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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–1497; Project Identifier AD–2023–00516–T; Amendment 39–22816; AD 2024–16–10]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2019–25–17, which applied to all The Boeing Company Model 737–600, –700, –700C, –800, –900, and –900ER series airplanes. AD 2019–25–17 required revising the existing airplane flight manual (AFM) to prohibit selection of certain runways for airplanes equipped with certain software. Since the FAA issued AD 2019–25–17, Boeing has developed new software to address the unsafe condition. This AD was prompted by reports of display electronic unit (DEU) software errors on airplanes with a selected instrument approach to a specific runway. This AD retains the requirements of AD 2019–25–17. This AD also requires installing the new software and performing a software configuration check, which terminates the AFM revision. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective October 28, 2024.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of October 28, 2024.

ADDRESSES:

AD Docket: You may examine the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA–2023–1497; 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, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For Boeing material identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminister Blvd., MC 110 SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; website myboeingfleet.com.

- 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. It is also available at [regulations.gov](https://www.regulations.gov) under Docket No. FAA–2023–1497.

FOR FURTHER INFORMATION CONTACT:

Douglas Y. Tsuji, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3548; email: Douglas.Tsuji@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2019–25–17, Amendment 39–21016 (84 FR 71304, December 27, 2019) (AD 2019–25–17). AD 2019–25–17 applied to all the Boeing Company Model 737–600, –700, –700C, –800, –900, and –900ER (Model 737 NG) series airplanes (although the scope of the AD requirements is limited to operation at specific runways in the U.S., Colombia, and Guyana). The NPRM published in the **Federal Register** on August 4, 2023 (88 FR 51739). The NPRM was prompted by reports of Display Units (DUs) blanking due to Display Electronics Unit (DEU) software errors on Model 737 NG airplanes flying into runway PABR in Barrow, Alaska. The investigation revealed that the problem occurs when a certain combination of software is installed and a susceptible runway with a 270-degree true heading is selected for instrument approach, although only seven runways worldwide have latitude and longitude values that cause the

blanking behavior. AD 2019–25–17 was issued to address the potential for blanking displays on flights into the affected airports. The software errors and consequent display blanking, if not addressed, could prevent continued safe flight and landing. In the NPRM, the FAA proposed to retain the requirements of AD 2019–25–17. The NPRM also proposed to require installing the new software, and performing a software configuration check, which would terminate the AFM revision requirement. The FAA is issuing this AD to address the potential for all six DUs to blank, which can prevent continued safe flight and landing.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from the Air Line Pilots Association, International (ALPA), who supported the NPRM without change.

The FAA received additional comments from three commenters, including Boeing, Southwest Airlines (SWA), and Pegasus Airlines. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Continue Utilizing Common Display System Block Point 06

Boeing requested that paragraph (m), “Alternative Methods of Compliance (AMOCs),” of the proposed AD be revised to allow airplanes with Common Display System (CDS) Block Point (BP) 06 an AMOC to the actions specified by paragraph (h) of the proposed AD. SWA requested allowing airplanes to continue to utilize CDS BP06 in lieu of the software update that would be required by paragraph (h) of the proposed AD (*i.e.*, CDS BP15a). Boeing and SWA stated that CDS BP06 does not contain the error that leads to the display blanking for the specific airports listed in AD 2019–25–17. SWA also cited a software incompatibility issue with the Rockwell Collins Head Up Display (HUD) HGS–2350 (currently installed on 15% of their fleet) and stated that the new CDS BP15a would require disabling the HUD, which provides the flightcrew a myriad of safety features enhancements.

The FAA agrees with allowing airplanes with CDS BP06 to be excepted

from the requirements of paragraph (h) of this AD, because CDS BP06 does not contain the error that leads to the display blanking for the specific airports listed in AD 2019–25–17. The FAA has added a statement in paragraph (i)(2) of this AD accordingly. The FAA does not agree with revising paragraph (m) of this AD, because this AD has been revised to except airplanes with CDS BP06 from the requirements of paragraph (h) of this AD, thus eliminating the need for the AMOC.

Request for Adding a Note to Paragraph (c), “Applicability”

Pegasus Airlines requested adding a note to paragraph (c), “Applicability,” of the proposed AD as follows: “The scope of the AD requirements is limited to operation at the seven runways identified in figure 1 to paragraph (g) of this AD.” The commenter stated that the note was in AD 2019–25–17 and should be included in this AD.

The FAA disagrees with the commenter. The requirements of this AD, notably the software update, must

be done by all applicable airplanes regardless of runway operation. The FAA has not changed this AD in this regard.

Effect of Winglets on Accomplishment of the Proposed Actions

Aviation Partners Boeing stated that the installation of winglets per Supplemental Type Certificate STC ST00830SE does not affect the accomplishment of the manufacturer’s service instructions.

The FAA agrees with the commenter that STC ST00830SE does not affect the accomplishment of the manufacturer’s service instructions. Therefore, the installation of STC ST00830SE does not affect the ability to accomplish the actions required by this AD. The FAA has not changed this AD in this regard.

Conclusion

The FAA reviewed the relevant data, considered any comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD

to address the unsafe condition on these products. Except for minor editorial changes, and any other changes described previously, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed Boeing Alert Requirements Bulletin 737–31A1880 RB, Revision 1, dated September 16, 2020. This material specifies procedures for installing the CDS DEU OPS block point 2015A and performing a software configuration check. 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.

Costs of Compliance

The FAA estimates that this AD affects 1,739 airplanes 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
Revise AFM (retained action from AD 2019–25–17).	1 work-hour × \$85 per hour = \$85.	\$0	\$85	\$147,815.
Install software and perform configuration check (new actions).	2 work-hours × \$85 per hour = \$170.	Up to \$975	Up to \$1,145	Up to \$1,991,155.

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,
- (2) Will not affect intrastate aviation in Alaska, and
- (3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

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:
 - a. Removing Airworthiness Directive (AD) 2019–25–17, Amendment 39–21016 (84 FR 71304, December 27, 2019); and
 - b. Adding the following new AD:
2024–16–10 The Boeing Company:
Amendment 39–22816; Docket No. FAA–2023–1497; Project Identifier AD–2023–00516–T.

(a) Effective Date

This airworthiness directive (AD) is effective October 28, 2024.

(b) Affected ADs

This AD replaces AD 2019–25–17, Amendment 39–21016 (84 FR 71304, December 27, 2019) (AD 2019–25–17).

(c) Applicability

This AD applies to all The Boeing Company Model 737–600, –700, –700C, –800, –900, and –900ER series airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 31, Instruments.

(e) Unsafe Condition

This AD was prompted by reports of display electronic unit (DEU) software errors on airplanes with a selected instrument approach to a specific runway. The FAA is proposing this AD to address the potential for all six display units (DUs) to blank, which can prevent continued safe flight and landing.

(f) Compliance

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

(g) Retained AFM Revision, with No Changes

This paragraph restates the requirements of paragraph (g) of AD 2019–25–17, with no changes. Within 14 days after December 27, 2019 (the effective date of AD 2019–25–17), revise the Miscellaneous Limitations section of the existing airplane flight manual (AFM) to include the information in figure 1 to paragraph (g) of this AD. This may be done by inserting a copy of figure 1 to paragraph (g) of this AD into the Miscellaneous Limitations section of the existing AFM.

Figure 1 to Paragraph (g)—AFM Revision**Common Display System****(Required by AD 2019-25-17)**

The following is applicable only if configured with CDS BP15 and FMC U12 or later.

Do not select the following runways in the FMC ARRIVALS page, as it may result in blanking of all six display units:

82V RW26 Pine Bluffs, Wyoming, USA

KBJJ RW28 Wayne County, Ohio, USA

KCIU RW28 Chippewa County, Michigan, USA

KCNM RW26 Cavern City, New Mexico, USA

PABR RW25 Barrow, Alaska, USA

SKLM RW28 La Mina, La Guajira, Colombia

SYCJ RW29 Cheddi Jagan, Georgetown, Guyana

(h) Software Update

Except as specified in paragraph (i) of this AD: At the applicable times specified in paragraph 1.E., “Compliance,” of Boeing Alert Requirements Bulletin 737–31A1880 RB, Revision 1, dated September 16, 2020, do all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Alert Requirements Bulletin 737–31A1880 RB, Revision 1, dated September 16, 2020.

Note 1 to paragraph (h): Guidance for accomplishing the actions required by paragraph (h) of this AD can be found in Boeing Alert Service Bulletin 737–31A1880, Revision 1, dated September 16, 2020, which is referred to in Boeing Alert Requirements Bulletin 737–31A1880 RB, Revision 1, dated September 16, 2020.

(i) Exceptions to Requirements Bulletin Specifications

(1) Where the Compliance Time columns of the tables in the “Compliance” paragraph of Boeing Alert Requirements Bulletin 737–31A1880 RB, Revision 1, dated September 16, 2020, use the phrase “Within 12 months—after the Revision 1 date of Requirements Bulletin 737–31A1880 RB,” this AD requires using “Within 12 months after the effective date of this AD.”

(2) The requirements of paragraph (h) of this AD do not apply to airplanes with Common Display System (CDS) Block Point 06 installed.

(j) Terminating Action for AFM Revision

Accomplishment of the actions specified by paragraph (h) of this AD by an operator's entire affected fleet terminates the actions required by paragraph (g) of this AD, and the AFM revision required by paragraph (g) of this AD may be removed from the AFM.

(k) Credit for Previous Actions

This paragraph provides credit for the actions specified in paragraph (h) of this AD, if those actions were performed before the effective date of this AD using Boeing Alert Requirements Bulletin 737–31A1880 RB, dated April 17, 2020, which is not incorporated by reference in this AD.

(l) Special Flight Permit

Special flight permits may be issued in accordance with 14 CFR 21.197 and 21.199 to operate the airplane to a location where the actions required by this AD can be performed, provided the airplane is operated in accordance with the AFM limitation required by paragraph (g) of this AD.

(m) Alternative Methods of Compliance (AMOCs)

(1) The Manager, 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 certification office, send it to the attention of the person identified in paragraph (n)(1) of this AD. Information may be emailed to: *AMOC@faa.gov*.

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

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by The Boeing Company Organization Designation Authorization (ODA) that has been authorized by the Manager, Continued Operational Safety Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(n) Related Information

(1) For more information about this AD, contact Douglas Y. Tsuji, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206-231-3548; email: *Douglas.Tsuji@faa.gov*.

(2) Material identified in this AD that is not incorporated by reference is available at the addresses specified in paragraph (o)(3) of this AD.

(o) 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 the AD specifies otherwise.

(i) Boeing Alert Requirements Bulletin 737-31A1880 RB, Revision 1, dated September 16, 2020.

(ii) [Reserved]

(3) For Boeing material identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminister Blvd., MC 110 SK57, Seal Beach, CA 90740-5600; telephone 562-797-1717; website *myboeingfleet.com*.

(4) 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.

(5) You may view this material that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov*, or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html*.

Issued on August 1, 2024.

Peter A. White,

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

[FR Doc. 2024-21557 Filed 9-20-24; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA-2016-N-2880]

Microbiology Devices; Reclassification of Cytomegalovirus Deoxyribonucleic Acid Quantitative Assay Devices Intended for Transplant Patient Management

AGENCY: Food and Drug Administration (FDA), Department of Health and Human Services (HHS).

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is issuing a final order to reclassify cytomegalovirus (CMV) deoxyribonucleic acid (DNA) quantitative assay devices intended for transplant patient management, a postamendments class III device (product code PAB) into class II (general controls and special controls), subject to premarket notification.

DATES: This order is effective October 23, 2024.

ADDRESSES: 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: Silke Schlottmann, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3258, Silver Spring, MD 20993-0002, 301-796-9551, *Silke.Schlottmann@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94-295), the Safe Medical Devices Act of 1990 (Pub. L. 101-629), the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115), the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107-250), the Medical Devices Technical Corrections Act (Pub. L. 108-214), the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-85), and the Food and Drug Administration Safety and

Innovation Act (Pub. L. 112-144), among other amendments, establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three classes of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three classes of devices are class I (general controls), class II (general controls and special controls), and class III (general controls and premarket approval).

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices) are automatically classified by section 513(f)(1) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until: (1) FDA reclassifies the device into class I or class II or (2) FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. FDA determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807), subpart E, of FDA’s regulations.

A postamendments device that has been initially classified in class III under section 513(f)(1) of the FD&C Act may be reclassified into class I or II under section 513(f)(3) of the FD&C Act. Section 513(f)(3) of the FD&C Act provides that FDA, acting by administrative order, can reclassify the device into class I or class II on its own initiative, or in response to a petition from the manufacturer or importer of the device. To change the classification of the device, the proposed new class must have sufficient regulatory controls to provide a reasonable assurance of the safety and effectiveness of the device for its intended use.

In the **Federal Register** of September 18, 2020 (85 FR 58300), FDA published a proposed order to reclassify CMV DNA quantitative assay devices intended for transplant patient management (“CMV transplant assays”) from class III into class II (general and special controls), subject to premarket notification. The comment period on the proposed order closed on November 17, 2020. FDA received two comments on the proposed order, both of which were supportive of the reclassification from Class III to Class II and agreed with FDA

that CMV transplant assays should be subject to premarket notification.

II. The Final Order

Based on the information discussed in the preamble to the proposed order (85 FR 58300), the supportive comments received on the proposed order, and FDA's experience over the years with this device type, FDA concludes that special controls, in conjunction with general controls, will provide reasonable assurance of the safety and effectiveness of CMV transplant assays. Therefore, in accordance with section 513(f)(3) of the FD&C Act, FDA is issuing this final order to reclassify CMV transplant assays from class III into class II, subject to premarket notification. This final order will be codified at 21 CFR 866.3180.¹ In this final order, FDA has identified special controls under section 513(a)(1)(B) of the FD&C Act, which in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device. FDA is reclassifying these devices and establishing the special controls as published in the proposed order without change.

Section 510(m) of the FD&C Act provides that a class II device may be exempted from the premarket notification requirements under section 510(k) of the FD&C Act, if the Agency determines that premarket notification is not necessary to reasonably assure the safety and effectiveness of the device. FDA has determined that premarket notification is necessary to reasonably assure the safety and effectiveness of CMV transplant assays. Therefore, the Agency does not intend to exempt these class II devices from premarket notification (510(k)) submission as provided under section 510(m) of the FD&C Act.

The devices that are the subject of this reclassification are assigned the generic name "quantitative CMV nucleic acid tests for transplant patient management." These devices are identified as a quantitative CMV nucleic acid test for transplant patient management, a device intended for prescription use in the detection of CMV and as an aid in the management of transplant patients to measure CMV DNA levels in human plasma and/or

whole blood using specified specimen processing, amplification, and detection instrumentation. The test is intended for use as an aid in the management of transplant patients with active CMV infection or at risk for developing CMV infection. The test results are intended to be interpreted by qualified healthcare professionals in conjunction with other relevant clinical and laboratory findings.

Under this final order, CMV transplant assays are prescription devices requiring the supervision of a practitioner licensed by law to direct the use of the devices in order to ensure accurate interpretation of results, ensuring the devices provide a reasonable assurance of safety and effectiveness. As such, the prescription device must satisfy prescription labeling requirements for in vitro diagnostic products (see 21 CFR 809.10(a)(4) and (b)(5)(ii)).

In addition, the Agency believes that certain changes could be made to CMV transplant assays that could significantly affect the safety and effectiveness of those devices and for which a new 510(k) is likely required.² Based on FDA's accumulated experience with these devices, changes that likely could significantly affect the safety and effectiveness of these devices include, but are not limited to, changes to critical reagents, changes to final release specifications, and changes in shelf life of the device. For more information about when to submit a new 510(k), manufacturers should refer to FDA's guidance entitled "Deciding When to Submit at 510(k) for a Change to an Existing Device" (Ref. 3).

III. Implementation Strategy

The order is effective 30 days after its date of publication in the **Federal Register**.

IV. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. Those collections of information are subject to review by the Office of Management and Budget

(OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120, the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073, and the collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910–0485.

VI. Codification of Orders

Under section 513(f)(3) of the FD&C Act, FDA may issue final orders to reclassify devices. FDA will continue to codify classifications and reclassifications in the Code of Federal Regulations (CFR). Changes resulting from final orders will appear in the CFR as newly codified orders. Therefore, under section 513(f)(3), CMV transplant assays are codified in the new 21 CFR 866.3180 under which CMV transplant assays are renamed quantitative CMV nucleic acid tests for transplant patient management and are reclassified from class III into class II.

VII. References

The following references marked with an asterisk (*) are on display in the Dockets Management Staff (see **ADDRESSES**; and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. References without asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. Ljungman P., M. Boeckh, H.H. Hirsch, et al., "Definitions of CMV Infection and Disease in Transplant Patients for Use in Clinical Trials," *Clinical Infectious Diseases*, 64(1):87–91, 2017.
2. Singh, N. and A.P. Limaye, "Infections in Solid-Organ Transplant Recipients," *Mandell, Douglas, and Bennett's Principles and Practice of Infectious Diseases*, 7th Edition, Philadelphia (PA):Elsevier, pp. 3440–3452, 2015.
- *3. "Deciding When to Submit a 510(k) for a Change to an Existing Device—Guidance for Industry and Food and Drug Administration Staff," issued October 25, 2017 (available at <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM514771>).

¹ In December 2019, FDA began adding the term "Final amendment" to the "ACTION" caption for these documents, typically styled "Final order," to indicate an amendment to the Code of Federal Regulations. This editorial change was made in accordance with the Office of Federal Register's interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

² See 21 CFR 807.81(a)(3)(i).

- *4. Transcript of the FDA Microbiology Devices Panel Meeting, November 9, 2016 (available at <https://www.fda.gov/advisory-committees/microbiology-devices-panel/2016-meeting-materials-microbiology-devices-panel>).
5. Kotton, C.N., D. Kumar, A.M. Caliendo, et al., "Updated International Consensus Guidelines on the Management of Cytomegalovirus in Solid-Organ Transplantation," *Transplantation* 96(4):333–360, 2013.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

- 1. The authority citation for part 866 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

- 2. Add § 866.3180 to subpart D to read as follows:

§ 866.3180 Quantitative cytomegalovirus nucleic acid tests for transplant patient management.

(a) *Identification.* A quantitative cytomegalovirus (CMV) nucleic acid test for transplant patient management is identified as a device intended for prescription use in the detection of CMV and as an aid in the management of transplant patients to measure CMV deoxyribonucleic acid (DNA) levels in human plasma and/or whole blood using specified specimen processing, amplification, and detection instrumentation. The test is intended for use as an aid in the management of transplant patients with active CMV infection or at risk for developing CMV infection. The test results are intended to be interpreted by qualified healthcare professionals in conjunction with other relevant clinical and laboratory findings.

(b) *Classification.* Class II (special controls). The special controls for this device are:

- (1) The labeling required under § 809.10(b) of this chapter must include:
- (i) A prominent statement that the device is not intended for use as a donor screening test for the presence of CMV DNA in blood or blood products.

(ii) Limitations, which must be updated to reflect current clinical practice. The limitations must include, but are not limited to, statements that indicate:

(A) Test results are to be interpreted by qualified licensed healthcare

professionals in conjunction with clinical signs and symptoms and other relevant laboratory results;

(B) Negative test results do not preclude CMV infection or tissue invasive CMV disease, and that CMV test results must not be the sole basis for patient management decisions.

(iii) A detailed explanation of the interpretation of results and acceptance criteria must be provided and include specific warnings regarding the potential for variability in CMV viral load measurement when samples are measured by different devices. Warnings must include the following statement, where applicable: "Due to the potential for variability in CMV viral load measurements across different CMV assays, it is recommended that the same device be used for the quantitation of CMV viral load when managing CMV infection in individual patients."

(iv) A detailed explanation of the principles of operation and procedures for assay performance.

(2) Design verification and validation must include the following:

(i) Detailed documentation of the device description, including all parts that make up the device, reagents required for use with the CMV assay but not provided, an explanation of the methodology, design of the primer/probe sequences, rationale for the selected gene target, and specifications for amplicon size, guanine-cytosine content, and degree of nucleic acid sequence conservation. The design and nature of all primary, secondary, and tertiary quantitation standards used for calibration must also be described.

(ii) A detailed description of the impact of any software, including software applications and hardware-based devices that incorporate software, on the device's function.

(iii) Documentation and characterization of all critical reagents (e.g., determination of the identity, supplier, purity, and stability) and protocols for maintaining product integrity throughout its labeled shelf life.

(iv) Stability data for reagents provided with the device and indicated specimen types, in addition to the basis for the stability acceptance criteria at all time points chosen across the spectrum of the device's indicated life cycle, which must include a time point at the end of shelf life.

(v) All stability protocols, including acceptance criteria.

(vi) Final lot release criteria, along with documentation of an appropriate justification that lots released at the extremes of the specifications will meet the claimed analytical and clinical

performance characteristics as well as the stability claims.

(vii) Risk analysis and documentation demonstrating how risk control measures are implemented to address device system hazards, such as Failure Modes Effects Analysis and/or Hazard Analysis. This documentation must include a detailed description of a protocol (including all procedures and methods) for the continuous monitoring, identification, and handling of genetic mutations and/or novel CMV stains (e.g., regular review of published literature and annual in silico analysis of target sequences to detect possible primer or probe mismatches). All results of this protocol, including any findings, must be documented.

(viii) Analytical performance testing that includes:

(A) Detailed documentation of the following analytical performance studies: Limit of detection, upper and lower limits of quantitation, inclusivity, precision, reproducibility, interference, cross reactivity, carryover, quality control, specimen stability studies, and additional studies as applicable to specimen type and intended use for the device.

(B) Identification of the CMV strains selected for use in analytical studies, which must be representative of clinically relevant circulating strains.

(C) Inclusivity study results obtained with a variety of CMV genotypes as applicable to the specific assay target and supplemented by in silico analysis.

(D) Reproducibility studies that include the testing of three independent production lots.

(E) Documentation of calibration to a standardized reference material that FDA has determined is appropriate for the quantification of CMV DNA (e.g., a recognized consensus standard).

(F) Documentation of traceability performed each time a new lot of the standardized reference material to which the device is traceable is released, or when the field transitions to a new standardized reference material.

(ix) Clinical performance testing that includes:

(A) Detailed documentation of device performance data from either a method comparison study with a comparator that FDA has determined is appropriate, or results from a prospective clinical study demonstrating clinical validity of the device.

(B) Data from patient samples, with an acceptable number of the CMV positive samples containing an analyte concentration near the lower limit of quantitation and any clinically relevant decision points.

(C) The method comparison study must include predefined maximum acceptable differences between the test and comparator method across all primary outcome measures in the clinical study protocol.

(D) The final release test results for each lot used in the clinical study.

Dated: September 17, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21616 Filed 9–20–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2024–0820]

RIN 1625–AA00

Safety Zone; Kernwood Avenue Bridge Repairs—Danvers River, Salem, MA, and Beverly, MA

AGENCY: Coast Guard, DHS.

ACTION: Temporary Interim Rule and request for comments.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the navigable waters at mile 1.0 Danvers River, within a 100-yard radius of the center point of the Kernwood Avenue Bridge between Salem, MA and Beverly, MA. The temporary safety zone is necessary to protect personnel, vessels and the marine environment from potential hazards created during bridge repairs. When enforced, entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Boston or a designated representative.

DATES:

Effective date: This rule is effective without actual notice from September 23, 2024 through 11:59 p.m. on December 31, 2024. For the purposes of enforcement, actual notice will be used from September 15, 2024, until September 23, 2024.

Comments due date: Comments and related material must be received by the Coast Guard on or before October 23, 2024.

ADDRESSES: You may submit comments identified by docket number USCG–2024–0820 using the Federal e-Rulemaking Portal at <http://www.regulations.gov>. See the “Public Participation and Request for Comments” portion of the

SUPPLEMENTARY INFORMATION section for

further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rulemaking, call or email Mr. Timothy Chase, Waterways Management Division, U.S. Coast Guard Sector Boston, telephone 617–447–1620, or email Timothy.w.chase@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
NAD 83 North American Datum 1983
§ Section
U.S.C. United States Code
MASSDOT Massachusetts Department of Transportation

II. Background Information and Regulatory History

On August 28, 2024, the Massachusetts Department of Transportation (MassDOT) bridge division notified the Waterways Management Division of U. S. Coast Guard Sector Boston that operations to make repairs to the Kernwood Avenue Bridge, spanning the Danvers River between Salem, MA, and Beverly, MA, will begin September 15, 2024.

The Coast Guard is issuing this temporary rule under the authority in 5 U.S.C. 553(b)(B). This statutory provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” The Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the construction schedule for Kernwood Avenue Bridge was only recently finalized and prompt action is needed to respond to the potential safety hazards associated with this project. It is impracticable and contrary to the public interest to publish an NPRM because prompt action is needed to establish this safety zone by September 15, 2024, to allow for the timely repairs to the Kernwood Avenue Bridge and ensure the safety of mariners transiting the area from the dangers associated with the operations associated with these repairs.

Also, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because prompt action is needed to

ensure public safety during repair operations to the Kernwood Avenue Bridge.

