pharmaceutical innovation.

Finally, in the third scenario, PBM services are estimated to provide between \$64 to \$81 billion more in societal value compared to a system in which self-insured group health plans perform all PBM functions internally, without relying on specialized PBM companies. This estimate reflects the model's assumption that self-insured group health plans would retain only a portion of PBM functions under this model, leading to decreased efficiency and increased operational costs.²²⁷

While these studies suggest the potential positive impact that PBMs may have in controlling costs, some studies have found that the absence of PBMs can result in higher costs for self-insured group health plans as well as State and federal government programs. For example, the Department of Labor's Inspector General conducted an audit of its Office of Workers' Compensation Programs (OWCP) in 2023 and concluded that the program lacked a "pharmacy benefit manager to help contain costs" between 2015 and 2020. Due to the absence of a PBM, OWCP was not able to capitalize on strategies typically facilitated by a PBM. For instance, OWCP did not have a process to identify other available pricing models or ensure its pricing was competitive with others in the industry. Specifically, OWCP did not compare its pricing to publicly available benchmarks, such as the MAC, NADAC, and the ACA Federal Upper Limit.

Additionally, OWCP did not have a mechanism, or a contract, to incorporate rebates for pharmacy expenditures in its Federal Employees' Compensation Act (FECA) pharmaceutical program. The report noted that these rebates could have resulted in substantial savings for brand-name prescription drugs. As a result, the failure to incorporate these measures reportedly led up to \$321.3 million in excess spending during the audit period.²²⁸

A 2021 study compared the experience of two State Medicaid programs managing their specialty pharmacy benefits with respect to Hepatitis C therapies: Michigan, which centralized purchasing Hepatitis C drugs from manufacturers, and Illinois which relied on PBMs to manage purchasing and utilization of the drugs. Using CMS drug purchasing data from 2015 to 2019, the study found that Illinois's PBMs purchased cheaper generic alternatives when they became available in 2019. In contrast, Michigan continued to purchase more expensive brand-name prescription drugs. These findings suggest that Illinois, through their PBM, was able to quickly pivot to cheaper generic alternatives as soon as they were available, while Michigan continued to rely on more expensive brand drugs, resulting in a 55 percent gap in unit prices between the two States. This translated into additional costs for Michigan of \$36 million in the latter part of 2019 alone.²²⁹

Following West Virginia's decision to carve prescription drugs out of their Medicaid managed care program in 2017, its Department of Health and Human Resources, Bureau for Medical Services commissioned a report to assess the potential savings they achieved from moving from a PBM-related managed care organization (MCO) to a fee-for-service approach. The report projected West Virginia would save \$50 million in administrative costs under the change.²³⁰

Anti-Competitive? International Journal of the Economics of Business, (2015) <https://www.tandfonline.com/doi/full/10.1080/13571516.2015.1045741>.

²²⁴ Visante, *Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers*, Prepared for Pharmaceutical Care Management Association (PCMA), (2016), <https://www.pcmanet.org/wp-content/uploads/2016/08/visante-pbm-savings-feb-2016.pdf>.

²²⁵ Casey B. Mulligan, *The Value of Pharmacy Benefit Management*, NBER Working Paper Series, Working Paper 30231, (2022), https://www.nber.org/system/files/working_papers/w30231/w30231.pdf.

²²⁶ Casey B. Mulligan, *The Value of Pharmacy Benefit Management*, NBER Working Paper Series, Working Paper 30231, (2022), https://www.nber.org/system/files/working_papers/w30231/w30231.pdf.

²²⁷ Casey B. Mulligan, *The Value of Pharmacy Benefit Management*, NBER Working Paper Series, Working Paper 30231, (2022), https://www.nber.org/system/files/working_papers/w30231/w30231.pdf.

²²⁸ U.S. Department of Labor, Office of Inspector General-Office of Audit, *Report to the Office of Workers' Compensation Programs, OWCP Did Not Ensure Best Prices and Allowed Inappropriate Potentially Lethal Prescriptions in The FECA Program*, (2023), <https://www.oig.dol.gov/public/reports/oa/2023/03-23-001-04-431.pdf>.

²²⁹ Ike Brannon & Anthony L. Sasso, *The Myth That the State Can Do It Better: Hepatitis C Drug Centralized Pharmaceutical Purchasing Versus Pharmacy Benefit Managers*, (2021), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3852446.

²³⁰ Navigant, *Pharmacy Savings Report: West Virginia Medicaid, Actuarial Assessment of the SFY18 Impact of Carving out Prescription Drugs from Managed Care for West Virginia's Medicaid Program*, (February 25, 2019), <https://dhhr.wv.gov/bms/News/Documents/WV%20BMS%20Rx%20Savings%20Final%20Report%202019-02-25.pdf>.

However, later that year, America's Health Insurance Plans (AHIP) commissioned a review of that West Virginia study, which argued the projection was overstated, as the actual savings accounted for less than five percent of MCO administrative expenses, totaling approximately \$9 million. The AHIP report found that, between April 2016 and June 2017, the use of generics declined by 0.6 percentage points (from 86.5 percent to 85.9 percent) resulting in a 12.5 percent increase in the cost per prescription. It also argued that while some administrative costs would be eliminated under a pharmacy carve-out, such as the need for a Medicaid pharmacy director and fewer provider calls related to the prescription drug benefit, these savings were minimal, amounting to only two to three percent of overall administrative costs. The carve-out model also introduced new costs for West Virginia as the health plan would still need to obtain and manage prescription drug data for patient care coordination. Additionally, under the carve-out model, MCOs no longer receive this data in the format they use, but instead according to the State's required transmission format. Adapting to this format may require modifying the data system, which would add to the administrative costs. As a result, the AHIP report argued that cost increases associated with the carve-out model outweighed the savings, leading to an additional \$18 million in annual Medicaid spending.²³¹

8.2. Research Finding That PBM Business Practices Lead to Higher Prescription Drug Costs

Other sources suggest that PBM business practices may lead to higher prescription drug costs for employers, health plans, participants, and pharmacies. For instance, a 2024 investigation by the New York Times found that PBMs pushed patients toward higher out-of-pocket costs, marked up low-cost prescription drugs excessively, and drove local pharmacies out of business. The investigation also found that PBMs restricted access to prescriptions by requiring patients to use their own mail-order or specialty pharmacies, even when a local pharmacy could have filled the prescription more quickly, resulting in a delay in treatment. The investigation

provided an example of one PBM that overcharged the State employee health plan in Oklahoma by more than \$120,000 annually for a cancer drug, charging the plan \$138,000 annually for a prescription drug that the patient could purchase online for \$14,000.²³²

The 2024 investigation discussed several PBM practices which ultimately contribute to higher prescription drug costs. First, PBM's demand for increasing discounts or rebates from drug manufacturers for a drug's formulary placement may raise prescription drug list prices as drug manufacturers attempt to maintain their profit margins. This can result in higher out-of-pocket costs for patients, particularly if their copay is a percentage of the list price. Additionally, this can lead to PBMs diverting patients toward brand-name prescription drugs, whose higher list prices result in greater rebates, rather than generic alternatives. However, these higher list prices can also lead to increased out-of-pocket costs for patients. Furthermore, PBMs influence the prescription cost options available to employers, who often select plans based on perceived cost savings. The cost controls that PBMs market to employers to reduce premiums or plan expenditures, however, can result in higher out-of-pocket costs for employees due to less favorable copayments or coinsurance.²³³

The U.S. Senate Committee on Finance considered the role of PBM rebates in its investigation on the cost of insulin and the role of PBMs and manufacturers in 2019. The Committee found insulin prices rose between 33 and 70 percent between 2014 and 2019, driven by both manufacturer pricing strategies and PBM practices. Manufacturers raised their WAC or list prices, repeatedly, often in tandem with competitors, without improvement in drug efficacy. Meanwhile, the three largest PBMs accepted generous rebates that were tied to these higher list prices, leveraging formulary exclusions to pressure manufacturers into offering large rebates in exchange for formulary placement.

Manufacturers maintained or raised list prices to ensure PBM rebates and protect their products' formulary

placement, resulting in dramatic increases in rebates for insulin prescriptions during that period. Examining the growth by specific manufacturers, the Committee reported that Sanofi's rebates increased by approximately 50 percent between 2013 and 2018, and Novo Nordisk's rebates increased by approximately 20 percent between 2014 and 2017. The Committee concluded that PBM contracting did little to control insulin pricing, and in many cases, made the problem worse.²³⁴

These findings were corroborated by a 2021 cross-sectional study which found that while average list prices for 32 insulin products increased by over 40 percent between 2014 and 2018, the average net prices received by manufacturers fell 31 percent. Moreover, while the share of insulin expenditures accruing to manufacturers and health plans fell respectively by one-third and one-quarter in that time period, the share of insulin expenditures retained by pharmacies increased by 229 percent, the share retained by PBMs increased 155 percent, and the share retained by wholesalers increased by 75 percent.²³⁵

Furthermore, a Delaware State auditor report examined the PBM Express Scripts' management of State employee prescription drug plans between 2018 and 2020 and found that administrative fees, spread pricing, and direct pharmacy fees led to \$24.5 million in excess costs. During this period, the average cost per prescription under the State plan increased by 14.3 percent, which was nearly triple the national drug inflation rate of 4.7 percent. Despite using a pass-through pricing model, Express Scripts charged the State over \$104 million in administrative fees, averaging \$21.05 per claim or nearly 13 percent of total claim costs. The report also highlighted that, in a sample from one independent pharmacy, Express Scripts paid nothing to the pharmacy for the 9,255 claims (39 percent of the sample), while still billing the State plan a total of \$109,504 for those claims. In many of these instances, the employees' copayments appeared to cover the cost of the drug, raising

²³⁴ U.S. Senate Committee on Finance, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug*, (2021), <https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf>.

²³⁵ Van Nuys K, Ribero R, Ryan M, Sood N. Estimation of the Share of Net Expenditures on Insulin Captured by US Manufacturers, Wholesalers, Pharmacy Benefit Managers, Pharmacies, and Health Plans From 2014 to 2018. *JAMA Health Forum*. 2021;2(11):e213409. Published 2021 Nov 5. doi:10.1001/jamahealthforum.2021.3409 <https://pubmed.ncbi.nlm.nih.gov/35977268/>.

²³¹ The Menges Group, *Assessment of Report on Impacts of West Virginia Medicaid Prescription Drug Carve-Out, Prepared for America's Health Insurance Plans*, (April 2019), https://themengessgroup.com/wp-content/uploads/2022/06/assessment_of_study_of_wv_rx_carve-out_impacts_april_2019.pdf.

²³² Rebecca Robbins & Reed Abelson, *The Opaque Industry Secretly Inflating Prices for Prescription Drugs*, The New York Times (2024), <https://www.nytimes.com/2024/06/21/business/prescription-drug-costs-pbm.html>.

²³³ Rebecca Robbins & Reed Abelson, *The Opaque Industry Secretly Inflating Prices for Prescription Drugs*, The New York Times (2024), <https://www.nytimes.com/2024/06/21/business/prescription-drug-costs-pbm.html>.

concerns that the PBM retained 100 percent of the amount billed as profit.²³⁶

9. Research on How PBM Disclosures Impact Prescription Drug Costs

Prior to 2023, the FTC had issued several advocacy letters and studies that had opposed greater PBM transparency and disclosure requirements, arguing that such disclosures could undermine competitive processes. However, the FTC reversed this position in 2023 and withdrew those letters and studies, cautioning that horizontal and vertical integration in the industry along with other practices meant that their prior materials may not reflect current market dynamics.²³⁷ This withdrawal underscores the need to assess how PBM disclosures affect the pharmaceutical market. Some studies suggest that PBM disclosures can lower prescription drug costs by improving the negotiation leverage of responsible plan fiduciaries, whereas other studies find that they may inadvertently increase costs by reducing competition among PBMs, pharmacies, and manufacturers. In contrast, other studies find that the effects of PBM disclosures vary depending on market conditions. These studies are discussed in greater detail below.

9.1. Research Finding That PBM Disclosures Lowers Prescription Drug Cost

Some studies have found that PBM disclosures may help reduce prescription drug costs. For example, in October 2024, CBO analyzed various approaches to reducing prescription drug prices, including price transparency. CBO estimated that requiring PBMs to share their prescription drug price information with health issuers would reduce prescription drug prices by 0.1 percent to 1.0 percent. CBO noted that increased transparency would help some PBM clients, particularly smaller plans, negotiate better contract terms. These plan sponsors often have limited access to pricing information, and such disclosure requirements would improve their bargaining position. However, CBO indicated that the overall impact of

these disclosures would be limited, as many existing contracts between PBMs and plan sponsors in the private health insurance market already include provisions for information sharing, suggesting a significant portion of the insured market would remain unaffected.²³⁸ The self-insured and level-funded plans covered in these proposed rules are not subject to state disclosure laws and thus the proposed rule could have a bigger impact than CBO's estimates.

Similarly, in December 2024, CBO estimated the budgetary effects of a bill, the *Pharmacy Benefit Manager Reform Act*, which would require PBMs to annually report detailed information to plan sponsors about their services, though disclosures to plans sponsors for businesses with fewer than 50 employees would be more limited.²³⁹ The bill would also ban spread pricing and require PBMs and their affiliates to pass 100 percent of the rebates, fees, discounts, or other remuneration received from pharmaceutical manufacturers, distributors, or other third parties related to use of prescription drugs by plan enrollees to plan sponsors.

CBO estimated that this bill could reduce net retail prescription drug costs by more than 0.5 percent in the first full year of implementation, which could lower average premiums for employment-based health insurance by less than 0.1 percent in the first year, compared to what they would be under current law. CBO estimated that the effect on premiums would diminish over time, reaching less than 0.01 percent by 2034 as PBMs employ new ways to generate revenue outside of the disclosure requirements. However, this does not imply that premiums would decline; rather, premiums are still expected to increase, but at a slower rate than they would have otherwise.²⁴⁰ As the proposed rule does not prohibit spread pricing or require that PBMs pass on 100 percent of rebates, fees, or discounts that they receive from manufacturers, the Department believes that PBMs may not need to offset these revenue sources and that the impacts of the proposed rule would not diminish to the extent that CBO had estimated for

the *Pharmacy Benefit Manager Reform Act*. The Department discusses the possibility of the proposed rule's impact diminishing over time in the Uncertainty Section of this regulatory analysis.

9.2. Research Finding That PBM Disclosures Increases Prescription Drug Cost

Other studies have found that PBM disclosures may increase prescription drug costs. For instance, a 2023 industry paper commissioned by PCMA, analyzed the impact of disclosure requirements, such as the *PBM Transparency Act of 2023*,²⁴¹ on competition among PBMs, manufacturers, and pharmacies. The paper argues that disclosure requirements could increase prescription drug prices by reducing competition across these groups. By requiring manufacturers to disclose pricing details, the author contends that manufacturers may hesitate to offer significant discounts, fearing competitors will mimic their pricing strategies. This can lead to implicit price coordination, where manufacturers keep prices higher to avoid undercutting each other, resulting in a potential cost of up to \$26.9 billion.²⁴²

This phenomenon is documented in the 2021 Senate Finance Committee Report, which found that PBMs' negotiations with insulin manufacturers, including the use of formulary exclusions, encouraged manufacturers to rapidly increase their list price in parallel with competitors. This practice, known as "shadow pricing," occurs when one manufacturer closely follows another's price increase to remain competitive for preferred formulary placement. This approach enables manufacturers to provide large rebates and maintain market access.²⁴³ The 2023 industry paper further argues that disclosures could increase costs of pharmacies by \$8.0 billion and PBMs by as much as \$48.0 billion if tax distortion

²³⁶ State of Delaware, Office of Auditor of Accounts, *Lack of Transparency & Accountability in Drug Pricing Could be Costing Taxpayers Millions*, (2021), https://auditor.delaware.gov/wp-content/uploads/sites/40/2021/06/RPT_PBM_061721_FINAL.pdf.

²³⁷ Federal Trade Commission, *Federal Trade Commission Statement Concerning Reliance on Prior PBM-Related Advocacy Statements and Reports That No Longer Reflect Current Market Realities*, (July 18, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/CLEANPBMSStatement7182023%28OPPFinalRevisionsnoon%29.pdf.

²³⁸ Congressional Budget Office, *Alternative Approaches to Reducing Prescription Drug Prices*, (2024), <https://www.cbo.gov/system/files/2024-10/58793-rx-drug-prices.pdf>.

²³⁹ S. 1339—*Pharmacy Benefit Manager Reform Act*, 118th Congress (2023–2024), <https://www.congress.gov/bill/118th-congress/senate-bill/1339>.

²⁴⁰ Congressional Budget Office, *Cost Estimate of S. 1339 Pharmacy Benefits Manager Reform Act*, (2024), <https://www.cbo.gov/system/files/2024-12/s1339.pdf>.

²⁴¹ S.127—*Pharmacy Benefit Manager Transparency Act of 2023*, 118th Congress (2023–2024), <https://www.congress.gov/bill/118th-congress/senate-bill/127>.

²⁴² Casey B. Mulligan, *Restrict the Middleman? Quantitative Models of PBM Regulations and Their Consequences*, (2023), No. w30998. National Bureau of Economic Research, https://www.nber.org/system/files/working_papers/w30998/w30998.pdf.

²⁴³ U.S. Senate Committee on Finance, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug*, (2021), <https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf>.

from rebates or discounts applied at the point of sale are included.²⁴⁴

However, as mentioned above, while the FTC issued 11 advocacy letters and reports prior to 2015 which argued that certain State and Federal proposals to increase PBM transparency could undermine competitive processes, the FTC issued a statement withdrawing this stance in 2023. In the statement, the FTC cautioned against reliance on those letters as they may no longer reflect current market realities, raising “its concerns about how PBMs may be using market power to undermine competition from independent pharmacies, and its concerns about the role of PBMs in determining the prices consumers pay for prescription drugs, including the impact of PBM rebates.”²⁴⁵

9.3. Research Finding That PBM Disclosures Have Mixed Impact on Prescription Drug Costs

In contrast, some research finds mixed results regarding PBM disclosures on prescription drug costs and other aspects of the market. Scanlon (2024) used outpatient prescription drug claims data for chronic conditions of employer-sponsored health plans from 2014 to 2022 to examine two types of State-level PBM disclosures: inter-firm disclosures²⁴⁶ and disclosures to regulators.²⁴⁷ Focusing on disclosures related to rebate/pricing information, the paper found that the impact of inter-firm disclosures, those most like the ones contemplated in this rulemaking increased prescription drug costs for plans (the plan’s share of the gross price for the prescription as negotiated between the health plan and PBM, after factoring in fee schedules and discounts) by 3.5 percent, but reduced out-of-pocket costs for participants (the

sum of the copayment and coinsurance) by 1 percent.²⁴⁸

However, the impact of inter-firm disclosures varied by the competitiveness of the drug market. In competitive markets, the disclosures increased costs to plans while the impact on participants was insignificant. Alternatively, in monopoly drug markets, there was no significant impact on plans while patient costs significantly declined. The author argues this was because in competitive markets, disclosing price information reduces competition between drug manufacturers which increased gross prices and the plans’ total costs; in a monopoly market, disclosures reduced information asymmetry and strengthened health plans’ bargaining power, resulting in a 9.4 percent decrease in out-of-pocket costs for these drugs. Additionally, States that required PBMs to disclose to pharmacies the sources used to determine MAC prices and update the information regularly, had 8.6 percent more pharmacies per capita and 10 percent more independent pharmacies overall than States that did not require those disclosures, improving patient access.²⁴⁹

The author concluded that inter-firm disclosures increase costs for plans but lower them for participants. This effect depended on the competitiveness of the drug market. For monopoly drugs, inter-firm disclosures resulted in more efficient contracting, which led to lower drug costs. When applied to more competitive markets, however, the disclosures discouraged competition among drug manufacturers. As a result, the author advocated for utilizing PBM disclosures in monopoly drug markets. The Department notes that the study was limited to actual amounts paid by plans and participants per prescription, and did not account for rebates and other incentive payments to health plans that may have been applied later. As a result, the negative impact on plan costs of inter-firm disclosures may be overstated.²⁵⁰

10. Benefits and Transfers

The Department expects that the proposed rule, if finalized, would improve transparency in PBM operations, as directed by Executive Order 14273.²⁵¹ The proposed rule is expected to assist responsible plan fiduciaries in their selection and monitoring of service providers providing prescription drugs, and to foster a more efficient and competitive prescription drug market. These improvements are anticipated to generate the following economic and societal effects experienced by participants, beneficiaries, enrollees, and the broader healthcare system:

- improved understanding of PBMs by self-insured group health plans’ responsible plan fiduciaries,
- greater ability for responsible plan fiduciaries to compare offerings across PBMs, fostering competition and improving pricing,
- stronger negotiating positions for responsible plan fiduciaries, enabling better contractual terms with PBMs,
- reduced conflicts of interest that currently influence PBMs’ key decisions regarding rebates, formulary design, and prescription drug pricing,
- reduced prescription costs for self-insured group health plans and participants,
- improved patient health outcomes due to increased treatment adherence from better access to more affordable prescription drugs,
- reduced costs to self-insured group plans and employers, allowing them to shift resources to other benefits or priorities.

This analysis provides a mainly qualitative discussion of the benefits and transfer impacts of the proposed rule and discusses how the proposed rule would enable self-insured group health plans, participants, and other stakeholders to better utilize the information provided by PBM disclosures.²⁵² It also includes a quantitative analysis on lowered negotiating costs to self-insured group health plans and plan sponsors and reduced prescription drug costs for self-insured group health plans and participants. Finally, it includes two alternative approaches, Quality Adjusted Life Years (QALY) and Willingness-to-Pay (WTP) to quantify the benefits from decreasing prices. The

²⁴⁴ Casey B. Mulligan, *Restrict the Middleman? Quantitative Models of PBM Regulations and Their Consequences*, (2023), No. w30998. National Bureau of Economic Research, https://www.nber.org/system/files/working_papers/w30998/w30998.pdf.

²⁴⁵ Federal Trade Commission, Statement Concerning Reliance on Prior PBM-Related Advocacy Statements and Reports that No Longer Reflect Current Market Realities, (July 20, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/CLEANPBMStatement7182023%28OPPFinalRevisionsnoon%29.pdf

²⁴⁶ “Inter-firm disclosures” are defined as disclosures where PBMs share pricing information with health plans, pharmacies, and drug manufacturers. As referred to in this paper, “health plans” include health insurance issuers.

²⁴⁷ “Disclosures to regulators” are defined as disclosures where PBMs report pricing details to government authorities. These included state regulations related to auditing, pharmacy networks and fiduciary duties.

²⁴⁸ Ginger Scanlon, *Prescription for Savings? Disclosure in the Drug Market*, (December 20, 2024), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5021179.

²⁴⁹ Ginger Scanlon, *Prescription for Savings? Disclosure in the Drug Market*, (December 20, 2024), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5021179.

²⁵⁰ The author utilizes the MarketScan prescription claim database for her analysis, which reports actual payment amounts paid by health plans and patients per prescription. The database does not include information on net costs to plans, meaning that rebates or other forms of incentive payments that may later offset costs to plans were not captured.

²⁵¹ 90 FR 16441, *Lowering Drug Prices by Once Again Putting Americans First*, (April 15, 2025), <https://www.govinfo.gov/content/pkg/FR-2025-04-18/pdf/2025-06837.pdf>.

²⁵² If the various mechanisms and outcomes discussed above could be quantified and were then summed simplistically, the result would almost certainly include double-counting.