Although this regulation is published as an interim rule without prior notice, public comment is nevertheless desirable to ensure that the regulation is both workable and reasonable. Accordingly, persons wishing to comment may do so by submitting written comments as set out under **ADDRESSES** in this preamble. Commenters should include their names and addresses, identify the docket number for the regulation, and give reasons for their comments. If the Coast Guard determines that changes to the temporary interim rule are necessary, we will publish a temporary final rule or other appropriate document.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Boston (COTP) has determined that potential hazards associated with bridge repair operations starting September 15, 2024, will be a safety concern for anyone within a 100-yard radius of the center point of the Kernwood Avenue Bridge. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while bridge repair operations are taking place.

IV. Discussion of Rule

This rule establishes a safety zone from September 15, 2024, through 11:59 p.m. on December 31, 2024. While the safety zone will be effective through this period, it will only be enforced during active repair operations, when work barges and cranes will be placed in the narrow navigable channel, or other instances which may create a hazard to navigation. The active repair operations will take place during the overnight hours, from 9 p.m. through 5 a.m., Sunday through Thursday, when boating traffic is minimal.

The safety zone will cover all navigable waters within a 100-yard radius of the center point of the MassDOT Kernwood Avenue Bridge, at mile 1.0, spanning the Danvers River, between Salem, MA, and Beverly, MA, in approximate position 42°32'34.8" N 70°53'54.2" W (NAD 83). During times of enforcement, all persons or vessels will be prohibited from entering the safety zone without permission from the COTP or a designated representative.

The Coast Guard will make notice of the safety zone via the Local Notice to Mariners and issue a Broadcast Notice to Mariners via marine channel 16 (VHF–FM) as soon as practicable in

response to an emergency or hazardous condition. In addition, if the project is completed before 11:59 p.m. on December 31, 2024, enforcement of the safety zone will be suspended, and notice given via Local Notice to Mariners. The First Coast Guard District Local Notice to Mariners can be found at: <http://www.navcen.uscg.gov>.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a “significant regulatory action,” under section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size, location, duration, and time of year of the safety zone. Vessel traffic will not be able to safely transit around this safety zone when enforced. As a result, enforcement of the safety zone will be limited in duration during active repair operations, in the overnight hours, Sunday through Thursday, during the winter months when vessel traffic is minimal. Additionally, the Salem, Beverly, and Danvers Harbor Masters will be on scene during work hours to inform any potential vessels of the safety zone. The Coast Guard will make notice of this safety zone via the Local Notice to Mariners and issue a Broadcast Notice to Mariners via marine channel 16 (VHF-FM) as soon as practicable in response to an emergency or hazardous condition. This rule also allows vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions

with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator because they are able to transit with permission from COTP or the COTP’s designated representative.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule will affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination

with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, 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 rule involves the establishment of a temporary safety zone for the navigable waters within 100-yard radius of the center point of the MassDOT Kernwood Avenue Bridge, at mile 1.0, spanning the Danvers River between Salem, MA, and Beverly, MA, from September 15, 2024, through December 31, 2024, during active repair operation on the bridge. The safety zone will only be enforced from 9 p.m. to 5 a.m. Sunday through Thursday, when work barges and cranes will be placed in the narrow navigable channel, or in response to an emergency or hazardous condition. 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. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protestors. Protesters are asked to contact the person listed in the **FOR FURTHER**

INFORMATION CONTACT section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

VI. 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. If we determine that changes to the temporary interim rule are necessary, the Coast Guard will publish a temporary final rule or other appropriate document. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

Submitting comments. We encourage you to submit comments through the Federal Decision-Making Portal at <https://www.regulations.gov>. To do so, go to <https://www.regulations.gov>, type USCG–2024–0303 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 rule for alternate instructions.

Viewing material in docket. To view documents mentioned in this temporary interim rule as being available in the docket, find the docket as described in the previous paragraph, and then select “Supporting & Related Material” in the Document Type column. Public comments will also be placed in our online docket and can be viewed by following instructions on the <https://www.regulations.gov> Frequently Asked Questions web page. Also, if you click on the Dockets tab and then the temporary interim rule, you should see a “Subscribe” option for email alerts. The option will notify you when comments are posted, or a subsequent document is published.

We review all comments received, but we will only post comments that address the topic of the rule. We may choose not to post off-topic, inappropriate, or duplicate comments that we receive.

Personal information. We accept anonymous comments. Comments we post to <https://www.regulations.gov> will include any personal information you have provided. For more about privacy and submissions to the docket in response to this document, see DHS’s

eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 46 U.S.C. 70034, 70051, 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. 01.3.

■ 2. Add § 165.T01–0820 to read as follows:

§ 165.T01–0820 Safety Zone; Kernwood Avenue Bridge Repairs—Danvers River, Salem, MA, and Beverly, MA.

(a) *Location.* The following area is a safety zone: all navigable waters within a 100-yard radius of the center point of the Massachusetts Department of Transportation (MassDOT) Kernwood Avenue Bridge, at mile 1.0 spanning the Danvers River between Salem, MA, and Beverly, MA, in approximate position 42°32′34.8″ N 70°53′54.2″ W.

(b) *Enforcement period.* The safety zone in paragraph (a) of this section is effective from September 15, 2024, through 11:59 p.m. on December 31, 2024. The section is subject to enforcement from 9 p.m. to 5 a.m. Sunday through Thursday, or in response to an emergency or hazardous condition during this period. The Coast Guard will make notice of this safety zone via the Local Notice to Mariners and issue a Broadcast Notice to Mariners via marine channel 16 (VHF–FM) as soon as practicable in response to an emergency or hazardous condition. In addition, if the project is completed before 11:59 p.m. on December 31, 2024, enforcement of the safety zone will be suspended, and notice given via Local Notice to Mariners. The First Coast Guard District Local Notice to Mariners can be found at: <http://www.navcen.uscg.gov>.

(c) *Definitions.* As used in this section:

(1) *Designated representative* means any Coast Guard commissioned, warrant, petty officer, or any federal, state, or local law enforcement officer who has been designated by the Captain of the Port Boston (COTP) to act on his or her behalf. The designated representative may be on an official

patrol vessel or may be on shore and will communicate with vessels via VHF–FM radio or loudhailer. In addition, members of the Coast Guard Auxiliary may be present to inform vessel operators of this regulation.

(2) *Official patrol vessels* mean any Coast Guard, Coast Guard Auxiliary, state, or local law enforcement vessels assigned or approved by the COTP to enforce this section.

(d) *Regulations.* When this safety zone is enforced, the following regulations, along with those contained in 33 CFR 165.23 apply:

(1) No person or vessel may enter or remain in the safety zone described in paragraph (a) of this section without the permission of the COTP or the COTP’s designated representatives. Any person or vessel permitted to enter the safety zone must comply with the lawful directions and orders of the COTP or the COTP’s designated representatives.

(2) To seek permission to enter the safety zone, individuals may reach the COTP or a COTP-designated representative via Channel 16 (VHF–FM) or (857) 416–3015 (Sector Boston Command Center).

J.J. Schock,

Commander, U.S. Coast Guard, Acting Captain of the Port Boston.

[FR Doc. 2024–21688 Filed 9–20–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2024–0755]

RIN 1625–AA00

Safety Zone; Lake Erie, Hamburg, NY

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone within 656 yards of the Andrew D. Byers Water Circular DZ, adjacent to Hamburg Beach on Lake Erie. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by a military exercise. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Eastern Great Lakes or a designated representative.

DATES: This rule is effective from 6 a.m. through 11:30 p.m. from September 26, 2024, through September 27, 2024.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2024–0755 in the search box and click “Search.” Next, in the Document Type column, select “Supporting & Related Material.”

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email Lieutenant William Kelley, Waterways Management, U.S. Coast Guard; telephone (716) 931–4680, email D09-SMB-SECBuffalo-WWM@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule under authority in 5 U.S.C. 553(b)(B). This statutory provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” The Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because insufficient notice was given by the sponsor to provide for a comment period prior to the date of safety zone implementation and prompt action is needed to prevent the endangerment of the general public.

Also, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. For the same reasons discussed in the preceding paragraph, waiting for a 30-day notice period to run would be impracticable and contrary to the public interest.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Eastern Great Lakes (COTP) has determined that potential hazards exist associated with U.S. Army SOF Water Operations from September 26, 2024 through September 27, 2024. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while exercises are being conducted.

IV. Discussion of the Rule

This rule establishes a safety zone from 6 a.m. through 11:30 p.m. from September 26, 2024 through September 27, 2024. The safety zone will cover all navigable waters within 656 yards of the Andrew D. Byers Water Circular DZ on Lake Erie near Hamburg, NY, during a military exercise. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters while the exercise is in progress. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. View the regulatory text at the end of this document to see the precise coordinates for the center of the radius.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a “significant regulatory action,” under section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the necessity to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while exercises are being conducted.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

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

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and

responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, 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 rule involves a safety zone lasting 35 hours over two days that will prohibit entry within 656 yards of 42°46′20.6″ N, 78°52′42.5″ W. It is categorically excluded from further review under paragraph L60a 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. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 46 U.S.C. 70034, 70051, 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. 01.3.

■ 2. Add § 165.T24–0755 to read as follows:

§ 165.T24–0755 Safety Zone; Lake Erie, Hamburg, NY.

(a) *Location.* The following area is a safety zone: All waters of Lake Erie, from surface to bottom, in a 656-yard radius of 42°46′20.6″ N, 78°52′42.5″ W.

(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 Eastern Great Lakes (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 by phone: (716) 843–9560. 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 from 6 a.m. through 11:30 p.m. from September 26, 2024, through September 27, 2024.

Dated: September 17, 2024.

S.M. Murray,

Commander, U.S. Coast Guard, Alternate Captain of the Port Eastern Great Lakes.

[FR Doc. 2024–21655 Filed 9–20–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 231215–0305; RTID 0648–XE310]

Fisheries of the Northeastern United States; Summer Flounder Fishery; Quota Transfer From North Carolina to New Jersey

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and

Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; quota transfer.

SUMMARY: NMFS announces that the State of North Carolina is transferring a portion of its 2024 commercial summer flounder quota to the State of New Jersey. This adjustment to the 2024 fishing year quota is necessary to comply with the Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan (FMP) quota transfer provisions. This announcement informs the public of the revised 2024 commercial quotas for North Carolina and New Jersey.

DATES: Effective September 20, 2024, through December 31, 2024.

FOR FURTHER INFORMATION CONTACT: Matthew Rigdon, Fishery Resource Management Specialist, (978) 281–9336.

SUPPLEMENTARY INFORMATION: Regulations governing the summer flounder fishery are found in 50 CFR 648.100 through 648.111. These regulations require annual specification of a commercial quota that is apportioned among the coastal states from Maine through North Carolina. The process to set the annual commercial quota and the percent allocated to each state is described in § 648.102, and the final 2024 allocations were published on December 21, 2023 (88 FR 88266).

The final rule implementing amendment 5 to the FMP, as published in the **Federal Register** on December 17, 1993 (58 FR 65936), provided a mechanism for transferring summer flounder commercial quota from one state to another. Two or more states, under mutual agreement and with the concurrence of the NMFS Greater Atlantic Regional Administrator, can transfer or combine summer flounder commercial quota under § 648.102(c)(2). The Regional Administrator is required to consider three criteria in the evaluation of requests for quota transfers or combinations: (1) the transfers or combinations would not preclude the overall annual quota from being fully harvested; (2) the transfers address an unforeseen variation or contingency in the fishery; and (3) the transfers are consistent with the objectives of the FMP and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). The Regional Administrator has determined these three criteria have been met for the transfer approved in this notification.

North Carolina is transferring 9,340 pounds (lb; 4,237 kilograms (kg)) to New Jersey through a mutual agreement between the states. This transfer was requested to repay landings made by an

out-of-state permitted vessel under a safe harbor agreement. The revised summer flounder quotas for 2024 are: North Carolina, 2,331,735 lb (1,057,657 kg); and New Jersey, 1,502,298 lb (681,431 kg).

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR 648.102(c)(2)(i) through (iv), which was issued pursuant to section 304(b) of the Magnuson-Stevens Act, and is exempted from review under Executive Order 12866.

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

Dated: September 17, 2024.

Karen H. Abrams,
Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.
[FR Doc. 2024–21641 Filed 9–20–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 240304–0068]

RTID 0648–XD950

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Ocean Perch in the Central Aleutian District of the Bering Sea and Aleutian Islands Management Area

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific ocean perch in the Central Aleutian district (CAI) of the Bering Sea and Aleutian Islands management area (BSAI) by vessels participating in the BSAI trawl limited access sector fishery. This action is necessary to prevent exceeding the 2024 total allowable catch (TAC) of Pacific ocean perch in the CAI allocated to vessels participating in the BSAI trawl limited access sector fishery.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), September 19, 2024, through 2400 hours, A.l.t., December 31, 2024.

FOR FURTHER INFORMATION CONTACT: Steve Whitney, 907–586–7228.

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

The 2024 TAC of Pacific ocean perch, in the CAI, allocated to vessels participating in the BSAI trawl limited access sector fishery was established as a directed fishing allowance of 487 metric tons by the final 2024 and 2025 harvest specifications for groundfish in the BSAI (89 FR 17287, March 11, 2024).

In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Pacific ocean perch in the CAI by vessels

participating in the BSAI trawl limited access sector fishery. While this closure is effective, the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

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

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be impracticable and contrary to the public interest, as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion, and would delay the closure of Pacific ocean perch directed fishery in the CAI for vessels participating in the BSAI trawl limited access sector fishery. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of September 13, 2024.

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

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

Dated: September 18, 2024.

Karen H. Abrams,
Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.
[FR Doc. 2024–21716 Filed 9–20–24; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register

Vol. 89, No. 184

Monday, September 23, 2024

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-2024-2142; Project Identifier AD-2024-00033-A]

RIN 2120-AA64

Airworthiness Directives; Piper Aircraft, Inc. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2020-26-16, which applies to certain Piper Aircraft, Inc. (Piper) Model PA-28-151, PA-28-161, PA-28-181, PA-28-235, PA-28R-180, PA-28R-200, PA-28R-201, PA-28R-201T, PA-28RT-201, PA-28RT-201T, PA-32-260, PA-32-300, PA-32R-300, PA-32RT-300, and PA-32RT-300T airplanes. AD 2020-26-16 requires calculating the factored service hours (FSH) for each main wing spar to determine when an inspection is required, inspecting the lower main wing spar bolt holes for crack(s), and replacing any cracked main wing spar. Since the FAA issued AD 2020-26-16, the FAA evaluated the reports required by AD 2020-26-16 and determined that repetitive inspections of the lower main wing spar bolt holes for crack(s) and non-crack damage (including deep scratches, gouges, and thread marks) and replacement or modification of the main wing spar should be required, calculated service hours (CSH) should be used instead of FSH to determine times for required actions for each main wing spar, and that certain airplanes should be removed from the applicability and a new airplane model added to the applicability. This proposed AD would require calculating the CSH for each main wing spar; repetitively inspecting the lower main wing spar bolt holes for crack(s) and non-crack damage and

taking corrective actions as needed; and replacing or modifying main wing spars at a specified time. This proposed AD would also revise the applicability by removing certain airplanes and adding a new airplane model. 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 November 7, 2024.

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-2024-2142; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For Piper material identified in this proposed AD, contact Piper Aircraft, Inc., 2926 Piper Drive, Vero Beach, Florida 32960; phone: (772) 567-4361; email: customerservice@piper.com; website: [piper.com](https://www.piper.com).
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222-5110.

FOR FURTHER INFORMATION CONTACT: Fred Caplan, Aviation Safety Engineer, FAA, 1701 Columbia Avenue, College Park, GA 30337; phone: (404) 474-5507; email: 9-ASO-ATLACO-ADS@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send

your comments to an address listed under **ADDRESSES**. Include “Docket No. FAA-2024-2142; Project Identifier AD-2024-00033-A” at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to [regulations.gov](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 Fred Caplan, Aviation Safety Engineer, FAA, 1701 Columbia Avenue, College Park, GA 30337. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued AD 2020-26-16, Amendment 39-21371 (86 FR 3769, January 15, 2021) (AD 2020-26-16), for certain Piper Model PA-28-151, PA-28-161, PA-28-181, PA-28-235, PA-28R-180, PA-28R-200, PA-28R-201, PA-28R-201T, PA-28RT-201, PA-28RT-201T, PA-32-260, PA-32-300, PA-32R-300, PA-32RT-300, and PA-

32RT–300T airplanes. AD 2020–26–16 was prompted by an accident involving wing separation on a Piper Model PA–28R–201 airplane. An investigation by the National Transportation Safety Board (NTSB) revealed a fatigue crack in a visually inaccessible area of the lower main wing spar cap. The applicability of the NPRM for AD 2020–26–16 included additional Piper model airplanes with similar main wing spar structures as the Model PA–28R–201. Based on airplane usage history, the FAA determined that only those airplanes with a higher risk for fatigue cracks (airplanes with a significant history of operation in flight training or other high-load environments) should be subject to the inspection requirements proposed in that NPRM.

AD 2020–26–16 requires calculating the FSH for each main wing spar to determine when an inspection is required, inspecting the lower main wing spar bolt holes for cracks, and replacing any cracked main wing spar. The agency issued AD 2020–26–16 to detect and correct fatigue cracks in the lower main wing spar cap bolt holes.

Actions Since AD 2020–26–16 Was Issued

The preamble to AD 2020–26–16 explains that the FAA considers the requirements “interim action” and was considering further rulemaking. The FAA has now determined that further rulemaking is necessary, and this proposed AD follows from that determination. The FAA evaluated the inspection reports submitted by operators as required by AD 2020–26–16 and determined that additional action is needed, including requiring repetitive inspections of the lower main wing spar bolt holes for crack(s) and non-crack damage and replacement or modification of the main wing spar, using CSH instead of FSH to determine times for required actions, and revising the applicability by removing certain serial-numbered Piper Model PA–32–300 airplanes and all Model PA–32R–300, PA–32RT–300, and PA–32RT–300T airplanes because those airplanes would be included in the applicability of a proposed separate rulemaking action. The FAA also determined that Piper Model PA–32S–300 airplanes should be added to the applicability.

Since the FAA issued AD 2020–26–16, the FAA has analyzed the accident history of the airplanes affected by AD 2020–26–16 and other Piper airplanes operated in a similar fashion. The following paragraphs communicate the FAA’s findings on this subject.

Accident History

Fatigue cracking was present in the main wing spars of Piper Model PA–28–181, Model PA–28R–201, and Model PA–28–161 airplanes involved in the following accidents. The following NTSB reports are related to this issue and can be found on [ntsb.gov](https://www.ntsb.gov).

- NTSB Accident Number FTW87FA088: March 30, 1987—Marlin, TX—Piper Model PA–28–181—7,490 hours time-in-service (TIS). This accident was determined to have been caused by fatigue cracking in the outboard bolt holes of the main wing spar. This airplane’s primary usage was a “Pipeline Patrol” mission.

- NTSB Accident Number NYC93FA140: August 2, 1993—Provincetown, MA—Piper Model PA–28–181—11,683 hours TIS. This accident was determined to have been caused by structural overloading related to weather, but fatigue cracks were present near the outboard bolt holes. This airplane’s usage history included personal use, flight instruction, and charter flights.

- NTSB Accident Number ERA18FA120: April 4, 2018—Daytona Beach, FL—Piper Model PA–28R–201—7,691 hours TIS. This accident was determined to have been caused by fatigue cracking in the outboard bolt holes of the main wing spar. This airplane’s primary usage was flight instruction.

Bolt Hole Cracks and Other Findings

Following the release of AD 2020–26–16, the FAA and Piper received over 2,800 bolt-hole eddy current inspection reports. The inspections performed in the field revealed a mix of observations that warrant further discussion. Of the total inspections, over 100 reported a positive eddy current indication, with several including pictures of the bolt hole showing the source of the indication.

Piper later conducted more detailed inspections in a study of 24 main wing spars with 20 having positive eddy current indications. Out of the 20 positive indications, 3 were identified as fatigue cracks, where 1 was confirmed by Piper, and 2 were confirmed by the NTSB. The remaining were determined to be features not consistent with a crack, and 1 overstress crack as confirmed by the NTSB.

Though not all are confirmed, many of the indications are likely not fatigue cracks but are a variety of anomalies in the hole. These can include corrosion pitting, scratches, gouges, and threading marks possibly caused by forceful insertion and removal of the close-fit

bolts without proper unloading of the wing or other reasons. While these may not present as fatigue cracks at the time of inspection, anomalies in the hole create a stress concentration where cracks can begin to grow. Therefore, it is still crucial to inspect the critical bolt holes for these issues and take corrective action to prevent the formation of fatigue cracks. Piper Service Bulletin No. 1345, Revision A, dated September 17, 2021 (Piper SB No. 1345, Revision A); and Piper Service Bulletin No. 1372, dated April 3, 2024 (Piper SB No. 1372), include procedures for distinguishing between indications caused by hole damage or other anomalies from those caused by cracks.

In addition to the various forms of non-crack hole damage, the inspections revealed several cracks in and around the bolt holes. As part of the AD 2020–26–16 inspection reports, 6 cracks were found, including 2 later verified by NTSB lab examination and 1 verified by Piper (from the Piper study referenced above), and 3 visible cracks in photos. Other known cracks include those found in an airplane of the same operator fleet as the 2018 accident airplane, a separately submitted crack finding confirmed with dye penetrant, and a crack located on the lower spar cap surface running alongside the inspection bolt holes. Given these findings, additional cracks may be present among the other unconfirmed reported indications.

Other cracks have been discovered that may be caused by overload rather than by fatigue. While use of the airplane within its limits should not cause an overload crack, some crack findings have revealed that airplanes have been operated outside their limits. Though cracks due to overload are not the primary source of this corrective action, this emphasizes the need for and importance of inspecting the spar bolt holes for evidence of any cracking.

Long-Term Continued Operational Safety

The AD 2020–26–16 inspection report results indicated that additional inspections are needed to manage the safety of the fleet. While AD 2020–26–16 addressed the immediate safety concern, data indicates that more airplanes will need to be inspected and, due to aging, the airplanes already inspected will need additional inspections. This includes the need to expand inspections to include Piper Model PA–32S–300 airplanes in the applicability of this proposed AD because these airplanes share a similar structural design of the main wing spar

with the airplane models addressed in AD 2020–26–16

Crack development is a function of many factors, including the design of the structure, how severely the aircraft is flown, and manufacturing processes. Small imperfections may exist in any aircraft structure from an early age; however, through operation, these imperfections may slowly grow into fatigue cracks. Fatigue cracks have the effect of weakening the structure and its ability to support the stresses the aircraft was originally designed to handle.

The 2018 accident, along with other accidents in this fleet attributed to fatigue cracking, and the AD 2020–26–16 inspection reports, indicate an aging fleet that requires intervention to ensure any fatigue cracking does not reach a critical state prior to being detected. This often takes the form of repetitive inspections to be able to capture the formation of a detectable crack, requiring repair or replacement. The FAA has also determined that inspections alone are not sufficient to keep the fleet risk acceptably low long-term. Cracks are more likely to develop with aging of the main wing spar, so over time it becomes more likely that cracks will exist throughout the fleet and could be missed by inspection, due in part to the inherent imperfections of the inspection method; therefore, replacement or modification of the spars is needed. Both the FAA and Piper attempted to determine an inspection program that would manage risk to an acceptable level using inspection alone; however, no method could be found that did not eventually require spar replacement.

Ensuring further damage is not caused by the inspection itself is important, especially with repetitive inspections; however, inspecting for fatigue cracks as well as other hole anomalies is critical and outweighs the risk associated with repetitive inspections. Additionally, repeated inspections inherently allow for continued direct observation of the bolt holes over time and correcting non-crack damage if necessary. Piper has developed service actions, most recently in Piper SB No. 1345, Revision A, and Piper SB No. 1372, that mitigate inspection-induced damage by emphasizing proper unloading of the wing for both bolt and wing removal and replacement, if necessary, along with other instructions for ensuring care of the bolt holes.

Corrective Action Development

Each requirement outlined in this proposed AD has been developed to both address the unsafe condition and

limit the number of required inspections, reducing the burden on operators where possible. A brief discussion of each aspect of the requirements continues below.

Airplane Model Grouping

The inspection data received via the reporting requirement in AD 2020–26–16, along with testing of the baseline spar common to all Piper Model PA–28 and PA–32 airplanes has shown that inspections should be extended to include all models that share a similar structural design by utilizing the same baseline spar. It is likely that a significant contributing factor in the formation of cracks found in the main wing spar bolt attachment area is the cold bending of the spar to achieve the wing's dihedral. This method of forming the spar dihedral combined with the proximity to the wing attachment bolt holes leads to high residual stress in that area. The potential for fatigue cracking in and around the bolt holes, as well as higher variability in crack location and severity, is higher under this constant additional stress.

In an attempt to support less onerous inspections and to understand the causal factors, Piper investigated the residual stresses in the critical bolt-hole area. That investigation showed that the residual stress due to the spar cold bending process is a significant contributing factor in reducing the fatigue life of the spar bolt holes. An additional outcome of this investigation is a change to all new manufactured spars having machined dihedral bends to eliminate the residual stresses in the critical area.