QALY approach is a quantitative analysis of the behavioral impacts of reduced out-of-pocket costs for three therapeutic classes resulting in improved adherence and health, and lowered utilization costs. While this quantitative analysis is only for a small subset of the prescription drug market impacted by this proposed rule, it is illustrative of the potential downstream benefits of this rulemaking on all therapeutic classes. The WTP approach more directly measures welfare improvements for patients from increasing consumption of their prescribed medications as prices decrease. The Department invites comments and data related to how it might quantify these benefits as part of the proposed rule, and which approach is more appropriate for this analysis and available data.

10.1. Benefits and Transfers to Self-Insured Group Health Plans

10.1.1. Improved Understanding of PBMs by Plans

PBM disclosures would provide self-insured group health plans with greater insight into previously hidden fees, rebates, and discounts, as well as potential conflicts, which would lead to a better understanding of PBM costs and practices. For example, these disclosures would reveal to self-insured group health plans how much of the negotiated rebates are retained by PBMs and their agents, versus being passed through to self-insured group health plans, participants, and beneficiaries, enabling them to accurately assess the true costs of pharmacy benefits and if they are reasonable. Self-insured group health plans would be able to compare the prices they were charged for pharmacy claims to the reimbursement rates pharmacies received from PBMs through “spread pricing,” and how much participants and beneficiaries paid at the point of sale through copays and coinsurance. This would allow self-insured group health plans to calculate how much the PBMs collected from each transaction. As a result, self-insured group health plans would more easily be able to monitor PBMs and the indirect fees they charge.

10.1.2. Increased PBM Market Place Competition and Self-Insured Group Health Plans Negotiating Better Contractual Terms

Increased transparency into compensation arrangements would help self-insured group health plans better assess costs across different PBM providers, leading to more informed decision-making when selecting a PBM,

increasing competition, and allowing self-insured group health plans to negotiate better contract terms.²⁵³ Requiring PBMs to disclose pricing structures, discounts, and rebates reasonably in advance of entering into a contract or arrangement with a self-insured or level-funded group health plan will help responsible plan fiduciaries determine the reasonableness of the proposed fees, including all direct and indirect compensation. Moreover, these disclosures could limit PBMs’ ability to engage in spread pricing or accept undisclosed rebates, helping to ensure that formulary and reimbursement decisions better reflect clinical value and affordability.²⁵⁴

When evaluating the potential impact of a bill requiring additional transparency by PBMs related to utilization and direct and indirect compensation (as well as banning spread pricing and requiring pass-through rebates), CBO estimated only minimal cost savings, with premiums reduced by 0.1 percent in its first year and those savings eroding over time.²⁵⁵ In their analysis, CBO stated that they also expected a portion of PBM clients, particularly sponsors of small- and medium-sized health plans, who had limited access to this information under current law, to obtain better terms in contract negotiations following these disclosures. The additional pressure from responsible plan fiduciaries coupled with more transparent pricing could lead to new entries in the PBM market, including pass-through and fee-based models, and could result in market-wide changes in pricing behavior. CBO did not, however, estimate these second-order effects.

Furthermore, a 2024 survey aimed to gauge U.S. employers’ perspectives on various factors, including PBM transparency and premiums, among private and public employers. The findings indicated that employers who used transparent PBMs were 1.6 times more likely to report lower premiums (42 percent compared to 27 percent) and 30 percent less likely to report higher

premiums (29 percent compared to 41 percent) than those utilizing the three largest PBMs.²⁵⁶

Additionally, by requiring disclosures that clearly define contract terms, responsible plan fiduciaries can better assess potential cost levers when evaluating proposals. Currently, PBMs may provide their own definitions for brand, generic and specialty drugs. In doing so, PBMs can change a drug’s classification to meet contracted guarantees or maximize their own fees. This can allow PBMs to classify certain prescription drugs as “specialty” drugs to justify higher markups or cost-sharing requirements.²⁵⁷ By requiring PBMs to disclose spread pricing at the individual drug and pharmacy channel level, how formulary placement incentives and arrangements affect services, and reasons why any reasonably available therapeutic equivalent alternative drugs were omitted from the formulary, responsible plan fiduciaries can attain more appropriate formulary placement, more equitable patient cost-sharing, and broaden access to prescription drugs that have been previously miscategorized, which could result in reduced prescription drug spending for self-insured group health plans and lower out-of-pocket costs for participants.

Similarly, definitions of rebates and discounts can be manipulated by PBMs to exclude “other” indirect payments in order to avoid contractual pass-through payments. This can be particularly problematic when PBMs contract with an affiliated service provider that can in turn influence how acquisition costs or rebates are defined, allowing gaming of contracts.²⁵⁸ By clarifying these terms prior to entering agreements, responsible plan fiduciaries can negotiate better contract terms. A 2024 survey found that 33 percent of employers had lower than average premiums following the adoption of more comprehensive definitions of the term “rebate” to include other revenue

²⁵³ Matthew Fiedler, Loren Adler, & Richard G. Frank, *A Brief Look at Current Debates About Pharmacy Benefit Managers*, The Brookings Institution (2023), <https://www.brookings.edu/articles/a-brief-look-at-current-debates-about-pharmacy-benefit-managers/>.

²⁵⁴ National Alliance of Healthcare Purchaser Coalitions, *A Playbook for Employers: Addressing Pharmacy Benefit Management Misalignment*, (2023) https://www.nationalalliancehealth.org/wp-content/uploads/NationalAlliance_PBM_PB_2023_A.pdf.

²⁵⁵ Congressional Budget Office, S. 1339, *Pharmacy Benefit Manager Reform Act*, (2024), <https://www.cbo.gov/system/files/2024-12/s1339.pdf>.

²⁵⁶ National Alliance of Healthcare Purchaser Coalitions, *Pulse of the Purchaser 2025 Survey Results*, (September 8, 2025), <https://www.nationalalliancehealth.org/resources/pulse-of-the-purchaser-2025-survey-results/>.

²⁵⁷ FTC, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies*, (2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

²⁵⁸ National Alliance of Healthcare Purchaser Coalitions, *A Playbook for Employers: Addressing Pharmacy Benefit Management Misalignment*, (2023), https://www.nationalalliancehealth.org/wp-content/uploads/NationalAlliance_PBM_PB_2023_A.pdf.

streams, such as access fees and credits in their contracts.²⁵⁹

The additional transparency and clarified terms can also reduce the complexity and scope of comparing proposals and contract negotiations, further reducing costs for self-insured group health plans. By removing the need for self-insured group health plans to independently verify price models, rebates, and fee structures, the required disclosures would limit search costs and reduce the resources needed to select a PBM and prepare for contract negotiations. Even a modest reduction in preparation costs, such as a one-hour reduction in the time for a legal professional to prepare for negotiations, could result in estimated cost savings of approximately \$69.4 million across the 383,528 impacted level-funded and self-insured group health plans that are expected to initiate new contracts, extend existing contracts, or renew contracts each year.²⁶⁰

By obtaining disclosures in advance of finalizing the contract, responsible plan fiduciaries can identify problematic provisions and negotiate modifications with the PBMs. For example, this allows responsible plan fiduciaries to negotiate the removal of certain contractual terms that may limit the fiduciary from obtaining data related to prescription drugs, and negotiate for stronger audit rights in order to verify claim accuracy, monitor the PBMs' performance, and ensure contract compliance.²⁶¹ As a result, increased transparency could foster greater competition within the market, leading to more competition, lower prices and improved contract terms, as well as better value and lower health-care costs for self-insured group health plans and their participants and beneficiaries. The resulting savings could in turn allow self-insured group health plans, employers, and plan sponsors to invest those resources elsewhere.²⁶² The

Department requests comments on these assumptions.

10.1.3. Reduced Conflicts of Interest in PBM Practices

Greater transparency in PBM operations could help reduce the conflicts of interest that influence PBMs' key decisions regarding rebates, formulary design, and reimbursement rates. Currently, PBMs often have significant existing relationships with consultants, manufacturers, rebate aggregators, and pharmacies which can circumvent claims of transparency in pricing. Even consultants advising plans on the selection of PBMs and the structure of their contracts may receive payments from PBMs based on the number of prescriptions or the number of covered employees, which may well influence their recommendations to plans.²⁶³ Employers that receive confirmation that advisors do not receive direct or indirect compensation from PBMs or related third parties reported reduced annual premiums.²⁶⁴

Even with pass-through pricing enshrined in PBM contracts, without disclosures detailing existing relationships, these agreements can be compromised if PBMs subcontract with affiliated service providers. PBMs may structure preferred pharmacy networks so that patients are directed or are required to fill prescriptions at PBM-affiliated pharmacies, which are then reimbursed at a greater rate than independent pharmacies.²⁶⁵ In contrast, requiring full disclosures of all revenue streams with affiliated pharmacy-related entities can result in reduced premiums.²⁶⁶ PBMs may also utilize rebate aggregators to negotiate and collect rebates from drug manufacturers, whose extracted fees have been estimated to have doubled between 2018 and 2022. PBMs that use affiliated rebate aggregators can reduce the rebate that would be passed through to plans while retaining the rebate portion

collected by the rebate aggregators if that relationship is not disclosed and addressed in the contract, resulting in higher plan costs.²⁶⁷

By requiring PBMs to disclose these relationships prior to entering into a formal agreement, the rule enables responsible plan fiduciaries to better evaluate whether there are sufficient mechanisms in place to ensure that those relationships do not adversely impact the self-insured group health plan and its participants and beneficiaries. Moreover, receiving updated information over the course of the contract will allow responsible plan fiduciaries to continue to monitor these relationships so that PBMs continue to perform their function without subordinating plan interests. As such, the proposed rule will help to reduce conflicts and mitigate the risks that arise from them, resulting in more efficient and cost-effective pharmacy benefits for self-insured group health plans, including the replacement of more expensive drugs with cheaper, yet equally effective alternatives on the formularies.

10.2. Benefits and Transfers to Participants and Beneficiaries

10.2.1. Reduced Prescription Payments for Participants and Beneficiaries

The Department believes that increased transparency from PBM disclosures will reduce prescription prices, resulting in a transfer, by correcting pricing distortions that currently inflate the prices that participants and beneficiaries face for prescription drugs. By highlighting preferential pricing for certain drugs and distribution channels, disclosures may result in self-insured group health plans retaining greater rebate shares, increasing the use of generics and biosimilars, and promoting less expensive pharmacy networks. This can result in cost savings for self-insured group health plans, which may share these cost savings with plan participants through reduced premium payments, as well as lower out-of-pocket costs that participants and beneficiaries face when filling their prescriptions.

Manufacturers factor rebates into their bottom line, which incentivizes them to increase list prices of covered drugs in order to protect their net prices. As a result, patients may pay cost-sharing based on the drug's list price, even

²⁵⁹ National Alliance of Healthcare Purchaser Coalitions, *Pulse of the Purchasers: 2024 Survey Reports*, (2024), <https://www.nationalalliancehealth.org/wp-content/uploads/Pulse-of-the-Purchaser-Fall-2024.pdf>. It is important to note that 9 percent of respondents reported high premiums following adoption of enhanced definitions of rebates.

²⁶⁰ This estimate is calculated as: 1,150,583 level-funded and self-insured group health plans $\times$ 1/3 of plans contracts with PBMs expiring annually = 383,528 level-funded and self-insured group health plans negotiating contracts annually $\times$ \$181.06 hourly wage of legal professional $\times$ 1 hour = \$69,441,580.

²⁶¹ Remy Samuels, *PLANSponsor Roadmap: A PBM Process*, (April 21, 2025) <https://www.plansponsor.com/plansponsor-roadmap-a-pbm-process/>.

²⁶² See discussion of the exclusive purpose rule in ERISA section 403(c), *supra* note.

²⁶³ Advisory Council of Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure*, (November 2014), <https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/about-us/erisa-advisory-council/2014-pbm-compensation-and-fee-disclosure.pdf>.

²⁶⁴ National Alliance of Healthcare Purchaser Coalitions, *Pulse of the Purchasers: 2024 Survey Reports*, (2024), <https://www.nationalalliancehealth.org/wp-content/uploads/Pulse-of-the-Purchaser-Fall-2024.pdf>.

²⁶⁵ U.S. House Committee on Oversight and Accountability, *The Role of Pharmacy Benefit Managers in Prescription Drug Markets*, (2024), <https://oversight.house.gov/wp-content/uploads/2024/07/PBM-Report-FINAL-with-Redactions.pdf>.

²⁶⁶ National Alliance of Healthcare Purchaser Coalitions, *Pulse of the Purchasers: 2024 Survey Reports*, (2024), <https://www.nationalalliancehealth.org/wp-content/uploads/Pulse-of-the-Purchaser-Fall-2024.pdf>.

²⁶⁷ Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies*, (2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

though the net price after rebates is substantially lower.²⁶⁸

A 2023 U.S. Senate Finance Committee hearing further discussed that rebate-driven models reward manufacturers with greater volume and market share, making it difficult for lower-cost or new competitors to gain formulary access. Existing manufacturers can offer large rebates by leveraging their sales volume or by bundling multiple drugs into a single rebate agreement. These arrangements can effectively exclude competitors that cannot match the financial value of rebates, even if they offer lower-price alternatives. The Committee characterized this dynamic as the “rebate trap,” in which rebates contribute to higher list prices, particularly for brand-name and specialty drugs. This dynamic reinforces market concentration and limits price competition, ultimately contributing to higher costs for self-insured group health plans and patients.²⁶⁹

As the prescription drug market becomes more transparent through the proposed disclosures, it may discourage PBM practices that favor high-rebate drugs over lower-cost drug alternatives. This shift could support more cost-effective and clinically driven formulary design. Moreover, PBMs may also pass through a greater share of the rebates to self-insured group health plans, ultimately helping to reduce prescription costs, particularly for specialty and brand-name drugs where rebate amounts tend to be the highest.²⁷⁰ This, coupled with cost reductions stemming from improved contract negotiations related to spread pricing, copay claw-backs, and pharmacy reimbursement, may result in lower costs to participants and beneficiaries at the point of sale. Such reductions resulting from these disclosures would be particularly meaningful for individuals who heavily rely on prescription medication or who manage chronic health conditions, where even modest price differences can lead to substantial savings over

time, and result in improved adherence to treatment plans.

Research from CBO on disclosures from PBMs to health plans estimated that requiring PBMs to share their drug price information with health issuers would lower the average net retail price of prescription drugs, approximately 0.1 percent to 1.0 percent.²⁷¹ Data from IQVIA indicates that expenditures for all prescription drugs from patients and issuers, less any rebates, totaled approximately \$667.0 billion in 2022.²⁷² The Department estimates that level-funded and self-insured group health plans account for approximately 16 percent, or \$108.8 billion, of these expenditures.²⁷³ Utilizing the CBO estimates for price reductions arising from PBM disclosures, the Department estimates that expenditures from patients and issuers will decline, producing a transfer ranging from approximately \$108.8 million and \$1.1 billion annually for the 57.3 million participants with a prescription in the 1.1 million level-funded and self-insured group health plans covered by the proposed rule.²⁷⁴ Because the policy estimated by CBO, however, is limited to only price disclosures and does not include information on conflicts of interest, audit rights and other additional elements of the proposed rule, this range of estimates may understate the impact of the proposed rule on prices. Given the mixed results in the literature reviewed above, however, the quantitative range may also overstate the impact (and may even inappropriately omit any quantification of transfers potentially flowing the opposite direction). The Department requests comments on these assumptions.

²⁷¹ Congressional Budget Office, *Alternative Approaches to Reducing Prescription Drug Prices*, (2024), <https://www.cbo.gov/system/files/2024-10/58793-rx-drug-prices.pdf>.

²⁷² IQVIA Institute, *Understanding the Use of Medicines in the U.S., 2025: Evolving Standards of Care, Patient Access, and Spending*, (2025), <https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/understanding-the-use-of-medicines-in-the-us-2025>.

²⁷³ This estimate is calculated as: 89,400,000 participants in level-funded and self-insured group plans x 6.72 average prescription fills annually = 600,768,000 prescriptions for participants in level-funded and self-insured group plans. 600,768,000 total prescriptions x \$181.15 total average patient out-of-pocket and insurer expenditure per prescription = \$108,831,984,000. This represents 16.3 percent of \$667,000,000,000 total annual prescription expenditures. (Source: 2022 Medical Expenditure Panel Survey, Agency for Healthcare Research and Quality, Department of Health and Human Services, (2024).)

²⁷⁴ These estimates are calculated as: \$108,831,984,000 x 1.00 percent = \$1,088,319,840. Additionally, \$108,831,984,000 x 0.10 percent = \$108,831,984.

10.2.2. Quantified Benefits

The Department, in estimating the benefits under the proposed rule, considered two approaches: WTP and QALY. These approaches differ both in their approach and in what they measure. In simplistic terms, WTP measures the amount consumers are willing and able to pay to acquire a good or service based on the consumer's utility function; in the cases relevant to this analysis, most payment flows through issuers. QALY, alternatively, quantifies the value of a health intervention in terms of the duration of quality of life, which is estimated by multiplying the amount of time an individual spends in a health state by a standardized measure of their health-related quality of life associated with that state.

There are advantages and limitations to both approaches. WTP is thought to better capture the value of welfare changes when compared to QALY, since it values non-health utility (such as income and risk) in addition to health-related welfare changes.²⁷⁵ WTP also benefits from having less restrictive assumptions.²⁷⁶ For example, QALY's are assumed to be equally valued and a constant proportional tradeoff between health states and longevity is also assumed. However, morbidity risks are diverse, differing in duration and severity as well as in the attributes of health that are affected (e.g., physical or cognitive functioning). Because high quality WTP estimates are not available for many morbidity risks, they often require the use of proxy measures, such as QALYs.²⁷⁷

While the WTP approach is attractive in that it considers the full universe of conditions that self-insured group health plan participants with prescriptions face, the Department is concerned that there is tremendous variability in the impact of drug use by condition, and that generalizing across the entire population fails to capture the significant health benefits of improved drug adherence for certain chronic conditions. The WTP approach could be implemented in a more tailored manner

²⁷⁵ Mohan V. Bala, Lisa L. Wood, Gary A. Zarkin, Edward C. Norton, Amiram Gafni, and Bernie O'Brien, *Valuing Outcomes in Health Care: A Comparison of Willingness to Pay and Quality-Adjusted Life-Years*, *J Clin Epidemiol* Vol. 51, No. 8, pp. 667–676, 1998.

²⁷⁶ Mohan Bala, Lisa Wood, Gary Zarkin, Edward Norton, Amiram Gafni, and Bernie O'Brien, *Valuing Outcomes in Health Care: A Comparison of Willingness to Pay and Quality-Adjusted Life Years*, *Journal of Clinical Epidemiology*, Vol. 51, No. 8, (1998).

²⁷⁷ https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/171981/HHS_RIAGuidance.pdf.

²⁶⁸ U.S. Senate Committee on Finance, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug*, (2021), <https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf>.

²⁶⁹ United States Senate Committee on Finance, *Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayer*, (March 30, 2023), https://www.finance.senate.gov/imo/media/doc/pharmacy_benefit_managers_and_the_prescription_drug_supply_chain_impact_on_patients_and_taxpayers.pdf.

²⁷⁰ U.S. Senate Committee on Finance, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug*, (2021), <https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf>.

than what appears below if usable data is found in the future. For now, disaggregation by type of condition being treated is illustrated with the QALY approach. The Department has included estimates using both the WTP and QALY approaches in the Summary of Impact table.

It should be noted that, with both the QALY and WTP benefits approaches, the specific price change that is primarily relevant (due to its most-direct prompting of different behavior) is the change in price experienced by consumers. Scanlon (2024) finds that consumer price, including copayments and coinsurance, can change in a different direction or magnitude than price paid by health plans; however, her primary estimates of the effect of inter-firm disclosure on consumer price (entries in her columns 5 and 6 of Table 6 are used to calculate a weighted

average) yield an estimate of a reduction in the net retail price of approximately one percent.²⁷⁸ The preceding transfers-focused section discussed *overall* drug price reductions ranging from 0.1 percent up to this one percent, and the same range will be used in the benefits analyses appearing below, with most of the explanatory narrative highlighting the one-percent input.

The Department requests comments on this range of inputs and other details about the two benefits approaches.

10.2.2.1 Improved Health Outcomes Among Patients Utilizing Quality Adjusted Life Years

Table 1 presents estimates of annual benefits and transfers under a range of assumptions about reductions in average net retail prescription drug prices. The Department uses a range of estimates to reflect uncertainty regarding the magnitude of potential

price reductions. The scenarios shown in this section’s tables present calculations based on a one percent reduction in average net retail prescription drug prices. This is the high-end estimate as well as the preferred estimate of that range. The additional estimates in Table 3 are calculated in the same manner but utilizing a different estimate of price reduction. Total benefits are calculated as the sum of the monetized value of QALY’s gained through improved medication adherence and reductions in insurer health care expenditures. Transfers associated with reduced prescription drug spending are reported separately. These estimates are intended to demonstrate a potential magnitude of benefits and transfers under plausible assumptions rather than to represent a single point estimate of expected effects.

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Table 3. Benefits and Transfers under Different Assumptions about Reductions in Average Net Retail Prescription Drug Prices

Assumed Percent Decrease in Average Net Retail Rx Price	Participants Improving Adherence	Incremental QALYs	Monetized Value of QALYs (\$ million)	Reduced Insurer Health Expenditures (\$ million)	Total Benefits (\$ million)	Transfers to Participants: Reduced Rx Spending (\$ million)
(a)	(b)	(c)	(d) = (c x QALY of \$35,160)	(e)	(f) = (d) + (e)	(g) = Baseline spending (\$108.8 B) x (a)
0.1%	2,593	2,038	\$71.7	\$3.2	\$74.8	\$108.8
0.5%	12,963	10,202	\$358.7	\$15.9	\$374.6	\$544.2
1.0%	25,926	20,399	\$717.1	\$31.9	\$749.0	\$1,088.3

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The disclosures required of PBMs in the proposed rule will help to reduce information asymmetry and aid self-insured group health plans’ responsible plan fiduciaries in their selection of and negotiations with PBMs, helping to reduce costs for the self-insured group health plans and lower prescription drug prices.²⁷⁹ By reducing prescription costs, the proposed rule could improve adherence to prescribed drugs, as patients are less likely to skip or reduce doses, delay refills, or forgo treatment due to financial concerns. Improved

²⁷⁸ Ginger Scanlon, *Prescription for Savings? Disclosure in the Drug Market*, (December 20, 2024), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5021179.

²⁷⁹ Congressional Budget Office, *Alternative Approaches to Reducing Prescription Drug Prices*, (October 2024), www.cbo.gov/publication/58793.

treatment adherence supports disease management and is associated with better overall health outcomes. In the context of the proposed rule, the required disclosures could enable plan sponsors to design benefits and formularies that help reduce out-of-pocket costs and improve prescription adherence, particularly for patients at high risk of hospitalization which could ultimately improve patient health outcomes over the long term. Price sensitivity towards drug adherence is reflected in the 2023 National Health Interview Survey, which found that

²⁸⁰ Laryssa Mykyta & Robin A. Cohen, *Characteristics of Adults Aged 18–64 Who Did Not Take Medication as Prescribed to Reduce Costs: United States, 2021*, NCHS Issue Brief No. 470, (2023) <https://www.cdc.gov/nchs/data/databriefs/db470.pdf>.

approximately 6.5 percent of respondents aged 18 to 64 with private insurance reported not taking their medication as prescribed in order to save money.²⁸⁰ Results from a meta-analysis of treatment adherence studies further indicated that nearly one-fourth (24.8 percent) of patients were non-adherent to medication for various reasons.²⁸¹ This is consistent with research on prescription drug price elasticity, where increases in direct consumer costs reduce prescription fills for chronic diseases, suggesting a price elasticity of demand between –0.1 and

²⁸¹ Robin DiMatteo, *Variations in Patients Adherence to Medical Recommendations: A Quantitative Review of 50 Years of Research*, *Medical Care*, (2004), <https://pubmed.ncbi.nlm.nih.gov/15076819/>.

–0.4.²⁸² Moreover, consumers' sensitivity to prescription drug prices, as evidenced by claims data showing that more than half of high-cost prescriptions go unfilled, suggests that even small price decreases could increase access to prescription drugs for participants and beneficiaries.²⁸³ Additionally, research corroborates that poor treatment adherence is associated with poorer health outcomes and significantly higher mortality rates.²⁸⁴ These findings suggest that by reducing prescription drug costs, PBM disclosures could improve treatment adherence and associated health outcomes.

To estimate the potential benefit to participants and beneficiaries of the proposed rule, the Department has provided an analysis that estimates the averted healthcare costs arising from increased prescription drug adherence for a subset of prescription drugs. The proposed rule is expected to have a small but meaningful effect on the net retail price of prescription drugs, which

the Department estimates will decrease by one percent. This estimate is consistent with the 2024 CBO analysis²⁸⁶ and other research on the effect of disclosures to group health plans and other service providers on prescription drugs.²⁸⁷ While these studies offer a comparable assessment of the potential impact of required rebate disclosures from PBMs to self-insured group health plans, the proposed rule is distinct as it contains more significant requirements that mandate the disclosure of all forms of direct and indirect compensation, including spread pricing, affiliate payments, as well as rebates. The proposed rule also includes enforceable rights, such as audit provisions and notification to the Department of incomplete disclosure, that will enhance compliance. These requirements may yield more substantial benefits, particularly to the smaller level-funded and self-insured group health plans, which are typically less informed and with fewer resources. As such, the Department believes that the proposed rule could reduce prices for prescription drugs more significantly, consistent with the effect of similar disclosures in other markets.²⁸⁸

The Department is not able to analyze the impact of reduced prescription drug prices on patient health outcomes for all health conditions and therapeutic classes; however, the Department does provide an analysis which focuses on participants aged 18–64 with three of the most common chronic conditions in the United States: diabetes, heart disease, and hypertension. Using Medical Expenditure Panel Survey (MEPS) data from AHRQ on the self-reported prevalence of diabetes, heart disease, and hypertension, the Department estimates that there are approximately 22.0 million participants aged 18 to 64 with such conditions in level-funded or self-insured group

health plans (see Table 4).²⁸⁹ Research on cost-related non-adherence suggests rates of prescription non-adherence for these conditions among privately insured individuals range from 33 to 37 percent, resulting in approximately 7.7 million participants in level-funded or self-insured group health plans with diabetes, heart disease, or hypertension that are non-adherent to prescription medication for reasons of cost.²⁹¹

A 2008 paper on the impact of reductions in copayments to drug adherence for privately insured adults aged 18 to 64 looked specifically at chronic conditions including diabetes, heart disease, hypertension, high cholesterol and found significant price elasticities in response to the copayment changes, ranging from –0.11 to –0.14 for these three conditions.²⁹³ Applying these elasticities to the estimated number of self-insured and level-funded group health plan participants and beneficiaries prescribed these

²⁸² Michael Chernew, Mayur Shah, Arnold Wegh, Stephen Rosenberg, Iver Juster, Allison Rosen, Michael Sokol, Kristina Yu-Iseberg, & A Mark Fendrick, *Impact of Decreasing Copayments on Medication Adherence within a Disease Management Environment*, Health Affairs, (2008), <https://pubmed.ncbi.nlm.nih.gov/18180484/>; Dana Goldman, Geoffrey Joyce, Jose Escarce, Jennifer Pace, Matthew Solomon, Marianne Laouri, Pamela Landsman, & Steven Teutsch, *Pharmacy Benefits and the Use of Drugs by the Chronically Ill*, Journal of the American Medical Association, (2004), <https://pubmed.ncbi.nlm.nih.gov/15150206/>; Abe Dunn, *Health Insurance and the Demand for Medical Care: Instrumental Variable Estimates Using Health Insurer Claims Data*, Journal of Health Economics (2016), <https://pubmed.ncbi.nlm.nih.gov/27107371/>.

²⁸³ IQVIA Institute, *Medicine Spending and Affordability in the United States: Understanding Patients' Costs for Medicines*, (August 2020), <https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/medicine-spending-and-affordability-in-the-us>.

²⁸⁴ Teresa B. Gibson, Xue Song, Berhanu Alemayehu, Sara S. Wang, Jessica L. Waddell, Jonathan R. Bouchard, and Felicia Forma, *Cost Sharing, Adherence, and Health Outcomes in Patients with Diabetes*, American Journal of Managed Care 16(7), (2010), <https://pubmed.ncbi.nlm.nih.gov/20712392/>; Scot Simpson, Dean Eurich, Sumit Majumdar, Rajdeep Padwal, Ross Tsuyuki, Janice Varney, & Jeffrey Johnson, *A Meta-Analysis of the Association Between Adherence to Drug Therapy and Mortality*, British Medical Journal, (2006), <https://pmc.ncbi.nlm.nih.gov/articles/PMC1488752/pdf/bmj33300015.pdf>; Donald Pittman, William Chen, Steven Bowlin, and JoAnne Foody, *Adherence to Statins, Subsequent Healthcare Costs, and Cardiovascular Hospitalizations*, American Journal of Cardiology 107(11), (2011), <https://pubmed.ncbi.nlm.nih.gov/21439533/>.

²⁸⁵ Scot Simpson, Dean Eurich, Sumit Majumdar, Rajdeep Padwal, Ross Tsuyuki, Janice Varney, & Jeffrey Johnson, *A Meta-Analysis of the Association Between Adherence to Drug Therapy and Mortality*, British Medical Journal, (2006), <https://pmc.ncbi.nlm.nih.gov/articles/PMC1488752/pdf/bmj33300015.pdf>.

²⁸⁶ Congressional Budget Office, *Alternative Approaches to Reducing Prescription Drug Prices*, (October 2024), www.cbo.gov/publication/58793. As noted earlier in this regulatory impact analysis, the price-reduction range suggested by this report is between 0.1 percent and one percent.

²⁸⁷ Ginger Scanlon, *Prescription for Savings? Disclosure in the Drug Market*, (2024), <https://ssrn.com/abstract=5021179>.

²⁸⁸ Christine Cuny, Omri Even-Tov, & Edward Watts, *From Implicit to Explicit: The Impact of Disclosure Requirements on Hidden Transaction Costs*, Journal of Accounting Research, (2021), <https://onlinelibrary.wiley.com/doi/10.1111/1475-679X.12340?msocid=18d7b391c5d560f015c7a5a9c4c7616c>; Dominique Badoer, Charles Costello, & Christopher Jones, *I Can See Clearly Now: The Impact of Disclosure Requirements on 401(k) Fees*, Journal of Financial Economics 136(2), (2020), <https://www.sciencedirect.com/science/article/abs/pii/S0304405X19302466>.

²⁸⁹ The prevalence estimates for privately insured adults aged 18 to 64 with diabetes (6.55 percent), heart disease (7.52 percent), and hypertension (21.94 percent) were applied to the number of participants 18 to 64 in level-funded and self-funded plans (61,212,180), resulting in an estimated population of 4,009,398 participants with diabetes ($0.0655 \times 61,212,180 = 4,009,398$), 4,603,156 participants with heart disease ($0.0752 \times 61,212,180 = 4,603,156$, and 13,429,952 participants with hypertension ($0.2194 \times 61,212,180 = 13,429,952$). Finally, $13,429,952 + 4,603,156 + 4,009,398 = 22,042,506$. (Source: Medical Expenditure Panel Survey, Agency for Healthcare Research and Quality, (2022).)

²⁹⁰ The Department has not adjusted this analysis to control for comorbid conditions, e.g. when a patient is diagnosed and receives treatment for both diabetes and heart disease. While this could potentially overstate the benefits of the proposed rule due to the inclusion of individuals accruing benefits from multiple health conditions, the Department believes that the following analysis continues to underestimate such benefits given the limited scope of the conditions observed and the potential health benefits to those with multiple chronic diseases.

²⁹¹ Sarah Van Alsten & Jenine Harris, *Cost-Related Nonadherence and Mortality in Patients with Chronic Disease: A Multiyear Investigation*, National Health Interview Survey, 2000–2014, Preventing Chronic Disease, Center for Disease Control and Prevention, (2020), <https://pubmed.ncbi.nlm.nih.gov/33274701/>.

²⁹² The standard threshold to establish adherence to medication is 80% of medication taken in compliance with medical directives. This threshold was generally thought to be consistent with the minimal therapy administered for successful treatment outcomes, (Source: Sarah Chapman and Amy Chan, *Medication Non-Adherence: Definition, Measurement, Prevalence, and Causes*, Frontiers in Pharmacology, (2025), <https://pmc.ncbi.nlm.nih.gov/articles/PMC11925869/>).

²⁹³ Michael E. Chernew, Mayur R. Shah, Arnold Wegh, Stephen N. Rosenberg, Iver A. Juster, Allison B. Rosen, Michael C. Sokol, Kristina, Yu-Iseberg, & A. Mark Fendrick, *Impact of Decreasing Copayments on Medication Adherence Within a Disease Management Environment*, Health Affairs Vol. 27(1), (2008), <https://pubmed.ncbi.nlm.nih.gov/18180484/>.

medications and assuming a one percent decrease in average drug price resulting from improved disclosures leads to a 0.11 percent to 0.14 percent change in participants and beneficiaries improving

their drug adherence. As a result, the Department estimates that 25,926 participants aged 18 to 64 in level-funded and self-insured group health plans with diabetes, heart disease, or

hypertension will improve their drug adherence following improved disclosures under this proposed rule.

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TABLE 4. Disease Prevalence and Estimated Adherence Improvements

Condition	Prevalence	Estimated Population*	Percent Change Implied by Price Elasticity of Adherence	Estimated Population Experiencing Adherence Improvement**
Diabetes	6.6%	4,009,398	0.14%	5,453
Heart Disease	7.5%	4,603,156	0.12%	5,432
Hypertension	21.9%	13,429,952	0.11%	15,042
Total***	-	22,042,506	-	25,926

Note: Some values in the table are rounded and may not result in precise calculations.

* Estimated population based on the level-funded and self-insured participants aged 18 to 64 is 61,212,180.

** Estimated adherence improvements based on 1 percent decrease in average drug price. Cells in Population columns would be 10% of the values presented if average drug price instead decreases by 0.1 percent.

*** These totals may include individuals with more than one of the health conditions which could result in an overestimation of the affected population.

Increased prescription adherence can reduce disease related medical costs due to improved health status and reduced utilization of medical care including hospitalizations, emergency room visits, and doctor appointments that would otherwise arise when medication for chronic diseases is not taken as prescribed.²⁹⁴ Using data on medical

²⁹⁴ Michael C. Sokol, Kimberly A. McGuigan, Robert R. Verbrugge, & Robert S. Epstein, *Medication Adherence on Hospitalization Risk and Healthcare Costs*, Medical Care Vol 43(6), (June 2008), <https://pubmed.ncbi.nlm.nih.gov/15908846/>.

events from the 2022 MEPS, the Department estimates healthcare utilization for privately insured participants aged 18 to 64 with diabetes, hypertension, or heart disease based on adherence status (see Table 5 below).²⁹⁵ Observing the average number of distinct medical events, such as inpatient hospitalizations or office-

²⁹⁵ Based on self-reporting of delaying taking or being unable to afford their medication. (Source: 2022 Medical Expenditure Panel Survey, Agency for Healthcare Research and Quality, Department of Health and Human Services, (2024).)

based visits to physicians, the data suggests that across most categories of healthcare, cost-related non-adherence is associated with higher utilization of care. Adherent participants with diabetes, for example, averaged 1.37 hospital outpatient admissions in 2022, compared with an average of 4.29 hospital outpatient admissions for non-adherent diabetic participants. This data supports other research suggesting medication adherence and compliance can reduce adverse health outcomes and healthcare utilization.

TABLE 5. Average Annual Healthcare Events Per Person, by Disease Condition and Adherence Status

	Average Utilization, Adherent			Average Utilization, Non-Adherent		
	Diabetes	Heart Disease	Hypertension	Diabetes	Heart Disease	Hypertension
Emergency Room Visits	0.18	0.24	0.17	0.49	0.48	0.38
Hospital, Inpatient Admissions	0.07	0.13	0.07	0.12	0.25	0.08
Hospital, Outpatient Admission	1.37	1.74	1.12	4.29	5.71	3.16
Office-Based Visits	8.84	9.20	7.98	10.62	13.96	10.04
Prescribed Medicines Filled	22.35	15.49	14.98	29.18	30.60	28.05

Note: The MEPS-HC data on healthcare utilization above represents the average number of distinct medical events in 2022 by facility type, based on the participants indicated disease condition and reported adherence status. The table above does not include all the healthcare utilization categories analyzed, such as telehealth or dental visits.

The Department further examined the cost savings of reduced utilization of medical services resulting from improved cost-related prescription adherence (see Table 6). Using 2022 MEPS data on healthcare expenditures

of privately insured patients aged 18 to 64 with diabetes, heart disease, or hypertension, the Department estimated the impact of adherence on health expenditures for those costs paid by the issuer. The reduced utilization of

medical services for these participants could lower the reimbursement requirements of private issuers to healthcare providers by approximately \$31.9 million annually.²⁹⁶

TABLE 6. Estimated Healthcare Expenditures and Savings, by Disease Condition and Adherence Status

	Issuer Health Expenditures	
	Adherent	Non-Adherent
Diabetes	\$49,860,374	\$60,834,609
Heart Disease	\$57,138,641	\$64,826,269
Hypertension	\$106,701,495	\$119,907,341
Total Expenditures	\$212,700,510	\$245,568,219
Total Cost Savings	\$31,867,708	

Note: These calculations utilize the average expenditure by payer for those indicating one of the three disease conditions based on reported adherence status. This average expenditure is then applied to the estimated number of participants improving adherence (5,453 participants with diabetes, 5,432 participants with heart disease, and 15,042 participants with hypertension) in level-funded and self-insured group health plans with the same conditions. The estimated cost-savings represent the expenditures for those improving adherence based on their adherence status (expenditures at non-adherence – expenditures at adherence = cost savings).

Source: Agency for Healthcare Quality and Research, MEPS-HC, 2022

²⁹⁶ Based on data reporting insurer expenditures for privately insured patients aged 18–64 diagnosed

with Diabetes, Heart Disease, or Hypertension. (Source: 2022 Medical Expenditure Panel Survey,

Agency for Healthcare Research and Quality, Department of Health and Human Services, (2024).)

Increased prescription adherence is also associated with a decreased risk of adverse health outcomes.²⁹⁷ For patients with chronic or severe diseases, the mortality risk associated with non-adherence to their medication can be considerable. A 2020 CDC study found that the increased risk of all-cause mortality due to cost-related non-adherence to their medication for individuals with diabetes, hypertension, and heart disease, ranged from 15 to 22 percent.²⁹⁸ While the population studied included higher-risk individuals (e.g., those without insurance), these findings are consistent with other research indicating increased health risks from non-adherence.²⁹⁹

²⁹⁷ Scot Simpson, Dean Eurich, Sumit Majumdar, Rajdeep Padwal, Ross Tsuyuki, Janice Varney, & Jeffrey Johnson, *A Meta-Analysis of the Association Between Adherence to Drug Therapy and Mortality*, BMJ, (2006), <https://pubmed.ncbi.nlm.nih.gov/16790458/>; P. Michael Ho, John Rumsfeld, Frederick Masoudi, David McClure, Mary Plomondon, John F. Steiner, & David Magid, *Effect of Medication Nonadherence on Hospitalization and Mortality Among Patients with Diabetes Mellitus*, Archives of Internal Medicine, (2022), <https://pubmed.ncbi.nlm.nih.gov/17000939/>; Donald Pittman, William Chen, Steven Bowlin, & JoAnne Foody, *Adherence to Statins, Subsequent Healthcare Costs, and Cardiovascular Hospitalizations*, American Journal of Cardiology, (2011).

²⁹⁸ Sarah Van Alsten & Jenine Harris, *Cost-Related Nonadherence and Mortality in Patients with Chronic Disease: A Multiyear Investigation*, National Health Interview Survey, 2000–2014, Preventing Chronic Disease, Center for Disease Control and Prevention (2020), <https://pubmed.ncbi.nlm.nih.gov/33274701/>.

²⁹⁹ Scot Simpson, Dean Eurich, Sumit Majumdar, Rajdeep Padwal, Ross Tsuyuki, Janice Varney, & Jeffrey Johnson, *A Meta-Analysis of the Association between Adherence to Drug Therapy and Mortality*, BMJ (2006), <https://pubmed.ncbi.nlm.nih.gov/16790458/>. See also, P. Michael Ho, John Rumsfeld,

Additionally, health-related quality of life data from MEPS indicates that adherence is also associated with significantly higher health-related quality of life scores for both mental and physical health.³⁰⁰

To assess the value of these health benefits, the Department estimates the changes in health status through a single metric: quality-adjusted life-years (QALYs), which quantify the changes to morbidity for affected participants.³⁰¹ To calculate the QALY for each condition, the number of participants improving adherence is first reduced by the estimated population mortality rate. Then the health utility metric, *Short Form Six-Dimension* (SF-6D),³⁰² is applied to all remaining participants in the group for that year, where their aggregate value is calculated as the annual QALYs.^{303 304} In subsequent

Frederick Masoudi, David McClure, Mary Plomondon, John F. Steiner, David Magid, *Effect of Medication Nonadherence on Hospitalization and Mortality Among Patients with Diabetes Mellitus*, Archives of Internal Medicine, (2022), <https://pubmed.ncbi.nlm.nih.gov/17000939/>.

³⁰⁰ Physical Health Summary Scores (PCS) and Mental Health Summary Scores (MCS) showed significant variation between adherent and non-adherent respondents aged 18 to 64 with private health insurance. (Source: 2022 Medical Expenditure Panel Survey, Agency for Healthcare Research and Quality, Department of Health and Human Services, (2024).)

³⁰¹ A quality-adjusted life-year is standardized on a scale of 0 to 1, where 1 represents a perfect state of health and 0 represents the worst state of health (death).

³⁰² SF-6D is a value indicating the quality of a participant's life based on health determinants derived from physical health and mental health summary scores of the 2022 MEPS.

³⁰³ The MEPS Mental Health Score (MCS) and Physical Health Score (PCS) are standardized health-related quality of life scores from the VR-12

years, these remaining participants are again subject to the same mortality risk, and their updated SF-6D scores are aggregated to calculate QALYs over time.

The post-rule, which captures the QALYs of participants in their adherent state, estimates an average SF-6D score of 0.81 for individuals aged 18 to 64 with private insurance, any of the three chronic diseases, and who indicated they are adherent to their treatment regimen. For the baseline, non-adherent state, the SF-6D score is approximately 0.08 less, or 0.73.³⁰⁵

The baseline and post-rule analysis both reflect an average mortality rate of 380.4 per 100,000 individuals aged 18 to 64, derived from mortality data from the National Center for Health Statistics.³⁰⁶ The baseline calculations are provided in Table 7 below while the post-rule calculations are presented in Table 8.

Assessment. The scores are adapted to a health utility metric, SF-6D using a peer-reviewed methodology. (Source: Hyun Song, Ji Haeng Heo, Debbie Wilson, Bui Shao, Haesuk Park, *National Catalog of Mapped Short-Form Six-Dimension Utility Scores for Chronic Conditions in the United States from 2010 to 2015*, Value in Health 25(8), (2022), (2003)).

³⁰⁴ Hyun Jin Song, Ji Haeng Heo, Debbie L. Wilson, Hui Shao, & Haesuk Park, *A National Catalog of Mapped Short-Form Six-Dimension Utility Scores for Chronic Conditions in the United States From 2010 to 2015*, Value in Health, (2022).

³⁰⁵ Based on a regression analysis of calculated SF-6D values derived from 2022 MEPS data reflecting reported cost-related non-adherence and controlling for race, income, sex, marital status, and insurance status.

³⁰⁶ Jiaquan Xu, Sherry Murphy, Kenneth Kochanek, & Elizabeth Arias, *Deaths: Final Data for 2022*, National Vital Statistics Reports 74(4), National Center for Health Statistics, (2025).

TABLE 7. Baseline QALY Estimates, by Condition

		Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Diabetes	N=	5,453	5,432	5,411	5,390	5,369	5,349	5,329	5,309	5,289	5,269
	Mortality Rate	380.4	380.4	380.4	380.4	380.4	380.4	380.4	380.4	380.4	380.4
	Deaths	21	21	21	21	20	20	20	20	20	20
	Alive	5,432	5,411	5,390	5,369	5,349	5,329	5,309	5,289	5,269	5,249
	QALYs	3,966	3,951	3,935	3,920	3,905	3,891	3,876	3,861	3,847	3,832
Heart Disease	N=	5,432	5,411	5,390	5,369	5,349	5,329	5,309	5,289	5,269	5,249
	Mortality Rate	380.4	380.4	380.4	380.4	380.4	380.4	380.4	380.4	380.4	380.4
	Deaths	21	21	21	20	20	20	20	20	20	20
	Alive	5,411	5,390	5,369	5,349	5,329	5,309	5,289	5,269	5,249	5,229
	QALYs	3,951	3,935	3,920	3,905	3,891	3,876	3,861	3,847	3,832	3,818
Hypertension	N=	15,042	14,984	14,927	14,870	14,813	14,757	14,701	14,645	14,589	14,534
	Mortality Rate	380.4	380.4	380.4	380.4	380.4	380.4	380.4	380.4	380.4	380.4
	Deaths	57	57	57	57	56	56	56	56	55	55
	Alive	14,984	14,927	14,870	14,813	14,757	14,701	14,645	14,589	14,534	14,479
	QALYs	10,940	10,898	10,857	10,815	10,774	10,733	10,692	10,651	10,611	10,571

Note: The all-cause mortality rate is 380.36 per 100,000 for patients with diabetes, heart disease, or hypertension, respectively, based on data from Sarah Van Alsten and Jenine Harris, *Cost-Related Nonadherence and Mortality in Patients with Chronic Disease: A Multiyear Investigation, National Health Interview Survey, 2000–2014*, Preventing Chronic Disease Vol. 17(151), Center for Disease Control and Prevention (2020). Baseline QALYs are estimated from the 2022 MEPS as 0.73 per participant based on an average of 0.81 for individuals aged 18 to 64 with private insurance and diabetes, heart disease, or hypertension that reported cost-related non-adherence, less the 0.08 associated with non-adherence.