Though there are differences between all Model PA–28 and PA–32 airplanes, such as additional reinforcing structure and lower operational loads, all airplane models share this same baseline spar with the cold bent dihedral. Differing characteristics allow for a grouping and tailoring of the requirements for each airplane model, but all airplane models need to be inspected. The current proposed requirements separate models into two groups, each requiring its own actions with a separate action for a third group under a separate proposed rulemaking action. The airplane models discussed share similar spar structure, while one group experiences higher operational loads than the other, due mostly to differences in gross weight and maximum airspeed. The remaining Piper Model PA–28 and PA–32 airplanes that would not be included in the applicability of this proposed AD either experience lower operational loads or have additional structure, both effectively lowering the stress

experienced in the subject bolt holes of the baseline spar.

Hours Calculation

The potential for fatigue cracking of the main wing spar bolt holes is highly influenced by the usage profile of the spar and airplane. For airplanes included in the applicability of this proposed AD, the primary usage is either flight instruction or personal use. Flight instruction consists of more hours spent flying at lower altitudes where the airplane is exposed to gusts and more takeoffs and landings than is typical for personal usage. These characteristics lead to reaching the fatigue life of the spar more quickly than personal usage, which generally involves a large time spent in cruise and fewer takeoffs and landings. As a result of the usage differences, the same TIS for an airplane used in flight instruction is not equivalent to the same time for a personal-use airplane.

An FSH equation was established in AD 2020–26–16 to account for the differences in usage and reduce the burden on personal use airplanes. This equation is still the best method available to account for different usage when determining when inspections should occur. In the United States, airplanes used in flight instruction for hire are required by FAA regulation to receive 100-hour inspections. Because instructional usage is unable to be tracked directly, a count of these inspections is used as a method for determining instructional usage to differentiate it from personal usage.

When AD 2020–26–16 was issued, available analysis indicated instructional usage was approximately 17 times more severe than personal usage, leading to this factor appearing in the FSH equation. After AD 2020–26–16 was published, further analysis completed by Piper estimated this factor was significantly lower. This has resulted in a new equation, now referred to as CSH in Piper SB No. 1372. The CSH calculation has the same instructions and intent as the FSH from AD 2020–26–16, but the value in the equation has been updated based on improved analysis and data. For Group 1 airplanes this proposed AD would require using a value of 3 instead of the value of 2 that is specified in Piper SB No. 1372, and a value of 2 would be used for Group 2 airplanes, as specified in Piper SB No. 1372.

Determination of Inspection and Spar Retirement or Modification Timing

The fleet corrective actions analyzed consist of an initial inspection, followed by repetitive inspections until a time is

reached when the spar should be modified or replaced. The FAA has worked with Piper to develop the specific timing for these actions using actual service data to determine current and future risk of fatigue cracks developing, and analysis using the physical properties of the structure to estimate formation and growth of cracks in the critical area of the spar. These efforts have resulted in inspection timing estimates that provide opportunities to locate cracks before reaching a critical size.

The proposed initial inspection time requirements for Group 1 and Group 2 airplanes have been determined using data from AD 2020–26–16 inspection reports and prior inspections consisting of known crack findings and known inspections that did not find an anomaly that exceeds the eddy current size threshold, to estimate times when a crack will exist in each group's fleet. An initial inspection time is then set just prior to when cracks would be expected in the fleet. This proposed initial inspection serves as a baseline inspection and will be followed by repetitive inspections to ensure a crack is not missed.

The proposed repetitive inspection programs have been set differently for each airplane group. For Group 1 airplanes, a tiered approach of inspecting more often with increasing age has been proposed as a method of reducing the burden on lower TIS airplanes. It is possible to inspect less used airplanes less often because these carry the least risk of developing a fatigue crack within the population. As age increases, and therefore risk increases, the proposed inspections are set to be more frequent. A similar approach would be possible for Group 2 airplanes, but the inspection intervals are estimated to be much shorter based on inspection data, structural design, and airplane performance, so stepping down with age would not be practical.

As an airplane ages, the likelihood or risk of a crack developing increases. A potential solution to this would be to continue to increase the frequency of inspections to ensure a crack is found before reaching a critical length; however, frequent and increased inspections are not a practical or safe approach due to the inherent risk in repeated bolt removal and reinsertion. At the fleet level, an ever-increasing age of the fleet means a higher risk that cracks are present in the fleet and may be missed, even with frequent inspections. This leaves a solution of removing or modifying the highest age spars to reduce and maintain the fleet risk, therefore spar retirement or

modification where possible is proposed.

These proposed fleet inspection requirements must be adjusted as needed to ensure cracks are found before they reach a critical size. A recent inspection of a Model PA–28–181 airplane main wing spar was performed at a time earlier than required by AD 2020–26–16 and revealed cracks at a TIS earlier than anticipated. A section of the main wing spar was sent to an independent materials lab, and under high magnification normally spaced fatigue striations were found, confirming this crack was caused by fatigue. This new finding required the FAA to adjust the Group 1 inspection schedules to earlier times to ensure a similar crack would be found in time.

Although this airplane was used almost exclusively for flight instruction, reducing the inspection times resulted in additional burden on all airplanes, including those for personal usage. Therefore, for this proposed AD, the FAA determined that for Group 1 airplanes a value of 3 should be used in the CSH instead of the value of 2 that is specified in Piper SB No. 1372. An increase in this value from 2 to 3 serves to mitigate the increased burden on Group 1 airplanes resulting from the reduced inspection times and provides relief for operators of personal-use airplanes.

Spar Modification and Replacement Options

Piper has developed a reinforcement kit as an option and alternative to retirement of the main wing spar, applicable to certain Group 1 airplanes. There is currently no spar modification developed for Piper Model PA–28R–180 and PA–28R–200 airplanes that are included in Group 1 or any airplanes designated as Group 2 airplanes, as specified in Piper SB No. 1372. The proposed inspection times after installing a reinforcement kit would provide an extended life of the main wing spar and longer intervals between the proposed repetitive inspections. The reinforcement kit provides additional structure that lowers and distributes the stress in the critical areas, allowing for slower crack growth. Piper used damage tolerance analysis when developing the inspection times after a reinforcement kit is installed.

Finally, new wing spars are available from Piper that have machined the spar dihedral bend instead of the cold bending process, eliminating the residual stress factor in these spars. These new wing spars have a different life limit and will not require any inspections.

Wing spars on the affected Piper airplanes could develop cracks that, if not addressed, would result in a wing separating from the fuselage in flight.

FAA's Determination

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

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed Piper SB No. 1372. This material specifies procedures for reviewing airplane maintenance records to determine the number of 100-hour inspections completed on the airplane since new and any record of main wing spar replacement; calculating the service hours; doing eddy current inspections of the main wing spar bolt holes for crack(s) and non-crack damage; repairing bolt holes with non-cracking damage; for certain airplanes installing a main wing spar reinforcement kit; and replacing a main wing spar.

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 **ADDRESSES**.

Proposed AD Requirements in This NPRM

This proposed AD would retain none of the requirements of AD 2020–26–16. This proposed AD would revise the applicability by removing certain serial-numbered Model PA–32–300 airplanes and all Piper Model PA–32R–300, PA–32RT–300, and PA–32RT–300T airplanes because those airplanes will be included in a separate proposed rulemaking action. This proposed AD would add serial-numbered Model PA–28R–200 and PA–28R–201 airplanes to the applicability to include all serial numbers and would also add Piper Model PA–32S–300 airplanes to the applicability. This proposed AD would require accomplishing the actions specified in the material already described, except as discussed under “Differences Between this AD and the Referenced Material.” This proposed AD would also require reporting inspection results to Piper and the FAA if any cracks are found during any inspection.

Differences Between This Proposed AD and the Referenced Material

For Group 1 airplanes, to determine the CSH, instead of using the value of 2 provided in the simplified formula in Part 1, paragraph 2.b of the Instructions

in Piper SB No. 1372, this proposed AD would require using a value of 3.

In addition, for Group 1 airplanes, the compliance times for the initial and repetitive inspections and the replacement or modification of the main

wing spars specified in paragraphs (i) and (j) of this proposed AD are different from what is in Table 1 of Piper SB No. 1372.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 10,665 airplanes of U.S. registry.

The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Review airplane maintenance records and determine CSH for each main wing spar.	3 work-hours × \$85 per hour = \$255, per records review.	\$0	\$255, per records review	\$2,719,575, per records review.

The FAA estimates the following costs to do any necessary actions that would be required based on the results

of the proposed airplane maintenance records review and CSH calculation. The agency has no way of determining

the number of airplanes that might need these actions:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Eddy current inspections of the left-hand (LH) and right-hand (RH) inspection areas LH and RH lower main wing spar (including access and restoring the airplane).	1 work-hour contracted service × \$600 per hour = \$600 for the eddy current inspection. 4 work-hours × \$85 per hour for access and restoring = \$340.	\$20	\$960 per inspection.
Report inspection results to the FAA and Piper Aircraft, Inc.	1 work-hour × \$85 per hour = \$85 per report.	0	85 per report.
Repair holes with non-crack damage	2 work-hours × \$85 per hour = \$170	20	190.
Replace main wing spar	40 work-hours × \$85 per hour = \$3,400 per main wing spar.	10,983	14,383 per main wing spar.
Install modification (reinforcement) kit	190 work-hours × \$85 per hour = \$16,150 per main wing spar.	4,000	20,150 per wing spar.

Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB Control Number. The OMB Control Number for this information collection is 2120-0056. Public reporting for this collection of information is estimated to be approximately 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. All responses to this collection of information are mandatory. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Information Collection Clearance Officer, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177-1524.

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 that the proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

Piper Aircraft, Inc.: Docket No. FAA–2024–2142; Project Identifier AD–2024–00033–A.

(c) Applicability

This AD applies to Piper Aircraft, Inc. (Piper) airplanes, certificated in any category, with a model and serial number shown in Table 1 to paragraph (c) of this AD.

Table 1 to Paragraph (c)—Applicability and Airplane Group

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive 2020–26–16, Amendment 39–21371 (86 FR 3769, January 15, 2021); and

■ b. Adding the following new airworthiness directive:

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by November 7, 2024.

(b) Affected ADs

This AD replaces AD 2020–26–16, Amendment 39–21371 (86 FR 3769, January 15, 2021) (AD 2020–26–16).

Model	Serial Numbers	Airplane Group
PA-28-151	All serial numbers	1
PA-28-161	All serial numbers	1
PA-28-181 Archer II	All serial numbers	1
PA-28-181 Archer III	All serial numbers lower than and including 2881687	1
PA-28-181 Piper Pilot	All serial numbers lower than and including 28020148	1
PA-28R-180	All serial numbers	1
PA-28R-200	All serial numbers	1
PA-28-235	All serial numbers	2
PA-28R-201	All serial numbers	2
PA-28R-201T	All serial numbers	2
PA-28RT-201	All serial numbers	2
PA-28RT-201T	All serial numbers	2
PA-32-260	All serial numbers	2
PA-32-300	All serial numbers lower than and including 32-7840202	2
PA-32S-300	All serial numbers	2

(d) Subject

Joint Aircraft System Component (JASC)
Code 5711, Wing Spar.

(e) Unsafe Condition

This AD was prompted by a report of a wing separation caused by fatigue cracking in a visually inaccessible area of the main wing lower spar cap. The FAA is issuing this AD to detect and correct fatigue cracks in the lower main wing spar cap bolt holes. The unsafe condition, if not addressed, could result in a wing separating from the fuselage in flight.

(f) Compliance

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

(g) Definitions

For the purpose of this AD the following definitions apply.

(1) Group 1 airplanes: Airplanes identified as Group 1 in Piper Service Bulletin No. 1372, dated April 3, 2024 (Piper SB No. 1372) and Table 1 to paragraph (c) of this AD.

(2) Group 2 airplanes: Airplanes identified as Group 2 in Piper SB No. 1372 and Table 1 to paragraph (c) of this AD.

(h) Review Airplane Maintenance Records and Determine Calculated Service Hours for Each Main Wing Spar

(1) Within 30 days after the effective date of this AD and thereafter at intervals not to exceed 100 hours time-in-service (TIS) or 12 months, whichever occurs first, review the airplane maintenance records and determine the number of 100-hour inspections completed on the airplane since new and any record of wing spar replacement(s) in accordance with Part I, paragraph 1, of the Instructions in Piper SB No. 1372. The owner/operator (pilot) holding at least a private pilot certificate may accomplish this and must enter compliance with this paragraph of the AD into the airplane

maintenance records in accordance with 14 CFR 43.9(a) and 91.417(a)(2)(v). The record must be maintained as required by 14 CFR 91.417, 121.380, or 135.439.

(2) Before further flight after doing the action required by paragraph (h)(1) of this AD, determine the calculated service hours (CSH) for each main wing spar using the applicable formula for your airplane group specified in Figure 1 or Figure 2 to paragraph (h)(2) of this AD and in accordance with Part I, paragraphs 2.a. through b., of the

Instructions in Piper SB No. 1372. Thereafter, after each 100-hour or annual inspection, recalculate the CSH for each main wing spar to determine the compliance time for the actions required by paragraphs (i) and (j) of this AD. If a factored service hour (FSH) inspection required by AD 2020–26–16 was done using Piper Service Bulletin No. 1345, dated March 27, 2020; or Piper Service Bulletin No. 1345A, dated September 17, 2021, you may use that data, including the TIS and number of 100-hour inspections at

the time of the last inspection, to calculate the CSH for that inspection using the requirements of paragraph (h) of this AD and Part I, paragraph 2.c. of the Instructions in Piper SB No. 1372 to determine the next required actions, including if an action is now due according to the requirements of paragraphs (i) and (j) of this AD.

Figure 1 to Paragraph (h)(2)—Group 1 Airplanes CSH Calculation

N is the number of 100-hour inspections; and T is the total hours TIS of the airplane main wing spar.

$$CSH = (N \times 100) + \frac{T - (N \times 100)}{3} \text{ for Group 1 airplanes}$$

Note 1 to Figure 1 to paragraph (h)(2): This calculation is not the same as the simplified calculation specified in Piper SB No. 1372

because this calculation uses a value of 3, for Group 1 airplanes only, and Piper SB No. 1372 uses a value of 2.

Figure 2 to paragraph (h)(2)—Group 2 Airplanes CSH Calculation

N is the number of 100-hour inspections; and T is the total hours TIS of the airplane main wing spar.

$$CSH = (N \times 100) + \frac{T - (N \times 100)}{2} \text{ for Group 2 airplanes}$$

Note 2 to Figure 2 to paragraph (h)(2): This calculation is the same as the simplified calculation specified in Piper SB No. 1372, but with a different form, and is for Group 2 airplanes only.

(i) Bolt Hole Inspections and Corrective Actions

(1) Do initial and repetitive eddy current inspections of the inner surface of each bolt hole in the lower wing spar cap for cracks and for non-crack damage (including deep

scratches, gouges, and thread marks), at the times in Table 2 and Table 3 to paragraph (i)(1) of this AD and in accordance with Part II, paragraph 4.a. of the Instructions in Piper SB No. 1372. Although Piper SB No. 1372 specifies NAS 410 Level II or Level III certification to perform eddy current and fluorescent penetrant inspections, this AD allows Level II or Level III qualification standards for inspection personnel using any inspector criteria approved by the FAA.

Note 3 to paragraph (i)(1): FAA Advisory Circular 65–31B, “Training, Qualification, and Certification of Nondestructive Inspection Personnel,” dated February 24, 2014, contains FAA-approved Level II and Level III qualification standards criteria for personnel doing nondestructive test inspections.

Table 2 to Paragraph (i)(1)—Compliance Times for Group 1 Airplane Inspections

Wing Spar Configuration	Initial Inspection	Repetitive Inspections			
		Tier A (3,000 through 7,499 Total CSH)	Tier B (7,500 through 11,999 Total CSH)	Tier C (12,000 through 13,499 Total CSH)	Tier D (14,000 through 25,000 Total CSH)
Unmodified Wing Spars	When wing spars reach 3,000 Total CSH , perform initial inspection within the next 100 hours TIS.	Perform repetitive inspection at intervals not to exceed 1,750 CSH	Perform repetitive inspection at intervals not to exceed 700 CSH	Perform repetitive inspection at intervals not to exceed 500 CSH	Perform the action required by paragraph (j) of this AD
Wing Spars modified with Piper Reinforcement Kit	Initial inspection upon installation of Piper Reinforcement Kit.	Perform repetitive inspection at intervals not to exceed 4,800 CSH			Perform repetitive inspection at intervals not to exceed 3,700 CSH

Note 4 to Table 2 to Paragraph (i)(1):

The compliance times are not the same as the times specified in Piper SB No. 1372 for Group 1 airplanes.

Table 3 to Paragraph (i)(1)—Compliance Times for Group 2 Airplane Inspections

Wing Spar Configuration	Initial Inspection	Repetitive Inspections	
		4,500 through 11,999 Total CSH	12,000 Total CSH
Unmodified Wing Spars	When wing spars reach 4,500 Total CSH , perform initial inspection within the next 100 hours TIS.	Perform repetitive inspection at intervals not to exceed 400 CSH	Perform the action required by paragraph (j) of this AD.

Note 5 to Table 3 to paragraph (i)(1): The compliance times are the same as the times specified in Piper SB No. 1372 for Group 2 airplanes.

(2) For any Group 1 or Group 2 airplane where the initial CSH cannot be calculated due to missing or incomplete airplane maintenance records: Do the initial inspection within 100 hours TIS or 60 days after the effective date of this AD, whichever occurs later.

(3) If an eddy current inspection does not identify any indications, then continue the repetitive eddy current inspections required by paragraph (i)(1) of this AD at the applicable times specified in Table 2 and Table 3 to paragraph (i)(1) of this AD.

(4) If any eddy current inspection identifies any indications or noisy signal, before further flight, do the applicable actions specified in Part II, paragraphs 4.b. through i., and if applicable the bolt hole oversize repair specified in Part III, paragraphs 1. through 7. and paragraph 9., of the Instructions in Piper SB No. 1372.

(5) If any eddy current inspection identifies any crack(s), before further flight, do the applicable actions specified in Part II, paragraph 4.k., of the Instructions in Piper SB No. 1372, and replace the affected main wing spar in accordance with Part IV, paragraphs 2.a. through d., of the Instructions in Piper SB No. 1372.

(j) Replace or Modify Main Wing Spar

For Group 1 and Group 2 airplanes:

(1) At the applicable time specified in Table 4 to paragraph (j) of this AD replace the affected main wing spars in accordance with Part IV, paragraphs 2.a. through d., of the Instructions in Piper SB No. 1372 or modify the main wing spars by installing the Piper reinforcement kit, in accordance with Part IV, paragraphs 1.a. through c., of the Instructions in Piper SB No. 1372.

(2) As required by paragraph (i)(5) of this AD, replace the affected main wing spars in

accordance with Part IV, paragraphs 2.a. through d., of the Instructions in Piper SB No. 1372.

Table 4 to Paragraph (j)—Compliance Times for Main Wing Spar Modification or Replacement

Airplane Group	Wing Spar Configuration	Compliance Time for Main Wing Spar Modification or Replacement
Group 1	Unmodified Wing Spars	Main wing spars must be replaced prior to 14,000 Total CSH or Main wing spars must be modified with Piper Reinforcement Kit to extend spar life beyond 14,000 Total CSH
	Wing Spars modified with Piper Reinforcement Kit	Modified main wing spars must be replaced prior to 25,000 Total CSH
Group 2	Unmodified Wing Spars	Main wing spars must be replaced prior to 12,000 Total CSH

If any cracks are found during any inspection required by paragraph (i) of this AD: After completing that inspection, using Appendix 1, "Inspection Results Form," of this AD, report the inspection results to the FAA, East Certification Branch, and to Piper Aircraft, Inc. Submit the report at the applicable time specified in paragraph (k)(1) or (2) of this AD.

(1) If the action was done on or after the effective date of this AD, submit the report within 30 days after the action was done.

(2) If the action was done before the effective date of this AD, submit the report within 30 days after the effective date of this AD.

(l) Special Flight Permit

A special flight permit may be issued in accordance with 14 CFR 21.197 and 21.199 to permit a one-time, non-revenue ferry flight to a location where the airplane can be inspected. This ferry flight must be performed with only essential flight crew. This AD prohibits a special flight permit if any inspection reveals a crack in the main wing spar.

(m) Alternative Methods of Compliance (AMOCs)

(1) The Manager, East Certification 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 East Certification Branch, send it to the attention of the person identified in paragraph (n) 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.

(3) AMOCs approved for AD 2020–26–16 are not approved as AMOCs for the corresponding provisions of this AD.

(n) Additional Information

(1) For more information about this AD, contact Fred Caplan, Aviation Safety Engineer, FAA, East Certification Branch, FAA, 1701 Columbia Avenue, College Park, GA 30337; phone: (404) 474–5507; email: 9-ASO-ATLACO-ADs@faa.gov.

(2) Piper material identified in this AD that is not incorporated by reference is available at the address specified in paragraph (o)(3) of this AD.

(3) FAA Advisory Circular 65–31B, "Training, Qualification, and Certification of Nondestructive Inspection Personnel," dated

February 24, 2014, maybe found at [drs.faa.gov](https://www.faa.gov/drs).

(o) 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 the AD specifies otherwise.

(i) Piper Service Bulletin No. 1372, dated April 3, 2024.

(ii) [Reserved].

(3) For Piper material identified in this AD, contact Piper Aircraft, Inc., 2926 Piper Drive, Vero Beach, FL 32960; phone: (772) 567–4361; email: customerservice@piper.com; website: [piper.com](https://www.piper.com).

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. 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-locationsoremailfr.inspection@nara.gov.

Appendix 1 to Docket No. FAA–2024–2142

Inspection Results Form

Email completed form to:
9-ASO-ATLCOS-Reporting@faa.gov
and
customer.service@piper.com

Or mail to: Federal Aviation Administration
East Certification Branch
1701 Columbia Avenue
College Park, GA 30337

SUBJECT line: Docket No. FAA-2024-2142

Include photos if applicable

Aircraft Model No.: PA-	Serial Number:
Aircraft Total Hours Time-In-Service (TIS):	Registration Number:
Calculated Service Hours Left-Hand (LH) Wing:	Right-Hand (RH) Wing:
(If both wings are factory installed original, these numbers should be the same)	
Date of previous inspection	
Inspection Results	
LH Wing Spar Fwd Accepted ☐ Rejected ☐ RH Wing Spar Fwd Accepted ☐ Rejected ☐	
LH Wing Spar Aft Accepted ☐ Rejected ☐ RH Wing Spar Aft Accepted ☐ Rejected ☐	
Inspector Comments	

Inspector Information

Name (print): _____Signature: _____

Certificate No.: _____Date: _____

Issued on September 10, 2024.

Victor Wicklund,

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

[FR Doc. 2024–21652 Filed 9–20–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 74

[Docket No. FDA–2024–C–4339]

DSM Biomedical; Filing of Color Additive Petition

AGENCY: Food and Drug Administration,
HHS.

ACTION: Notification of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by DSM Biomedical, proposing that the color additive regulations be amended to provide for the safe use of phthalocyanine green to color surgical sutures made of ultra-high molecular weight polyethylene (UHMWPE) for use in general surgery, at a concentration of no more than 0.5 percent by weight of the suture.

DATES: The color additive petition was filed on August 15, 2024.

ADDRESSES: For access to the docket to read background documents or 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.

FOR FURTHER INFORMATION CONTACT: Stephen DiFranco, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2710.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 721(d)(1) (21 U.S.C. 379e(d)(1))), we are giving notice that we have filed a color additive petition (CAP 4C0335), submitted by DSM Biomedical, 735 Pennsylvania Dr., Exton, PA 19341. The petition proposes to amend the color additive regulations in 21 CFR part 74, “Listing of Color Additives Subject to Certification,” to provide for the safe use of phthalocyanine green to color surgical sutures made of UHMWPE for use in general surgery, at a concentration of no

more than 0.5 percent by weight of the suture.

The petitioner claims that this action is categorically excluded under 21 CFR 25.32(l) because the substance is used in sutures. If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

Dated: September 18, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21684 Filed 9–20–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–108920–24]

RIN 1545–BR26

Guidance on Clean Electricity Low- Income Communities Bonus Credit Amount Program; Correction

AGENCY: Internal Revenue Service (IRS),
Treasury.

ACTION: Notice of proposed rulemaking;
correction.

SUMMARY: This document contains corrections to REG–108920–24, which was published in the **Federal Register** on Tuesday, September 3, 2024. REG–108920–24 contained proposed regulations concerning the program to allocate clean electricity low-income communities bonus credit amounts established pursuant to the Inflation Reduction Act of 2022 for calendar years 2025 and succeeding years.

DATES: Written or electronic comments and requests for a public hearing must be received by October 3, 2024.

ADDRESSES: Commenters were strongly encouraged to submit public comments electronically.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed rules, Office of Associate Chief Counsel (Passthroughs & Special Industries) at (202) 317–6853 (not a toll-free number); concerning submissions of comments or the public hearing, the Publications and Regulations Section at (202) 317–6901 (not a toll-free number) or by email at publichearings@irs.gov (preferred).

SUPPLEMENTARY INFORMATION:

Background

The notice of proposed rulemaking (REG–108920–24) that is the subject of this correction is under section 48E of the Internal Revenue Code.