TABLE 8. Post-Rule QALY Estimates, by Condition

		Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Diabetes	N=	5,453	5,432	5,411	5,390	5,369	5,349	5,329	5,309	5,289	5,269
	Mortality Rate	380.4	380.4	380.4	380.4	380.4	380.4	380.4	380.4	380.4	380.4
	Deaths	21	21	21	21	20	20	20	20	20	20
	Alive	5,432	5,411	5,390	5,369	5,349	5,329	5,309	5,289	5,269	5,249
	QALYs	4,402	4,385	4,368	4,351	4,335	4,319	4,303	4,286	4,270	4,254
Heart Disease	N=	5,432	5,411	5,390	5,369	5,349	5,329	5,309	5,289	5,269	5,249
	Mortality Rate	380.4	380.4	380.4	380.4	380.4	380.4	380.4	380.4	380.4	380.4
	Deaths	21	21	21	20	20	20	20	20	20	20
	Alive	5,411	5,390	5,369	5,349	5,329	5,309	5,289	5,269	5,249	5,229
	QALYs	4,385	4,368	4,351	4,335	4,319	4,303	4,286	4,270	4,254	4,238
Hypertension	N=	15,042	14,984	14,927	14,870	14,813	14,757	14,701	14,645	14,589	14,534
	Mortality Rate	380.4	380.4	380.4	380.4	380.4	380.4	380.4	380.4	380.4	380.4
	Deaths	57	57	57	57	56	56	56	56	55	55
	Alive	14,984	14,927	14,870	14,813	14,757	14,701	14,645	14,589	14,534	14,479
	QALYs	12,144	12,097	12,051	12,005	11,960	11,914	11,869	11,824	11,779	11,734

Note: The all-cause mortality rate is estimated as 380.36 per 100,000 individuals, aged 15-64 based on data from *National Vital Statistics Report, Deaths: Final Data for 2022*, National Center for Health Statistics, Centers for Disease Control and Prevention (2025). QALYs is estimated from the 2022 MEPS as 0.81 per adherent participant based on an average for individuals aged 18 to 64 with private insurance and diabetes, heart disease, or hypertension that did not report cost-related non-adherence.

The difference between the baseline and post-rule estimates indicates that, each year, increased medication adherence among the 25,926 participants will result, on average, in

2,040 additional QALYs.³⁰⁷ The Department uses an estimate for the value of a QALY (VQALY) of approximately \$334,600,^{308 309} suggesting an average annual value of

approximately \$717.1 million from improvements to quality of life.³¹⁰ These calculations and estimates are provided in Table 9 below.

³⁰⁷ This estimate is calculated as: 205,761 post-rule QALYs—185,362 baseline QALYs = 20,399 additional QALYs, averaging 2,040 additional QALYs across the first ten years of the rule.

³⁰⁸ The estimate is calculated as the value of statistical life ÷ the present value of QALY remaining = Value of each QALY. The VSL estimate utilized here is a low estimate of \$6.3 million. The QALYs remaining is discounted at 3 percent which

estimates 18.9 remaining QALYs per participant and is derived from: *HHS, Standard Values for Regulatory Impact Analysis, 2025*, Office of Science and Data Policy, Department of Health and Human Services, (2025).

³⁰⁹ The value of a QALY in year one is estimated as \$334,612 and is adjusted upward 1.1 percent each year to account for projected earnings growth.

This results in an average value of QALY of \$351,671 over the 10 years observed.

³¹⁰ The undiscounted benefits related to QALY improvements result in an average annual value of approximately \$421.7 million. The benefits related to QALY improvements, when discounted at 7 percent, result in an average annual value of approximately \$1,175.6 million.

TABLE 9. Estimated Value of QALY Improvements

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
QALY Gain – Diabetes	436	435	433	431	430	428	427	425	423	422
QALY Gain – Heart Disease	435	433	431	430	428	427	425	423	422	420
QALY Gain – Hypertension	1,204	1,199	1,195	1,190	1,186	1,181	1,177	1,172	1,168	1,163
Total QALY Gains	2,075	2,067	2,059	2,051	2,044	2,036	2,028	2,020	2,013	2,005
VQALY	\$334,612	\$338,293	\$342,014	\$345,776	\$349,580	\$353,425	\$357,313	\$361,243	\$365,217	\$369,235
Total Value (in \$ millions)	\$694.36	\$699.30	\$704.28	\$709.30	\$714.41	\$719.54	\$724.70	\$729.88	\$735.12	\$740.39

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While the Department was able to quantify the impact of improved adherence to certain prescribed medications following reduced out-of-pocket costs in response to this proposed rule, these estimates were limited to a small subset of participants and beneficiaries being treated for diabetes, hypertension, and heart disease. The Department lacked data, however, on other therapeutic areas, including those for oncology drugs, autoimmune, and respiratory diseases, which are associated with some of the highest prescription drug spending in the United States. As a result, while the benefits quantified by the Department associated with improved health outcomes stemming from this proposed rule are significant, they likely are only a fraction of those actual benefits as the quantified benefits do not account for changes in morbidity or quality of life that would arise from increased adherence for these and other classes of drugs.

In total, the proposed rule is estimated to generate approximately \$749.0 million in undiscounted benefits annually, accounting for averted medical costs, reduced prescription drug expenditures, and improved health outcomes from greater treatment adherence.³¹¹ The Department requests comments on these assumptions and calculations.

10.2.2.2 Consumer Benefits Measured by Willingness-to-Pay

The high rates of non-adherence for reasons of cost (CRN) indicate a price

level for many drugs that exceeds participant willingness-to-pay. This suggests that lowering prices will provide additional consumer surplus to participants as many will improve their welfare from increasing consumption of their prescribed medications at lower prices. As insurers also contribute toward the cost of the drug through cost-sharing for the net retail price, the Department anticipates that insurers will also benefit from the additional consumer surplus gained from the proposed rule. Utilizing data from MEPS on average out-of-pocket expenditures for prescription drugs of participants in private group health plans in 2022 (\$122), as well as the average expenditures from insurers for those in private group health plans (\$1,096), the Department finds that the average annual expenditures for prescription drugs total \$1,217.³¹² This data also reports an annual average of 6.7 prescription fills for those participants, suggesting an average prescription cost of \$181 for combined insurer and participant expenditures.³¹³ Given an estimate of 89.4 million participants in self and level-funded group health plans and assuming a similar utilization and cost of prescription drugs, the Department estimates total prescription drug expenditures for this population at approximately \$108.8 billion arising from an estimated 600.8 million prescription fills annually.³¹⁴

³¹² Agency for Healthcare Research and Quality, *2022 Medical Expenditure Panel Survey*, Department of Health and Human Services, (2014).

³¹³ This estimate is calculated as: \$1,217.36 annual prescription expenditures ÷ 6.72 average annual prescriptions = \$181.15 average cost of prescription for patient out-of-pocket and insurer expenses.

³¹⁴ This estimate is calculated as: 89,400,000 participants in self and level-funded plans × 6.72 average prescription fills annually = 600,768,000

Research on demand for prescription drugs among those with commercial insurance indicates a price elasticity of approximately –0.36 across all prescriptions, slightly more elastic demand than those for chronic diseases discussed earlier.³¹⁵ Utilizing the stated price elasticity, estimated price decrease, and prescription demand, the Department estimates that approximately 2.2 million additional prescription drugs will be purchased as a result of lower prices.³¹⁶ Given an average price of \$181 and an estimated price decrease of one percent, the Department estimates that the value of the gross consumer willingness to pay would result in up to \$389.6 million of benefits annually.³¹⁷ Table 10 presents these estimates with a further range of assumptions about the reductions in average net retail prescription drug prices. It is worth noting that this approach does not account for the marginal cost associated with the newly-filled prescriptions and therefore may overstate societal benefits of the proposed rule. The Department requests comments on refining the approach to account for both consumer and producer surplus, and more generally on the preceding assumptions and calculations.

annual prescription fills for self and level-funded plan participants. \$181.15 average cost × 600,768,000 = \$108,831,984,000 annual expenses for prescription drugs in self and level-funded plans.

³¹⁵ Abe Dunn, *Health Insurance and the Demand for Medical Care: Instrumental Variable Estimates Using Health Insurer Claims Data*, Journal of Health Economics, Vol. 48 (2016).

³¹⁶ This estimate is calculated as: 1 percent price reduction × 0.36 price elasticity × 600,768,000 prescriptions = 2,150,749 prescriptions.

³¹⁷ This estimate is calculated as: \$181.15 average prescription cost × 2,150,749 prescriptions = \$389,618,503.

³¹¹ This estimate is calculated as: \$717,127,901 quality-adjusted life years + \$31,867,708 in averted healthcare expenditures = \$748,995,610 in total undiscounted benefits. Using a 3 percent discount rate, this results in annualized benefits of \$637,845,854. Using a 7 percent discount rate, this results in annualized benefits of \$524,073,852.

TABLE 10. Participant Welfare Gains Measured by Willingness-to-Pay under Varying Assumptions about Reductions in Average Net Retail Prescription Drug Price

Decrease in Average Net Retail Prescription Price	Prescription Quantity in Baseline	Price Elasticity Estimate	Additional Prescriptions Filled	Average Price per Prescription (\$)	Monetized Value of Willingness-to-Pay (\$ million)	Transfers to Participants: Reduced Rx Spending (\$ million)
(a)	(b)	(c)	(d)	(e)	(f) = (d × e)	(g) = Baseline spending (\$108.8 B) x (a)
0.1%	600,768,000	-0.358	215,075	\$181.15	\$39.0	\$108.8
0.5%	600,768,000	-0.358	1,075,375	\$181.15	\$194.8	\$544.2
1.0%	600,768,000	-0.358	2,150,749	\$181.15	\$389.6	\$1,088.3

10.2.3. Transfers From Standard Traditional PBMs to Transparent PBMs

In response to the disclosure requirements, responsible plan fiduciaries may be increasingly inclined to utilize transparent PBMs like fully pass-through PBMs rather than PBMs using the standard business model. Under a fully pass-through pricing strategy, PBMs rely much more on administrative fees instead of other income streams, which can reduce hidden costs and conflicts of interest. This may be more attractive for responsible plan fiduciaries as it could potentially simplify auditing PBMs, lessening oversight and monitoring costs. One fully pass-through PBM testified before Congress that their first year clients reported an average reduction in costs of 11 percent compared to other PBMs³¹⁸ while other fully pass-through PBMs have reported savings of as much as 30 percent.³¹⁹ As a result, in response to the proposed rule, responsible plan fiduciaries may engage fully pass-through PBMs in lieu of standard PBMs for their prescription drug services, resulting in a transfer of business across PBM type.³²⁰

10.2.4. Transfers From PBM Affiliated Pharmacies to Unaffiliated Pharmacies

The proposed rule includes disclosures related to spread pricing, requiring information on the cost reimbursements for each drug on the

self-insured group health plans' formulary for each pharmacy channel. Because PBMs often favor affiliated pharmacies, these disclosures may highlight price discrimination which has traditionally resulted in lower reimbursements and utilization rates for non-affiliated pharmacies. With the greater transparency required by the proposed rule, PBMs may choose to equalize treatment across all distribution channels which in turn may shift business from affiliated to non-affiliated pharmacies.

11. Costs

This proposed rule aims to enhance the responsible plan fiduciaries' ability to monitor costs and the administration of prescription drug benefits by PBMs, their agents, and affiliates, by requiring PBMs to provide disclosures regarding fees, pricing structures and potential conflicts of interest both prior to entering a service provider agreement, and semiannually during the agreement. In addition, PBMs must make available to responsible plan fiduciaries all information required to conduct audits to confirm the accuracy of any disclosure made to comply with the regulations.

Prior to this rulemaking, service providers that engage in consulting or provide brokerage services to self-insured group health plans for certain identified sub-services were already required under the CAA 2021 to disclose to responsible plan fiduciaries a description of the service provided, direct and indirect compensation received, and the provider's fiduciary status with respect to the self-insured group health plan.³²¹ The statute, however, did not specifically name PBMs, generally, as covered service

providers. Moreover, while the Department did not issue specific rules governing these disclosures at the time, it provided guidance stating that the statute made unambiguous that covered service providers, as defined in the statute, must now disclose both direct and indirect fee compensation.³²²

When questioned by Congress in 2023 regarding PBMs' compliance with Section 408(b)(2), PCMA responded that they believed their companies were in compliance and provided the appropriate disclosures related to direct and indirect compensation.³²³ Additionally, several States have adopted disclosure requirements for PBMs regarding elements included in this proposed rule, including rebate payments, spread pricing and drug prices.³²⁴ As such, the Department assumes that PBMs already compile and provide to various parties the information similar to what is required under this proposed rule, though not necessarily at the same level of detail or frequency.

The Department acknowledges that PBMs, in revising their approach to documenting and disclosing their business practices to self-insured group health plans to be consistent with this proposed rulemaking, will incur additional costs. Moreover, by providing disclosures at a more granular level prior to entering into a formal

³¹⁸ Sharon Faust, *Prepared Testimony Before the United States Judiciary Committee*, (May 11, 2025), https://www.judiciary.senate.gov/imo/media/doc/2025-05-13_testimony_faust.pdf.

³¹⁹ Alliance of Community Health Plans, *A Unique Approach: Transparent PBMs*, (April 2019), https://achp.org/wp-content/uploads/PBM-Infographic_4.5.19.pdf.

³²⁰ Pharmaceutical Strategies Group, *2025 Trends in Drug Benefit Design Report*, (June 2025), <https://link.psgconsults.com/2025-trends-in-drug-benefit-design-report>.

³²² Field Assistance Bulletin No. 2021-03, <https://www.dol.gov/agencies/ebsa/employers-and-advisers/guidance/field-assistance-bulletins/2021-03>.

³²³ Committee on Education and the Workforce Subcommittee on Health, Employment, Labor and Pensions, *Competition and Transparency: The Pathway Forward for a Stronger Health Care Market*, (June 21, 2023).

³²⁴ Government Accountability Office, *Prescription Drugs: Selected States' Regulation of Pharmacy Benefit Managers*, (March 2024), <https://www.gao.gov/assets/d24106898.pdf>.

agreement, the Department expects the self-insured group health plans may demand additional concessions, resulting in lower revenues for PBMs. This collection of costs would appropriately be included in any comparison with the benefits described, and in some cases illustratively quantified, elsewhere in this RIA.

11.1. Rule Familiarization and Compliance Costs

The Department anticipates that the costs related to this proposed rule will consist of both initial and annual costs. Initial costs include review of the regulation and identifying new requirements, developing templates for the new disclosures, and developing processes for capturing the necessary data (including automating systems). The Department does not intend to develop a template disclosure form, instead expecting regulated entities to develop their own templates that conform to regulatory requirements, but we welcome comments regarding the potential value and composition of such a Department-developed template.

Ongoing costs will include the cost of producing the disclosures, transmitting them to responsible plan fiduciaries, and responding to audit requests.

Self-insured group health plans, issuers/State combinations, and TPAs are expected to review the proposed rule in order to familiarize themselves with the new requirements and how they will impact them.³²⁵ Large, self-insured group health plans with 1,000 or more employees are expected to review the rule themselves. In contrast, small, self-insured group health plans, including level-funded group health plans, and self-insured group health plans with less than 1,000 employees, are expected to utilize a TPA, issuer, or other service provider to review the proposed rule on the self-insured group health plan's behalf.

The Department assumes that it will take, on average, 5 hours for a legal professional for a large, self-insured group health plan to review the proposed rule, and 20 hours for a TPA or issuer to review the rule on behalf of each self-insured group health plan.³²⁶ The Department further assumes a wage

rate of \$181.06 per hour for the legal review³²⁷ and that this burden would only be incurred in the first year. The Department requests comments on these assumptions.

PBMs would also need to review the proposed rule and evaluate whether their current disclosure practices comply with the requirements. Because the majority of the rule is focused on PBM policies and actions, the Department assumes that similar to TPAs or issuers, this initial review will take four times as long for PBMs to review and identify current practices that are not consistent with the proposed rule's requirements than responsible plan fiduciaries. As such, the Department assumes that it will take, on average, 20 hours for a legal professional to review the proposed rule on behalf of PBMs at a wage rate of \$181.06 per hour. The Department assumes this burden would only be incurred in the first year. Please see Table 11 for calculations and burden totals.

TABLE 11. Rule Familiarization Costs

	Number of Entities	Number of Hours per Entity	Total Hour Burden	Hourly Wage	Cost
	(A)	(B)	(C) = (A x B)	(D)	(E) = (A x B x C)
Self-insured group health plans with 1,000 or more employees	15,362	5	76,810	\$181.06	\$13,907,219
TPAs on behalf of client level-funded plans and self-insured group health plans with less than 1,000 employees	205	20	4,100	\$181.06	\$742,346
Issuers on behalf of client level-funded plans and self-insured group health plans with less than 1,000 employees	809	20	16,180	\$181.06	\$2,929,551
PBMs	73	20	1,460	\$181.06	\$264,348
First-year Total	16,449	-	98,550	-	\$17,843,463

As stated above, the Department believes that most PBMs already have the required information needed to fulfill the disclosure requirements, as

they manage complex healthcare operations and track the flow of pharmaceuticals and payments within the healthcare system as part of their

regular business practices. Moreover, PBMs already provide this information, or elements of it, to self-insured group health plans and other entities, as

³²⁶ On average, the reading rate is 250 words per minute (WPM), which also corresponds to the typical length of a page. Therefore, a regulation document that is approximately 300 pages long would take about 300 minutes to read, translating to 5 hours (300 pages x 250 words per page ÷ 250 words per minute ÷ 60 minutes = 5 hours). The

Department notes that this estimate applies to the plans. In contrast, TPAs, issuers, and PBMs are anticipated to require more time for their review, as discussed in the following paragraph.

³²⁷ Internal DOL calculation based on 2025 labor cost data. For a description of DOL's methodology

for calculating wage rates, see <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-june-2019.pdf>.

required under the CAA and State laws.³²⁸ Therefore, the Department does not expect that PBMs will need to devote significant resources to obtain or share information on the services provided under the agreement, direct and indirect compensation, rebates, drug prices and the pricing methodology, reimbursement rates, formulary placement incentives, and agreements with agents, affiliates and subcontractors. The Department requests comments on this assumption.

Nonetheless, greater transparency could identify practices such as rebates and spread pricing that are often regarded as hidden revenue mechanisms. As a result, PBMs may explore alternative revenue strategies, including fee-based models, and renegotiate contracts with self-insured group health plans, manufacturers, and wholesalers. Moreover, the Department anticipates that PBMs will need to revise current disclosure documents to include: revised definitions of contract terms that are objectively determinable; a description of all arrangements and compensation received by the PBM and any agents, affiliates or subcontractors related to providing these benefits; pricing and reimbursement information for all drugs on the formulary by distribution channel; more detailed descriptions of the services provided including the development and ongoing management of the formulary; as well as projecting potential costs and extracting actual payments to the level stipulated in this proposed rule. The Department acknowledges that these updates and revisions may require substantial effort and coordination by PBMs and their agents, affiliates and subcontractors.

In Table 12, the Department estimates the costs associated with PBMs developing and maintaining the IT infrastructure system necessary to collect and report the required data. To develop these estimates, the Department reviewed IT infrastructure costs associated with reporting complex, sensitive, or high-frequency data for similar disclosure regulations, including

Prescription Drug Data Collection,³²⁹ ACA Medical Loss Ratio (MLR) Reporting,³³⁰ Medicare Part D Reporting Requirements,³³¹ and the Hospital Price Transparency Requirements.³³² Of these rules, the IT costs associated with Prescription Drug Data Collection rule seemed most analogous to this proposed rule, as it specifically identified costs for PBMs to develop, implement, and maintain IT system changes to come into compliance with rulemaking related to prescription drug disclosures.

The Department used the Prescription Drug Data Collection rule as a benchmark but made a few notable adjustments. First, because the Department of Health and Human Services utilizes a different source for labor categories and wage rates than the Department, that information was mapped to the Department's source. Additionally, the hour burdens from the Prescription Drug Data Collection rule were adjusted downward by 50 percent to account for both the Prescription Drug Data Collection rule requiring additional information and calculations not found in this proposed rule, and the fact that the proposed rule relies on contract and pricing data that PBMs already track for commercial and compliance purposes, which should mitigate the associated costs. Finally, while data submission began in the second year for Prescription Drug Data Collection disclosures, the proposed rule requires reporting in the first year, and so the Department reallocated hour burdens from Prescription Drug Data Collection's second year into first and

subsequent year categories for the proposed rule. Based on these considerations, the Department estimates the average, first-year per-PBM cost for designing, developing, and implementing the IT system to be \$1,000,000.³³³ In subsequent years, the estimated per-PBM average cost for maintaining and updating the IT system is \$200,000.³³⁴ This includes providing quality assurance, conducting maintenance and making updates, and updating any needed security measures.

The Department acknowledges that these costs likely vary by the size of PBMs as well as their business model (*i.e.*, fully pass-through PBMs and traditional PBMs may face very different costs to bring systems into compliance). Additionally, while the Department discounted the Prescription Drug Data Collection costs to reflect its impact on more of the overall market and requiring additional calculations and standardized submissions, the chosen discount rate may not have been appropriate. The Department requests comments on these assumptions.

³³³ The Department estimates that each PBM will incur a one-time first-year cost and burden to design, develop, and implement any necessary IT system changes to collect and report the required data. The Department estimates that for each PBM, on average, it will take project management specialists 2,250 hours (at \$126.72 per hour), business operations specialists 750 hours (at \$120.40 per hour), as well as software and web developers, programmers, and testers 3,500 hours (at \$171.89 per hour) to complete this task. The Department estimates the total burden per PBM will be approximately 6,500 hours, with an equivalent cost of approximately \$977,035, rounded to \$1,000,000. For all 73 PBMs, the total one-time first-year implementation and reporting burden is estimated to be 474,500 hours with an equivalent total cost of approximately \$71,323,555.

³³⁴ In addition to the one-time first-year costs and burdens previously estimated, PBMs will incur ongoing annual costs related to maintaining and updating IT systems, providing ongoing quality assurance, and submitting the required data to the Department. The Department estimates that for each PBM it will take project management specialists 500 hours (at \$126.72 per hour), business operations specialists 50 hours (at \$120.40 per hour), as well as software and web developers, programmers, and testers 750 hours (at \$171.89 per hour) to perform these tasks. The Department estimates the total annual burden for each PBM will be 1,300 hours, with an equivalent cost of approximately \$198,298, rounded to \$200,000. For all 73 PBMs, the total annual maintenance and submission burden is estimated to be 94,900 hours with an equivalent total cost of approximately \$14,475,718.

³²⁸ National Academy for State Health Policy, *State Pharmacy Benefit Manager Legislation*. Last accessed on July 11, 2025, see <https://nashp.org/state-tracker/state-pharmacy-benefit-manager-legislation/>.

³²⁹ 86 FR 66662, *Prescription Drug and Health Care Spending*, (November 23, 2021), <https://www.federalregister.gov/documents/2021/11/23/2021-25183/prescription-drug-and-health-care-spending>.

³³⁰ 77 FR 28790, *Medical Loss Ratio Requirements Under the Patient Protection and Affordable Care Act*, (May 16, 2012), <https://www.federalregister.gov/documents/2012/05/16/2012-11753/medical-loss-ratio-requirements-under-the-patient-protection-and-affordable-care-act>.

³³¹ CMS, *Part D Reporting Requirements*, <https://www.cms.gov/medicare/coverage/prescription-drug-coverage-contracting/part-d-reporting-requirements>.

³³² 84 FR 65524, *Price Transparency Requirements for Hospitals To Make Standard Charges Public*, (November 27, 2019), <https://www.federalregister.gov/documents/2019/11/27/2019-24931/medicare-and-medicaid-programs-cy-2020-hospital-outpatient-pps-policy-changes-and-payment-rates-and#p-40>.

TABLE 12. IT Infrastructure Costs

Task	Number of PBMs	Average Costs	Total Cost
	(A)	(B)	(C)
PBMs design, develop, and implement needed IT systems changes (first year)	73	\$1,000,000	\$73,000,000
PBMs maintain and update the IT system (subsequent years)	73	\$200,000	\$14,600,000
Three-year Average Costs	73	\$466,667	\$34,066,667

11.2. Disclosure Costs

11.2.1. Number of Notices From PBMs

11.2.1.1 Number of Initial Notices From PBMs

The proposed rule would require PBMs or other covered service providers to provide initial disclosures to responsible plan fiduciaries of self-insured group health plans, reasonably in advance of the date on which the contracts or arrangements are entered into, extended or renewed. Standard industry contracts appear to be for three-year periods, though it is unclear if the agreements themselves are extended or renewed during that time.³³⁵ Currently, the Department anticipates that approximately one-third of the self-insured group health plans will annually initiate new contracts, extend existing contracts, or renew contracts. The Department requests comments on this assumption.

11.2.1.2 Number of Semi-Annual Notices From PBMs

The proposed rule also requires that PBMs or other covered service providers furnish disclosures on a semiannual basis, within 30 calendar days following the conclusion of each six-month period starting from the contract or arrangement initiation date. The Department estimates that PBMs or other covered service providers would submit these disclosures to each self-insured group health plan twice each year. The Department requests comments on these assumptions.

11.2.2. Number of Notices Upon Requests From PBMs

The proposed rule also requires PBMs or other covered service providers to

provide any other information related to the contract or arrangement that is required for the self-insured group health plan to comply with the reporting and disclosure requirements of Title I of ERISA and the regulations, forms, and schedules issued, upon request of the responsible plan fiduciary. Without a strong data source for determining the number of expected requests, the Department assumes that approximately ten percent of responsible plan fiduciaries will request covered information annually. The Department requests comments on this assumption.

11.2.3. Number of Notices From Self-Insured Group Health Plans

11.2.3.1 Exemption for Responsible Plan Fiduciaries

The proposed rule also includes a proposed administrative class exemption that would provide relief from ERISA section 406(a)(1)(C) and (D) for responsible plan fiduciaries who enter into a contract or arrangement, where the PBM or covered service provider fails to comply with its obligations under the regulation. To rely on the exemption, the responsible plan fiduciary must not have been aware that that the PBM or covered service provider failed or would fail to meet these requirements and, upon discovering this omission, requests in writing that the PBM or other covered service provider furnish the required information or comply with the audit requirement. The Department does not have data on how often responsible plan fiduciaries do not receive all of the required disclosures from a covered service provider. In this analysis, the Department assumes that 0.3 percent of arrangements may experience an omission or error that will require the responsible plan fiduciary to send the

request to the PBM.³³⁶ This assumption is based on the Department's experience that it is rare for pension plans to submit a notice under the requirement in 29 CFR 2550.408b-2.

If the PBM or other covered service provider does not respond within 90 calendar days, the responsible plan fiduciary must notify the Department of the failure and further must assess whether to terminate or continue the service contract or arrangement consistent with the duty of prudence under section 404 of ERISA. The Department assumes that approximately 10 notices will be submitted, based on the same experience that pension plans rarely submit these notices under the requirement in 29 CFR 2550.408b-2. The Department requests comments on this assumption. Please see Table 12 for the estimated number of disclosures.

11.2.3.2 Number of Notices From Self-Insured Group Health Plans Requesting Audits Information

As part of their oversight responsibilities, responsible plan fiduciaries must assess the quality of the PBM or other covered service provider's performance under the contract or arrangement (e.g., review and analyze claims data, network discounts, rebates, administrative fees), ensure that PBMs are meeting their contractual obligations, and ensure that self-insured group health plans are only paying reasonable and necessary costs. The proposal contains audit rights which are needed for fiduciaries to carry out these functions. While the cost of performing an audit of PBMs and other service

³³⁵ Scott McEachern and Patrick Cambel. "PBM Contracts: Understand then Optimize. Milliman White Paper, August 2, 2020. <https://us.milliman.com/en/insight/pbm-contracts-understand-then-optimize>.

³³⁶ Based on a review of the 2022 Form 5500 Schedule C filings, approximately 0.3 percent of ERISA-covered group health plans that filed Schedule C reported service providers who failed or refused to provide some of the information required to complete Part I. This estimate is used as a proxy for the percentage of self-insured group health plans that may need to request missing information from PBMs.

providers is borne by the self-insured group health plan itself, service providers are required to provide the necessary information to the self-insured group health plan or its auditor. This proposed regulation provides a self-insured group health plan's right to audit the PBM or other covered service provider not less than once per year. The PBM or other covered service	provider must confirm receipt of the audit request within 10 business days and must provide the information within a commercially reasonable period. The Department estimates that one-third of self-insured group health plans will annually submit a request to their PBM or other covered service provider for all information necessary to perform	an audit. The Department does not anticipate level-funded group health plans or smaller, self-insured group health plans to submit a request themselves, but expects all issuers or TPAs that market to those self-insured group health plans to request audit materials. Please see Table 13 for calculations on the number of notices. BILLING CODE 4510-29-P

TABLE 13. Number of Notices

Notice	Number of plans	Percent of plans that will initiate new contracts, extend existing contracts, or renew contracts	Percent of plans receiving or sending notices	Number of notices sent each year	Number of notices
	(A)	(B)	(C)	(D)	(E) = (A x C x D) or (A x B x C x D)
<i>Disclosures from PBMs to Self-insured Group Health Plans</i>					
PBMs provide initial disclosures to plans whose contract is entered, extended, or renewed	1,150,583	33%	100%	1	383,528
PBMs provide missing/additional information requested by plans	1,150,583	33%	10%	1	38,353
PBM provides semiannual disclosures to plans	1,150,583	100%	100%	2	2,301,167
<i>Disclosures from Self-insured Group Health Plans</i>					
Plans send request to PBMs to disclose other/missing information	1,150,583	33%	0.3%	1	1,151
Plan send notice to DOL after PBMs has not responded in 90 days	10	-	100%	1	10
<i>Self-insured Group Health Plans send audit requests to PBM</i>					
Self-insured plans with 1,000 or more employees send requests for audits to PBMs	15,362	33%	100%	1	5,121
Issuers, on behalf of client level-funded plans and self-insured plans with less than	809	100%	100%		809

11.2.4. Costs of Disclosures

11.2.4.1 Initial Disclosures

The Department acknowledges that the proposed rule will impose costs associated with producing initial disclosures before a service contract or arrangement is entered into, extended or renewed. While the Department expects that much of this information will have already been provided to the self-insured group health plan under the solicitation process and in response to a Request for Proposal, it acknowledges that the rule requires additional elements to be included or expanded upon in the required disclosures. Moreover, while it is expected that PBMs have the necessary underlying information readily available, PBMs will need to prepare plan-specific disclosures such as detailed descriptions of projected compensation, payments, formulary placement incentives, and drug pricing.

The Department assumes that disclosures for large, self-insured group health plans with 1,000 or more employees will generally require more time as these disclosures will need to be customized. In contrast, the Department assumes that disclosures for small plans, including level-funded group health plans and self-insured group health plans with less than 1,000 employees, will require less time as PBMs managing hundreds of small, self-insured group health plans often rely on standardized templates and batch processing. Therefore, for those small, self-insured group health plans whose contracts are initiated, extended, or renewed in a given year, the Department estimates it will take 15 minutes for a legal professional and a benefit specialist, at a composite wage rate of \$155.10,³³⁷ to prepare and send the disclosures. For large, self-insured group health plans, the Department estimates that it will take 30 minutes, due to the greater customization and review required. Please see Table 13 for calculations and burden.

Finally, paragraph (e)(9) of the proposal requires that the initial disclosure must provide that the responsible plan fiduciary will be notified in advance of any modifications to the formulary that, individually or in the aggregate, are reasonably expected to have a material impact on the reasonableness of compensation under the contract or arrangement. The Department considers that this is a regular business activity and PBMs are

providing this information prior to the proposed regulation. Therefore, PBMs will not incur any additional cost burden. The Department requests comments on these assumptions.

11.2.4.2 Semiannual Disclosures From PBMs

The proposed rule requires that PBMs or covered service providers furnish disclosures on a semiannual basis, within 30 calendar days following the conclusion of each six-month period starting from the contract or arrangement initiation date, disclosing the actual compensation that the PBM or other covered service provider received, under the specific categories that were estimated in the initial disclosures, as discussed earlier. This includes all direct compensation, rebate payments, spread compensation, copay claw-backs recouped from a pharmacy by the PBM or other covered service provider, price protection payments, and other compensation. If any category of compensation, in the aggregate, materially exceeds the corresponding estimate described in the initial disclosure, the PBM or other covered service provider must provide an identification of the amount and a reason for the overage. For this purpose, “materially” means 5 percent or more, or a lower dollar amount or percentage agreed to by the responsible plan fiduciary and set forth in writing in the contract or arrangement.

It is anticipated that the PBM or other covered service provider will already possess the necessary information to fulfil this requirement, as these breakouts are already required in the initial disclosure and standard practice in PBM contracts is to regularly provide self-insured group health plans with invoices or statements that include claims payments, rebates, and administrative fees. The Department assumes these semiannual disclosures will require less time, as they often involve system-generated data, draw on similar information from initial disclosures, and rely on standardized templates. The Department assumes PBMs will rely on standardized templates and batch processing to prepare the notice. Therefore, the Department estimates that requiring PBMs to compile and disclose this information will require 15 minutes of work from a benefits specialist for compilation and distribution of the information semiannually, resulting in 30 minutes of benefit specialist time each year. Please see Table 13 for calculations and burden.

11.2.4.3 Information Upon Request

Paragraph (i) of the proposal provides that, upon the written request of the responsible plan fiduciary, the covered service provider must furnish any other information relating to the contract or arrangement that is required for the self-insured group health plan to comply with the reporting and disclosure requirements of Title I of the Act and the regulations, forms and schedules issued thereunder. Paragraph (i) of the proposal would require the covered service provider to disclose the information requested reasonably in advance of the date upon which such responsible plan fiduciary states that it must comply with the applicable reporting or disclosure requirement, unless such disclosure is precluded due to extraordinary circumstances beyond the covered service provider's control, in which case the information must be disclosed as soon as practicable. The Department assumes that PBMs will rely on automated IT systems to prepare the information. Therefore, the Department estimates that it would only require 15 minutes of a benefit specialist's time to prepare and distribute the covered information for each plan annually. Please see Table 13 for the estimated costs of disclosures.

11.2.4.4 Notice to PBMs and DOL

The exemption contained in paragraph (n) of the proposed rule provides relief from the restrictions of ERISA section 406(a)(1)(C) and (D) for plan fiduciaries who enter into a contract or arrangement, where the PBM or other covered service provider fails to comply with its obligations under the regulation. Upon discovering that a PBM or other covered service provider failed to comply, the responsible plan fiduciary must request in writing that the PBM or other covered service provider furnish the information or comply with the audit requirement. As discussed earlier, the Department assumes that 0.3 percent of arrangements may experience an omission or error that will require the responsible plan fiduciary to send the request to the PBM or other covered service provider.³³⁸ This assumption is based on the Department's experience that it is rare for pension plans to submit a notice under the requirement

³³⁷ The wage rate is calculated in the following manner: [(\$181.06 for a legal professional × 0.5)] + (\$129.14 for a benefits specialist × 0.5) = \$155.10.

³³⁸ Based on a review of the 2022 Form 5500 Schedule C filings, approximately 0.3 percent of ERISA-covered group health plans that filed Schedule C reported service providers who failed or refused to provide some of the information required to complete Part I. This estimate is used as a proxy for the percentage of self-insured group health plans that may need to request missing information from PBMs.

in 29 CFR 2550.408b-2. The Department also assumes that PBMs will rely on standardized templates and batch processing to prepare the notice. Therefore, the Department estimates that it will take 15 minutes of a benefit specialist's time to prepare and send the notice.

If the PBM or other covered service provider does not respond within 90

calendar days, the responsible plan fiduciary must notify the Department and further must assess whether to terminate or continue the service contract or arrangement consistent with the duty of prudence under section 404 of ERISA. As discussed earlier, the Department assumes that approximately 10 notices will be submitted. Similar to other notices, the Department assumes

that PBMs will rely on standardized templates and batch processing to prepare the notice. Therefore, the Department estimates that it will take 15 minutes of a benefit specialist's time to prepare and send the notice. Please see Table 14 for the estimated costs of disclosures.

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TABLE 14. Annual Disclosure Costs

	Number of Notices (first year)	Number of Hours Per Notice	Total Hour Burden	Hourly Wage Rate	Cost Equivalent of Hour Burden
	(A)	(B)	(C) = (A x B)	(D)	(E) = (C x D)
<u>PBMs send disclosures to self-insured group health plans</u>					
<u>PBMs provide initial disclosures to self-insured group health plans</u>					
Legal professionals and benefit specialists prepare disclosures for level-funded group health plans and self-insured group health plans with less than 1,000 employees	378,407	0.25	94,602	\$155.10	\$14,672,731
Legal professionals and benefit specialists prepare disclosures for level-funded group health plans and self-insured group health plans with 1,000 or more employees	5,121	0.50	2,561	\$155.10	\$397,134
<u>PBMs provide missing/other information requested by self-insured group health plans</u>					
Benefit specialists prepare and send information	38,353	0.25	9,588	\$129.14	\$1,238,227
<u>PBMs provide semiannual disclosures to self-insured group health plans</u>					
Benefit specialists prepare and send disclosures	2,301,167	0.25	575,292	\$129.14	\$74,293,177
<u>Self-insured group health plans send notice to PBMs and DOL</u>					
<u>Self-insured group health plans send request to PBMs to disclose missing/other information</u>					
Benefits specialists prepare and send request	1,151	0.25	288	\$129.14	\$37,160
<u>Self-insured group health plans send notice to DOL after the PBM has not responded within 90 days</u>					
Benefits specialists prepare and send notice	10	0.25	3	\$129.14	\$323
Total	2,724,209	-	682,333	-	\$90,638,751

11.3. Audit Right Costs

A right to audit the veracity of any and all disclosures made by the PBM or other covered service provider to a responsible plan fiduciary under the terms of the contract or arrangement as

required by this regulation, including the responsibility of the PBM or other covered service provider to deliver all necessary information to conduct such an audit, is an essential part of the proposal's framework for establishing

transparency in the marketplace for pharmacy benefit management services. The proposed regulation requires that the PBM or other covered service provider allow, not less than once per year, for the self-insured group health

plan to request such an audit for accuracy of any disclosures made to comply with the regulation.

While the cost of selecting an auditor and performing an audit of PBMs and other service providers is borne by the plan itself, service providers are required to provide the necessary information to the self-insured group health plan or its auditor without conditions that would restrict the self-insured group health plan’s right to conduct the audit. The PBM or other covered service provider must confirm receipt of the audit request within 10 business days and must provide the information within a commercially reasonable period.

The Department estimates that only one-third of self-insured group health plans will annually submit a request to their PBM or other covered service provider for all information necessary to perform an audit. This assumption is based on PBM contracts being structured around a three-year master agreement and audits typically taking six to nine months to complete, making it challenging to conduct more than one audit in a given contract period.³³⁹ The

Department does not anticipate level-funded group health plans submitting a request themselves but expects all issuers or TPAs that market to those plans to request audit materials. The Department requests comments on these assumptions.

Given that self-insured group health plans are requesting the data required to assess the services provided and fees charged for their prescription drug benefits, the Department assumes that PBMs already have or have access to all information and data readily available, but may require time to compile the records, data and other necessary information, including contracts with retail pharmacies and drug manufacturers for each self-insured group health plan. Additionally, because this disclosure will also include contracts with agents, affiliates and service providers such as retail pharmacies and drug manufacturers, the PBM may also require additional legal assistance to put in place confidentiality agreements to prevent sharing of the disclosed information.

The Department assumes that most PBMs maintain the underlying data

needed for invoices, rebate reconciliation, and contractual compliance. Audit responses are often generated through standardized templates or automated reports, though custom data pulls may be required in some cases. The Department also assumes that PBMs will rely on standardized templates and batch processing to prepare the audit request. Therefore, the Department estimates it will take 15 minutes for a benefit specialist at a TPA or issuer to prepare and send the audit request on the behalf of level-funded group health plans and self-insured group health plans with less than 1,000 employees. The Department also assumes it will take 2 hours of a PBM’s benefit specialist and IT staff’s time to prepare and disclose information needed for each requested audit, at a composite wage rate of \$150.52.³⁴⁰ This includes the time to retrieve documents, gather data and put in place any necessary confidentiality agreements. The Department requests comments on these assumptions.

Please see Table 15 for calculations and burden.

TABLE 15. Annual Audit Cost

	Number of Notices (first year)	Number of Hours Per Notice	Total Hour Burden	Hourly Wage	Cost Equivalent of Hour Burden
	(A)	(B)	(C) = (A x B)	(D)	(E) = (C x D)
<i>Self-insured group health plans with 1,000 or more employees send audit request</i>					
Benefit specialists prepare and send audit request	5,121	0.5	2,561	\$129.14	\$330,663
<i>Issuers send audit request on behalf of level-funded group health plans and self-insured group health plans with less than 1,000 employees</i>					
Benefit specialists prepare and send audits request	1,403	0.25	351	\$129.14	\$45,296
<i>PBMs prepare and disclose the needed info for the audit</i>					
Benefit specialists and IT staff prepare for requested audit	6,524	2	13,048	\$150.52	\$1,963,985
Total	6,524		15,959	-	\$2,339,944

11.4. Disclosure Mailing Costs

The proposed regulation does not preclude distribution through the use of

electronic technology. Consequently, the Department has assumed that interactions between parties will be carried out electronically. As a result,

all costs associated with distributing the disclosures have already been included in Section 11.2.3. The Department requests comments on this assumption.

³³⁹ Janus Desquitado and Francis Ayson, PBM Best Practice Series: Pharmacy Benefit Claims Auditing, Milliman White Paper, September 21, 2023, <https://www.milliman.com/en/insight/pbm-best-practices-pharmacy-benefits-claims-auditing>.

³⁴⁰ The wage rate is calculated in the following manner: [(\$129.14 for a benefits specialist × (½)) + (\$171.89 for an IT Professional) × (½)] = \$150.52.

11.5. Summary of Total Costs

The total costs associated with the proposed rule have been provided below in Table 16. In comparison,

according to the SEC 10-k filings, CVS Caremark, Express Scripts, and Optum Rx respectively reported \$162.5 billion,³⁴¹ \$185.4 billion,³⁴² and \$133.2 billion³⁴³ in revenue in 2024, resulting

in a total of \$481.1 billion. Therefore, the total three-year estimated average cost for this proposed rule represents 0.03 percent of total revenue of the three largest PBMs.

TABLE 16. Summary of Total Costs

	First Year	Subsequent Year	Three-Year Average
Rule Familiarization	\$17,843,463	\$0	\$5,947,821
IT Infrastructure	\$73,000,000	\$14,600,000	\$34,066,667
Disclosure	\$90,638,751	\$90,638,751	\$90,638,751
Audit	\$2,339,944	\$2,339,944	\$2,339,944
Total Costs	\$183,822,158	\$107,578,695	\$132,993,183

11.6. Sensitivity Analyses of Costs

Given the uncertainty surrounding these cost estimates, particularly due to variation in plan complexity and PBM

system capabilities, the Department conducted a sensitivity analysis to examine how the estimated costs would change if there was a decrease or increase in the hour burden from the

baseline assumptions of 10 or 25 percent Please see Tables 17, 18, and 19 for the results of this sensitivity analysis.

³⁴¹ The Form 10-K does not directly report the revenue for CVS Caremark. However, it provides revenue for the pharmacy services within the Health Services segment, which includes the pharmacy network, mail order pharmacies, and specialty pharmacies, and these services are generally managed by the PBM. (Source: SEC, Form 10-K, CVS Health Corporation. Annual Report,

(2024), <https://www.sec.gov/Archives/edgar/data/64803/000006480325000007/cvs-20241231.htm>.

³⁴² The Form 10-K does not directly report the revenue for Express Scripts. However, it provides revenue for the pharmacy services, and these services are generally managed by the PBM. (Source: SEC, Form 10-K, Cigna. Annual Report, (2024), <https://d18rn0p25nwr6d.cloudfront.net/CIK->

[0001739940/64c4c39f-1b4e-4979-8b4a-bfc403377665.pdf](https://www.sec.gov/Archives/edgar/data/0001739940/64c4c39f-1b4e-4979-8b4a-bfc403377665.pdf)).

³⁴³ The Form 10-K directly reports revenue for Optum Rx. (Source: SEC, Form 10-K, UnitedHealth Group. Annual Report, (2024) <https://www.unitedhealthgroup.com/content/dam/UHG/PDF/investors/2024/UNH-Q4-2024-Form-10-K.pdf>).