Correction

Accordingly, FR Doc. 2024–19617 (REG–108920–24), appearing on page 71193 in the **Federal Register** on Tuesday, September 3, 2024, is corrected as follows:

1. On page 71195, in the third column, in the first full paragraph, by correcting the fourth line from the top of the paragraph to read, “most recently released by American Community Survey (ACS) low-income”.

2. On page 71196, in the second column, in the sixth bullet point from the top of the page, by correcting the first line of the bullet point to read, “Department of Agriculture (USDA) Section 515 Rural Rental”.

3. On page 71204, in the third column, in the fourth full paragraph, by correcting the fifth sentence from the top of the paragraph to read, “records are required for the IRS to validate”.

4. On page 71206, in the second column, in the third full paragraph, by correcting the twelve line from the top of the paragraph to read “The proposed regulations do not have substantial”.

Kalle L. Wardlow,

*Federal Register Liaison, Publications & Regulations Section, Associate Chief Counsel,
(Procedure and Administration).*

[FR Doc. 2024–21639 Filed 9–20–24; 8:45 am]

BILLING CODE 4830–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2024–0418; FRL–12225–
01–R9]

Air Plan Revisions; California; San Diego County Air Pollution Control District and Mojave Desert Air Quality Management District

AGENCY: Environmental Protection
Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve revisions to the San Diego County Air Pollution Control District (SDCAPCD) and Mojave Desert Air Quality Management District (MDAQMD) portions of the California State Implementation Plan (SIP). These revisions concern negative declarations for the Control Techniques Guidelines

(CTG) for the Oil and Natural Gas Industry (Oil and Natural Gas CTG). We are taking comments on this proposal to approve the SDCAPCD and MDAQMD negative declarations into the California SIP. We plan to follow with a final action.

DATES: Comments must be received on or before October 23, 2024.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2024–0418 at <https://www.regulations.gov>. For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. 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, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>. If you need assistance in a language other than English or if you are a person with a disability who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Eugene Chen, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105. By phone: (415) 947–4304 or by email at chen.eugene@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document, “we,” “us” and “our” refer to the EPA.

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- III. Statutory and Executive Order Reviews

I. The State’s Submittal

A. What documents did the State submit?

Table 1 lists the documents addressed by this proposal with the dates that they were adopted by the local air agencies and submitted by the California Air Resources Board (CARB).

TABLE 1—SUBMITTED DOCUMENTS

Local agency	Document	Adopted	Submitted to EPA
SDCAPCD	2020 Reasonably Available Control Technology Demonstration for the National Ambient Air Quality Standards for Ozone in San Diego County (“2020 RACT SIP”)—Negative Declaration for Oil and Natural Gas CTG.	10/14/2020	12/28/2020
MDAQMD	70 ppb Ozone Standard Implementation Evaluation: RACT SIP Analysis; Federal Negative Declarations; and Emission Statement Certification—Negative Declaration for Oil and Natural Gas CTG.	10/28/2019	12/20/2019

For the SDCAPCD submittal, we are only proposing action on the negative declaration for the Oil and Natural Gas CTG in Attachment B and are not proposing action on any other elements of the submittal. Similarly, for the MDAQMD submittal, we are only proposing action on the negative declaration for the Oil and Natural Gas CTG in Table 2 and are not proposing action on any other elements of the submittal. In both cases, the negative declaration for the Oil and Natural Gas CTG was submitted for the 2008 and 2015 ozone National Ambient Air Quality Standards (NAAQS).^{1 2}

On May 6, 2021, the EPA determined that the SDCAPCD negative declaration for the Oil and Natural Gas CTG met the SIP submittal completeness criteria in 40 CFR part 51, appendix V.³ On June

20, 2020, the MDAQMD submittal, including the Oil and Gas CTG negative declaration, was deemed by operation of law to meet the SIP completeness criteria in 40 CFR part 51, appendix V.

B. Are there other versions of these documents?

There are no other versions of the SDCAPCD submittal, but we previously approved the negative declarations from the 2020 RACT SIP for the CTGs titled *Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products* (EPA–450/2–78–029), *Control of Volatile Organic Emissions from Miscellaneous Metal and Plastic Parts Coatings* (EPA–453/R–08–003), Tables 3 through 6, and *Control Techniques Guidelines for Fiberglass Boat Manufacturing Materials* (EPA–453/R–08–004).⁴ There are no other versions of the MDAQMD submittal, and we have not previously

taken action on any elements of the submittal.

C. What is the purpose of the submitted documents?

Volatile organic compounds (VOC) and nitrogen oxides (NO_x) in the presence of sunlight can lead to the formation of ground-level ozone or “smog,” which can result in significant impacts to human health and the environment. Section 110(a) of the CAA requires states to submit regulations that control VOC emissions.

Clean Air Act (CAA) sections 182(b)(2) and (f) require that SIPs for ozone nonattainment areas classified as “Moderate” or above implement reasonably available control (RACT) for any source covered by a Control Techniques Guidelines (CTG) document and for any major source of VOCs or NO_x. On October 26, 2015, the EPA finalized action to revise the 8-hour ozone NAAQS from 0.075 to 0.070 ppm.⁵ On June 4, 2018, the EPA

¹ Page 10 of MDAQMD 70 ppb O₃ Evaluation, Final Staff Report.

² Page B–10 of SDCAPCD 2020 RACT SIP, Attachment B.

³ See Docket Item B–01, Letter dated May 6, 2021, from Elizabeth J. Adams, Director, Air Division,

EPA Region IX, to Richard W. Corey, Executive Officer, CARB.

⁴ 87 FR 38665 (June 29, 2022).

⁵ 80 FR 65292.

originally designated San Diego County as Moderate nonattainment for the 2015 8-hour ozone NAAQS.⁶ San Diego County has subsequently been reclassified from Moderate to “Severe” nonattainment.⁷ On June 4, 2018, the EPA also designated the West Mojave Desert area, which includes portions of San Bernardino and Los Angeles Counties, as Severe nonattainment for the 2015 8-hour ozone NAAQS. The SDCAPCD has jurisdiction over the entirety of San Diego County, and the MDAQMD has jurisdiction over the San Bernardino County portion of the West Mojave Desert nonattainment area.

As a result of their Severe classifications for the 2015 ozone NAAQS, SDCAPCD, and MDAQMD must, at a minimum, adopt RACT-level controls for all sources covered by a CTG document and for all major non-CTG sources of VOCs or NO_x within their respective nonattainment areas. Any stationary source that emits or has the potential to emit at least 25 tons per year (tpy) of VOCs or NO_x is considered a major stationary source in a Severe ozone nonattainment area.⁸

Section III.D of the preamble to the EPA’s final rule to implement the 2008 ozone NAAQS discusses RACT requirements.⁹ It states, in part, that RACT SIPs must contain adopted RACT regulations and certifications (where appropriate) that existing provisions meet the RACT requirement.¹⁰ Alternatively, for a source category covered by a CTG document where a District has no applicable stationary sources or emitting facilities, a District may adopt and submit a negative declaration documenting that there are no sources covered by the CTG. The submitted documents we are acting upon represent these Districts’ negative declarations for the Oil and Natural Gas CTG for the 2008 and 2015 ozone NAAQS.¹¹

⁶ 83 FR 25776.

⁷ 86 FR 29522. San Diego County voluntarily requested reclassification from Moderate to Severe nonattainment. The applicable attainment date would be as expeditious as practicable but no later than August 3, 2033 for the 2015 ozone NAAQS.

⁸ CAA sections 182(d) and (f) and 302(j).

⁹ 80 FR 12264 (March 6, 2015). Per 83 FR 62998 (December 6, 2018), these provisions were retained without significant revision for purposes of implementing the 2015 ozone NAAQS.

¹⁰ *Id.* at 12278.

¹¹ Publication of the Oil and Natural Gas CTG occurred in October 2016, which was after several Districts had already adopted their RACT SIP revisions for the 2008 ozone NAAQS. Due to this timing, some Districts submitted their negative declaration for this CTG under separate cover, or, in the case of SDCAPCD and MDAQMD, relied upon their respective RACT SIP revisions for the 2015 ozone NAAQS to also address this CTG for the 2008 ozone NAAQS.

II. The EPA’s Evaluation and Action

A. How is the EPA evaluating the documents?

As discussed in section I.C., SDCAPCD and MDAQMD must demonstrate that the Districts’ rules implement RACT for all sources covered by a CTG document as well as each major source of VOCs or NO_x. If a District has no sources covered by a particular CTG document, thus not requiring a RACT rule for such sources, then States may submit negative declarations for those CTGs for approval into the SIP. To do so, the submittal should provide reasonable assurances that no sources subject to the CTG’s requirements currently exist in the relevant ozone nonattainment area.

Guidance and policy documents that we used to evaluate the negative declarations include the following:

1. “State Implementation Plans; General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990,” 57 FR 13498 (April 16, 1992); 57 FR 18070 (April 28, 1992).

2. EPA 453/B–16–001, Control Techniques Guidelines for the Oil and Natural Gas Industry.

B. Do the documents meet the evaluation criteria?

The submitted documents contain the SDCAPCD and MDAQMD’s certifications that there are no sources within the ozone nonattainment areas under their respective jurisdictions that are subject to the Oil and Natural Gas CTG for the 2008 and 2015 8-hour ozone NAAQS. The Districts based their negative declarations on reviews of their permitting files, emission inventories, and in consultation with District enforcement staff. We reviewed available permitting, enforcement, and emission inventories for these two Districts.¹² In addition, we accessed the California Department of Conservation (CalGEM) Well Finder website, which contains an online mapping application of oil and gas industry information.¹³ Based on our review of this information, we did not identify any sources that would be subject to the Oil and Natural Gas CTG, and we agree with the SDCAPCD and MDAQMD negative declarations.¹⁴

¹² See Docket Item B–03, “CARB EI 2020 SD and MD.xlsx”.

¹³ Available at <https://www.conservation.ca.gov/calgem/Pages/WellFinder.aspx>.

¹⁴ We note that while there are several natural gas compressor stations operating in MDAQMD, they are not subject to the Oil and Natural Gas CTG because they are located after custody transfer and do not engage in the production of natural gas.

C. Proposed Action and Public Comment

As authorized in section 110(k)(3) of the Act, the EPA proposes to approve the SDCAPCD and MDAQMD negative declarations for the Oil and Natural Gas CTG because they fulfill the relevant requirements in CAA sections 110(a), 110(l), and 182(b)(2). We will accept comments from the public on this proposal until October 23, 2024. If we take final action to approve the submitted negative declarations as proposed, our final action will incorporate these negative declarations into the federally enforceable SIP. In addition, it will address the EPA’s obligation to promulgate a FIP for the SDCAPCD arising from our November 16, 2020 finding of failure to submit for the Oil and Natural Gas CTG.¹⁵

III. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA’s role is to approve State choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this proposed action merely proposes to approve State law as meeting Federal requirements and does not impose additional requirements beyond those imposed by State law. For that reason, this proposed action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 14094 (88 FR 21879, April 11, 2023);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive

¹⁵ 85 FR 72963. Our November 16, 2020 finding of failure to submit also triggered offset sanctions and highway funding sanctions. These sanctions clocks were extinguished by SDCAPCD’s December 29, 2020 submittal and our May 6, 2021 letter determining that the District’s negative declaration submittal was complete. See Docket Item B–01.

Order 13132 (64 FR 43255, August 10, 1999);

- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it proposes to approve a State program;

- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and

- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act.

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rulemaking does not have Tribal implications and will not impose substantial direct costs on Tribal governments or preempt Tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, February 16, 1994) directs Federal agencies to identify and address “disproportionately high and adverse human health or environmental effects” of their actions on communities with environmental justice (EJ) concerns to the greatest extent practicable and permitted by law. The EPA defines EJ as “the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.” The EPA further defines the term fair treatment to mean that “no group of people should bear a disproportionate burden of

environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies.”

The State did not evaluate EJ considerations as part of its SIP submittal; the CAA and applicable implementing regulations neither prohibit nor require such an evaluation. The EPA did not perform an EJ analysis and did not consider EJ in this action. Consideration of EJ is not required as part of this action, and there is no information in the record inconsistent with the stated goal of Executive Order 12898 of achieving EJ for communities with EJ concerns.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: September 16, 2024.

Martha Guzman Aceves,
Regional Administrator, Region IX.

[FR Doc. 2024–21646 Filed 9–20–24; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1 and 64

[WC Docket No. 24–213; MD Docket No. 10–234; FCC 24–85; FR ID 245867]

Improving the Effectiveness of the Robocall Mitigation Database; Amendment of CORES Registration System; Correction

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; correction.

SUMMARY: The Federal Communications Commission published a document in the **Federal Register** of September 12, 2024, proposing changes to procedural steps filers must take in the Robocall Mitigation Database. The document contained an incorrectly identified docket. This document corrects the misidentified docket, GN Docket No. 24–213, to the correct docket, WC Docket No. 24–213.

FOR FURTHER INFORMATION CONTACT: Erik Beith, Competition Policy Division, Wireline Competition Bureau, at (202) 418–0756, or email: erik.beith@fcc.gov.

SUPPLEMENTARY INFORMATION:

Correction

1. In the **Federal Register** of September 12, 2024, in FR Doc. 2024–20176, on page 74184, in the second column, under document headings, correct the identified docket to read: [WC Docket No. 24–213; MD Docket No. 10–234; FCC 24–85; FR ID 240720]

2. In the third column, in the **SUPPLEMENTARY INFORMATION** section, in the first sentence, correct “GN Docket No. 24–213” to read “WC Docket No. 24–213.”

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2024–21642 Filed 9–20–24; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register

Vol. 89, No. 184

Monday, September 23, 2024

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.

AGENCY FOR INTERNATIONAL DEVELOPMENT

60-Day Notice of Public Information Collection

AGENCY: U.S. Agency for International Development.

ACTION: Notice of public information collection.

SUMMARY: The U.S. Agency for International Development (USAID) seeks Office of Management and Budget (OMB) approval for the information collection described below. In accordance with the Paperwork Reduction Act of 1995, USAID requests public comment on this collection from all interested individuals and organizations.

DATES: Submit comments on or before November 22, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 60 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: Wayne Cohee, at (202) 230-4575 or via email at polycymailbox@usaid.gov.

SUPPLEMENTARY INFORMATION: The purpose of this notice is to allow 60 days for public comment preceding submission of the collections to OMB. USAID previously received approval, under OMB approval number 0412-0510, for information collection required under USAID’s Standard Provisions in its Automated Directives System (ADS) Chapter 303, USAID Grants and Cooperative Agreements to Non-Governmental Organizations. USAID will be adding three new Standard Provisions to ADS Chapter 303 later in calendar year 2024, entitled: 1.

Activity Monitoring, Evaluation, and Learning Plans (AMELPs); 2. Planning, Collection, and Submission of Digital Information to USAID With Data Management Plan (DMP); and 3. Planning, Collection, and Submission of Digital Information to USAID Without Data Management Plan (DMP). These three new Standard Provisions require information collection approval under the Paperwork Reduction Act. USAID thus, for purposes of organization and efficiency, seeks approval for this new information collection via revision to the existing OMB approval for ADS Chapter 303 information collection (0412-0510). Estimated annual responses, estimated annual burden hours, and estimated total public burden (in cost) for the new information collection are listed later in this notice.

All comments must be in writing and submitted through the method(s) specified in the Addresses section above. All submissions must include the information collection title. Please include your name, title, organization, postal address telephone number, and email address in the text of the message. Please note that comments submitted in response to this Notice are public record. We recommend that you do not submit detailed personal information, Confidential Business Information, or any information that is otherwise protected from disclosure by statute. USAID will only address comments that explain why the proposed collection would be inappropriate, ineffective, or unacceptable without a change. Comments that are insubstantial or outside the scope of the notice of request for public comment may not be considered.

OMB No: 0412-0510.

Form: No Form associated with this collection.

Title of Information Collection: United States Agency for International Development (USAID) Automated Directives System (ADS) Chapter 303 Standard Provisions Information Collection.

Type of Review: Revision of a currently approved collection (OMB No. 0412-0510).

Purpose: USAID is authorized to make grants to and enter cooperative agreements with Non-Governmental Organizations in or outside of the United States in furtherance of the purposes and within limitations of the

Foreign Assistance Act (FAA). The information collection requirements placed on the public are published in Standard Provisions that are included, as required or as applicable, in Notices of Funding Opportunities to potential applicants and resulting awards to recipients. The pre-award requirements are based on a need for prudent management in the determination that an applicant either has or can obtain the ability to competently manage development assistance programs using public funds. The requirements for information collection during the post-award period are based on the need to prudently administer public funds.

Respondents: USAID grant and cooperative agreement applicants and recipients.

For the three new Standard Provisions:

Estimated Number of Annual Responses: 2,525.

Estimated Number of Annual Burden Hours: 123,725.

Estimated total public burden (in cost): \$7,299,775.

These estimated totals were calculated using the below burden estimates per response for each of the named Standard Provisions, which are published internally in the Agency’s Automated Directives System (ADS) Chapter 303 and included by Agreement Officers, as required or as applicable, in Notices of Funding Opportunities and resulting awards:

*Activity Monitoring, Evaluation, and Learning Plan (TBD 2024)—*65 hours.

*Submission of Digital Information with a Data Management Plan (TBD 2024)—*53 hours.

*Submission of Digital Information without a Data Management Plan (TBD 2024)—*9 hours.

Jami J. Rodgers,

Senior Procurement Executive, USAID.

[FR Doc. 2024-21650 Filed 9-20-24; 8:45 am]

BILLING CODE 6116-01-P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B-49-2024]

**Foreign-Trade Zone (FTZ) 250,
Notification of Proposed Production
Activity; Boss Laser LLC; (Laser
Machines); Sanford, Florida**

Boss Laser LLC submitted a notification of proposed production activity to the FTZ Board (the Board) for its facility in Sanford, Florida, within FTZ 250. The notification conforming to the requirements of the Board's regulations (15 CFR 400.22) was received on September 4, 2024.

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: fiber laser marking machines (with stand and safety enclosure; with stand and no safety enclosure; desktop); fiber laser cutting machines; fiber laser cutting machines with pipe cutting attachment; fiber laser welding machines; carbon dioxide laser cutting and marking machines; dual source carbon dioxide laser and fiber laser cutting machines; and, ultraviolet laser desktop marking machines (duty rate ranges from duty-free to 3.5%).

The proposed foreign-status materials/components include: acrylic paint; windows (polycarbonate; safety glass); universal serial bus Wi-Fi routers; rubber components (exhaust tubing; O-rings); aluminum components (honeycomb tables; worktable knife blade supports; laser nozzles); mild steel worktable knife blade supports; casters with metal legs and rubber wheels; machine leveling feet with metal legs and rubber feet; rotary tools (for fiber laser marking machines; for carbon dioxide laser machines); water chillers; carbon dioxide laser glass tubes; fiber laser power converters; electric ballasts; zinc alloy handles; gas spring shock absorbing struts; fans (centrifugal exhaust; internal cooling); air compressors; metal components (latches for external machinery doors; door and hood hinges; body panels and doors; laser mirror and lens housings; linear guide components (rails; bearings; blocks); cogs; pulleys; plates; shims;

rulers and scale plates; clamps and clips; retaining rings; bushings; laser lens and nozzle removal tools; flow valves); water pumps (submersible; water chiller); plastic components (door and hood hinges; mounting brackets; cogs; pulleys; fittings; cases for packaging); laser components (mirrors; lenses; control cards); electric motors (for fiber laser cutting machinery; for carbon dioxide laser machinery); electric motor drivers; nylon and silicone tubing (for lubrication; for water; for air); decals and labels with adhesive backing; voltage stabilizers; electrical components (cables; wires; plugs for laser rotary tools; breakers; connectors; resistors; capacitors; filters); residual current terminal blocks; locksets and accompanying keys; fittings (brass; copper); iron components (fittings; bolts; screws); steel components (fittings; flanges; bolts; screws); light emitting diode components (indicator panels; strips); pin terminals for electrical wires; polyvinyl chloride bellows; electromechanical switches and relays; laser head assemblies; wiring harness assemblies; liquid crystal display control panels; connecting and worm rods; mechanical ball bearings; integral shaft bearings; filters for fume and odor extractor machines; fume and odor extractor machines; handheld remote controls for laser controller software; wireless computer components (mouses; keyboards); standalone computer towers without monitors; oil pumps; solenoids; water flow sensors and meters; proximity sensors and limit switches; laser safety glasses; shafts (wheel and reduction; drive); digital components (controller software; cameras; video recorders); metal flathead screwdrivers with plastic handles; magnets; random access memory for computers; computer mousepads (duty rate ranges from duty-free to 9.0%). The request indicates that certain materials/components are subject to duties under section 301 of the Trade Act of 1974 (section 301), depending on the country of origin. The applicable section 301 decisions require subject merchandise to be admitted to FTZs in privileged foreign status (19 CFR 146.41).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: ftz@trade.gov. The closing period for their receipt is November 4, 2024.

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 Juanita Chen at juanita.chen@trade.gov.

Dated: September 17, 2024.

Elizabeth Whiteman,
Executive Secretary.

[FR Doc. 2024-21658 Filed 9-20-24; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-122-857]

**Certain Softwood Lumber Products
From Canada: Notice of Final Results
of Antidumping Duty Changed
Circumstances Review**

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On July 15, 2024, the U.S. Department of Commerce (Commerce) published the preliminary results of the changed circumstances review (CCR) of the antidumping duty (AD) order on certain softwood lumber from Canada. For these final results, Commerce continues to find that TRAPA Forest Products Ltd. (TRAPA) is the successor-in-interest to Trans-Pacific Trading Ltd. (Trans-Pacific).

DATES: Applicable September 23, 2024.

FOR FURTHER INFORMATION CONTACT: Robert Bolling, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-3434.

SUPPLEMENTARY INFORMATION:**Background**

On July 15, 2024, Commerce published the preliminary results of this expedited CCR, determining that TRAPA is the successor-in-interest to Trans-Pacific for purposes of determining AD cash deposits and liabilities, and provided all interested parties with an opportunity to comment.¹ No interested party submitted comments on the *Preliminary Results*. Accordingly, the final results remain unchanged from the *Preliminary Results*.

Scope of the Order

The merchandise subject to the order is certain softwood lumber.² The product is currently classified under the following Harmonized Tariff Schedule

¹ See *Certain Softwood Lumber from Canada: Notice of Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review*, 89 FR 57394 (July 15, 2024) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

² For a complete description of the scope of the order, *Preliminary Results* PDM.

of the United States (HTSUS) numbers:

4406.11.0000; 4406.91.0000;
4407.10.01.01; 4407.10.01.02;
4407.10.01.15; 4407.10.01.16;
4407.10.01.17; 4407.10.01.18;
4407.10.01.19; 4407.10.01.20;
4407.10.01.42; 4407.10.01.43;
4407.10.01.44; 4407.10.01.45;
4407.10.01.46; 4407.10.01.47;
4407.10.01.48; 4407.10.01.49;
4407.10.01.52; 4407.10.01.53;
4407.10.01.54; 4407.10.01.55;
4407.10.01.56; 4407.10.01.57;
4407.10.01.58; 4407.10.01.59;
4407.10.01.64; 4407.10.01.65;
4407.10.01.66; 4407.10.01.67;
4407.10.01.68; 4407.10.01.69;
4407.10.01.74; 4407.10.01.75;
4407.10.01.76; 4407.10.01.77;
4407.10.01.82; 4407.10.01.83;
4407.10.01.92; 4407.10.01.93;
4407.11.00.01; 4407.11.00.02;
4407.11.00.42; 4407.11.00.43;
4407.11.00.44; 4407.11.00.45;
4407.11.00.46; 4407.11.00.47;
4407.11.00.48; 4407.11.00.49;
4407.11.00.52; 4407.11.00.53;
4407.12.00.01; 4407.12.00.02;
4407.12.00.17; 4407.12.00.18;
4407.12.00.19; 4407.12.00.20;
4407.12.00.58; 4407.12.00.59;
4407.19.05.00; 4407.19.06.00;
4407.19.10.01; 4407.19.10.02;
4407.19.10.54; 4407.19.10.55;
4407.19.10.56; 4407.19.10.57;
4407.19.10.64; 4407.19.10.65;
4407.19.10.66; 4407.19.10.67;
4407.19.10.68; 4407.19.10.69;
4407.19.10.74; 4407.19.10.75;
4407.19.10.76; 4407.19.10.77;
4407.19.10.82; 4407.19.10.83;
4407.19.10.92; 4407.19.10.93;
4409.10.05.00; 4409.10.10.20;
4409.10.10.40; 4409.10.10.60;
4409.10.10.80; 4409.10.20.00;
4409.10.90.20; 4409.10.90.40;
4418.50.0010; 4418.50.0030;
4418.50.0050; and 4418.99.10.00.
Although the HTSUS numbers are provided for convenience and customs purposes, the written product description remains dispositive.

Final Results of CCR

For the reasons stated in the *Preliminary Results*, and because we received no comments from interested parties challenging our preliminary finding, Commerce continues to find that TRAPA is the successor-in-interest to Trans-Pacific. As a result of this determination and consistent with our established practice, we find that TRAPA should receive the AD cash deposit rate previously assigned to Trans-Pacific. Because there are no changes from the *Preliminary Results*, there is no decision memorandum accompanying this notice and we are

adopting the *Preliminary Results* as the final results of this CCR.

Consequently, Commerce will instruct U.S. Customs and Border Protection to suspend liquidation of all shipments of subject merchandise produced and/or exported by Trans-Pacific and entered, or withdrawn from warehouse, for consumption on or after the publication date of this notice in the **Federal Register** at 7.80 percent, which is the current AD cash deposit rate for Trans-Pacific.³ This cash deposit requirement shall remain in effect until further notice.

Administrative Protective Order

This notice serves as the final reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing this determination and publishing these final results and notice in accordance with sections 751(b)(1) and 777(i)(1) and (2) of the Tariff Act of 1930, as amended, and 19 CFR 351.216(e), 351.221(b), and 351.221(c)(3).

Dated: September 16, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2024–21649 Filed 9–20–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–555–003, A–557–830, A–549–851, A–552–841]

Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From Cambodia, Malaysia, Thailand, and the Socialist Republic of Vietnam: Postponement of Preliminary Determinations in the Less-Than-Fair-Value Investigations

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable September 23, 2024.

FOR FURTHER INFORMATION CONTACT:

Hermes Pinilla or Joshua Weiner (Cambodia) at (202) 482–3477 or (202) 482–3902, respectively; Patrick Barton or Elizabeth Talbot Russ (Malaysia) at (202) 482–0012 or (202) 482–5516, respectively; Drew Jackson (Thailand) at (202) 482–4406; and Laurel LaCivita and Deborah Cohen (the Socialist Republic of Vietnam (Vietnam)) at (202) 482–4243 and (202) 482–4521, respectively, AD/CVD Operations, Offices I, III, and IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On May 14, 2024, the U.S. Department of Commerce (Commerce) initiated less-than-fair-value (LTFV) investigations of imports of crystalline silicon photovoltaic cells, whether or not assembled into modules (solar cells), from Cambodia, Malaysia, Thailand, and Vietnam.¹ On July 22, 2024, Commerce tolled certain deadlines in this administrative proceeding by seven days.² Currently, the preliminary determinations are due no later than October 8, 2024.

Postponement of Preliminary Determinations

Section 733(b)(1)(A) of the Tariff Act of 1930, as amended (the Act), requires Commerce to issue the preliminary determination in an LTFV investigation within 140 days after the date on which Commerce initiated the investigation.

¹ See *Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from Cambodia, Malaysia, Thailand, and the Socialist Republic of Vietnam: Initiation of Less-Than Fair-Value Investigations*, 89 FR 43809 (May 20, 2024) (Initiation Notice).

² See Memorandum, “Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings,” dated July 22, 2024.

³ See *Certain Softwood Lumber Products from Canada: Final Results of Antidumping Duty Administrative Review, Partial Rescission of Administrative Review, and Final Determination of No Shipments*, 2022, 89 FR 67067 (August 19, 2024).

However, section 733(c)(1)(A)(b)(1) of the Act permits Commerce to postpone the preliminary determination until no later than 190 days after the date on which Commerce initiated the investigation if: (A) the petitioner³ makes a timely request for a postponement; or (B) Commerce concludes that the parties concerned are cooperating, that the investigation is extraordinarily complicated, and that additional time is necessary to make a preliminary determination. Under 19 CFR 351.205(e), the petitioner must submit a request for postponement 25 days or more before the scheduled date of the preliminary determination and must state the reasons for the request. Commerce will grant the request unless it finds compelling reasons to deny the request.

On September 9, 2024, the petitioner submitted a timely request that Commerce postpone the preliminary determinations in these LTFV investigations.⁴ The petitioner stated that it requests postponement because Commerce “only recently received responses to the initial questionnaire,” and “this extension would allow {petitioner’s} counsel and other interested parties sufficient time to analyze the respondents’ questionnaire responses and provide comments on those responses.”⁵ Additionally, the extension “would allow {Commerce} to issue supplemental questionnaires and receive responses prior to making its preliminary . . . determination.”⁶

For the reasons stated above, and because there are no compelling reasons to deny the request, Commerce, in accordance with section 733(c)(1)(A) of the Act, is postponing the deadline for the preliminary determinations by 50 days (*i.e.*, 190 days after the date on which these investigations were initiated). As a result, Commerce will issue its preliminary determinations no later than November 27, 2024.⁷ In accordance with section 735(a)(1) of the Act and 19 CFR 351.210(b)(1), the deadline for the final determinations of these investigations will continue to be 75 days after the date of the preliminary determinations, unless postponed at a later date.

This notice is issued and published pursuant to section 733(c)(2) of the Act and 19 CFR 351.205(f)(1).

Dated: September 17, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2024–21696 Filed 9–20–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

National Artificial Intelligence Advisory Committee

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice of open meeting.

SUMMARY: The National Institute of Standards and Technology (NIST) announces that the National Artificial Intelligence Advisory Committee (NAIAC or Committee) will hold an open meeting in-person and virtually via web conference on October 10, 2024, from 10 a.m.–3 p.m. Pacific time. The primary purpose of this meeting is for the Committee to report working group findings, identify actionable recommendations, and receive public briefings. The briefings are from outside subject matter experts to the full Committee from areas such as industry, nonprofit organizations, the scientific community, the defense and law enforcement communities, and other appropriate organizations. The final agenda will be posted on the NAIAC Upcoming Meeting Page on the NIST website <https://www.nist.gov/itl/national-artificial-intelligence-advisory-committee-naiac>.

DATES: The NAIAC will meet on Thursday, October 10, 2024, from 10 a.m.–3 p.m. Pacific time.

ADDRESSES: The meeting will be held in person and virtually via web conference. The in-person meeting will be located at Tower West, Building 1, 10176 Scholars Drive, La Jolla, CA 92093. For instructions on attending or participating in the meeting, either in person or virtually, please see the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT:

Cheryl L. Gendron, Designated Federal Officer, Information Technology Laboratory, National Institute of Standards and Technology, Telephone: (301) 975–2785, Email address: cheryl.gendron@nist.gov. Please direct any inquiries to the committee at naiac@nist.gov.

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C. 1001 *et seq.*, notice is hereby given that the NAIAC will meet virtually as set forth in the **DATES** section of this notice. The meeting will be open to the public.

The NAIAC is authorized by section 5104 of the National Artificial Intelligence Initiative Act of 2020 (Pub. L. 116–283), in accordance with the provisions of the Federal Advisory Committee Act, as amended (FACA), 5 U.S.C. 1001 *et seq.* The Committee advises the President and the National Artificial Intelligence Initiative Office on matters related to the National Artificial Intelligence Initiative. Additional information on the NAIAC is available at <https://ai.gov/naiac/>.

The agenda will include NAIAC working group chair updates and work product deliberation, a UN High-Level Advisory Body briefing, and a NAIAC Discussion on the 2024 planned Transition Report. Members of the public interested in reviewing the agenda in advance are encouraged to visit <https://www.nist.gov/itl/national-artificial-intelligence-advisory-committee-naiac> for details and to register to watch virtually. The agenda items may change to accommodate NAIAC business. The final agenda will be posted on the NAIAC Upcoming Meeting Page on the NIST website at <https://www.nist.gov/itl/national-artificial-intelligence-advisory-committee-naiac>.

Comments: Individuals and representatives of organizations who would like to offer comments and suggestions related to items on the Committee’s agenda for this meeting are invited to submit comments in advance of the conference. Approximately ten minutes will be reserved for public comments, as time allows, which will be heard on a first-come, first-served basis. Speakers may be limited to two minutes each. Please note that all comments submitted via email will be treated as public documents and will be made available for public inspection. All comments must be submitted via email with the subject line “October 10, 2024, NAIAC Public Meeting” to naiac@nist.gov by 5 p.m. Pacific time, Tuesday, October 8, 2024. NIST will not accept comments accompanied by a request that part or all of the comment be treated confidentially because of its business proprietary nature or for any other reason. Therefore, do not submit confidential business information or otherwise sensitive, protected, or personal information, such as account numbers, Social Security numbers, or names of other individuals. Members of

³ The petitioner is the American Alliance for Solar Manufacturing Trade Committee.

⁴ See Petitioner’s Letter, “Request to Postpone Preliminary Determination,” dated September 9, 2024.

⁵ *Id.* at 2.

⁶ *Id.*

⁷ This deadline has been tolled by seven days. See footnote 2, *supra*.

the public may also submit written comments to the NAIAC at any time.

Virtual Meeting Registration Instructions: The meeting will be broadcast via web conference. Registration is required to view the web conference. Instructions on how to register will be made available <https://www.nist.gov/itl/national-artificial-intelligence-advisory-committee-naiac>. Registration will remain open until the conclusion of the meeting.

In-Person Admittance Instruction: Limited space is available on a first-come, first-served basis for anyone who wishes to attend in person. Registration is required for in-person attendance. Registration details will be posted on the NAIAC Upcoming Meeting Page on the NIST website at <https://www.nist.gov/itl/national-artificial-intelligence-advisory-committee-naiac>. Registration for in-person attendance will close at 5 p.m. Pacific time on Tuesday, October 8, 2024, or if the space is full.

Alicia Chambers,

NIST Executive Secretariat.

[FR Doc. 2024–21635 Filed 9–20–24; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XE300]

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The New England Fishery Management Council (Council) is holding a hybrid meeting of its Scientific and Statistical Committee (SSC) to consider actions affecting New England fisheries in the exclusive economic zone (EEZ).

Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Wednesday, October 9, 2024, beginning at 9 a.m.

ADDRESSES:

Meeting address: This meeting will be held at the Hilton Providence, 21 Atwells Avenue, Providence, RI 02903; telephone: (401) 831–3900.

Webinar Registration information: https://nefmc-org.zoom.us/webinar/register/WN_PcPsOJDT3K-IgFdnfJZfA.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950

FOR FURTHER INFORMATION CONTACT: Cate O’Keefe, Ph.D., Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Scientific and Statistical Committee (SSC) will meet to review the information provided by the Council’s Scallop Plan Development Team (PDT) and recommend the overfishing limits (OFL) and acceptable biological catches (ABC) for Atlantic sea scallops for fishing years (FY) 2025–2026. They will also review the information provided by the Council’s Groundfish PDT, review stock assessment information and recommend the OFLs and ABCs for witch flounder for FY 2025–2027.

The SSC will review draft outcomes of the 8th National Workshop of the Council Coordination Committee’s Scientific and Statistical Subcommittee held in August 2024 and discuss potential next steps for the SSC. They also plan to review outcomes of the May 2024 workshop on Implementing Social Science Methods for Fisheries Decision-Making, discuss a proposal for a formal committee on social science; discuss potential next steps for the SSC. Other business will be discussed, as necessary.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council’s intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Cate O’Keefe, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: September 18, 2024.

Rey Israel Marquez,

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

[FR Doc. 2024–21692 Filed 9–20–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XE282]

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to Geophysical Surveys Related to Oil and Gas Activities in the Gulf of Mexico

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

ACTION: Notice of issuance of letter of authorization.

SUMMARY: In accordance with the Marine Mammal Protection Act (MMPA), as amended, its implementing regulations, and NMFS’ MMPA Regulations for Taking Marine Mammals Incidental to Geophysical Surveys Related to Oil and Gas Activities in the Gulf of Mexico, notification is hereby given that NMFS has issued a Letter of Authorization (LOA) to LLOG Exploration Offshore, LLC (LLOG) for the take of marine mammals incidental to geophysical survey activity in the Gulf of Mexico (GOM).

DATES: The LOA is effective from September 16, 2024, through April 19, 2026.

ADDRESSES: The LOA, LOA request, and supporting documentation are available online at: <https://www.fisheries.noaa.gov/action/incidental-take-authorization-oil-and-gas-industry-geophysical-survey-activity-gulf-mexico>. In case of problems accessing these documents, please call the contact listed below (see **FOR FURTHER INFORMATION CONTACT** section).

FOR FURTHER INFORMATION CONTACT: Rachel Wachtendonk, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking 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 either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

An authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth. NMFS has defined “negligible impact” in 50 CFR 216.103 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.

Except with respect to certain activities not pertinent here, the MMPA defines “harassment” as: any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

On January 19, 2021, we issued a final rule with regulations to govern the unintentional taking of marine mammals incidental to geophysical survey activities conducted by oil and gas industry operators, and those persons authorized to conduct activities on their behalf (collectively “industry operators”), in U.S. waters of the GOM over the course of 5 years (86 FR 5322, January 19, 2021). The rule was based on our findings that the total taking from the specified activities over the 5-year period will have a negligible impact on the affected species or stock(s) of marine mammals and will not have an unmitigable adverse impact on the availability of those species or stocks for subsistence uses, and became effective on April 19, 2021.

The regulations at 50 CFR 217.180 *et seq.* allow for the issuance of LOAs to industry operators for the incidental take of marine mammals during geophysical survey activities and prescribe the permissible methods of taking and other means of effecting the least practicable adverse impact on marine mammal species or stocks and

their habitat (often referred to as mitigation), as well as requirements pertaining to the monitoring and reporting of such taking. Under § 217.186 (e), issuance of an LOA shall be based on a determination that the level of taking will be consistent with the findings made for the total taking allowable under these regulations and a determination that the amount of take authorized under the LOA is of no more than small numbers.

NMFS subsequently discovered that the 2021 rule was based on erroneous take estimates. We conducted another rulemaking using correct take estimates and other newly available and pertinent information relevant to the analyses supporting some of the findings in the 2021 final rule and the taking allowable under the regulations. We issued a final rule in April 2024, effective May 24, 2024 (89 FR 31488, April 24, 2024).

The 2024 final rule made no changes to the specified activities or the specified geographical region in which those activities would be conducted, nor to the original 5-year period of effectiveness. In consideration of the new information, the 2024 rule presented new analyses supporting affirmation of the negligible impact determinations for all species, and affirmed that the existing regulations, which contain mitigation, monitoring, and reporting requirements, are consistent with the “least practicable adverse impact” standard of the MMPA.

Summary of Request and Analysis

LLOG plans to conduct a Zero Offset, Offset, or Walkaway vertical seismic profile (VSP), Salt Proximity Survey, and/or Checkshot survey in lease block OCS-G 36103 AC 337, with water depths ranging from approximately 1,200 to 1,500 meters (m). LLOG plans to use either a 12-element, 2,400 cubic inch (in³) airgun array, or a 6-element, 1,500 in³ airgun array. See section G of the LOA application for a map of the area.

Consistent with the preamble to the final rule, the survey effort proposed by LLOG in its LOA request was used to develop LOA-specific take estimates based on the acoustic exposure modeling results described in the preamble (89 FR 31488, April 24, 2024). In order to generate the appropriate take number for authorization, the following information was considered: (1) survey type; (2) location (by modeling zone ¹); (3) number of days; (4) source; and (5)

month.² In this case, the 4,130 in³ airgun array was selected. The acoustic exposure modeling performed in support of the rule provides 24-hour exposure estimates for each species, specific to each modeled source and survey type in each zone and month.

No VSP surveys were included in the modeled survey types, and use of existing proxies (*i.e.*, two-dimensional (2D), 3D (narrow-azimuth) NAZ, 3D (wide-azimuth) WAZ, Coil) is generally conservative for use in evaluation of VSP survey effort, largely due to the greater area covered by the modeled proxies. Summary descriptions of these modeled survey geometries are available in the preamble to the 2018 proposed rule (83 FR 29212, 29220, June 22, 2018). Coil was selected as the best available proxy survey type in this case because the spatial coverage of the planned survey is most similar to the coil survey pattern.

For the planned survey, the seismic source array will be deployed in one of the following forms: Zero Offset VSP—deployed from a drilling rig at or near the borehole, with the seismic receivers (*i.e.*, geophones) deployed in the borehole on wireline at specified depth intervals; Offset VSP—in a fixed position deployed from a supply vessel on an offset position; Walkaway VSP—attached to a line, or a series of lines, towed by a supply vessel; 3D VSP—source moves along a spiral or line swaths towed by a supply vessel; Salt-Proximity—consists typically of a combination of both Zero Offset VSP plus a fixed Offset VSP; or Checkshot—similar to Zero Offset VSP, typically hung from a platform and a sensor placed at a few depths in the well, where only the first energy arrival is recorded. The coil survey pattern in the model was assumed to cover approximately 144 kilometers squared (km²) per day (compared with approximately 795 km², 199 km², and 845 km² per day for the 2D, 3D NAZ, and 3D WAZ survey patterns, respectively). Among the different parameters of the modeled survey patterns (*e.g.*, area covered, line spacing, number of sources, shot interval, total simulated pulses), NMFS considers area covered per day to be most influential on daily modeled exposures exceeding Level B harassment criteria. Because LLOG’s planned survey is expected to cover no additional area as a stationary source, the coil proxy is most

² Acoustic propagation modeling was performed for two seasons: winter (December–March) and summer (April–November). Marine mammal density data is generally available on a monthly basis, and therefore further refines take estimates temporally.

¹ For purposes of acoustic exposure modeling, the GOM was divided into seven zones. Zone 1 is not included in the geographic scope of the rule.

representative of the effort planned by LLOG in terms of predicted Level B harassment.

The survey will take place over approximately 5 days in zone 6. The monthly distribution of survey days is not known in advance. Take estimates for each species are based on the month that produces the greatest value.

Based on the results of our analysis, NMFS has determined that the level of taking expected for this survey and authorized through the LOA is consistent with the findings made for the total taking allowable under the regulations. See table 1 in this notice and table 6 of the rule (89 FR 31488, April 24, 2024).

Small Numbers Determination

Under the GOM rule, NMFS may not authorize incidental take of marine mammals in an LOA if it will exceed “small numbers.” In short, when an acceptable estimate of the individual marine mammals taken is available, if the estimated number of individual animals taken is up to, but not greater than, one-third of the best available abundance estimate, NMFS will determine that the numbers of marine mammals taken of a species or stock are small (89 FR 31535, May 24, 2024). For more information please see NMFS’ discussion of small numbers in the 2021 final rule (86 FR 5438, January 19, 2021).

The take numbers for authorization are determined as described above in

the Summary of Request and Analysis section, are used by NMFS in making the necessary small numbers determinations, through comparison with the best available abundance estimates (see discussion at 86 FR 5322, 5391, January 19, 2021). For this comparison, NMFS’ approach is to use the maximum theoretical population, determined through review of current stock assessment reports (SAR; <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments>) and model-predicted abundance information (<https://seamap.env.duke.edu/models/Duke/GOM/>). Information supporting the small numbers determinations is provided in table 1.

TABLE 1—TAKE ANALYSIS ¹

Species	Authorized take	Abundance ²	Percent abundance
Rice’s whale	0	51	n/a
Sperm whale	38	3,007	1.3
<i>Kogia</i> spp	³ 15	980	1.5
Beaked whales	15	803	1.9
Rough-toothed dolphin	103	4,853	2.1
Bottlenose dolphin	154	165,125	0.1
Clymene dolphin	190	4,619	4.1
Atlantic spotted dolphin	248	21,506	1.2
Pantropical spotted dolphin	751	67,225	1.1
Spinner dolphin	⁴ 0	5,548	n/a
Striped dolphin	112	5,634	2.0
Fraser’s dolphin	⁵ 65	1,665	3.9
Risso’s dolphin	28	1,974	1.4
Blackfish ⁶	296	6,113	4.8
Short-finned pilot whale	153	2,741	5.6

¹ Scalar ratios were not applied in this case due to brief survey duration.

² Best abundance estimate. For most taxa, the best abundance estimate for purposes of comparison with take estimates is considered here to be the model-predicted abundance (Garrison *et al.*, 2023). For Rice’s whale, Atlantic spotted dolphin, and Risso’s dolphin, the larger estimated SAR abundance estimate is used.

³ Includes 1 take by Level A harassment and 14 takes by Level B harassment. Small numbers determination made on basis of scaled Level B harassment take plus authorized Level A harassment take.

⁴ Modeled take of 1 rounded down to 0.

⁵ Modeled take of 41 increased to account for potential encounter with a group of average size (Maze-Foley and Mullin, 2006).

⁶ The “blackfish” guild includes melon-headed whales, false killer whales, pygmy killer whales, and killer whales.

Based on the analysis contained herein of LLOG’s proposed survey activity described in its LOA application and the anticipated take of marine mammals, NMFS finds that small numbers of marine mammals will be taken relative to the affected species or stock sizes (*i.e.*, less than one-third of the best available abundance estimate) and therefore the taking is of no more than small numbers.

Authorization

NMFS has determined that the level of taking for this LOA request is consistent with the findings made for the total taking allowable under the incidental take regulations and that the amount of take authorized under the

LOA is of no more than small numbers. Accordingly, we have issued an LOA to LLOG authorizing the take of marine mammals incidental to its geophysical survey activity, as described above.

Dated: September 17, 2024.

Kimberly Damon-Randall,

*Director, Office of Protected Resources,
National Marine Fisheries Service.*

[FR Doc. 2024–21612 Filed 9–20–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XE290]

Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The Pacific Fishery Management Council’s (Pacific Council) Ad Hoc Marine Planning Committee (MPC) will hold an online public meeting.

DATES: The online meeting will be held Wednesday, October 9, 2024, from 10 a.m. to 4 p.m., Pacific Daylight Time or until business for the day has been completed.

ADDRESSES: This meeting will be held online. Specific meeting information, including a proposed agenda and directions on how to attend the meeting and system requirements, will be provided in the meeting announcement on the Pacific Council's website (see www.pcouncil.org). You may send an email to Mr. Kris Kleinschmidt (kris.kleinschmidt@noaa.gov) or contact him at (503) 820-2412 for technical assistance.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220-1384.

FOR FURTHER INFORMATION CONTACT: Kerry Griffin, Staff Officer, Pacific Council; telephone: (503) 820-2409.

SUPPLEMENTARY INFORMATION: The purpose of this online meeting is for the MPC to consider current offshore wind (OSW) energy and aquaculture issues and to provide information and recommendations to the Pacific Council for consideration at its September 2024 meeting. Topics will include updates on Bureau of Ocean Energy Management activities, updates from coastal states and the National Marine Fisheries Service, a Tribal update, discussion of long-term OSW cumulative impacts, and other OSW or aquaculture topics, as appropriate.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt (kris.kleinschmidt@noaa.gov; (503) 820-2412) at least 10 days prior to the meeting date.

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

Dated: September 18, 2024.

Rey Israel Marquez,

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

[FR Doc. 2024-21693 Filed 9-20-24; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XE289]

Fisheries of the U.S. Caribbean; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

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

ACTION: Notice of SEDAR 91 Pre-Data Workshop Webinar for U.S Caribbean Spiny Lobster.

SUMMARY: The SEDAR 91 assessment process of U.S. Caribbean spiny lobster will consist of a Data Workshop, and a series of assessment webinars, and a Review Workshop. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR 91 Pre-Data Workshop webinar will be held October 10, 2024, from 2 p.m. to 4 p.m., eastern time.

ADDRESSES:

Meeting address: The meeting will be held via webinar. The webinar is open to members of the public. Those interested in participating should contact Julie A. Neer at SEDAR (see **FOR FURTHER INFORMATION CONTACT**) to request an invitation providing webinar access information. Please request webinar invitations at least 24 hours in advance of each webinar.

SEDAR address: 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Julie A. Neer, SEDAR Coordinator; phone: (843) 571-4366; email: Julie.neer@safmc.net

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a multi-step process including: (1) Data Workshop, (2) a series of assessment webinars, and (3) A Review Workshop. The product of the Data Workshop is a report that compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The assessment webinars produce a report that describes the fisheries, evaluates the status of the stock, estimates biological benchmarks,

projects future population conditions, and recommends research and monitoring needs. The product of the Review Workshop is an Assessment Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, HMS Management Division, and Southeast Fisheries Science Center. Participants include data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and NGO's; International experts; and staff of Councils, Commissions, and State and Federal agencies.

The items of discussion during the pre-Data Workshop webinar are as follows:

Participants will discuss what data may be available for use in the assessment.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office (see **ADDRESSES**) at least 5 business days prior to each workshop.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: September 18, 2024.

Rey Israel Marquez,

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

[FR Doc. 2024-21690 Filed 9-20-24; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration**

[RTID 0648-XE194]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Marine Site Characterization Surveys off New York and New Jersey in the New York Bight

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

ACTION: Notice; issuance of renewal incidental harassment authorization.

SUMMARY: In accordance with the regulations implementing the Marine Mammal Protection Act (MMPA), as amended, notification is hereby given that NMFS has issued a renewal incidental harassment authorization (IHA) to Attentive Energy, LLC (Attentive Energy), associated with marine site characterization surveys in coastal waters off of New York and New Jersey in the New York Bight, specifically within the Bureau of Ocean Energy Management (BOEM) Commercial Lease of Submerged Lands for Renewable Energy Development on the Outer Continental Shelf (Lease) Area OCS-A 0538 and associated export cable route (ECR) area.

DATES: This renewal IHA is effective from September 18, 2024 through June 19, 2025.

ADDRESSES: Electronic copies of the original application, renewal request, and supporting documents (including the **Federal Register** notices of the original proposed and final authorizations, and the previously issued and renewal IHA), 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-other-energy-activities-renewable>. In case of problems accessing these documents, please call the contact listed below.

FOR FURTHER INFORMATION CONTACT: Kelsey Potlock, Office of Protected Resources, NMFS, (301) 427-8401.