TABLE 17. Sensitivity Analysis of IT Infrastructure Costs

Adjustment	Number of PBMs	Average Costs	Total Cost	Change in Cost
	(A)	(B)	(C) = A x B	(D) = (C) – Baseline Cost
<u>Total costs in first year: Design, develop, and implement necessary IT system changes to collect and report the required data</u>				
Lower estimate (25%)	73	\$750,000	\$54,750,000	-\$18,250,000
Lower estimate (10%)	73	\$900,000	\$65,700,000	-\$7,300,000
Baseline assumption	73	\$1,000,000	\$73,000,000	\$0
Higher estimate (10%)	73	\$1,100,000	\$80,300,000	\$7,300,000
Higher estimate (25%)	73	\$1,250,000	\$91,250,000	\$18,250,000
<u>Total costs in second year: Maintain and update IT systems, provide ongoing quality assurance, and report the required data</u>				
Lower estimate (25%)	73	\$150,000	\$10,950,000	-\$3,650,000
Lower estimate (10%)	73	\$180,000	\$13,140,000	-\$1,460,000
Baseline assumption	73	\$200,000	\$14,600,000	\$0
Higher estimate (10%)	73	\$220,000	\$16,060,000	\$1,460,000
Higher estimate (25%)	73	\$250,000	\$18,250,000	\$3,650,000
<u>Three-year average costs</u>				
Lower estimate (25%)	73	\$350,000	\$25,550,000	-\$8,516,667
Lower estimate (10%)	73	\$420,000	\$30,660,000	-\$3,406,667
Baseline assumption	73	\$466,667	\$34,066,667	\$0
Higher estimate (10%)	73	\$513,333	\$37,473,333	\$3,406,667
Higher estimate (25%)	73	\$583,333	\$42,583,333	\$8,516,667

TABLE 18. Sensitivity Analysis of Sending Disclosure Notices

Activity	Notices	Hour per entity	Hourly Wage Rate	Equivalent Cost	Change in Cost
<u>Cost for PBMs to prepare initial disclosure notices to send to level-funded group health plans and self-insured health plans with less than 1,000 employees</u>					
	378,407	0.08	\$155.10	\$4,890,910	-\$9,781,821
	378,407	0.17	\$155.10	\$9,781,821	-\$4,890,910
Baseline assumption	378,407	0.25	\$155.10	\$14,672,731	\$0
	378,407	0.33	\$155.10	\$19,563,642	\$4,890,910
	378,407	0.50	\$155.10	\$29,345,463	\$14,672,731
	378,407	1.00	\$155.10	\$58,690,926	\$44,018,194
<u>Cost for PBMs to prepare initial disclosure notices by PBMs to send to self-insured group health plans with more than 1,000 employees</u>					
	5,121	0.08	\$155.10	\$66,189	-\$330,945
	5,121	0.17	\$155.10	\$132,378	-\$264,756
	5,121	0.25	\$155.10	\$198,567	-\$198,567
Baseline assumption	5,121	0.50	\$155.10	\$397,134	\$0
	5,121	0.75	\$155.10	\$595,700	\$198,567
	5,121	1	\$155.10	\$794,267	\$397,134
<u>Cost for self-insured group health plans to request to disclose missing/other information</u>					
	38,353	0.08	\$129.14	\$412,742	-\$825,484
	38,353	0.17	\$129.14	\$825,484	-\$412,742
Baseline assumption	38,353	0.25	\$129.14	\$1,238,227	\$0
	38,353	0.50	\$129.14	\$2,476,453	\$1,238,227
	38,353	0.75	\$129.14	\$3,714,680	\$2,476,453
	38,353	1	\$129.14	\$4,952,906	\$3,714,680
<u>Cost for PBMs to send semiannual disclosure notices by PBMs</u>					
	2,301,167	0.08	\$129.14	\$24,764,392	-\$49,528,784
	2,301,167	0.17	\$129.14	\$49,528,784	-\$24,764,392
Baseline assumption	2,301,167	0.25	\$129.14	\$74,293,177	\$0
	2,301,167	0.50	\$129.14	\$148,586,353	\$74,293,177
	2,301,167	0.75	\$129.14	\$222,879,530	\$148,586,353
	2,301,167	1	\$129.14	\$297,172,706	\$222,879,530
<u>Costs for self-insured group health plans to send request to PBM to disclose missing/other information</u>					
	1,151	0.08	\$129.14	\$12,387	-\$24,773
	1,151	0.17	\$129.14	\$24,773	-\$12,387
Baseline assumption	1,151	0.25	\$129.14	\$37,160	\$0
	1,151	0.50	\$129.14	\$74,320	\$37,160
	1,151	0.75	\$129.14	\$111,480	\$74,320
	1,151	1.00	\$129.14	\$148,640	\$111,480
<u>Cost for self-insured group health plans to send notice to DOL after the PBM has not responded within 90 days</u>					

	10	0.08	\$129.14	\$108	-\$215
	10	0.17	\$129.14	\$215	-\$108
Baseline assumption	10	0.25	\$129.14	\$323	\$0
	10	0.50	\$129.14	\$646	\$323
	10	0.75	\$129.14	\$969	\$646
	10	1	\$129.14	\$1,291	\$969
Lower Bound Cost	-	-	-	\$30,146,728	-\$60,492,023
Baseline Assumption Cost	-	-	-	\$90,638,751	\$0
Upper Bound Cost	-	-	-	\$361,760,737	\$271,121,986

TABLE 19. Sensitivity Analysis of Audit Costs

Activity	Notices	Hour per entity	Hourly Wage rate	Equivalent Cost	Change in Cost
	(A)	(B)	(C)	(D) = (A x B x C)	(E) = (D) – Baseline Cost
<u>Cost for self-insured group health plans to send audit requests to PBMs</u>					
	5,121	0.08	\$129.14	\$55,110	-\$275,552
	5,121	0.17	\$129.14	\$110,221	-\$220,442
Baseline assumption	5,121	0.50	\$129.14	\$330,663	\$0
	5,121	0.75	\$129.14	\$495,994	\$165,331
	5,121	1.00	\$129.14	\$661,326	\$330,663
<u>Cost for issuers to send audit requests to PBMs</u>					
	1,403	0.08	\$129.14	\$15,099	-\$30,197
	1,403	0.17	\$129.14	\$30,197	-\$15,099
Baseline assumption	1,403	0.25	\$129.14	\$45,296	\$0
	1,403	0.50	\$129.14	\$90,592	\$45,296
	1,403	0.75	\$129.14	\$135,888	\$90,592
	1,403	1.00	\$129.14	\$181,183	\$135,888
<u>Cost for PBMs to prepare requested information for audits</u>					
	6,524	0.5	\$150.52	\$490,996	-\$1,472,989
	6,524	1	\$150.52	\$981,992	-\$981,992
Baseline assumption	6,524	2	\$150.52	\$1,963,985	\$0
	6,524	3	\$150.52	\$2,945,977	\$981,992
	6,524	4	\$150.52	\$3,927,970	\$1,963,985
Lower Bound Cost	-	-	-	\$561,205	-\$1,778,738
Baseline Assumption Cost	-	-	-	\$2,339,944	\$0
Upper Bound Cost	-	-	-	\$4,770,479	\$2,430,535

12. Uncertainty

12.1. Uncertainty Related to Level-Funded Group Health Plans

The Department has generally treated the service provider arrangements for level-funded group health plans as similar to those of self-insured group health plans. The form of the arrangements would affect the costs associated with providing disclosure. Level-funded group health plans tend to be significantly smaller than purely self-insured group health plans, therefore, while it is likely that larger, self-insured group health plans may contract directly with PBMs, smaller level-funded group health plans may contract with a TPA for provision of their health benefits, including administering payment of hospital charges, medical/surgical claims and prescription coverage, as well as procuring reinsurance. In this case, PBMs would be a subcontractor to the TPA for level-funded group health plans rather than a contractor with the plan itself.

While under this scenario, PBMs would still be responsible for providing disclosure information regarding their compensation to the TPA as the covered service provider, it is less clear whether it would impact the manner and cost of providing this information. PBMs may instead provide more aggregated data to issuers who would in turn provide more granular disclosures to the level-funded group health plans. It is unclear whether this would result in additional costs or cost savings to level-funded group health plans, compared to the Department's current assumptions.

12.2. Uncertainty Over Rebates' Impact on Costs

The Department expects that the proposed rule will have a significant impact on rebates, as PBMs will be required to disclose not only how much of the rebate the self-insured group health plan will receive, but also how much will be retained by the PBM and other service providers. The Department expects that highlighting these payments will result in responsible plan fiduciaries negotiating a greater share of rebates, potentially leading PBMs to fully pass through all rebates to the self-insured group health plan, which could lower plan costs or cause changes in other forms of payment. Furthermore, increased transparency could enable responsible plan fiduciaries to compare offerings across PBMs, fostering competition and improving drug pricing.

However, their effects on the patients' out-of-pocket costs remain uncertain, as discussed in Sections 8.1 and 8.2. This

is primarily because rebates are typically paid to issuers or plan administrators rather than directly to group health plan participants, and the portion of those rebates passed through to participants can vary depending on plan design.³⁴⁴

12.3. Uncertainty Over Other PBM Practices on Costs

The proposed rule may also impact other PBM pricing strategies, including reducing the use of copay claw-backs, exclusionary formularies, and pharmacy network restrictions. However, their effects on employer costs and patients' out-of-pocket costs remain uncertain. These mechanisms are opaque,³⁴⁵ and the variability in how they are implemented across self-insured group health plans contributes to significant uncertainty about their financial impact on patients. For example, copay clawbacks are difficult to identify in the claims data, and patients are often unaware that they have paid more than the actual cost of the drug. This lack of visibility makes it challenging to measure how frequently claw-backs occur or to evaluate their overall impact on patient spending. Since there is limited publicly available data on how these practices affect patient costs, it is difficult to assess whether any particular PBM arrangement is delivering cost-savings for patients or merely shifting costs in ways that are not easily understood or tracked.

12.4. Uncertainty Over the Impact of the Audit Rights on the Number of Audits Requested

The proposed rule intends to facilitate self-insured group health plan oversight of PBMs by enabling plans to request an audit so that they may have access to all information needed to assess the completeness and accuracy of the required disclosures. As discussed in the preamble of this regulation, PBMs often limit self-insured group health plans' audit rights by providing only a sample of records relating to contractual performance, requiring that the auditor be approved by the PBM, or requiring that the audit be conducted on-site at a facility chosen by the PBM. By removing these barriers, the audit requirement ensures that PBMs provide

accurate and complete information to plans and their auditors, permitting plans to better determine if PBMs are complying with contract terms and to take corrective action as needed.

Currently, plans conduct audits, though often with less information and control over the audit process than the proposed rule ensures. Industry best practices suggest that "plan sponsors should have their pharmacy claims audited. If the plan sponsor suspects the PBM is not adhering to the contract, or if the plan frequently changes benefits, then it is best to audit every year."³⁴⁶ Because these audits can take up to nine months to perform, the Department has assumed that plans only conduct these audits once in a given three-year contract period.

By clarifying and standardizing audit rights, the proposed rule would provide plan fiduciaries with additional information relevant to oversight. However, it is uncertain whether the proposed rule would result in changes to the number of audits requested. In some cases, improved disclosures may reduce the need for additional audits by increasing transparency into PBM practices. In other cases, greater clarity regarding audit rights and available information may lead some plans to elect to make greater use of audits. To the extent that plans choose to increase their use of audits, any associated costs would be borne by the plan.

12.5. Uncertainty Over the Impact of the Rule on the PBM Market

The PBM market has been facing significant market consolidation in recent years, with the three largest PBMs controlling roughly 80 percent of the market.³⁴⁷ Since the proposed rule would require PBMs to provide disclosures at a more granular level, the Department expects that self-insured group health plans may demand additional concessions during the contract negotiation process, putting downward pressure on prices. CBO suggested in their 2019 analysis of S.1895, *Lower Health Care Costs Act*, that "smaller PBMs compete with larger PBMs by offering more transparent contracts. Removing that point of leverage may reduce the competitiveness of those smaller PBMs,

³⁴⁴ Patricia M. Danzon, *Pharmacy Benefit Management: Are Reporting Requirements Pro or Anti-Competitive?* *International Journal of the Economics of Business*, (2015) <https://www.tandfonline.com/doi/full/10.1080/13571516.2015.1045741>.

³⁴⁵ Rebecca Robbins & Reed Abelson, *The Opaque Industry Secretly Inflating Prices for Prescription Drugs*, *The New York Times* (2024), <https://www.nytimes.com/2024/06/21/business/prescription-drug-costs-pbm.html>.

³⁴⁶ Janus Desquitado and Francis Ayson, PBM Best Practice Series: Pharmacy Benefit Claims Auditing, Milliman White Paper, September 21, 2023, <https://www.milliman.com/en/insight/pbm-best-practices-pharmacy-benefits-claims-auditing>.

³⁴⁷ Federal Trade Commission, *Interim Staff Report: Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies*, (2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

which could reduce competition if larger PBMs garner greater market share as a result.”³⁴⁸

The Department notes, however, that those PBMs that already leverage transparency in their contracts may not have their revenues significantly impacted by the proposed rule. While all PBMs would bear the costs of additional disclosures, more transparent PBMs would be less prone to contract revisions following those disclosures given that the required information has already been shared with the plan sponsor or issuer, and presumably priced into the contract. Less transparent PBMs, however, may need to make additional concessions and revisions in response to the disclosures, which would likely reduce their revenues. As such, the Department is unclear whether the proposed rule would impact market consolidation in the PBM space and if so, in what direction.

12.6. Uncertainty Over the Longevity of the Impact of Proposed Rule

The Department, when considering the impact of this proposed rule, relied heavily on analyses conducted by CBO for several prescription drug reform bills. In particular, CBO reviewed S. 1339 the *Pharmacy Benefit Manager Reform Act* which banned spread pricing, required PBMs to pass-through all rebates and required disclosures related to enrollees’ use of prescription drugs, costs, rebates, fees, and cost-sharing amounts to plan sponsors.³⁴⁹ CBO estimated that the reduction in plan premiums resulting from this bill would diminish significantly over time as “contract terms between parties are redefined and PBMs find more ways to generate revenue outside of the disclosure requirements.”³⁵⁰ While the Department’s proposal includes similar disclosure requirements as that of the CBO bill described above, it does not include all the elements CBO analyzed. As a result, the Department is unclear on whether its impacts of the proposed rule would abate over time. The Department seeks comments on this assumption.

³⁴⁸ Congressional Budget Office, *Cost Estimate: S. 1895, Lower Health Care Cost Act*, July 16, 2019, https://www.cbo.gov/system/files/2019-07/s1895_0.pdf.

³⁴⁹ Congressional Budget Office, *Cost Estimate: S. 1339, Pharmacy Benefit Manager Reform Act*, December 5, 2024, <https://www.cbo.gov/system/files/2024-12/s1339.pdf>.

³⁵⁰ Congressional Budget Office, *Cost Estimate: S. 1339, Pharmacy Benefit Manager Reform Act*, December 5, 2024, <https://www.cbo.gov/system/files/2024-12/s1339.pdf>.

13. Alternatives

In addition to the regulatory approach outlined in the proposed rule, the Department considered an alternative approach during the development of the proposed rule. It is discussed in greater detail below.

13.1. Inclusion of Fully Insured Group Health Plans

The Department considered applying the proposed regulation to fully insured group health plans. In doing so, the full universe of ERISA covered group health plans could benefit from these disclosures, which would aid responsible plan fiduciaries in fulfilling their fiduciary responsibilities, assist them in monitoring service providers to ensure that only reasonable costs are paid and that any conflicts of interest are disclosed and mitigated. This would in turn benefit plan participants and their beneficiaries.

Upon review, the Department found that fully insured group health plans generally do not enter into separate agreements for prescription drug benefits through carve-out arrangements but rather contract with issuers for comprehensive health insurance coverage with prescription drug benefits bundled into the larger package. A 2023 study on vertical integration in Medicare Part D market finds that consolidation of PBMs and insurers can raise premiums for non-integrated insurers and lowers premiums for vertically integrated insurers. This research suggests that vertical integration may limit competition and increase costs even in markets, such as the fully-insured group market, where prescription drugs benefits are bundled rather than separately carved out.³⁵¹ As such, it is not clear that responsible plan fiduciaries would find the disclosures required under this proposed helpful when negotiating or monitoring their benefit plan as to justify the costs associated with the disclosures (both to the covered service provider providing the disclosures and the responsible plan fiduciary reviewing and analyzing the disclosures). Therefore, the required disclosures under the proposal may not meaningfully reduce information asymmetry in the fully insured group health plan market, given that prescription drug benefits are bundled and negotiated at the issuer level rather than directly by plan fiduciaries. Based

³⁵¹ Gray, Charles, Abby E. Alpert, and Neeraj Sood, *Disadvantaging Rivals: Vertical Integration in the Pharmaceutical Market*, (2023), No. w31536. National Bureau of Economic Research, https://www.nber.org/system/files/working_papers/w31536/w31536.pdf.

on these considerations, the Department has instead reserved obligations with respect to fully insured group health plans for future action.

13.2. Exempting Smaller Entities

The Department considered exempting smaller entities, such as level-funded group health plans which are self-funded arrangements that utilize rich stop-loss policies to emulate characteristics of fully insured arrangements, such as predictable spending. Smaller level-funded plans, in particular, tend to rely on TPAs and issuers to carry out their claims, administrative, and pharmacy benefit management functions. In such a case, while the entity contracting or arranging with the group health plan is not providing the services itself, it would be responsible for making the disclosures to the responsible plan fiduciary required under the proposal, and therefore must be able to obtain information from the provider performing the pharmacy benefit management services necessary for those disclosures.

The Department believes that providing an exemption for these smaller entities would risk reducing transparency in a segment of market where disclosures are most needed. The Department estimates there are 1,031,098 level-funded group health plans, accounting for 90 percent of affected ERISA-covered group health plans. For these reasons, the Department determined that a small entity exemption would not achieve the intended goals of the proposed rules.

13.3. Annual Disclosures From PBMs

The Department did consider requiring annual disclosures from PBMs but determined that this information needed to be provided more frequently. Given that level-funded group health plans account for approximately 90 percent of affected ERISA-covered group health plans, the timing of the required disclosures has market-level effects. Requiring disclosures only on an annual basis would delay actionable information for a substantial portion of the market, increasing the likelihood of inefficient pricing, foregone renegotiations opportunities, and higher plan costs. Semiannual disclosures reduce these market inefficiencies by improving the timeliness and useful of information available to plan fiduciaries. Therefore, the Department is requiring that PBMs or covered service providers furnish disclosures on a semiannual basis within 30 calendar days following the conclusion of each six-month period starting from the

contract or arrangement initiation date. The Department is seeking comments on the proposed timing requirements.

13.4. Enhanced Disclosure for Bundled Services

The Department considered enhanced disclosures regarding direct compensation for bundled services. As proposed, the initial disclosure requirements would require a description of direct compensation that the covered service provider, an affiliate, agent, or subcontractor reasonably expects to receive in connection with the pharmacy benefit management services under the contract or arrangement. The term “direct compensation” means compensation received directly from the self-insured group health plan, or from the plan sponsor on behalf of the self-insured group health plan regardless of whether such compensation is paid from plan assets. The proposal would require a description of the amount of all direct compensation, both in the aggregate and by service, that the covered service provider, an affiliate, agent, or subcontractor reasonably expects to receive on a quarterly basis in connection with pharmacy benefit management services under the contract or arrangement.

The Department considered whether to require the description of direct compensation for a bundled services option to include additional information, such as the bundled discounted value along with a description of services provided in the bundle. Greater additional disclosures could further reduce information asymmetries associated with bundled pricing by enabling fiduciaries to better compare compensation arrangements across providers. However, the Department was uncertain whether this level of detail would provide additional benefits to self-insured group health plan fiduciaries beyond the other disclosure requirements in the proposal, particularly given potential increases in compliance and administrative costs. Instead of an affirmative requirement, the Department determined to request public comment on that option.

13.5. Conclusion

The proposed rule is intended to allow responsible plan fiduciaries of level-funded and self-insured group health plans to better fulfill their

statutorily mandated role to determine that the service contracts or arrangements are reasonable under ERISA section 408(b)(2). The Department is of the view that increased transparency in PBM practices will empower responsible plan fiduciaries to increase market competition, negotiate more favorable contractual terms, reduce PBMs’ conflicts of interest, and promote greater competition across the prescription drug supply chain. The proposed rule is expected to result in more accurate prescription drug classifications by PBMs, leading to more cost-effective and clinically appropriate formularies. Taken together, these outcomes will enhance market efficiency and ultimately improve access to affordable prescription drugs for consumers.

F. Paperwork Reduction Act

As part of its continuing effort to reduce paperwork and respondent burden, the Department conducts a preclearance consultation program to allow the general public and Federal agencies to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA).³⁵² This helps to ensure that the public understands the Department’s collection instructions, respondents can provide the requested data in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the Department can properly assess the impact of collection requirements on respondents.

Currently, the Department is soliciting comments concerning the proposed information collection request (ICR) included in the *PBM Fee Disclosure Regulation under 408(b)(2)*. To obtain a copy of the ICR, contact the PRA addressee shown below or go to <https://www.RegInfo.gov>.

The Department has submitted a copy of the proposed rule to OMB in accordance with 44 U.S.C. 3507(d) for review of its information collections. The Department and OMB are particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the functions of the agency, including whether the information will have practical utility;

- Evaluate the accuracy of the agency’s estimate of the burden for the collection of information, including the validity of the methodology and assumptions used;

- Enhance the quality, utility, and clarity of the information to be collected; 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 (for example, permitting electronically delivered responses).

Commenters may send their views on the Department’s PRA analysis in the same way they send comments in response to the proposed rule (for example, through the www.regulations.gov website), including as part of a comment responding to the broader NPRM.

PRA Addressee: Address requests for copies of the ICR to PRA Clearance Officer, Office of Research and Analysis, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW, Room N-5718, Washington, DC 20210; ebbsa.opr@dol.gov (<https://www.reginfo.gov/public/do/PRAMain>).

For a full discussion of burden related to this information collection please see the supporting statement which is part of the ICR available at <https://www.reginfo.gov/public/do/PRAMain>.

The proposed rule is intended to help responsible plan fiduciaries better monitor prescription drug costs and benefit administration. The proposed rule requires PBMs and other covered service providers, and their affiliates, and agents, and subcontractors, to disclose pricing structures and potential conflicts of interest before entering, extending or renewing a service agreement and on a semiannual basis afterward. PBMs and other covered service providers must also make available all the information needed for responsible plan fiduciaries to audit their disclosures provided under the regulation. Please see Table 20 for a summary of the hour and cost burden. For a description of how the estimates are obtained please see the Cost section of the RIA.

³⁵² 44 U.S.C. 3506(c)(2)(A) (1995).

TABLE 20. Summary of Hour and Cost Burden

	Hour Burden	Cost Equivalent of Hour Burden	Cost Burden
IT Infrastructure (first year)	474,500	\$73,000,000	\$0
IT Infrastructure (subsequent years)	94,900	\$14,600,000	\$0
Disclosure (annual)	682,333	\$90,638,751	\$0
Audit (annual)	15,959	\$2,339,944	\$0
First Year Total	1,172,792	\$165,978,695	\$0
Subsequent Year Total	793,192	\$107,578,695	\$0
Three-Year Average Total	919,725	\$127,045,362	\$0

Below is a summary of the burden associated with the information collection.

Type of Review: New.

Agency: Employee Benefits Security Administration, U.S. Department of Labor.

Title: PBM Fee Disclosure Regulation under 408(b)(2).

OMB Control Number: 1210–New.

Affected Public: Businesses or other for-profits.

Estimated Number of Respondents: 1,151,392.

Estimated Number of Annual Responses: 2,730,806.

Frequency of Response: Annual, Semi-annual.

Estimated Total Annual Burden Hours: 919,725.

Estimated Total Annual Burden Cost: \$0.

G. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA)³⁵³ imposes certain requirements with respect to Federal rules that are subject to the notice-and-comment requirements of section 553(b) of the Administrative Procedure Act and are likely to have a significant economic impact on a substantial number of small entities. Unless the head of an agency determines that a final rule is not likely to have a significant economic impact on a substantial number of small entities, section 603³⁵⁴ of the RFA requires the agency to present an initial regulatory flexibility analysis of the proposed rule.

The Department has limited data to determine if this proposed rule would have a significant impact on a substantial number of small entities. The Department has prepared this

initial regulatory flexibility analysis (IRFA) and requests data or other information it would need to make a final determination.

1. Need for the Rule

Research suggests that PBMs contribute to high prescription drug prices in the United States by extracting economic rents in their role as intermediaries between self-insured group health plans and prescription drug manufacturers. PBMs are often responsible for developing prescription drug formularies and benefit designs for self-insured group health plans, negotiating rebates with drug manufacturers for placement on those formularies, establishing preferred pharmacy networks, and processing prescription drug claims. In providing these services, PBMs often operate in ways that make it difficult for small, self-insured group health plans to compare different PBM services, due to the non-transparent nature of the information.³⁵⁵

Employers that sponsor health plans and other responsible plan fiduciaries have expressed concerns about PBM practices, especially regarding rebates, transparency, and the complexity of contracts. Many plan sponsors believe that PBMs' goals are not aligned with the plans they service, and they often do not fully understand their self-insured group health plans' contracts with PBMs.³⁵⁶ A 2024 survey found that for

firms offering health benefits with 500 or more employees, 37 percent had no idea how much of PBM negotiated rebates they received.³⁵⁷ Responsible plan fiduciaries of small self-insured group health plans, in particular, often have limited access to pricing information compared to larger self-insured group health plans, which receive higher retail discounts on brand and generic prescription drugs, pay lower dispensing fees, and are more likely to receive manufacturer rebates than small self-insured group health plans.³⁵⁸

2. Objective of the Rule

The proposed rule aims to improve transparency in PBM arrangements by requiring disclosures similar to those in the Department's 2012 pension disclosure regulation. Covered service providers, including PBMs, must disclose detailed information to responsible plan fiduciaries to help them assess the reasonableness of compensation and fulfill their duties under ERISA.

PBMs and other covered service providers would be required to disclose, both before entering into an agreement and throughout the term of the contract, the full range of services provided, including those delivered through affiliates, agents, and subcontractors. They must also report all compensation,

www.npcnow.org/sites/default/files/media/npc-employer-pbm-survey-final.pdf.

³⁵⁷ KFF, 2024 Employer Health Benefits Survey, (Oct. 9, 2024), <https://www.kff.org/report-section/ehbs-2024-section-13-employer-practices-provider-networks-coverage-for-glp-1s-abortion-and-family-building-benefits/>.