SUPPLEMENTARY INFORMATION:**Background**

The MMPA prohibits the “take” of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not

intentional, taking 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 either regulations are promulgated or, if the taking is limited to harassment, an incidental harassment authorization is issued.

Authorization for incidental takings shall be granted if NMFS 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 measures”). NMFS must also prescribe requirements pertaining to monitoring and reporting of such takings. The definition of key terms such as “take,” “harassment,” and “negligible impact” can be found in the MMPA and NMFS’s implementing regulations (see 16 U.S.C. 1362; 50 CFR 216.103).

NMFS’ regulations implementing the MMPA at 50 CFR 216.107(e) indicate that IHAs may be renewed for additional periods of time not to exceed 1 year for each reauthorization. In the notice of proposed IHA for the initial IHA, NMFS described the circumstances under which we would consider issuing a renewal for this activity, and requested public comment on a potential renewal under those circumstances. Specifically, on a case-by-case basis, NMFS may issue a one-time 1-year renewal IHA following notice to the public providing an additional 15 days for public comments when (1) up to another year of identical, or nearly identical, activities as described in the Detailed Description of Specified Activities section of the initial IHA issuance notice is planned, or (2) the activities as described in the Description of the Specified Activities and Anticipated Impacts section of the initial IHA issuance notice would not be completed by the time the initial IHA expires and a renewal would allow for completion of the activities beyond that described in the **DATES** section of the notice of issuance of the initial IHA, provided all of the following conditions are met:

1. A request for renewal is received no later than 60 days prior to the needed

renewal IHA effective date (recognizing that the renewal IHA expiration date cannot extend beyond 1 year from expiration of the initial IHA).

2. The request for renewal must include the following:

- An explanation that the activities to be conducted under the requested renewal IHA are identical to the activities analyzed under the initial IHA, are a subset of the activities, or include changes so minor (*e.g.*, reduction in pile size) that the changes do not affect the previous analyses, mitigation and monitoring requirements, or take estimates (with the exception of reducing the type or amount of take).

- A preliminary monitoring report showing the results of the required monitoring to date and an explanation showing that the monitoring results do not indicate impacts of a scale or nature not previously analyzed or authorized.

3. Upon review of the request for renewal, the status of the affected species or stocks, and any other pertinent information, NMFS determines that there are no more than minor changes in the activities, the mitigation and monitoring measures will remain the same and appropriate, and the findings in the initial IHA remain valid.

An additional public comment period of 15 days (for a total of 45 days), with direct notice by email, phone, or postal service to commenters on the initial IHA, is provided to allow for any additional comments on the proposed renewal. A description of the renewal process may be found on our website at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-harassment-authorization-renewals>.

History of Request

On June 20, 2023, NMFS issued an IHA to Attentive Energy, a company registered in the state of Delaware, to take marine mammals incidental to marine site characterization surveys in coastal waters off of New York and New Jersey in the New York Bight region, specifically within BOEM Lease Area OCS-A-0538 and associated ECR area (88 FR 41888, June 28, 2023), effective from June 20, 2023, through June 19, 2024. On May 24, 2024, NMFS received an application from Attentive Energy for the renewal of the 2023 IHA. As described in the application for renewal IHA, the activities for which incidental take was requested consisted of activities that were analyzed for the initial 2023 authorization, but were not able to be completed prior to its expiration. As required, Attentive

Energy also provided a final monitoring report (available at <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-other-energy-activities-renewable>) which confirms that Attentive Energy had implemented the required mitigation and monitoring, and also showed that no impacts of a scale or nature not previously analyzed or authorized have occurred as a result of the activities conducted. The notice of the proposed renewal incidental harassment authorization was published for public comment on August 7, 2024 (89 FR 64414). There are no changes from the proposed authorization to this final authorization.

Description of the Specified Activities and Anticipated Impacts

Under the initial IHA, Attentive Energy planned to conduct marine site characterization surveys, including high-resolution geophysical (HRG) surveys, in coastal waters off of New Jersey and New York in the New York Bight, specifically within BOEM Lease Area OCS-A 0538 and associated ECR areas. Challenges and delays with procurement, mobilization, and downtime contributed to less survey being completed during the initial IHA period than anticipated.

The surveys were designed to obtain data sufficient to meet BOEM guidelines for providing geophysical, geotechnical, and geo-hazard information for site assessment plan surveys and/or construction and operations plan development. The objective of the surveys was to support the site characterization, siting, and engineering design of offshore wind project facilities including wind turbine generators, offshore substations, and submarine cables within the Lease Area. At least two survey vessels would operate as part of the planned surveys with a maximum of two nearshore (<20 meters (m); <65.6 feet (ft)) vessels and a maximum of two offshore (≥20 m (≥65.6 ft)) vessels operating concurrently.

Attentive Energy plans to continue to conduct these survey activities, as per the initial IHA application, up to approximately 6,936 kilometers (km; 4,309.8 miles (mi)) of trackline. This is a subset of the survey trackline included in the initial IHA; the initial survey plan included 21,745 km (13,511.72 mi) across the entire project area (maximum-case scenario), which was split up by approximately 14,025 km (8,714.7 mi) in the Lease Area and 7,720 km (4,797 mi) in the ECR area. We note here that the Project Area is minimally expanded (primarily to the south) in the current survey plan as compared with

the survey plan associated with the initial IHA (see figure 1 in the proposed renewal **Federal Register** notice); however, this expansion of the survey area will not result in any increase to the amount of planned survey trackline distance. NMFS has determined that this slight change to the survey area constitutes a minor change that does not affect the previous analyses, mitigation and monitoring requirements, or take estimates.

The potential impacts of Attentive Energy's planned activities on marine mammals involve potential acoustic stressors and are unchanged from the impacts described in the **Federal Register** notice for the proposed 2023 IHA (88 FR 24553, April 21, 2023). Underwater sound, resulting from particular components of Attentive Energy's HRG survey activities, has the potential to result in incidental take of marine mammals, in the form of Level B harassment only, in the specified geographic region.

This renewal IHA is for the remainder of work that was not completed by the expiration date of the 2023 IHA. The renewal IHA authorizes incidental take, by Level B harassment only, of 15 species (comprising 16 stocks) of marine mammals for a subset of marine site characterization survey activities to be completed in less than 1 year (*i.e.*, by June 19, 2025), in the same general area, using survey methods identical to those conducted under the initial 2023 IHA. Neither Attentive Energy nor NMFS expects serious injury or mortality to result from this activity and, therefore, an IHA is appropriate. Take by Level A harassment (injury) is unlikely, even absent mitigation, based on the characteristics of the signals produced by the acoustic sources planned for use. Therefore, the anticipated effects on marine mammals and the affected stocks also remain the same. All mitigation, monitoring, and reporting measures would remain exactly as described in the **Federal Register** notice for the issued 2023 IHA (88 FR 41888, June 28, 2023).

Detailed Description of the Specified Activity

A detailed description of the marine site characterization survey activities for which incidental take is authorized here may be found in the **Federal Register** notice of the proposed 2023 IHA (88 FR 24553, April 21, 2023). The specific geographic region and specified activities, including the types of survey equipment and number of survey vessels planned for use, are identical to those described in the previous notices, with the exception of a minor increase

in the size of the survey area to the south to accommodate expanded survey options for the ECR.

Description of Marine Mammals

A description of the marine mammals in the area of the activities for which authorization of take is proposed here, including information on abundance, status, distribution, and hearing, may be found in the **Federal Register** notice of the proposed IHA for the initial authorization (88 FR 24553, April 21, 2023). Since the publication of the final **Federal Register** notice (88 FR 41888, June 28, 2023), NMFS has reviewed the monitoring data from the initial IHA, the draft 2023 stock assessment reports (SARs), which included updates to certain stock abundances since the initial IHA was issued, information on relevant unusual mortality events (UME), and other scientific literature. The draft 2023 SAR updated the population estimate (N_{best}) of North Atlantic right whales from 338 to 340 and annual mortality and serious injury from 31.2 to 27.2. The updated population estimate in the draft 2023 SAR is based upon sighting history through December 2021 (89 FR 5495, January 29, 2024). Total annual average observed North Atlantic right whale mortality during the 2017–2021 period was 7.1 animals and annual average observed fishery mortality was 4.6 animals, however, estimates of 27.2 total mortality and 17.6 fishery mortality account for undetected mortality and serious injury (89 FR 5495, January 29, 2024). In October 2023, NMFS released a technical report identifying that the North Atlantic right whale population size based on sighting history through 2022 was 356 whales, with a 95 percent credible interval ranging from 346 to 363 (Linden, 2023).

The draft 2023 SARs include updates for additional marine mammal species and stocks (*i.e.*, North Atlantic right whale, fin whale, sei whale, minke whale, sperm whale, Atlantic spotted dolphin, Atlantic white-sided dolphin, bottlenose dolphin (Western North Atlantic—Offshore stock), common dolphin, long-finned pilot whales, Risso's dolphin, harbor porpoise, and gray seal), which are specifically included in table 1 in the proposed renewal **Federal Register** notice (89 FR 64414, August 7, 2024). For species for which there has been no change between the finalization of the final 2022 SARs to the release of the draft 2023 SARs, NMFS has also noted this in table 1 of the proposed renewal **Federal Register** notice.

On August 1, 2022, NMFS announced proposed changes to the existing North

Atlantic right whale vessel speed regulations to further reduce the likelihood of mortalities and serious injuries to endangered North Atlantic right whales from vessel collisions, which are a leading cause of the species' decline and a primary factor in an ongoing Unusual Mortality Event (87 FR 46921, August 1, 2022). Should a final vessel speed rule be issued and become effective during the effective period of this proposed renewal IHA (or any other MMPA incidental take authorization), the authorization holder would be required to comply with any and all applicable requirements contained within the final rule. Specifically, where measures in any final vessel speed rule are more protective or restrictive than those in this or any other MMPA authorization, authorization holders would be required to comply with the requirements of the rule. Alternatively, where measures in this or any other MMPA authorization are more restrictive or protective than those in any final vessel speed rule, the measures in the MMPA authorization would remain in place. These changes would become effective immediately

upon the effective date of any final vessel speed rule and would not require any further action on NMFS's part.

NMFS has determined that no new information has been presented that may affect or change any other information in the Description of the Marine Mammals in the Area of Specified Activities contained in the supporting documents and in the **Federal Register** notice for the proposed renewal IHA (89 FR 64414, August 7, 2024).

Potential Effects on Marine Mammals and Their Habitat

A description of the potential effects of the specified activity on marine mammals and their habitat for the activities for which take is authorized here may be found in the **Federal Register** notice of the proposed IHA for the initial authorization (88 FR 24553, April 21, 2023). NMFS has reviewed the monitoring data from the initial IHA, recent Stock Assessment Reports, information on relevant Unusual Mortality Events, other scientific literature, and the public comments, and determined that there is no new

information that affects our initial analysis of impacts on marine mammals and their habitat.

Estimated Take

A detailed description of the methods and inputs used to estimate take for the specified activity are found in the **Federal Register** notices of the proposed and final IHAs for the initial authorization (88 FR 24553, April 21, 2023; 88 FR 41888, June 28, 2023) and referenced in the **Federal Register** notice for the proposed renewal IHA (89 FR 64414, August 7, 2024). Specifically, the source levels, days of operation, and marine mammal density/occurrence data applicable to this authorization remain unchanged from the previously issued IHA. Similarly, the stocks taken, methods of take, and types of take remain unchanged from the previously issued IHA. The number of takes authorized in this renewal IHA are a subset of the initial authorized takes that better represent the amount of activity that Attentive Energy has left to complete. These estimated takes, which reflect the remaining survey days, are indicated below in table 1.

TABLE 1—NUMBER OF TAKES BY LEVEL B HARASSMENT BY SPECIES AND STOCK AND PERCENT OF TAKE BY STOCK

Common name	Population abundance	Percentage of trackline remaining in relevant habitat	Authorized takes based on remaining trackline	Percent of population
North Atlantic right whale	340	32	4	1.18
Fin whale	6,802	32	12	0.18
Humpback whale	1,396	32	8	0.57
Minke whale	21,968	32	57	0.26
Sei whale	6,292	32	4	0.06
Sperm whale	5,895	32	1	0.02
Atlantic spotted dolphin	31,506	32	28	0.09
Atlantic white-sided dolphin	93,233	32	66	0.07
Bottlenose dolphin—Western North Atlantic Offshore	64,587	28	489	0.76
Bottlenose dolphin—Northern Migratory Coastal	6,639	93	362	5.45
Common dolphin	93,100	32	658	0.71
Long-finned pilot whale	39,215	32	7	0.02
Risso's dolphin	44,067	32	7	0.02
Harbor porpoise	85,765	32	350	0.41
Gray seal	27,911	32	511	1.83
Harbor seal	61,336	32	511	0.83

Description of Mitigation, Monitoring and Reporting Measures

The required mitigation, monitoring, and reporting measures included as requirements in this authorization are identical to those included in the **Federal Register** notice announcing the issuance of the initial IHA (88 FR 41888, June 28, 2023), the **Federal Register** notice for the proposed renewal IHA (89 FR 64414, August 7, 2024), and the discussion of the least practicable adverse impact included in that

document and the **Federal Register** notice of the proposed IHA (88 FR 24553, April 21, 2023) remains accurate. The following measures are required for this renewal IHA:

- **Ramp-up:** A ramp-up procedure would be used for geophysical survey equipment capable of adjusting energy levels (*i.e.*, any acoustic source with a non-binary switch) at the start or re-start of survey activities;
- **Protected Species Observers (PSOs):** A minimum of one NMFS-approved PSO must be on duty and conducting

visual observations at all times during daylight hours (*i.e.*, from 30 minutes prior to sunrise through 30 minutes following sunset). Two PSOs would be on duty during nighttime operations;

- **Pre-Operation Clearance Protocols:** Prior to initiating HRG survey activities, Attentive Energy would be required to implement a 30-minute pre-operation clearance period. If any marine mammals are detected within the Exclusion Zones prior to or during ramp-up, the HRG equipment would be shut down (as described below);

- **Shutdown Zones:** If an HRG source is active and a marine mammal is observed within or entering a relevant shutdown zone, an immediate shutdown of the HRG survey equipment would be required. We note that this shutdown requirement would be waived for certain genera of small delphinids (*i.e.*, *Delphinus*, *Lagenorhynchus*, *Stenella*, or *Tursiops*) and pinnipeds;

- **Vessel Strike Avoidance Measures:** 500 m (1,640 ft) separation distances for North Atlantic right whales and other large Endangered Species Act (ESA) listed whales (*i.e.*, fin whale, sei whale, and sperm whale), 100 m (328 ft) for other non-ESA listed baleen whales (*i.e.*, minke whale and humpback whale), and 50 m (164 ft) for all other marine mammals); as well as restricted vessel speeds and operational maneuvers; and

- **Reporting:** Attentive Energy would submit a marine mammal report within 90 days following their completion of the surveys.

Comments and Responses

A notice of NMFS' proposal to issue a renewal IHA to Attentive Energy was published in the **Federal Register** on August 7, 2024 (89 FR 64414). That notice either described, or referenced descriptions of, Attentive Energy's activity, the marine mammal species that may be affected by the activity, the anticipated effects on marine mammals and their habitat, estimated amount and manner of take, and proposed mitigation, monitoring and reporting measures.

During the 15-day public comment period, NMFS received one comment from a member of the public and one comment letter from a non-governmental organization, Clean Ocean Action (COA). NMFS has reviewed all public comments received on the Attentive Energy renewal HRG IHA. All relevant, substantive comments, and NMFS' responses, are provided below. Comments indicating general opposition to offshore wind construction are not relevant to the proposed action and therefore were not considered and are not addressed here. The comments and recommendations are available online at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-other-energy-activities-renewable>. Please see the comment submissions for full details regarding the recommendations and supporting rationale.

Comment 1: COA expressed concern with the slight modification to the survey area described in Attentive Energy's renewal request (89 FR 64414, August 7, 2024). COA asserts that NMFS has provided insufficient support for its

determination that this is a minor change to the initial action that would not affect any previous analysis, mitigation and monitoring requirements, and take estimates. COA states that NMFS should provide additional support for its conclusion and that it does not believe that the survey area is "nearly identical." COA claims that the expanded survey area now includes additional haulout sites for seals along Barnegat Light on Long Beach Island (Normandeau Associates, Inc., 2019) and a migratory corridor for several marine mammals (*i.e.*, humpback whale, fin whale, and North Atlantic right whales) not previously included. COA also stated that NMFS did not adjust the number of takes proposed for authorization based on this additional information and, therefore, should not issue the renewal IHA to Attentive Energy.

Response: Regarding the take estimates, NMFS disagrees with COA's suggestion that the minor change to the planned survey area presents new information requiring additional analysis. We note that the total amount of trackline planned to be surveyed under this renewal IHA has not increased, when compared to what remains from the initial IHA even given the minor shift in the planned survey area. Changes to the density values over the entirety of the survey area are, overall, inconsequential and do not result in meaningful changes to the take numbers which, in context of the subset of activity that remains, are less than those estimated and authorized through the initial IHA.

NMFS agrees with COA that the expanded area, inclusive of the initial project area as well, includes habitat for marine mammals, including pinniped haulouts and migratory habitat for certain cetacean species. The survey area described for the initial IHA included the same migratory habitat for the same cetacean species, as well as coastal habitat where pinnipeds may choose to haul out. Contrary to COA's assertion that the minor expansion of the survey area to cover a new potential ECR would affect new habitat areas not previously considered, cetacean migratory habitat is typically broad and there are not differences in the type, location, or use of such habitat over the relatively fine scales considered here. Regarding pinniped haulout habitat, such locations are typically opportunistic and, given their shore-based locations, unlikely to be affected at all by the planned survey activity. Furthermore, while they may now fall within the slightly expanded project area, there is no new information about

the haulout sites along Barnegat Light on Long Beach Island to suggest that they are dissimilar from those off the Long Island area, as compared with those previously analyzed for pinnipeds under the initial **Federal Register** notice. Therefore, there is nothing new to consider in relation to the analysis described herein. NMFS adequately considered all available information regarding potential impacts to all marine mammal habitat in its analysis supporting the issuance of the initial IHA, and the minor change considered as part of this renewal IHA presents no new information regarding potential impacts to marine mammal habitat.

Comment 2: COA asserted that NMFS should reject Attentive Energy's application until the cumulative impacts of every incidental take authorization on marine mammals are considered. COA also stated that NMFS must fully consider the discrete effects of each activity and the cumulative effects of the suite of approved, proposed, and potential offshore wind activities on marine mammals and ensure that the cumulative effects are not excessive before issuing or renewing an IHA.

Response: NMFS is required to authorize the requested incidental take if it finds the incidental take by harassment of small numbers of marine mammals by U.S. citizens "while engaging in that [specified] activity" within a specified geographic region will have a negligible impact on such species or stock and where appropriate, will not have an unmitigable adverse impact on the availability of such species or stock for subsistence uses (see 16 U.S.C. 1371(a)(5)(D)). Negligible impact is defined 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). Neither the MMPA, nor NMFS' implementing regulations, require consideration of other unrelated activities and their impacts on marine mammal populations in the negligible impact determination. Additionally, NMFS' implementing regulations 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 (50 CFR 216.104(a)(1)). 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. Consistent with the preamble of NMFS' implementing regulations (54 FR 40338,

September 29, 1989), the impacts from other past and ongoing anthropogenic activities are factored into the baseline, which is used in the negligible impact analysis. Here, 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 preamble of NMFS' implementing regulations (54 FR 40338, September 29, 1989) also addresses cumulative effects from future, unrelated activities. Such effects are not considered in making the negligible impact determination under MMPA section 101(a)(5). NMFS considers (1) cumulative effects that are reasonably foreseeable when preparing a National Environmental Policy Act (NEPA) analysis, and (2) reasonably foreseeable cumulative effects under section 7 of the ESA for listed species, as appropriate. Accordingly, NMFS has written Environmental Assessments (EA) that addressed cumulative impacts related to substantially similar activities in similar locations (e.g., the 2019 Avangrid EA for survey activities offshore North Carolina and Virginia; the 2017 Ocean Wind, LLC EA for site characterization surveys off New Jersey; and the 2018 Deepwater Wind EA for survey activities offshore Delaware, Massachusetts, and Rhode Island). Cumulative impacts regarding issuance of IHAs for site characterization survey activities such as those planned by Attentive Energy have been adequately addressed under NEPA in prior environmental analyses that support NMFS' determination that this action is appropriately categorically excluded from further NEPA analysis. NMFS independently evaluated the use of a categorical exclusion (CE) for issuance of Attentive Energy's IHA, which included consideration of extraordinary circumstances.

Separately, the cumulative effects of substantially similar activities in the northwest Atlantic Ocean have been analyzed in the past under section 7 of the ESA when NMFS has engaged in formal intra-agency consultation, such as the 2013 programmatic Biological Opinion for BOEM Lease and Site Assessment Activities on the Atlantic Outer Continental Shelf in Rhode Island, Massachusetts, New York, and New Jersey Wind Energy Areas (<https://repository.library.noaa.gov/view/noaa/29291>). Analyzed activities include those for which NMFS issued previous IHAs (82 FR 31562, July 7, 2017; 83 FR 28808, June 21, 2018; 83 FR 36539, July

30, 2018; and 86 FR 26465, May 10, 2021), which are similar to those planned by Attentive Energy under this current IHA request. This Biological Opinion determined that NMFS' issuance of IHAs for site characterization survey activities associated with leasing, individually and cumulatively, are not likely to adversely affect listed marine mammals. NMFS notes that, while issuance of this IHA is covered under a different consultation, this Biological Opinion remains valid. Additionally, to date, Biological Opinions have been developed and competed for several ongoing offshore wind construction projects, which all include HRG surveys within the scope of the proposed actions (see the final Biological Opinions for Ocean Wind 1 (<https://repository.library.noaa.gov/view/noaa/49689>), Revolution Wind's original (<https://repository.library.noaa.gov/view/noaa/51759>) and reinitiated (<https://www.fisheries.noaa.gov/s3/2024-05/2024-Rev-Wind-BiOp-508.pdf>), CVOW-C (<https://repository.library.noaa.gov/view/noaa/55495>), Empire Wind (<https://repository.library.noaa.gov/view/noaa/55324>), Sunrise Wind (<https://repository.library.noaa.gov/view/noaa/55726>), New England Wind (<https://repository.library.noaa.gov/view/noaa/60610>), and Maryland Wind (<https://repository.library.noaa.gov/view/noaa/61632>)). These Biological Opinions for larger-scale construction and development projects have all assessed the cumulative activities occurring within the relevant project areas, which include HRG activities occurring under IHAs, as well as HRG surveys and other construction activities occurring under Incidental Take Regulations and associated issued Letters of Authorization. In all cases, the HRG surveys analyzed within these Biological Opinions are of substantially similar activities, using the same or similar acoustic sources as those planned for use by Attentive Energy under this renewal IHA. Based on this information, NMFS believes the discrete and cumulative effects have been adequately analyzed and considered under these existing documents.

Comment 3: COA states its opposition to the use of a categorical exclusion under NEPA for this renewal action.

Response: NMFS does not agree with COA's comment. A CE is a category of actions that an agency has determined does not individually or cumulatively have a significant effect on the quality of the human environment, and is appropriately applied for such categories of actions so long as there are

no extraordinary circumstances present that would indicate that the effects of the action may be significant. Extraordinary circumstances are situations for which NOAA has determined further NEPA analysis is required because they are circumstances in which a normally excluded action may have significant effects. A determination of whether an action that is normally excluded requires additional evaluation because of extraordinary circumstances focuses on the action's potential effects and considers the significance of those effects in terms of both context (consideration of the affected region, interests, and resources) and intensity (severity of impacts). Potential extraordinary circumstances relevant to this action include (1) adverse effects on species or habitats protected by the MMPA that are not negligible; (2) highly controversial environmental effects; (3) environmental effects that are uncertain, unique, or unknown; and (4) the potential for significant cumulative impacts when the proposed action is combined with other past, present, and reasonably foreseeable future actions.

The relevant NOAA CE associated with issuance of incidental take authorizations is CE B4, "Issuance of incidental harassment authorizations under section 101(a)(5)(A) and (D) of the MMPA for the incidental, but not intentional, take by harassment of marine mammals during specified activities and for which no serious injury or mortality is anticipated." This action falls within CE B4. In determining whether a CE is appropriate for a given incidental take authorization, NMFS considers the applicant's specified activity and the potential extent and magnitude of takes of marine mammals associated with that activity along with the extraordinary circumstances listed in the Companion Manual for NOAA Administrative Order (NAO) 216-6A and summarized above. The evaluation of whether extraordinary circumstances (if present) have the potential for significant environmental effects is limited to the decision NMFS is responsible for, which is issuance of the incidental take authorization. While there may be environmental effects associated with the underlying action, potential effects of NMFS' action are limited to those that would occur due to the authorization of incidental take of marine mammals. NMFS prepared numerous EAs analyzing the environmental impacts of the categories of activities encompassed by CE B4 which resulted in Findings of No Significant Impacts and, in particular,

numerous EAs prepared in support of issuance of IHAs related to similar survey actions are part of NMFS' administrative record supporting CE B4. These EAs demonstrate that the issuance of a given incidental harassment authorization does not affect other aspects of the human environment because the action only affects the marine mammals that are the subject of the IHAs. These EAs also addressed factors in 40 CFR 1508.27 regarding the potential for significant impacts and demonstrate the issuance of IHAs for the categories of activities encompassed by CE B4 do not individually or cumulatively have a significant effect on the human environment.

Specifically for this action, NMFS independently evaluated the use of the CE for issuance of Attentive Energy's IHA, which included consideration of extraordinary circumstances. As part of that analysis, NMFS considered whether this IHA issuance would result in cumulative impacts that could be significant. In particular, the issuance of an IHA to Attentive Energy is expected to result in minor, short-term behavioral effects on marine mammal species due to exposure to underwater sound from site characterization survey activities. Behavioral disturbance is possible to occur intermittently in the vicinity of Attentive Energy's survey area during the 1-year timeframe. Level B harassment will be reduced through use of mitigation measures described herein. Additionally, as discussed elsewhere, NMFS has determined that Attentive Energy's activities fall within the scope of activities analyzed in the Greater Atlantic Regional Fisheries Office's (GARFO) programmatic consultation regarding geophysical surveys along the U.S. Atlantic coast in the three Atlantic Renewable Energy Regions (completed June 29, 2021; revised September 2021), which concluded surveys such as those planned by Attentive Energy are not likely to adversely affect endangered listed species or adversely modify or destroy critical habitat. Accordingly, NMFS has determined that the issuance of this IHA will result in no more than negligible (as that term is defined by the Companion Manual for NAO 216-6A) adverse effects on species protected by the ESA and the MMPA.

Further, the issuance of this IHA will not result in highly controversial environmental effects or result in environmental effects that are uncertain, unique, or unknown because numerous entities have been engaged in site characterization surveys that result in Level B harassment of marine mammals in the United States. This type of activity is well documented; prior

authorizations and analysis demonstrates issuance of an IHA for this type of action only affects the marine mammals that are the subject of the specific authorization and, thus, no potential for significant cumulative impacts are expected, regardless of past, present, or reasonably foreseeable actions, even though the impacts of the action may not be significant by itself. Based on this evaluation, we concluded that the issuance of the IHA qualifies to be categorically excluded from further NEPA review.

Comment 4: COA suggested that a Letter of Authorization (LOA) would be more appropriate than an IHA for the proposed survey activities as the survey activities have spanned more than 1 year and "it is not clear how long the proposed activities would span given past delays."

Response: NMFS disagrees with the commenter that an LOA would be more appropriate for the planned survey activities than an IHA. All IHAs issued, whether an initial IHA or a renewal, are valid for a period of not more than 1 year. Attentive Energy's request for the initial IHA indicated a project duration of 1 year. As delays may be encountered, applicants may apply for a renewal IHA if the work under the initial IHA is not able to be completed within the effective period of the authorization. In order to qualify for a renewal IHA, the proposed renewal must consist of up to another year of identical, or nearly identical, activities as were covered by the initial IHA or a subset of the activities covered by the initial IHA. Attentive Energy's request falls under the latter requirements and the necessary preliminary monitoring data collected under the initial IHA were provided. Therefore, Attentive Energy's request is appropriate for a renewal IHA.

Regarding clarification on authorizations, as described on our website, IHAs are 1-year authorizations and Incidental Take Regulations (ITR) are 5-year regulations that allow for the issuance of LOA. An ITR must be used if authorization of take by mortality is necessary (although not all ITRs include mortality). However, both options are available for applicants requesting authorization of harassment only. While applicants may request a 5-year regulation for HRG survey activities, NMFS has not received any such requests to date and there is no expectation presented in the MMPA or Congressional record that activities continuing for more than 1 year must seek ITR and authorization under section 101(a)(5)(A) of the MMPA. Therefore, a determination of which

option to take is not dependent on any expectation regarding whether the activity will continue for more than 1 year or not.

Comment 5: COA urged NMFS to deny the proposed project and/or postpone any offshore wind activities until NMFS determines effects of all offshore wind-related activities on marine mammals in the region and determines that the recent whale deaths are not related to offshore wind activities. COA stated general concerns regarding recent whale stranding events on the Atlantic Coast, including speculation that the strandings may be related to wind energy development activities.

Response: NMFS authorizes take of marine mammals incidental to marine site characterization surveys but does not authorize the surveys themselves. NMFS has the authority to modify, suspend, or revoke an IHA if the IHA holder fails to abide by the conditions prescribed therein (including, but not limited to, failure to comply with monitoring or reporting requirements), or if NMFS determines that (1) the authorized taking is having or is likely to have more than a negligible impact on the species or stocks of affected marine mammals, or (2) the prescribed measures are likely not or are not effecting the least practicable adverse impact on the affected species or stocks and their habitat. NMFS has analyzed the planned activity, as proposed by Attentive Energy, within the discrete context for which it was requested (*i.e.*, as a stand-alone activity and not part of a larger programmatic survey effort or group of specific activities). It is in this context that NMFS has authority to authorize incidental take and to prescribe mitigation, monitoring, and reporting requirements, as appropriate, and can revoke or suspend any IHA issued under the MMPA if and when action is warranted.

In this comment letter, COA speaks more broadly about all offshore wind efforts along the U.S. East Coast, not just specific to this discrete IHA. It is not within NMFS' jurisdiction to impose a moratorium on all offshore wind development activities unrelated to this specific IHA request and planned activities. NMFS reiterates that there is no evidence that noise resulting from offshore wind development-related site characterization surveys could potentially cause marine mammal stranding, and there is no evidence linking recent large whale mortalities and currently ongoing surveys. The commenters offer no such evidence to the contrary. NMFS will continue to gather data to help us determine the

cause of death for these stranded whales. We note the Marine Mammal Commission's recent statement: "There continues to be no evidence to link these large whale strandings to offshore wind energy development, including no evidence to link them to sound emitted during wind development-related site characterization surveys, known as HRG surveys. Although HRG surveys have been occurring off New England and the mid-Atlantic coast, HRG devices have never been implicated or causatively-associated with baleen whale strandings" (Marine Mammal Commission Newsletter, Spring 2023). Furthermore, NMFS does not expect that the marine site characterization survey activities planned by Attentive Energy will create conditions of acute or chronic acoustic exposure leading to long-term physiological impacts in whales.

There is an ongoing Unusual Mortality Event for humpback whales along the Atlantic coast from Maine to Florida, which includes animals stranded since 2016. Partial or full necropsy examinations were conducted on approximately half of the whales. Necropsies were not conducted on other carcasses because they were too decomposed, not brought to land, or stranded on protected lands (e.g., national and state parks) with limited or no access. Of the whales examined (roughly 90), about 40 percent had evidence of human interaction, either vessel strike or entanglement. Vessel strikes and entanglement in fishing gear are the greatest human threats to large whales. The approximately 50 remaining necropsied whales either had an undetermined cause of death (due to a limited examination or decomposition of the carcass), or had other causes of death including parasite-caused organ damage and starvation. As discussed herein, HRG sources may behaviorally disturb marine mammals (e.g., avoidance of the immediate area). But these HRG surveys are very different from seismic airguns used in oil and gas surveys or tactical military sonar. They produce much smaller impact zones because, in general, they have lower source levels and produce output at higher frequencies. The area within which HRG sources might behaviorally disturb a marine mammal is orders of magnitude smaller than the impact areas for seismic airguns or military sonar. Any marine mammal exposure would be at significantly lower levels and shorter duration, which is associated with less severe impacts to marine mammals. For these reasons, NMFS observes a lack of evidentiary support

for a link between wind energy development activities and whale stranding.

Changes From Proposed to Final Renewal IHA

No changes were made from the proposed renewal IHA to the final renewal IHA.

Determinations

Attentive Energy's planned activities consist of a subset of activities analyzed in the initial IHA. In analyzing the effects of the activities for the initial IHA, NMFS determined that Attentive Energy's activities would have a negligible impact on the affected species or stocks and that authorized take numbers of each species or stock were small relative to the relevant stocks (e.g., less than one-third the abundance of all stocks). The required mitigation measures and monitoring and reporting requirements, as described above, are identical to the initial IHA.

NMFS has concluded that there is no new information suggesting that our analysis or findings should change from those reached for the initial IHA. This includes consideration of the draft 2023 SAR estimated abundance of the North Atlantic right whale stock and other stocks, as shown in table 1 of the **Federal Register** notice for the proposed renewal IHA (89 FR 64414, August 7, 2024). NMFS has authorized four takes of North Atlantic right whales, by Level B harassment only, and the impacts resulting from the project's activities are neither reasonably expected nor reasonably likely to adversely affect the stock through effects on annual rates of recruitment or survival. Additionally, only about 1.2 percent of this stock's abundance is authorized to be taken by Level B harassment.

Based on the information and analysis contained here and in the referenced documents, NMFS has determined the following: (1) the required mitigation measures will effect the least practicable adverse impact on marine mammal species or stocks and their habitat; (2) the authorized takes would have a negligible impact on the affected marine mammal species or stocks; (3) the authorized takes represent small numbers of marine mammals relative to the affected stock abundances; (4) Attentive Energy's activities will not have an unmitigable adverse impact on taking for subsistence purposes as no relevant subsistence uses of marine mammals are implicated by this action; and (5) appropriate monitoring and reporting requirements are included. This includes consideration of the estimated abundance of 13 stock(s)

decreasing or increasing slightly, specific to each stock.

National Environmental Policy Act

This action is consistent with categories of activities identified in Categorical Exclusion B4 (incidental take authorizations with no anticipated serious injury or mortality) of the Companion Manual for NOAA Administrative Order 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 determined that the issuance of the initial IHA qualified to be categorically excluded from further NEPA review. NMFS has determined that the application of this categorical exclusion remains appropriate for this renewal IHA.

Endangered Species Act

Section 7(a)(2) of the ESA of 1973 (16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure 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 Office of Protected Resources consults internally whenever we propose to authorize take of endangered or threatened species.

NMFS has authorized the incidental take of four species of marine mammals which are listed under the ESA, including the North Atlantic right, fin, sei, and sperm whale, and has determined that this activity falls within the scope of activities analyzed in NMFS GARFO's programmatic consultation regarding geophysical surveys along the U.S. Atlantic coast in the three Atlantic Renewable Energy Regions (completed June 29, 2021; revised September 2021).

Renewal

NMFS has issued a renewal IHA to Attentive Energy for the take of 15 species (comprising 16 stocks) of marine mammals incidental to conducting marine site characterization surveys offshore from New York to New Jersey in the BOEM Lease Area OCS-A-0538 and associated ECR areas, which include the previously explained mitigation, monitoring, and reporting requirements.

Dated: September 18, 2024.

Kimberly Damon-Randall,

*Director, Office of Protected Resources,
National Marine Fisheries Service.*

[FR Doc. 2024-21670 Filed 9-20-24; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XE305]

South Atlantic Fishery Management Council; Public Meetings

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

ACTION: Notice of a public meeting.

SUMMARY: The South Atlantic Fishery Management Council's (Council) will hold a meeting of the Outreach and Communications Advisory Panel (AP) October 9–10, 2024. The meeting will be held in North Charleston, SC.

DATES: The Outreach and Communications AP meeting will be held October 9, 2024, from 9 a.m. until 5 p.m. and October 10, 2024, from 9 a.m. until 12 p.m.

ADDRESSES:

Meeting address: The meeting will be held at the Embassy Suites by Hilton Charleston Airport, 5055 International Blvd., North Charleston, SC 29418; phone: (843) 747-1882. The meeting is open to the public and will also be available via webinar.

Webinar registration, an online public comment form, and briefing book materials will be available two weeks prior to the meeting at: <https://safmc.net/advisory-panel-meetings/>.

Council address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, SAFMC; phone: (843) 571-4366 or toll free: (866) SAFMC-10; fax: (843) 769-4520; email: kim.iverson@safmc.net.

SUPPLEMENTARY INFORMATION: Agenda items for the Outreach and Communications AP meeting include: updates from AP members on recent outreach and communication efforts and needs; update on the Council's Best Fishing Practices Program and the Citizen Science Program and projects; a review of the Council's draft Habitat Blueprint relative to outreach and communication needs; and an update on the Council's digital communications

efforts and needs. AP members will also receive an update on port meetings conducted for the mackerel fishery in 2024 and plans to conduct stakeholder meetings in 2025. The AP will review draft outreach documents being developed for the upcoming 50th anniversary of the regional fishery management councils and the Magnuson-Stevens Fishery Conservation and Management Act. The AP will address other business as needed and provide recommendations for Council consideration.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the Council office (see **ADDRESSES**) 5 days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: September 18, 2024.

Rey Israel Marquez,

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

[FR Doc. 2024-21691 Filed 9-20-24; 8:45 am]

BILLING CODE 3510-22-P

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Determination Under the Textile and Apparel Commercial Availability Provision of the Dominican Republic-Central America-United States Free Trade Agreement ("CAFTA-DR")

AGENCY: The Committee for the Implementation of Textile Agreements.

ACTION: Determination to add a product in unrestricted quantities to Annex 3.25 of the CAFTA-DR.

SUMMARY: The Committee for the Implementation of Textile Agreements ("CITA") has determined that certain two-way stretch woven polyester, rayon, spandex fabric, as specified below, is not available in commercial quantities in a timely manner in the CAFTA-DR countries. The product is added to the list in Annex 3.25 of the CAFTA-DR in unrestricted quantities.

DATES: *Applicable Date:* September 23, 2024.

ADDRESSES: <https://otexaproducts.trade.gov/otexacpublicsite/requests/cafta> under "Approved Requests," File Number: CA2024004.

FOR FURTHER INFORMATION CONTACT:

Kayla Johnson, Office of Textiles and Apparel, U.S. Department of Commerce,

(202) 482-2532 or Kayla.Johnson@trade.gov.

SUPPLEMENTARY INFORMATION:

Authority: The CAFTA-DR; Section 203(o)(4) of the Dominican Republic-Central America-United States Free Trade Agreement Implementation Act ("CAFTA-DR Implementation Act"), Public Law 109-53; the Statement of Administrative Action accompanying the CAFTA-DR Implementation Act; and Presidential Proclamation 7987 (February 28, 2006).

Background: The CAFTA-DR provides a list in Annex 3.25 for fabrics, yarns, and fibers that the Parties to the CAFTA-DR have determined are not available in commercial quantities in a timely manner in the territory of any Party. The CAFTA-DR provides that this list may be modified pursuant to Article 3.25.4, when the United States determines that a fabric, yarn, or fiber is not available in commercial quantities in a timely manner in the territory of any Party. See Annex 3.25 of the CAFTA-DR; see also section 203(o)(4)(C) of the CAFTA-DR Implementation Act.

The CAFTA-DR Implementation Act requires the President to establish procedures governing the submission of a request and providing opportunity for interested entities to submit comments and supporting evidence before a commercial availability determination is made. In Presidential Proclamation 7987, the President delegated to CITA the authority under section 203(o)(4) of CAFTA-DR Implementation Act for modifying the Annex 3.25 list. Pursuant to this authority, on September 15, 2008, CITA published modified procedures it would follow in considering requests to modify the Annex 3.25 list of products determined to be not commercially available in the territory of any Party to the CAFTA-DR (*Modifications to Procedures for Considering Requests Under the Commercial Availability Provision of the Dominican Republic-Central America-United States Free Trade Agreement*, 73 FR 53200) ("CITA's Procedures").

On August 12, 2024, CITA received a Commercial Availability Request ("Request") from CFI Textiles ("CFI") for certain two-way stretch woven polyester, rayon, spandex fabric, as specified below. On August 14, 2024, in accordance with CITA's Procedures, CITA notified interested parties of the Request, which was posted on the dedicated website for CAFTA-DR Commercial Availability proceedings. In its notification, CITA advised that any Response with an Offer to Supply

(“Response”) must be submitted by August 26, 2024, and any Rebuttal to a Response (“Rebuttal”) must be submitted by August 30, 2024, in accordance with sections 6 and 7 of CITA’s Procedures. No interested entity submitted a Response to the Request advising CITA of its objection to the Request with an offer to supply the subject product in accordance with CITA’s Procedures.

In accordance with section 203(o)(4)(C) of the CAFTA–DR Implementation Act, and section 8(c)(2) of CITA’s Procedures, as no interested entity submitted a Response objecting to the Request and providing an offer to supply the subject product in accordance with CITA’s Procedures, CITA has determined to add the specified fabric to the list in Annex 3.25 of the CAFTA–DR.

The subject product has been added to the list in Annex 3.25 of the CAFTA–DR Agreement in unrestricted quantities. A revised list has been posted on the dedicated website for CAFTA–DR Commercial Availability proceedings, at <https://otexaprod.trade.gov/otexacapublicsite/shortsupply/cafta>.

Specifications: Certain Two-Way Stretch Woven Polyester, Rayon, Spandex Fabric

HTS: 5515.11.00.

Fiber Content: 50 to 77 percent polyester; 18 to 47 percent rayon; 3 to 8 percent spandex (for fabrics comprising single yarns in the warp, the polyester content may be higher).

Staple Length (where applicable): 4.44 to 6.99 centimeters (1.75 to 2.75 inches).

Note: The staple length designation 1.75”–2.75” inches describes a range of long staple fiber in its raw griegre condition before spinning, weaving, dyeing and finishing of the fabric. It is intended as a specification to be followed by the mill in sourcing long staple fiber used to produce the yarn and fabric. Spinning, weaving, dyeing and finishing alter the characteristic of the staple fiber as it appears in the finished fabric. This specification therefore includes staple appearing in the finished fabric as shorter than 1.75” inches provided that the shorter appearance occurs solely as the result of such processes.

Yarn (Three Configurations)

#1: Warp and filling: plied polyester/rayon staple of various yarn sizes, combined with spandex filament of various deniers.

#2: Warp and filling 34/1 (English 20/1) or finer polyester/rayon staple, combined with spandex filament of various deniers.

#3: Warp: 34/1 (English 20/1) or finer polyester/rayon staple, or plied

polyester/rayon staple of various yarn sizes, combined with spandex filament of various deniers;

Filling: singles or plied polyester filament of various yarn sizes, combined with spandex filament of various deniers.

Note: The designation “34/1 (English 20/1) or finer” describes a range of yarn specifications for yarn at its greige condition before dyeing and finishing of the yarn (if applicable) and before weaving, dyeing and finishing of the fabric. It is intended as a specification to be followed by the mill in sourcing yarn used to produce the fabric. Dyeing, finishing and weaving can alter the characteristic of the yarn as it appears in the finished fabric. This specification therefore includes yarns appearing in the finished fabric as coarser than 34/1 (English 20/1) provided that the coarser appearance occurs solely as the result of such processes.

Thread Count: 23 to 51 warp ends by 16 to 39 filling picks per centimeter (60 to 130 warp ends by 40 to 100 filling picks per inch).

Weave Type: Various (including plain and twill).

Weight:

Fabrics comprising single yarns in the warp—200 to 290 grams per square meter (5.9 to 8.6 ounces per square yard).

Fabrics comprising plied yarns in the warp—200 to 310 grams per square meter (5.9 to 9.1 ounces per square yard).

Width: 121 to 165 centimeters (English 48 to 65 inches).

Finish: Dyed and of yarns of different colors.

Megan Crowe,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 2024–21679 Filed 9–20–24; 8:45 am]

BILLING CODE 3510–DR–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Request for Information on Direct and Indirect Labor

AGENCY: Committee for Purchase from People Who Are Blind or Severely Disabled.

ACTION: Request for information.

SUMMARY: The Committee for Purchase From People Who Are Blind or Severely Disabled (operating as the U.S. AbilityOne Commission (Commission)) is seeking information on proposed definitions of direct labor and categories of indirect labor; and ideas about categorizing employment tasks as direct labor or indirect labor on Federal

contracts for the purposes of compliance with the Javits-Wagner-O’Day (JWOD) Act (41 U.S.C. Chapter 85). The information provided in response to this request for information (RFI) will inform the Commission as it seeks to modernize the AbilityOne Program.

DATES: Comments must be received by October 22, 2024.

ADDRESSES: Electronic Submission of Comments. Please submit any comments electronically through <https://www.regulations.gov> and follow the instructions for submitting comments. To locate the RFI, search for Docket No. CPPBSD–2024–0010.

Accessible Format: Individuals with disabilities can obtain this document, as well as the comments or other documents in the public rulemaking record for this RFI, in an alternative accessible format by contacting the individual listed in the **FOR FURTHER INFORMATION** section of this document.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at www.govinfo.gov. You may also access Commission documents published in the **Federal Register** by using the article search feature at: www.federalregister.gov.

FOR FURTHER INFORMATION CONTACT:

Cassandra Assefa, Regulatory and Policy Attorney, Office of General Counsel, Committee for Purchase From People Who Are Blind or Severely Disabled, 355 E Street SW, Suite 325, Washington, DC 20024; telephone: (202) 430–9886; email: cassefa@abilityone.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In 1938, the legislation that became the JWOD Act was signed to create jobs for blind individuals. In 1971, the Act was amended to expand the JWOD Program’s scope to include employing individuals with severe disabilities.¹ In 2006, the JWOD Program was renamed the AbilityOne Program by the Committee for Purchase From People Who Are Blind or Severely Disabled. In 2011, the Committee began operating as the U.S. AbilityOne Commission.

The JWOD Act continues to serve as an employment catalyst by making it mandatory for Federal agencies to procure certain products and services from NPAs employing individuals who are blind or have significant disabilities. The Commission votes to place on a

¹ 41 U.S.C. Chapter 85, Committee For Purchase From People Who Are Blind or Severely Disabled.

Procurement List suitable products and services that government agencies must then procure from a qualified nonprofit agency (NPA). Federal agencies do not have to follow the normal government competitive procedures when acquiring Procurement List items from an authorized NPA, making it more efficient for both the Federal agencies and the qualified NPA.²

For an NPA to be eligible to provide goods or services on the Procurement List, it must be authorized by the Commission as qualified to serve as an authorized source in the program.

II. The Direct Labor Hour Ratio Mandate

To serve as an authorized source, an NPA must, at a minimum, satisfy the statutory conditions described at 42 U.S.C. 8501, paragraphs 6 and 7. Of note, part (C) of both paragraphs require that 75 percent of the direct labor hours required to produce or provide products or services must be performed by individuals who are blind or significantly disabled.

In calculating the 75 percent direct labor hour ratio, an NPA is required to count not only the DLH performed in support of Procurement List items, but pursuant to the statute, all direct labor performed by every individual employed by the NPA.³ The statute defined direct labor as all work required to prepare, process, and pack a product, or work that directly relates to the performance of the service. The statute specifically excludes supervision, administration, inspection, or shipping as direct labor.

This means that when calculating the 75 percent direct labor hour ratio, an NPA excludes “indirect labor” hours—*i.e.*, “Work that supports the manufacturing process or delivery of services but does not directly produce or add value to the products or services sold to a customer. This includes supervision, administration, inspection, and shipping.”⁴ Historically, these exclusions were perceived as helpful because they reduce the number of hours an NPA must count toward the 75% direct labor hour ratio. However, when an employee who is blind or has a significant disability moves from a direct labor hour position to an indirect labor hour position, the NPA cannot count that employee’s indirect labor hours toward the 75 percent direct labor

hour ratio—a situation that potentially creates a disincentive for the NPA to promote that employee to a supervisory or administrative position.

The Commission believes that many “indirect labor” task or positions could serve as an opportunity to promote employee career advancement. However, there is little incentive for an NPA to create a framework that actively encourages direct labor hour employees to move to indirect labor hour positions if doing so compromises the NPA’s ability to remain in the Program by impeding its ability to meet the Program’s direct labor hour ratio requirement.

III. Request for Information

As noted above, section 8501, paragraphs 6 and 7 of the JWOD Act list the qualifications for an NPA to serve as an authorized source for a product or service on the Procurement List. The Commission’s interpretation of the statutory language is promulgated in the Code of Federal Regulations (CFR) at Title 41, Chapter 51. More specifically, the CFR adopts the JWOD Act’s 75 percent direct labor hour ratio requirement and adds a list of additional qualifications under Part 51–4. In the CFR at Part 51–1.3, the Commission does not elaborate on the statutory direct labor hour ratio requirement or the definition of direct labor.

Commission policies are generally derived from Commission regulations grounded in statute. As such, the authority to deviate from the 75 percent direct labor hour ratio requirement, or to redefine what counts as direct labor, is expressly limited by statute. Notwithstanding these limitations, the Commission is exploring ways to leverage its regulatory and sub-regulatory authority to encourage employment opportunities that promote career mobility without conflicting with the JWOD Act. This RFI is designed to collect information for that purpose, through the questions below.

IV. Questions

(1) How could direct labor be defined to expand the types of tasks or positions that can be counted as direct labor without conflicting with the definition in the JWOD Act? The purpose of this change would include increasing the number of direct labor hours that an NPA could count toward meeting the direct labor hour ratio requirement.

(2) In what ways could indirect labor categories (*e.g.*, supervision, administration, inspection, or shipping) be defined to maximize employee career development without adversely

impacting the ratio requirement, and without a statutory change?

(3) What types of jobs or tasks traditionally categorized as “indirect labor” in accordance with the JWOD Act fall outside of “supervision, administration, inspection, or shipping”?