³⁵⁸ Patricia M. Danzon, *Pharmacy Benefit Management: Are Reporting Requirements Pro or Anti-Competitive?* International Journal of the Economics of Business, (2015) <https://www.tandfonline.com/doi/full/10.1080/13571516.2015.1045741>.

³⁵³ 5 U.S.C. 601 *et seq.* (1980).

³⁵⁴ 5 U.S.C. 603 (1980).

³⁵⁵ Véronique C. Raimond, William B. Feldman, Benjamin N. Rome, & Aaron S. Kesselheim, *Why France Spends Less than the United States on Drugs: A Comparative Study of Drug Pricing and Pricing Regulation*, The MilBank Quarterly, (2021), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7984670/>.

³⁵⁶ National Pharmaceutical Council, *Toward Better Value: Employer Perspectives on What's Wrong with the Management of Prescription Drug Benefits and How to Fix it*, (2017), <https://www.npcnow.org/sites/default/files/media/npc-employer-pbm-survey-final.pdf>.

including manufacturer payments, spread pricing, copay claw-backs, and incentives related to formulary placement or price protection agreements. Disclosures must include enough information to allow responsible plan fiduciaries to independently estimate the cost of each drug by pharmacy channel. On a semiannual basis, PBMs and other covered service providers must provide updated disclosures summarizing the actual amounts received in manufacturer payments, spread pricing, copay claw-backs, and any other compensation received. They must also provide additional information upon request from the responsible plan fiduciary.

The proposed rule also specifies the responsible plan fiduciary's right to audit PBM and other covered service providers compliance once per year. Although the self-insured group health plan is responsible for audit costs, PBMs and other covered service providers must provide access to all necessary records, including contracts with pharmacies, drug manufacturers, and affiliates. The covered service provider must confirm receipt of the audit

request within 10 business days and must provide the information within a commercially reasonable period.

The Department expects that the proposed rule would increase transparency in PBM compensation arrangements and enable self-insured group health plans to better understand these practices. This increased transparency would help responsible plan fiduciaries to compare offerings across PBMs more effectively, helping them enter into the most appropriate PBM contracts for their needs. The proposal is intended to allow fiduciaries of level-funded and self-insured group health plans to fulfill their statutorily mandated role to determine that the service contracts or arrangements are reasonable under ERISA section 408(b)(2).

3. Affected Small Entities

The number of small, affected entities are discussed in greater detail later in this IRFA.

3.1. Group Health Plans

For the purposes of the IRFA, the Department considers employee benefit plans with fewer than 100 participants

to be small entities.³⁵⁹ The basis of this definition is found in ERISA Section 104(a)(2), which permits the Secretary of Labor to prescribe simplified annual reports for plans that cover fewer than 100 participants. Under ERISA Section 104(a)(3), the Secretary may also provide for exemptions or simplified annual reporting and disclosure for welfare benefit plans. Pursuant to the authority of Section 104(a)(3), the Department has previously issued (see 29 CFR 2520.104–20, § 2520.104–21, § 2520.104–41, § 2520.104–46, and § 2520.104b–10) simplified reporting provisions and limited exemptions from reporting and disclosure requirements for small plans, including unfunded or insured welfare plans, that and satisfy certain requirements.

As discussed in subsection 7.1 of the RIA, the proposed rule would affect all self-insured ERISA-covered group health plans. The Department estimates that the proposed rule would affect approximately 1,031,098 level-funded group health plans.³⁶⁰ The number of affected level-funded group health plans by participant count has been provided below in Table 21.³⁶¹

TABLE 21. Number of Affected Level-Funded Group Health Plans by Participant Count

Participant Count	Less than 10 participants	10 to 24 participants	25 to 99 participants	Total
Level-Funded Group Health Plans	544,035	260,432	226,631	1,031,098

3.2. TPAs and Issuers

The Department also estimates that the proposed rule will indirectly affect 205 TPAs and 373 issuers in the group market with 809 issuers/State combinations.³⁶² These are service providers acting on behalf of level-funded group health plans and self-insured group health plans, who typically provide plan management, regulatory compliance, and administrative services.

Health insurance companies are generally classified under the North American Industry Classification System (NAICS) code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of \$47 million or less are considered small entities for this NAICS code.³⁶³ The Department believes that few, if any, insurance companies underwriting comprehensive health insurance

policies (in contrast, for example, to travel insurance policies or dental discount policies) fall below these size thresholds. Based on data from the CMS Medical Loss Ratio (MLR) annual report submissions for the 2023 reporting year, approximately 65³⁶⁴ out of 373 health insurance companies had total premium revenue of \$47 million or less.³⁶⁵ The Department estimates that approximately 80 percent of these small issuers belong to larger holding groups

³⁵⁹ The Department consulted with the Small Business Administration in making this determination, as required by 5 U.S.C. 603(c) and 13 CFR 121.903(c). Memorandum received from the U.S. Small Business Administration, Office of Advocacy on July 10, 2020.

³⁶⁰ The Department estimates that 42 percent of ERISA-covered group health plans with less than 100 participants are level-funded, based on the 2023 Medical Expenditure Panel Survey Insurance Component (MEPS-IC), the 2021 County Business Patterns from the Census Bureau and the 2024 KFF Employer Health Benefits Survey. Therefore,

2,454,996 ERISA-covered group health plans × 42 percent = 1,031,098 level-funded group health plans.

³⁶¹ Plan assets are not an appropriate measure for health plans, as many self-insured plans pay benefits directly from the employer's general assets. Therefore, this analysis uses participant count as a proxy for plan size.

³⁶² An "issuer/state combination" refers to a health insurance issuer and the state in which it offers coverage, such that the same issuer operating in multiple states is treated as separate issuer/state combinations. Data source: Centers for Medicare

and Medicaid Services, *2023 Medical Loss Ratio Data*, <https://www.cms.gov/marketplace/resources/data/medical-loss-ratio-data-systems-resources>.

³⁶³ SBA, *Table of Size Standards*, https://www.sba.gov/sites/default/files/2023-06/Table%20of%20Size%20Standards_Effective%20March%2017%2C%202023%20%282%29.pdf, as of March 2023.

³⁶⁴ Projection using 2023 MLR Data.

³⁶⁵ Centers for Medicare and Medicaid Services, *2023 Medical Loss Ratio Data*, <https://www.cms.gov/marketplace/resources/data/medical-loss-ratio-data-systems-resources>.

based on the MLR data, and many, if not all, of these small companies are likely to have non-health lines of business that result in their revenues exceeding \$47 million. Therefore, the Department assumes approximately 20 percent, or 13, of the 65 potential small issuers are in fact small issuers for purposes of this analysis. The Department believes this is an overestimate, as many if not all of these small issuers are likely to have non-health lines of business that result in their revenues exceeding \$47 million, but the Department uses 13 small issuers for purposes of this analysis. The Department seeks comments on these estimates.

3.3. Participants, Beneficiaries, and Enrollees

There are approximately 14.8 million participants and beneficiaries in small self-insured and level-funded ERISA-covered group health plans.³⁶⁶ According to the 2022 Center for Disease Control's (CDC) National Center for Health Statistics, United States, 64.1 percent of individuals under the age of 65 with private health insurance used a prescription medication in the past year.³⁶⁷ Therefore, the Department estimates that approximately 9.5 million participants and beneficiaries in these self-insured group health plans will be affected by the proposed rule.

3.4. PBMs

In 2023, there were 73 full-service PBMs in the marketplace.³⁶⁸ These PBMs may also provide brokerage services to self-insured group health plans with respect to pharmacy benefit management services. PBMs fall under the NACIS Code 524292, or "Pharmacy Benefit Management and Other Third-Party Administration of Insurance and Pension Funds," and the SBA considers businesses with up to \$45.5 million in annual receipts to be small.³⁶⁹ Notably, 92 percent of businesses within this industry are small businesses according to the SBA size standards. However, the

Department believes that the distribution of revenue for this entire category does not reflect the distribution of PBM revenues. This is because the size distribution for TPAs is different than the size distribution for PBMs—PBMs are larger than TPAs and the annual receipts of most PBMs exceed this threshold. In particular, the three largest PBMs, CVS Caremark, Express Scripts, and Optum Rx respectively reported \$162.5 billion,³⁷⁰ \$185.4 billion,³⁷¹ and \$133.2 billion³⁷² in revenue in 2024, according to the SEC 10-K filings. Even for "small" PBMs, the Department expects that annual receipts would not be significantly below the SBA threshold and that few PBMs have annual receipts levels below 25 percent of the SBA threshold. The Department requests comments on this assumption and would appreciate any data to inform the Department on the size distribution of PBMs by revenue and clients served.

4. Cost of Proposed Rule

The Department expects small PBMs to review the proposed rule, evaluate their current disclosure practices, and make any necessary changes to ensure compliance. Increased transparency may reveal revenue strategies such as rebates and spread pricing, causing some PBMs to shift toward fee-based compensation models and renegotiate contracts with level-funded group health plans, manufacturers, and wholesalers. Small issuers, TPAs, and level-funded group health plans are also expected to review the proposed requirements for compliance.

Under the proposed rule, PBMs must provide fee disclosures to self-insured group health plans and permit self-insured group health plans to audit the covered service provider at least once per year. The Department estimates that only one-third of self-insured group health plans will submit an annual request for all information necessary to conduct such an audit. While level-

funded plans are not expected to make these requests directly, the Department anticipates that issuers or TPAs providing services to self-insured group health plans will submit audit requests on their behalf.

4.1. Illustration of Costs for Small PBMs

Tables 22 and 23 illustrate how the estimated costs for PBMs compare to revenue in the first year and subsequent years, respectively. Table 22 specifically presents a range of potential cost impacts at different revenue levels. The Department does not have data on the revenue distribution of PBMs or on how many self-insured group health plans a small PBM typically provides services for. Since both the disclosure and audit costs depend on the number of self-insured group health plans, these tables present a range of per-entity costs as a percentage of revenue, varying both the average number of self-insured group health plans serviced by a PBM and the revenue relative to the SBA small business threshold.

It is important to note that this illustration is not intended to reflect current market conditions. As previously discussed, while the Department uses the SBA threshold for NACIS Code 524292, or "Pharmacy Benefit Management and Other Third-Party Administration of Insurance and Pension Funds" in this analysis, the Department expects that the size distribution for TPAs to be different than the size distribution for PBMs. Based on these assumptions, the Department estimates that the proposed rule's costs for most PBMs are likely less than three percent of revenues in the first year and two percent in subsequent years. The Department requests comments on the parameters used in this illustration, particularly any data on the revenues of small PBMs and how many self-insured group health plans a small PBM typically provides services for.

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³⁶⁶ Employee Benefits Security Administration, Health Insurance Coverage Bulletin and Abstract of Auxiliary Data for the March 2023 Annual Social and Economic Supplement to the Current Population Survey, (August 30, 2024), <https://www.dol.gov/sites/dolgov/files/EBSA/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2023.pdf>.

³⁶⁷ Centers for Disease Control and Prevention, National Center for Health Statistics, *Prescription Medication Use Among Adults*, United States (2023), <https://nchsdata.cdc.gov/DQS/?topic=prescription-medication-use-among-adults&subtopic=&group=health-insurance-coverage-younger-than-65-years&subgroup=private&range=2019-to-2023>.

³⁶⁸ The PCMA article estimated the total number of PBMs in 2023 in the following manner: 70 full-service PBMs + 6 new full-service PBMs—8 acquired PBMs + 5 PBMs that expanded services = 73 full-service PBMs.

³⁶⁹ SBA, *Table of Size Standards*, <https://www.sba.gov/sites/default/files/2023-06/Table%20of%20Size%20Standards%20Effective%20March%202017%2C%202023%20%282%29.pdf>, as of March 2023.

³⁷⁰ The Form 10-K does not directly report the revenue for CVS Caremark. However, it provides revenue for the pharmacy services within the Health Services segment, which includes the pharmacy network, mail order pharmacies, and specialty pharmacies, and these services are generally managed by the PBM. (Source: SEC, *Form*

10-K, CVS Health Corporation, Annual Report, (2024), <https://www.sec.gov/Archives/edgar/data/64803/000006480325000007/cvs-20241231.htm>.

³⁷¹ The Form 10-K does not directly report the revenue for Express Scripts. However, it provides revenue for the pharmacy services, and these services are generally managed by the PBM. (Source: SEC, *Form 10-K, Cigna. Annual Report*, (2024), <https://d18m0p25nwr6d.cloudfront.net/CIK-0001739940/64c4c39f-1b4e-4979-8b4a-bfc403377665.pdf>).

³⁷² The Form 10-K directly reports revenue for Optum Rx. (Source: SEC, *Form 10-K, UnitedHealth Group, Annual Report*, (2024) <https://www.unitedhealthgroup.com/content/dam/UHG/PDF/investors/2024/UNH-Q4-2024-Form-10-K.pdf>).

TABLE 22. PBM Per Entity Costs as a Percentage of Revenue, First Year

	Per-Entity Cost	Cost as a Percent of 100% of SBA Threshold	Cost as a Percent of 75% of SBA Threshold	Cost as a Percent of 50% of SBA Threshold	Cost as a Percent of 25% of SBA Threshold	Cost as a Percent of 10% of SBA Threshold
<i>PBM</i>						
<i>Dollar Amount of Percent of SBA Small Business Threshold (\$ millions)</i>		\$45.5 million	\$34.1 million	\$22.8 million	\$11.4 million	\$4.6 million
<i>Rule Familiarization</i>	\$3,621 ^a	0.008%	0.011%	0.016%	0.032%	0.080%
<i>IT Infrastructure</i>	\$1,000,000 ^b	2.198%	2.930%	4.396%	8.791%	21.978%
<i>Disclosure</i>	^c					
<i>Servicing 50 Plans</i>	\$4,586	0.010%	0.013%	0.020%	0.040%	0.101%
<i>Servicing 100 Plans</i>	\$9,171	0.020%	0.027%	0.040%	0.081%	0.202%
<i>Servicing 150 Plans</i>	\$13,757	0.030%	0.040%	0.060%	0.121%	0.302%
<i>Servicing 200 Plans</i>	\$18,342	0.040%	0.054%	0.081%	0.161%	0.403%
<i>Audit</i>	^d					
<i>Servicing 50 Plans</i>	\$15,052	0.033%	0.044%	0.066%	0.132%	0.331%
<i>Servicing 100 Plans</i>	\$30,104	0.066%	0.088%	0.132%	0.265%	0.662%
<i>Servicing 150 Plans</i>	\$45,156	0.099%	0.132%	0.198%	0.397%	0.992%
<i>Servicing 200 Plans</i>	\$60,208	0.132%	0.176%	0.265%	0.529%	1.323%
Total						
Servicing 50 Plans	\$1,023,259	2.249%	2.999%	4.498%	8.996%	22.489%
Servicing 100 Plans	\$1,042,896	2.292%	3.056%	4.584%	9.168%	22.921%
Servicing 150 Plans	\$1,062,534	2.335%	3.114%	4.670%	9.341%	23.352%
Servicing 200 Plans	\$1,082,172	2.378%	3.171%	4.757%	9.514%	23.784%

Note:

^a Calculated as 20 hours per PBM x an hourly labor cost of \$181.06.^b Calculated as an hourly labor cost of \$126.72 x 2,250 hours + an hourly labor cost of \$120.40 business operations specialists x 750 hours + an hourly labor cost of \$171.89 x 3,500 hours.^c The costs associated with the initial disclosure are calculated as: 0.5 hour per PBM x an hourly labor cost of \$155.10 x 1/3 x the number of self-insured group health plans serviced by the PBM. The costs associated with the semiannual disclosure are calculated as: 0.25 hour x an hourly labor cost of \$129.14 x 2 x the number of self-insured group health plans serviced by the PBM. The costs associated with providing missing information are calculated as: 0.25 hour x an hourly wage rate of \$129.14 x 3.3 percent x the number of self-insured group health plans serviced by the PBM.^d Calculated as: 2 hours x an hourly labor cost of \$150.52 x 1/3 x the number of self-insured group health plans serviced by the PBM.

TABLE 23. PBM Per Entity Costs as a Percentage of Revenue, Subsequent Years

	Per-Entity Cost	SBA Small Business Threshold (\$ millions)	Cost as a Percent of Threshold (100%)	Cost as a Percent of 75% of Threshold	Cost as a Percent of 50% of Threshold	Cost as a Percent of 25% of Threshold	Cost as a Percent of 10% of Threshold
<i>PBMs</i>		\$45.5					
<i>IT Infrastructure</i>	\$200,000 ^a		0.440%	0.586%	0.879%	1.758%	4.396%
<i>Disclosure Cost</i>	^b						
Servicing 50 Plans	\$4,586		0.010%	0.013%	0.020%	0.040%	0.101%
Servicing 100 Plans	\$9,171		0.020%	0.027%	0.040%	0.081%	0.202%
Servicing 150 Plans	\$13,757		0.030%	0.040%	0.060%	0.121%	0.302%
Servicing 200 Plans	\$18,342		0.040%	0.054%	0.081%	0.161%	0.403%
<i>Audit</i>	^c						
Servicing 50 Plans	\$15,052		0.033%	0.044%	0.066%	0.132%	0.331%
Servicing 100 Plans	\$30,104		0.066%	0.088%	0.132%	0.265%	0.662%
Servicing 150 Plans	\$45,156		0.099%	0.132%	0.198%	0.397%	0.992%
Servicing 200 Plans	\$60,208		0.132%	0.176%	0.265%	0.529%	1.323%
<i>Total</i>							
Servicing 50 Plans	\$219,638		0.483%	0.644%	0.965%	1.931%	4.827%
Servicing 100 Plans	\$239,275		0.526%	0.701%	1.052%	2.104%	5.259%
Servicing 150 Plans	\$258,913		0.569%	0.759%	1.138%	2.276%	5.690%
Servicing 200 Plans	\$278,550		0.612%	0.816%	1.224%	2.449%	6.122%

Note:

^a Calculated as 73 PBMs x an hourly labor cost of \$126.72 x 500 hours + an hourly labor cost of \$120.40 business operations specialists x 50 hours + an hourly labor cost of \$171.89 x 750 hours.

^b The costs associated with the initial disclosure are calculated as: 0.5 hours per PBM x an hourly labor cost of \$155.10 x 1/3 x the number of self-insured group health plans serviced by the PBM. The costs associated with the semiannual disclosure are calculated as: 0.25 hours x an hourly labor cost of \$129.14 x 2 x the number of self-insured group health plans serviced by the PBM. The costs associated with providing missing information are calculated as: 0.25 hours x an hourly wage rate of \$129.14 x 3.3 percent x the number of self-insured group health plans serviced by the PBM.

^c Calculated as: 2 hours x an hourly labor cost of \$150.52 x 1/3 x the number of self-insured group health plans serviced by the PBM.

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4.2. Illustration of Costs for Small Self-Insured Group Health Plans

Similarly, Table 24 illustrates how the estimated costs for self-insured group health plans compare to plan premiums in each year by the number of participants. This illustration assumes that a self-insured group health plan's premiums are equal to the number of participants multiplied by the weighted average of annual health insurance premiums for family and single coverage. In this analysis, the Department estimates average annual premiums to be \$14,104.³⁷³

³⁷³ According to the 2023 Medical Expenditure Panel Survey Insurance Component (MEPS-IC), the average annual health insurance premiums in 2023 for self-insured plans were \$8,363 for single coverage (represents 55 percent of enrollees), \$16,495 for employees-plus-one coverage (represents 19 percent of enrollees), and \$24,596 for family coverage (represents 26 of enrollees). Based on these shares, the weighted average annual self-insured premiums is \$14,104.

Under the proposed rule, small, self-insured group health plans would incur costs (1) if they send a request to the PBM for missing information, (2) if they send a request to the Department notifying that the aforementioned information has not been disclosed within 90 calendar days, or (3) if they request an audit of the PBM or other covered service provider.

It is important to note that as explained in Section 11.2 of the RIA, these costs will not necessarily be incurred by all self-insured group health plans every year. In the RIA, the Department assumed that only ten percent of arrangements may experience an omission or error that will require the responsible plan fiduciary to send the request to the PBM and other covered service providers, only 10 notices will be submitted the Department, and only one-third of self-insured group health plans will annually submit a request to their PBM

or other covered service provider for all information necessary to perform an audit. The Department requests comments on how this may differ for small, self-insured group health plans.

The Department expects that small, self-insured group health plans would rely on TPAs to review the proposed rule and that some small, self-insured group health plans may also rely on TPAs to send audit requests. Some of these TPAs may be considered small entities. However, the Department expects that these TPAs would pass along these costs to self-insured group health plans. The Department requests comments on what functions small, self-insured group health plans would perform in-house versus relying on a TPA, how large any costs passed along to small, self-insured group health plans would be, and how many of these TPAs would be small entities.

As such, this illustration likely overestimates the average costs to self-

insured group health plans as a percentage of premiums. Nevertheless,

even as an overestimate, the costs borne by self-insured group health plans are

expected to account for a small proportion of annual premiums.

TABLE 24. Per Plan Costs as a Percentage of Premiums

	Per-Entity Cost	Cost as Average Assets for Plans with 100 Participants	Cost as Average Assets for Plans with 75 Participants	Cost as Average Assets for Plans with 50 Participants	Cost as Average Assets for Plans with 25 Participants	Cost as Average Assets for Plans with 10 Participants
<i>Average Premiums by Plan Size</i>		\$1,410,400	\$1,057,800	\$705,200	\$352,600	\$141,040
Disclosure	\$64.57	0.005%	0.006%	0.009%	0.018%	0.046%
Audit	\$64.57	0.005%	0.006%	0.009%	0.018%	0.046%
Total	\$129.14	0.009%	0.012%	0.018%	0.037%	0.092%

5. Alternatives

The Department considered whether smaller entities, such as level-funded group health plans, should be exempted. Since smaller level-funded plans often depend on TPAs and insurers to handle claims, administrative, and pharmacy benefit management. The Department acknowledges that entity contracting or arranging with the group health plan is not performing these functions themselves. However, the contracting entity would still be responsible for making disclosures to the responsible plan fiduciary required under the proposal and obtaining information from the provider performing the pharmacy benefit management services necessary for those disclosures.

The Department believes that providing an exemption for these smaller entities would risk reducing transparency in a segment of market where disclosures are most needed. The Department estimates there are 1,031,098 level-funded group health plans, accounting for 90 percent of affected ERISA-covered group health plans. As a result, the Department determined that a small entity exemption would not achieve the intended goals of the proposed rules.

6. Duplicate, Overlapping, or Relevant Federal Rules

There are no duplicate, overlapping, or relevant Federal rules.

H. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final

agency rule that may result in an expenditure of \$100 million or more (adjusted annually for inflation with the base year 1995) in any one year by State, local, and Tribal governments, in the aggregate, or by the private sector.³⁷⁴ For purposes of the UMRA, this rulemaking is expected to have such an impact on the private sector. For the purposes of this rulemaking, the RIA shall meet the UMRA obligations.

I. Federalism Statement

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by Federal agencies in the process of their formulation and implementation of policies that have “substantial direct effects” on the States, the relationship between the Federal Government and States, or on the distribution of power and responsibilities among the various levels of government.³⁷⁵ Federal agencies promulgating regulations that have federalism implications must consult with State and local officials and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to the proposed rule.

The proposed rule does not have federalism implications because it has no substantial direct effect on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. Section 514 of ERISA provides, with certain exceptions specifically enumerated, that the provisions of Titles I and IV of ERISA

supersede any and all laws of the States as they relate to any employee benefit plan covered under ERISA. The Department acknowledges that the proposed rule may have some implications for States, particularly if the proposed rule is found to preempt State laws affecting PBMs providing services to self-insured group health plans. The Department welcomes input from affected States regarding this assessment.

List of Subjects in 29 CFR Part 2550

Employee benefit plans, Individual retirement accounts, Pensions, Plans.

For the reasons set forth in the preamble, the Department is proposing to amend part 2550 of subchapter F of chapter XXV of title 29 of the Code of Federal Regulations as follows:

PART 2550—RULES AND REGULATIONS FOR FIDUCIARY RESPONSIBILITY

■ 1. The authority citation for part 2550 continues to read as follows:

Authority: 29 U.S.C. 1135 and Secretary of Labor's Order No. 1–2011, 77 FR 1088 (January 9, 2012). Sec. 102, Reorganization Plan No. 4 of 1978, 5 U.S.C. App. at 727 (2012). Sec. 2550.401c–1 also issued under 29 U.S.C. 1101. Sec. 2550.404a–1 also issued under sec. 657, Pub. L. 107–16, 115 Stat. 38. Sec. 2550.404a–2 also issued under sec. 657 of Pub. L. 107–16, 115 Stat. 38. Sections 2550.404c–1 and 2550.404c–5 also issued under 29 U.S.C. 1104. Sec. 2550.408b–1 also issued under 29 U.S.C. 1108(b)(1). Sec. 2550.408b–19 also issued under sec. 611, Pub. L. 109–280, 120 Stat. 780, 972. Sec. 2550.412–1 also issued under 29 U.S.C. 1112.

■ 2. Amend § 2550.408b-2 by revising paragraph (c)(2) to read as follows:

³⁷⁴ 2 U.S.C. 1501 *et seq.* (1995).

³⁷⁵ *Federalism*, 64 FR 153 (Aug. 4, 1999).

§ 2550.408b-2 General statutory exemption for services or office space.

* * * *

(c) * * *

(2) *Welfare plan disclosure.* See § 2550.408b-22.

* * * *

■ 3. Add § 2550.408b-22 to read as follows:

§ 2550.408b-22 Compensation transparency; pharmacy benefit management services.

(a) *General.* Section 408(b)(2) of the Employee Retirement Income Security Act of 1974 (the Act) exempts from the prohibitions of section 406(a) of the Act payment by a plan to a party in interest, including a fiduciary, for office space or any service (or a combination of services) if such office space or service is furnished under a contract or arrangement which is reasonable. No contract or arrangement for services between a covered plan and a covered service provider, nor any extension or renewal, is reasonable within the meaning of section 408(b)(2) of the Act unless, in addition to meeting the general requirements in § 2550.408b-2, the disclosure requirements of this section are satisfied.

(b) *Covered plan.* For purposes of this section, a “covered plan” means a group health plan as defined in section 733(a) of the Act, other than a group health plan in which all of the benefits are provided exclusively through a contract or policy of insurance issued by a health insurance issuer as defined in § 2590.701-2 of this chapter.

(c) *Covered service provider.* (1) For purposes of this section, a “covered service provider” means a service provider that enters into a contract or arrangement with the covered plan and reasonably expects \$1,000 or more in compensation, direct or indirect, to be received in connection with:

(i) Providing any pharmacy benefit management services, as defined in paragraph (d) of this section, pursuant to the service contract or arrangement, regardless of whether such services will be performed, or such compensation received, by the covered service provider, an affiliate, an agent, or a subcontractor; or

(ii) Providing advice, recommendations, or referrals regarding the provision of pharmacy benefit management services, as defined in paragraph (d) of this section, pursuant to the service contract or arrangement, and is the entity described in paragraph (c)(1)(i) of this section or an affiliate of such entity.

(2) No person or entity is a “covered service provider” solely on the basis of

providing services as an affiliate, agent, or subcontractor of the covered service provider, with respect to performing one or more of the services described in paragraph (c)(1)(i) or (ii) of this section under the contract or arrangement with the covered plan.

(d) *Pharmacy benefit management services*—(1) *General.* For purposes of this section, the term “pharmacy benefit management services” means services necessary for the management or administration of a covered plan’s prescription drug benefits (including the covered plan’s provision of prescription drugs through the plan’s medical benefit), regardless of whether the person, business, or entity performing the service identifies itself as a “pharmacy benefit manager.”

(2) *Examples.* Pharmacy benefit management services include but are not limited to:

(i) Acting as a negotiator or aggregator of rebates, fees, discounts and other price concessions for prescription drugs.

(ii) Establishing or maintaining prescription drug formularies.

(iii) Establishing or maintaining pharmacy networks, through contract or otherwise, including a mail order pharmacy, a specialty pharmacy, a retail pharmacy, a nursing home pharmacy, a long-term care pharmacy, and an infusion or other outpatient pharmacy, to provide prescription drugs.

(iv) Processing and payment of claims for prescription drugs.

(v) Performing utilization review and management, including the processing of prior authorization requests for drugs, step therapy protocols, patient compliance analyses, conducting therapeutic intervention, and administering generic substitution programs.

(vi) Adjudicating appeals or grievances related to the covered plan’s prescription drug benefits.

(vii) Recordkeeping related to the covered plan’s prescription drug benefits; and

(viii) In conjunction with any of these other services, performing regulatory compliance with respect to the covered plan’s prescription drug benefits under the service contract or arrangement.

(e) *Initial disclosure requirements.* A covered service provider shall disclose to a responsible plan fiduciary, in writing, the following information in paragraphs (e)(1) through (12) of this section, not later than the date that is reasonably in advance of the date on which the service contract or arrangement is entered, and extended or renewed (for extensions and renewals, 30 calendar days in advance is deemed to be a reasonable period of time):

(1) *Description of services.* A description of each pharmacy benefit management service, or of the advice, recommendations, or referrals regarding the provision of pharmacy benefit management services, to be provided to the covered plan pursuant to the service contract or arrangement.

(2) *Direct compensation.* A description of the amount of all direct compensation, both in the aggregate and by service, that the covered service provider, an affiliate, an agent, or a subcontractor reasonably expects to receive on a quarterly basis in connection with services under the service contract or arrangement. For purposes of this paragraph (e)(2), the term “direct compensation” means compensation received directly from a covered plan or from the plan sponsor on behalf of the plan (regardless of whether such compensation is paid from plan assets). An example is an administrative fee calculated on a per-participant, per-month basis.

(3) *Manufacturer payments.* A description of the amount of any payment, both in the aggregate and for each drug on the formulary, reasonably expected to be paid on a quarterly basis by the manufacturer or an aggregator to the covered service provider, an affiliate, an agent, or subcontractor in connection with the service contract or arrangement, specifying both the amount that will be passed on to the plan and, if applicable, plan sponsor and the amount that will be retained by the covered service provider, an affiliate, an agent, or a subcontractor.

(4) *Spread compensation.* A description of the quarterly amount of spread compensation reasonably expected to be received by the covered service provider, an affiliate, an agent, or subcontractor in connection with the service contract or arrangement. For purposes of this paragraph (e)(4), spread compensation is defined as the difference between the negotiated rate reasonably expected to be paid by the covered plan to the covered service provider, an affiliate, an agent, or subcontractor and the negotiated rate reasonably expected to be paid by such entity to the pharmacy for dispensing drugs, both in the aggregate and for each drug on the formulary, and for each pharmacy channel (*i.e.*, retail, mail order, and specialty pharmacy).

(5) *Copay claw-backs.* A description of the quarterly amount of copay claw-back compensation reasonably expected to be recouped from a pharmacy by a covered service provider, an affiliate, an agent, or subcontractor in connection with prescription drugs dispensed under the service contract or

arrangement, specifying the anticipated total number of transactions resulting in recoupment. For purpose of this paragraph (e)(5), copay claw-back compensation means the dollar amount of the difference between a copayment or coinsurance amount paid to the pharmacy by a plan participant or beneficiary and the reimbursement to the pharmacy.

(6) *Price protection agreements.* A description of any inflation protection or price protection agreements that the covered service provider, an affiliate, an agent, or a subcontractor has entered with any drug manufacturer or other party in connection with prescription drugs dispensed under the service contract or arrangement, specifying the quarterly amount reasonably expected to be retained by the covered service provider, an affiliate, an agent, or a subcontractor in connection with each such inflation protection or price protection contract or arrangement and the amount that will be passed on to the plan and, if applicable, plan sponsor.

(7) *Compensation for termination of service contract or arrangement.* A description of any compensation that the covered service provider, an affiliate, an agent, or a subcontractor reasonably expects to receive in connection with termination of the service contract or arrangement, and how any prepaid amounts will be calculated and refunded upon such termination.

(8) *Description of other compensation.* To the extent not already disclosed under paragraphs (e)(1) through (7) of this section—

(i) A description of all compensation that the covered service provider, an affiliate, an agent, or a subcontractor reasonably expects to receive on a quarterly basis in connection with the service contract or arrangement;

(ii) The identification of the payer of such compensation;

(iii) An identification of the services for which such compensation will be received; and

(iv) A description of the arrangement between the payer and the covered service provider, an affiliate, an agent, or a subcontractor, as applicable, pursuant to which such compensation is paid.

(9) *Description of formulary placement incentives.* (i) A description of any formulary placement incentives and arrangements that the covered service provider, an affiliate, an agent, or a subcontractor has entered with any drug manufacturer in connection with the service contract or arrangement, along with an explanation of how the incentives and arrangements affect

services to and are aligned with the interests of the plan and/or its participants and beneficiaries (e.g., incentives or arrangements are to control prescription drug costs, provide clinically superior drugs, or both).

(ii) For any drug on the formulary with respect to which the covered service provider, an affiliate, an agent, or a subcontractor reasonably expects to receive any payment by the manufacturer or aggregator in connection with the service contract or arrangement (and that is not passed through to the plan), an identification of any reasonably available therapeutically equivalent alternatives, and the reason for omitting the alternatives from the formulary.

(iii) If the covered service provider, an affiliate, an agent, or a subcontractor retains authority to modify the formulary during the term of the service contract or arrangement, such as by adding or deleting drugs or changing their tiering, an explanation of the reasons for retaining such authority, the expected frequency of such changes, and that the responsible plan fiduciary will be notified reasonably in advance of any modifications that, individually or in the aggregate, are reasonably expected to have a material impact on the reasonableness of compensation under the service contract or arrangement, as well as the covered plan's right to terminate the service contract or arrangement on reasonably short notice under the circumstances. For purposes of this paragraph (e)(9)(iii), the term "material" means an amount that is 5 percent or more, or such lower percentage or dollar amount as may be agreed to by the responsible plan fiduciary and set forth in writing in the contract or arrangement, of the aggregate compensation (on a quarterly basis) disclosed pursuant to paragraph (e)(3) of this section, adjusted for any increases previously disclosed under this paragraph (e).

(10) *Drug pricing methodology.* A description of the net cost to the covered plan of each drug on the formulary, for each pharmacy channel, expressed as a monetary amount. If a monetary amount is not ascertainable, the covered service provider must disclose the methodology used by the covered service provider, an affiliate, an agent, or a subcontractor, under the service contract or arrangement, to determine the cost the covered plan will pay for each drug on the formulary, for each pharmacy channel, along with an objective means to verify the accuracy.

(11) *Statement of fiduciary status.* If applicable, a statement that the covered service provider, an affiliate, an agent,

or a subcontractor will provide, or reasonably expects to provide, services pursuant to the service contract or arrangement directly to the covered plan as a fiduciary (within the meaning of section 3(21) of the Act). Along with this statement, such entity must disclose any activity or policy that may create a conflict of interest, including, for example, if such entity will benefit financially from drug substitution, from incentivizing use of affiliated pharmacies when other network pharmacies offer lower costs, or from step therapy or "fail first" protocols that require participants and beneficiaries to use drugs that generate greater manufacturer rebates than other therapeutically equivalent drugs on the formulary.

(12) *Statement of audit right.* A statement of the covered plan's right to the audit described in paragraph (j) of this section and the procedures for requesting such an audit.

(f) [Reserved]

(g) *Semiannual disclosure requirements.* A covered service provider shall disclose to a responsible plan fiduciary, in writing, on a semiannual basis no later than 30 calendar days after the end of each six-month period beginning on the date the service contract or arrangement is entered, the following information with respect to the preceding six-month period:

(1) *Direct compensation.* A description of all direct compensation (within the meaning of paragraph (e)(2) of this section), both in the aggregate and by service, that the covered service provider, an affiliate, an agent, or a subcontractor received on a quarterly basis in connection with the service contract or arrangement.

(2) *Manufacturer payments.* A description of all payments, both in the aggregate and for each drug on the formulary, paid on a quarterly basis by a manufacturer or aggregator to the covered service provider, an affiliate, an agent, or a subcontractor in connection with the service contract or arrangement, specifying both the amount passed on to the plan and, if applicable, plan sponsor and the amount retained by the covered service provider, an affiliate, and agent, or a subcontractor.

(3) *Spread compensation.* A description of all spread compensation (within the meaning of paragraph (e)(4) of this section) received on a quarterly basis by a covered service provider, an affiliate, an agent, or subcontractor in connection with the service contract or arrangement, both in the aggregate and for each drug on the formulary, and for

each pharmacy channel (*i.e.*, retail, mail order, and specialty pharmacy).

(4) *Copay claw-backs.* A description of all amounts of copay claw-back compensation (as described in paragraph (e)(5) of this section) recouped on a quarterly basis from a pharmacy by a covered service provider, an affiliate, an agent, or subcontractor in connection with prescription drugs dispensed under the service contract or arrangement, specifying the total number of transactions.

(5) *Price protection agreements.* A description of all amounts received on a quarterly basis by the covered service provider, an affiliate, an agent, or subcontractor pursuant to any inflation protection or price protection agreements that the covered service provider, an affiliate, an agent, or subcontractor entered with any drug manufacturer or other party in connection with prescription drugs dispensed under the service contract or arrangement, specifying both the amount passed on to the plan and, if applicable, plan sponsor and the amount retained by the covered service provider, an affiliate, and agent, or a subcontractor.

(6) *Other compensation.* To the extent not already disclosed under paragraphs (g)(1) through (5) of this section—

(i) All compensation that the covered service provider, an affiliate, an agent, or subcontractor received in connection with the service contract or arrangement;

(ii) The identification of the payer of indirect compensation;

(iii) An identification of the services for which indirect compensation was received; and

(iv) A description of the arrangement between the payer and the covered service provider, an affiliate, an agent, or a subcontractor, as applicable, pursuant to which such compensation was paid.

(7) *Overage explanation.* If any category of compensation described in this paragraph (g), in the aggregate, materially exceeds the corresponding quarterly estimate described in paragraph (e) of this section, an identification of the amount of the overage (in the aggregate) and the reason for the overage. For purposes of this paragraph (g)(7), the term “materially” means 5 percent or more, or such lower percentage or dollar amount as may be agreed to by the responsible plan fiduciary and set forth in writing in the contract or arrangement.

(8) *Statement of audit right.* A statement of the covered plan’s right to the audit described in paragraph (j) of

this section and the procedures for requesting such an audit.

(h) [Reserved]

(i) *Information on request.* (1) Upon the written request of the responsible plan fiduciary, the covered service provider must furnish any other information relating to the contract or arrangement that is required for the covered plan to comply with the reporting and disclosure requirements of Title I of the Act, the regulations in this chapter, and forms and schedules issued under Title I.

(2) The covered service provider must disclose the information required by paragraph (i)(1) of this section reasonably in advance of the date upon which such responsible plan fiduciary states that it must comply with the applicable reporting or disclosure requirement, unless such disclosure is precluded due to extraordinary circumstances beyond the covered service provider’s control, in which case the information must be disclosed as soon as practicable.

(j) *Right to audit*—(1) *Frequency and scope.* Not less than once per year, at the written request of the covered plan, the covered service provider shall allow for an audit of the covered service provider for accuracy of any disclosure made to comply with this section.

(2) *Auditor.* A responsible plan fiduciary of the covered plan shall have the right to select an auditor. The covered service provider shall not impose any limitations on the selection of such auditor.

(3) *Provision of information.* The covered service provider shall make available to the auditor all records, data, and other information reasonably necessary to confirm the accuracy of any disclosure made to comply with this section, including contracts with retail pharmacies and drug manufacturers, subject to reasonable confidentiality agreements to prevent redisclosure of such information.

(4) *Fees.* The covered plan shall bear responsibility for all expenses related to the selection and retention of the auditor. The covered service provider shall bear the cost of providing the requested information.

(5) *Timing.* The covered service provider shall confirm receipt of a request for an audit under this section no later than ten (10) business days after the information is requested. The covered service provider shall provide the information required under paragraph (j)(3) of this section within a commercially reasonable period.

(6) *Restrictions.* The covered service provider may not impose conditions that would restrict the covered plan’s

right to conduct an audit under this section, including restrictions on the period of the audit, the location of the audit, or the number of records to be provided, except that the scope of the audit may be limited to the period covered by the disclosures under this section.

(7) *Information from affiliates and subcontractors.* The covered service provider shall be responsible for providing such auditor with the information required under paragraph (j)(3) of this section that is owned or held by an affiliate, an agent, or a subcontractor of the covered service provider.

(k) *Manner of disclosure*—(1) *General.* All disclosures under this section must be clear and concise, free of misrepresentations, and contain sufficient specificity to permit evaluation of the reasonableness of the service contract or arrangement. For example, the Department will consider the use of generic industry terms, jargon, or legalese, without definition, to lack the sufficient specificity required under the preceding sentence unless the language in question specifically refers to objectively determinable definitions, standards, or other similar guidelines, that are publicly available or will be provided by the covered service provider to the responsible plan fiduciary free of charge and within a reasonable period of time following the request.

(2) *Descriptions of compensation.* Descriptions of compensation or amounts required under this section must be expressed as a monetary amount (*e.g.*, \$1,000) and may be estimated to the extent that the actual amount is not reasonably ascertainable but shall contain sufficient information and specificity to permit evaluation of the reasonableness of the compensation received by the covered service provider, an affiliate, an agent, or a subcontractor.

(3) *Machine-readability format.* Upon request of a responsible plan fiduciary of a covered plan, descriptions of compensation required under this section must also be provided, within a reasonable time after such request, in a standard machine-readable file. For purposes of this paragraph (k)(3), “machine-readable file” means a digital representation of data or information in a file that can be imported or read by a computer system for further processing without human intervention, while ensuring no semantic meaning is lost. Drugs must be referred to using an industry standard name and include a useful, non-proprietary identifier such as the National Drug Code, promulgated

by the U.S. Food and Drug Administration.

(4) *Confidentiality agreements.* Except as provided in paragraph (j)(3) of this section, the covered service provider and its affiliates, agents, and subcontractors may not impose restrictions on the covered plan's use of disclosures required under this section, or the contract or arrangement described in paragraph (c)(1) of this section, except that the covered contract or arrangement may require the responsible plan fiduciary to require third parties to whom it rediscloses such information to execute reasonable confidentiality agreements preventing redisclosure by such parties.

(l) *Disclosure errors.* No service contract or arrangement will fail to be reasonable under this section solely because the covered service provider, acting in good faith and with reasonable diligence, makes an error or omission in disclosing the information required pursuant to paragraph (e), (g), or (j) of this section, provided that the covered service provider discloses the correct information to the responsible plan fiduciary as soon as practicable, but not later than 30 calendar days from the date on which the covered service provider knows of such error or omission.

(m) *Definitions*—(1) *Affiliate.* A person's or entity's "affiliate" directly or indirectly (through one or more intermediaries) controls, is controlled by, or is under common control with such person or entity; or is an officer, director, or employee of, or partner in, such person or entity. Unless otherwise specified, an "affiliate" in this section refers to an affiliate of the covered service provider.

(2) *Agent.* An "agent" is any person or entity authorized (whether that authorization is expressed or implied) to represent or act on behalf of another person or entity. Unless otherwise specified, an "agent" in this section refers to an agent of the covered service provider.

(3) *Compensation.* The term "compensation" means anything of monetary value but does not include any item or service valued at \$250 or less, in the aggregate, during the term of the service contract or arrangement.

(4) *Responsible plan fiduciary.* A "responsible plan fiduciary" is a fiduciary with authority to cause the covered plan to enter into, or extend or renew, the service contract or arrangement.

(5) *Subcontractor.* A "subcontractor" is any person or entity (or an affiliate of such person or entity) that is not an affiliate of the covered service provider and that, pursuant to a contract or arrangement with the covered service provider or an affiliate, reasonably expects to receive \$1,000 or more in compensation for performing one or more services described pursuant to paragraph (d) of this section provided for by the service contract or arrangement with the covered plan.

(n) *Exemption for responsible plan fiduciary*—(1) *General.* Pursuant to section 408(a) of the Act, the restrictions of section 406(a)(1)(C) and (D) of the Act shall not apply to a responsible plan fiduciary, notwithstanding any failure by a covered service provider to meet the requirements in paragraphs (e) through (l) of this section, if the following conditions are met:

(i) The responsible plan fiduciary did not know that the covered service provider failed or would fail to meet the requirements in paragraphs (e) through (l) of this section and reasonably believed that such requirements had been met.

(ii) The responsible plan fiduciary, upon discovering that the covered service provider failed to meet any requirement in paragraphs (e) through (l) of this section, requests in writing that the covered service provider correct the failure, *e.g.*, to furnish required information or comply with the audit requirement.

(iii) If the covered service provider fails to comply with the written request described in paragraph (n)(1)(ii) of this section within 90 calendar days of the request, the responsible plan fiduciary notifies the Secretary of the covered service provider's failure, in accordance with paragraphs (n)(2) and (3) of this section.

(2) *Notice content.* The notice to the Secretary shall contain—

(i) The name of the covered plan;

(ii) The plan number used for the annual report on the covered plan;

(iii) The plan sponsor's name, address, and employer identification number;

(iv) The name, address, and telephone number of the responsible plan fiduciary;

(v) The name, address, phone number, and, if known, employer identification number of the covered service provider;

(vi) A description of the services provided to the covered plan;

(vii) A description of the covered service provider's failure;

(viii) The date on which the corrective action described in paragraph (n)(1)(ii) of this section was requested in writing from the covered service provider; and

(ix) A statement as to whether the covered service provider continues to provide services to the plan.

(3) *Notice timing.* The notice described in paragraph (n)(2) of this section shall be filed with the Department not later than 30 calendar days following the earlier of—

(i) The covered service provider's refusal to correct the failure identified in the written request described in paragraph (n)(1)(ii) of this section; or

(ii) 90 calendar days after the written request described paragraph (n)(1)(ii) of this section is made.

(4) *Where to file notice.* The notice described in paragraph (n)(2) of this section shall be furnished to the U.S. Department of Labor electronically in accordance with instructions published by the Department; or may be sent to the following address: U.S. Department of Labor, Employee Benefits Security Administration, Office of Enforcement, P.O. Box 75296, Washington, DC 20013.

(5) *Termination of service contract or arrangement.* If the covered service provider fails to comply with the written request under paragraph (n)(1)(ii) of this section within 90 calendar days of such request, the responsible plan fiduciary shall determine whether to terminate or continue the service contract or arrangement consistent with its duty of prudence under section 404 of the Act.

(o) *Severability.* If any provision of this section is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof.

(p) *Effective and applicability dates.*

(1) This section is effective [60 days after date of publication of final rule].

(2) This section shall apply to plan years beginning on or after July 1, 2026.

Signed at Washington, DC.

Daniel Aronowitz,

Assistant Secretary, Employee Benefits Security Administration, U.S. Department of Labor.

[FR Doc. 2026-01907 Filed 1-29-26; 4:15 pm]

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