(4) With respect to meeting the direct labor hour ratio requirement, describe any challenges or successes associated with facilitating or supporting AbilityOne employees’ mobility into jobs outside the Program; particularly, whether such mobility causes challenges with ratio compliance, and if applicable, the steps taken to mitigate such challenges.

Michael R. Jurkowski,

Director, Business Operations.

[FR Doc. 2024–21709 Filed 9–20–24; 8:45 am]

BILLING CODE 6353–01–P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meeting

TIME AND DATE: Wednesday, September 25, 2024—10 a.m.

PLACE: Meeting will be held remotely and in person at 4330 East West Highway, Bethesda, Maryland, Room 420.

STATUS: Commission Meeting—Closed to the Public.

MATTERS TO BE CONSIDERED:

Meeting Matter: Briefing Matter.

CONTACT PERSON FOR MORE INFORMATION: Alberta E. Mills, Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, 301–504–7479 (Office) or 240–863–8938 (Cell).

Dated: September 18, 2024.

Alberta Mills,

Commission Secretary.

[FR Doc. 2024–21741 Filed 9–19–24; 11:15 am]

BILLING CODE 6355–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 23–28]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense (DoD).

ACTION: Arms sales notice.

SUMMARY: The DoD is publishing the unclassified text of an arms sales notification.

² Federal Acquisition Regulation 8.7, Acquisition From Nonprofit Agencies Employing People Who Are Blind or Severely Disabled.

³ 41 U.S.C. 8501(6)(C) and (7)(C).

⁴ U.S. AbilityOne Commission Policy 51.404, Direct Labor Hour Ratio Requirements, effective October 1, 2024.

FOR FURTHER INFORMATION CONTACT:

Pamela Young at (703) 953-6092, pamela.a.young14.civ@mail.mil, or dsca.ncr.rsrcmgmt.list.cns-mbx@mail.mil.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is

published to fulfill the requirements of section 155 of Public Law 104-164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives with attached Transmittal 23-28 and Policy Justification.

Dated: September 18, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 6001-FR-P



DEFENSE SECURITY COOPERATION AGENCY
2800 Defense Pentagon
Washington, DC 20301-2800

May 2, 2023

The Honorable Kevin McCarthy
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 23-28, concerning the Navy's proposed Letter(s) of Offer and Acceptance to the Government of Latvia for defense articles and services estimated to cost \$110 million. We will issue a news release to notify the public of this proposed sale upon delivery of this letter to your office.

Sincerely,

James A. Hursch
Director

Enclosures:

1. Transmittal
2. Policy Justification

BILLING CODE 6001-FR-C

Transmittal No. 23-28

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Government of Latvia

(ii) *Total Estimated Value:*

Major Defense Equipment *	\$ 0 million
Other	\$ 110 million

TOTAL \$ 110 million

Funding Source: National Funds and Foreign Military Financing

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE):

None
Non-MDE:

Included is a Naval Strike Missile Coastal Defense System (NSM CDS), including tactical, telemetered, and training missiles; containers; mobile operational platforms; integration equipment; ordnance handling equipment (OHE); training equipment and aids; technical publications and data; training; spares; U.S. Government and

contractor technical and product support or assistance; and other related elements of logistical and program support.

(iv) *Military Department:* Navy (LG-P-SAB)

(v) *Prior Related Cases, if any:* None
(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* None

(viii) *Date Report Delivered to Congress:* May 2, 2023

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Latvia—Naval Strike Missile Coastal Defense System

The Government of Latvia has requested to buy a Naval Strike Missile Coastal Defense System (NSM CDS), including tactical, telemetered, and training missiles; containers; mobile operational platforms; integration equipment; ordnance handling equipment (OHE); training equipment and aids; technical publications and data; training; spares; U.S. Government and contractor technical and product support or assistance; and other related elements of logistical and program support. The estimated total cost is \$110 million.

This proposed sale will support the foreign policy goals and national security objectives of the United States by improving the security of a NATO ally that is an important force for political stability and economic progress in Europe.

The proposed sale will improve Latvia's capability to meet current and future threats in the Baltic Sea maritime domain. Latvia's increased coastal defense capability and interoperability with U.S. and NATO armed forces will contribute to both U.S. and Latvian defense and security objectives in the Baltics. Latvia will have no difficulty absorbing this equipment into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractor is to be determined. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will not require the assignment of any U.S. Government or contractor representatives to Latvia.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

[FR Doc. 2024–21701 Filed 9–20–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2024–OS–0081]

Submission for OMB Review; Comment Request

AGENCY: Defense Acquisition University (DAU), Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The DoD has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by October 23, 2024.

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:

Reginald Lucas, (571) 372–7574, whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Data Services Management; OMB Control Number 0704–0591.

Type of Request: Extension.

Number of Respondents: 2,500.

Responses per Respondent: 1.

Annual Responses: 2,500.

Average Burden per Response: 5 minutes.

Annual Burden Hours: 208.

Needs and Uses: The Data Services Management provides administrative and academic capabilities and functions related to student registrations, account requests, courses attempted and completed, and graduation notifications to DoD training systems.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID 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.

DOD Clearance Officer: Mr. Reginald Lucas.

Requests for copies of the information collection proposal should be sent to Mr. Lucas at whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

Dated: September 17, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024–21628 Filed 9–20–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2024–HA–0037]

Submission for OMB Review; Comment Request

AGENCY: Office of the Assistant Secretary of Defense for Health Affairs (OASD(HA)), Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The DoD has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by October 23, 2024.

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:

Reginald Lucas, (571) 372–7574, whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: TRICARE Select Enrollment, Disenrollment, and Change Form; DD Form 3043; OMB Control Number 0720–0061.

Type of Request: Revision.

Number of Respondents: 116,105.

Responses per Respondent: 1.

Annual Responses: 116,105.

Average Burden per Response: 15 minutes.

Annual Burden Hours: 29,026.

Needs and Uses: The information collection requirement is necessary to obtain each non-active-duty TRICARE beneficiary's personal information

needed to: (1) Complete his/her enrollment into the TRICARE Select health plan option, (2) dis-enroll a beneficiary, or (3) change a beneficiary's enrollment information (e.g., address, add a dependent, report other health insurance). This information is required to ensure the beneficiary's TRICARE benefits and claims are administered based on their TRICARE plan of choice. Without this new enrollment form, each non-active-duty TRICARE beneficiary is automatically defaulted into direct care, limiting their health care options to beneficiaries would have no TRICARE coverage when using the TRICARE network of providers for services not available at their local military hospital or clinic.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Mr. Matt Eliseo.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket

ID 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.

DOD Clearance Officer: Mr. Reginald Lucas.

Requests for copies of the information collection proposal should be sent to Mr. Lucas at whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

Dated: September 17, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024–21632 Filed 9–20–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 23–30]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense (DoD).

ACTION: Arms sales notice.

SUMMARY: The DoD is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT:

Pamela Young at (703) 953–6092, pamela.a.young14.civ@mail.mil, or dsca.ncr.rsrcmgmt.list.cns-mbx@mail.mil.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives with attached Transmittal 23–30, Policy Justification, and Sensitivity of Technology.

Dated: September 18, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 6001–FR–P



DEFENSE SECURITY COOPERATION AGENCY
2800 Defense Pentagon
Washington, DC 20301-2800

April 28, 2023

The Honorable Kevin McCarthy
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 23-30, concerning the Navy's proposed Letter(s) of Offer and Acceptance to the Government of the United Kingdom for defense articles and services estimated to cost \$31.2 million. We will issue a news release to notify the public of this proposed sale upon delivery of this letter to your office.

Sincerely,

James A. Hursch
Director

Enclosures:

1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

BILLING CODE 6001-FR-C

Transmittal No. 23-30

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Government of the United Kingdom

(ii) *Total Estimated Value:*

Major Defense Equipment *	\$28.8 million
Other	\$ 2.4 million

TOTAL \$31.2 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE):
Seven hundred sixty-eight (768)

Advanced Precision Kill Weapon System-II (APKWS-II) All Up Rounds (AURs) (Single Variant)

Non-MDE:

Also included is support equipment; spare and repair parts; publications and technical documentation; transportation; U.S. Government and contractor engineering, technical and logistical support services; and other related elements of logistical and program support.

(iv) *Military Department:* Navy (UK-P-AIH)

(v) *Prior Related Cases, if any:* None

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex

(viii) *Date Report Delivered to Congress:* April 28, 2023

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

United Kingdom—Advanced Precision Kill Weapon System

The Government of the United Kingdom has requested to buy up to seven hundred sixty-eight (768) Advanced Precision Kill Weapon System-II (APKWS-II) All Up Round (AURs) (Single Variant). Also included

is support equipment; spare and repair parts; publications and technical documentation; transportation; U.S. Government and contractor engineering, technical and logistical support services; and other related elements of logistical and program support. The total estimated cost is \$31.2 million.

This proposed sale will support the foreign policy goals and national security objectives of the United States by improving the security of a NATO Ally that is a force for political stability and economic progress in Europe.

The proposed sale will improve the United Kingdom's capability to meet current and future threats by ensuring its aviation forces' interoperability with United States and other allied forces as well as its ability to contribute to missions of mutual interest. By deploying the Advanced Precision Kill Weapon System, the United Kingdom would contribute to global readiness and enhance the capability for U.S. forces operating globally alongside them. The United Kingdom will have no difficulty absorbing this equipment into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractors will be BAE Systems, Nashua, New Hampshire. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will require multiple trips by approximately five (5) U.S. Government representatives and the assignment of approximately five (5) contractor representatives to the United Kingdom on an intermittent basis for a period of approximately five (5) years to support delivery and integration of items and to provide supply support management, inventory control, and equipment familiarization.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 23-30

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The Advanced Precision Kill Weapon System-II (APKWS-II) is a design conversion of an unguided Hydra 2.75-inch rocket with a laser guidance kit to give it precision-kill capability. As a low cost weapon, it is intended as an inexpensive means to destroy targets while limiting collateral damage in

close combat. The APKWS consists of an APKWS-II Guidance Section (GS) developed by BAE systems, legacy 2.75-inch MK66 Mod 4 rocket motor, and a legacy Mk151 and Mk435/436 warhead/fuze. These guided rockets are steered to the target by following reflected laser beam energy directed onto the target either by the launching aircraft, a second aircraft, or ground-based troops operating a laser designator. The APKWS is a tactical rocket system that can be launched from several platforms, including rotary wing, fixed wing, and ground-based vehicles, offering multi-mission, multi-target capability, and precision-strike lethality.

2. The highest level of classification of defense articles, components, and services included in this potential sale is SECRET.

3. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures that might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

4. A determination has been made that the United Kingdom can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

5. All defense articles and services listed in this transmittal have been authorized for release and export to the Government of the United Kingdom.

[FR Doc. 2024-21702 Filed 9-20-24; 8:45 am]

BILLING CODE 6001-FR-P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD-2024-OS-0056]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Intelligence and Security (OUSD(I&S)), Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The DoD has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by October 23, 2024.

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:

Reginald Lucas, (571) 372-7574, whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Defense Information System for Security; OMB Control Number 0705-0008.

Type of Request: Revision.

Number of Respondents: 20,994.

Responses per Respondent: 258.

Annual Responses: 5,416,452.

Average Burden per Response: 20 minutes.

Annual Burden Hours: 1,805,484.

Needs and Uses: This information collection is necessary as the DISS system requires personal data collection to facilitate the initiation, investigation, and adjudication of information relevant to DoD security clearances and employment suitability determinations for active-duty military, civilian employees, and contractors requiring such credentials. The respondents for this information collection are 45,377 Facility Security Officers (FSOs) working in industry companies, who are responsible for the regular servicing and updating of the DISS records of individuals with an industry person category. The specific purpose of this information collection is for FSOs to update the DISS records of contractor personnel within their company and Security Management Office (SMO) to facilitate DoD Adjudicators and Security Managers obtaining accurate up-to-date eligibility and access information on contractor personnel. FSO respondents electronically collect, update, and complete the collection directly into the DISS application.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Sehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket

ID 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.

DOD Clearance Officer: Mr. Reginald Lucas.

Requests for copies of the information collection proposal should be sent to Mr. Lucas at whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

Dated: September 17, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024-21626 Filed 9-20-24; 8:45 am]

BILLING CODE 6001-FR-P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 23-0F]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense (DoD).

ACTION: Arms sales notice.

SUMMARY: The DoD is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT:

Pamela Young at (703) 953-6092, pamela.a.young14.civ@mail.mil, or dsca.ncr.rsrcmgmt.list.cns-mbx@mail.mil.

SUPPLEMENTARY INFORMATION: This 36(b)(5)(C) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104-164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives with attached Transmittal 23-0F.

Dated: September 18, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 6001-FR-P



DEFENSE SECURITY COOPERATION AGENCY

2800 Defense Pentagon
Washington, DC 20301-2800

April 28, 2023

The Honorable Kevin McCarthy
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(5)(C) of the Arms Export Control Act (AECA), as amended, we are forwarding Transmittal No. 23-0F. This notification relates to enhancements or upgrades from the level of sensitivity of technology or capability described in the Section 36(b)(1) AECA certification 12-32 of September 21, 2012.

Sincerely,

A handwritten signature in black ink that reads "James A. Hursch".

James A. Hursch
Director

Enclosure:

1. Transmittal

BILLING CODE 6001-FR-C

Transmittal No. 23-0F

REPORT OF ENHANCEMENT OR UPGRADE OF SENSITIVITY OF TECHNOLOGY OR CAPABILITY (SEC. 36(B)(5)(C), AECA)

(i) *Purchaser*: Republic of Korea
(ii) *Sec. 36(b)(1), AECA Transmittal No.*: 12-32
Date: September 21, 2012
Military Department: Army
(iii) *Description*: On September 21, 2012, Congress was notified by Congressional certification transmittal number 12-32, of the possible sale under Section 36(b)(1) of the Arms Export Control Act of 36 AH-64 D APACHE Longbow Block III Attack Helicopters; 84 T-700-GE-701 D Engines; 42 Modernized Target Acquisition and Designation Sight/ Modernized Pilot Night Vision Sensors; 36 AN/APG-78 Fire Control Radar (FCR) with Radar Electronics Unit (Longbow Component); 36 AN/APR-48A Radar Frequency Interferometers; 42 AN/APR-39 Radar Signal Detecting Sets; 45 AN/AVR-2B Laser Warning Sets; 43 AAR-57(V) 3/5 Common Missile Warning Systems (CMWS) with 5th Sensor and Improved Countermeasure Dispensers; 42 AN/APX-123 Transponders; 120 Improved Helmet Display Sight Systems (IHDS-21); 81 Embedded Global Positioning Systems with Inertial Navigation; 38 30mm Automatic Chain Guns (Aircraft Component); 90 AN/ARC-201E Single Channel Ground and Airborne Radio System (SINCGARS) Radios; 90 AN/ARC-231 Radios; 42 AN/ARC-220 Radios; 80 M299 HELLFIRE or Missile Launchers; 400 AGM-114R1 HELLFIRE Missiles Semi-Active Lasers (SAL); 438 STINGER Block I 92H Missiles; 774,144 30 mm Cartridge HEDP High Explosive Dual Purpose M789s 11,020 2.75 Inch HYDRA Rockets (Unguided); 108 APACHE Aviator Integrated Helmets (AAIH). Also included were training devices, simulators, generators, transportation, wheeled vehicles and organizational equipment, tools and test equipment, communication equipment, spare and repair parts, support equipment, personnel training and training equipment, publications and technical documentation, U.S. Government and contractor engineering, technical and logistics support services, and other related elements of program support. The estimated total cost was \$3.6 billion. Major Defense Equipment (MDE) constituted \$2.5 billion of this total.

This transmittal notifies the inclusion of the following additional MDE item: forty-one (41) AAR-57(V) 3/5 Common

Missile Warning Systems (CMWS). The estimated total value of the new MDE items is \$27 million, resulting in a new MDE total of \$2.527 billion. The total case value will increase to \$3.627 billion.

(iv) *Significance*: The proposed sale will sustain the Republic of Korea's Army (ROKA) AH-64 fleet readiness, increase combat survivability and allow the ROKA to fulfill security requirements related to the defense of Korea, as outlined in bilateral operational plans.

(v) *Justification*: This proposed sale will support the foreign policy goals and national security objectives of the United States by improving the security of a Major Non-NATO Ally that is a force for political stability and economic progress in the Indo-Pacific region.

(vi) *Sensitivity of Technology*: The Sensitivity of Technology statement contained in the original notification applies to items reported here.

The highest level of classification of defense articles, components, and services included in this potential sale is SECRET.

(vii) *Date Report Delivered to Congress*: April 28, 2023

[FR Doc. 2024-21699 Filed 9-20-24; 8:45 am]

BILLING CODE 6001-FR-P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD-2024-OS-0060]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Research and Engineering (OUSD(R&E)), Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The DoD has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by October 23, 2024.

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:

Reginald Lucas, (571) 372-7574, whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Certification of Qualified Products; DD Form 1718; OMB Control Number 0704-0487.

Type of Request: Revision.

Number of Respondents: 932.

Responses per Respondent: 1.

Annual Responses: 932.

Average Burden per Response: 30 minutes.

Annual Burden Hours: 466.

Needs and Uses: The information collection requirement is necessary to obtain, certify, and record qualification of products or processes falling under the DoD Qualification Program. Qualification ensures continued product performance, quality, and reliability. DD Form 1718 is sent to manufacturers every two years by the Qualifying Activity when the applicable specification does not contain complete requalification testing, and requests that manufacturers complete the form, certifying that their products still meet the specification requirements as originally tested. DD Form 1718 is included as an exhibit in an appeal or hearing case file as evidence of the reviewers' products or process qualifications in advance of, and independent of, acquisition.

Affected Public: Business or other for-profit.

Frequency: Biennially.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID 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.

DOD Clearance Officer: Mr. Reginald Lucas.

Requests for copies of the information collection proposal should be sent to Mr. Lucas at whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

Dated: September 17, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison
Officer, Department of Defense.

[FR Doc. 2024-21630 Filed 9-20-24; 8:45 am]

BILLING CODE 6001-FR-P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD-2024-OS-0078]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness (OUSD (P&R)), Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The DoD has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by October 23, 2024.

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:

Reginald Lucas, (571) 372-7574,
whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

SUPPLEMENTARY INFORMATION: The DoD Civilian Employee Workplace and Gender Relations Survey (WGRC) will assess the attitudes and opinions of DoD civilian employees on gender issues including their experiences of and the climate surrounding sexual harassment, gender discrimination, and unwanted sexual contact in the DoD civilian workplace. These indicators provide primary data on estimated prevalence rates of unwanted gender-related experiences and historically provide the ability to evaluate the impact of policies and programs with regard to DoD civilian employees. The surveys are benchmarks by which senior DoD officials can track trends over time.

All Workplace and Gender Relations surveys are Congressionally-mandated to estimate rates of gender-based assaults, assess the effectiveness of policies and programming to prevent

sexual harassment and sexual assault, and assess the overall gender relations climate within the Department in accordance with 10 U.S.C. 481. Historically, these surveys have been conducted with military members only, with the first congressionally mandated Workplace and Gender Relations survey conducted in 2002 for active-duty service members and 2004 for Reserve component members. Section 1073 of the FY 2015 NDAA extended this requirement to DoD Civilian employees as well, including an amendment that inserted Section 481a into 10 U.S.C. 481 outlining the survey requirement. The first administration of the WGRC was in FY 2016 per these statutory requirements and was administered to appropriated fund (APF) civilian employees only. The second administration of the WGRC was in 2018 and expanded the target population to include nonappropriated fund (NAF) civilian employees.

Title; Associated Form; and OMB Number: Department of Defense Civilian Employee Workplace and Gender Relations Survey; OMB Control Number 0704-0614.

Type of Request: Revision.

Number of Respondents: 91,286.

Responses per Respondent: 1.

Annual Responses: 91,286.

Average Burden per Response: 30 minutes.

Annual Burden Hours: 45,643.

Needs and Uses: The WGRC fulfills the Congressional mandate outlined in 10 U.S.C. 481a for a biennial survey assessment of gender relations in the DoD civilian workplace. The mandate requires that the survey (1) provides indicators of positive and negative trends for professional and personal relationships between male and female employees; (2) estimates the prevalence of unwanted gender-related behaviors for DoD civilian employees within the preceding fiscal year; (3) examines the effectiveness of policies designed to improve professional relationships between male and female employees; and (4) examines the effectiveness of current processes for complaints and investigations concerning unwanted gender-related behaviors, including sexual assault, sexual harassment, and gender discrimination. The legal requirements for the WGRC can be found in the following:

- FY15 NDAA, Section 1073.
- 10 U.S.C. 481a.
- 10 U.S.C. 136.
- 10 U.S.C. 2358.
- Public Law (Pub. L.) 111-383, Sections 1602 and 1631; 113-291, Section 1073.

These legal requirements mandate that the WGRC solicit information on gender issues, including issues relating to sexual assault, sexual harassment, and gender discrimination, as well as the climate in the Department for forming professional relationships between male and female employees. They also give the Department authority to conduct such surveys under the guidance of the USD(P&R).

Overall, the results of the survey will assess progress, identify shortfalls, and revise policies and programs as needed related to issues directly affecting DoD civilian employees. Data from this survey will be presented to the OUSD(P&R), and DoD policy and program offices to assess and improve policies, programs, practices, and training related to gender relations in the DoD informed by current and statistically reliable information. Analysis will include OPA's standard products: a results and trends report (a set of relative frequency distributions of each question, and cross-tabulations of survey questions by key stratifying variables), briefing slides, reports highlighting key findings, and a statistical methodology report. Ad hoc analyses requested by the policy office sponsors and other approved organizations may be conducted as needed and based on available staff.

Affected Public: Individuals or households.

Frequency: Biennially.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Sehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID 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.

DOD Clearance Officer: Mr. Reginald Lucas.

Requests for copies of the information collection proposal should be sent to Mr. Lucas at dodhra.mc-alex.dhra-hq.mbx.information-collections@mail.mil.

Dated: September 17, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison
Officer, Department of Defense.

[FR Doc. 2024-21629 Filed 9-20-24; 8:45 am]

BILLING CODE 6001-FR-P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD-2024-OS-0101]

Privacy Act of 1974; System of Records

AGENCY: Defense Human Resources Activity (DHRA), Department of Defense (DoD).

ACTION: Notice of a modified system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the Office of the Secretary of Defense (OSD) is modifying a current system of records titled, Defense Civilian Human Resource Management System (DCHRMS), DHRA 23 DoD. The records within this system are used to provide human resource information and system support for the DoD civilian workforce worldwide that manages the HR processing and reporting, including position, compensation and benefits, and performance management, as well as create efficiencies in Human Capital Management. This system of records notice (SORN) is being updated to cover compensation records and administrative appeals relating to claims filed under the Helping American Victims Afflicted by Neurological Attacks Act (HAVANA). This SORN modification expands the Category of Individuals section to cover current and former DoD employees, and dependents of current or former employees who on or after January 1, 2016, experienced a qualifying brain injury. Additionally, the DoD is modifying the Routine Use section to allow additional sharing outside of DoD. Lastly, the DoD is also modifying various other sections within the SORN to improve clarity or update information that has changed.

DATES: This system of records is effective upon publication; however, comments on the Routine Uses will be accepted on or before October 23, 2024. The Routine Uses are effective at the close of the comment period.

ADDRESSES: You may submit comments, identified by docket number and title, by either of the following methods:

* *Federal Rulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments.

* *Mail:* Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Attn: Mailbox 24, Suite 05F16, Alexandria, VA 22350-1700.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at <https://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Samuel Peterson, DHRA Component Privacy Officer, 400 Gigling Rd., Seaside, CA 93955, dodhra.mc-alex.dhra-hq.mbx.privacy@mail.mil or 831-220-7330.

SUPPLEMENTARY INFORMATION:

I. Background

DoD is modifying the Defense Civilian Human Resource Management System, DHRA 23 DoD to support amendment of the Helping American Victims Afflicted by Neurological Attacks Act (HAVANA). In 2016, Department of State employees stationed in Havana, Cuba, began reporting a sudden onset of symptoms, including headaches, pain, nausea, disequilibrium, and hearing loss, in conjunction with sensory events. Federal agencies have called such incidents Anomalous Health Incidents ("AHIs"). Since 2016, Federal employees in numerous countries reported suspected AHIs.

Beginning on December 20, 2019, the Department of State was authorized by statute to pay benefits to employees and their dependents for injuries suffered in the Republic of Cuba, the People's Republic of China, or other foreign countries designated by the Secretary of State incurred after January 1, 2016, in connection with certain hostile or other incidents designated by the Secretary of State (Pub. L. 116-94, Division J, Title IX, section 901) (codified in 22 U.S.C. 2680b). These benefits were limited to Department of State employees only (*i.e.*, not other U.S. Government employees under Chief of Mission (COM) authority). On January 1, 2021, this law was amended, authorizing other Federal Government agencies (such as the DoD) to provide benefits to their own employees under COM authority who suffered similar injuries. (Pub. L. 116-283, div. A, title XI, section 1110).

On October 8, 2021, the President signed the HAVANA Act of 2021 (Pub. L. 117-46). The HAVANA Act amended section 901 to authorize Federal Government agencies to compensate affected employees, former employees, and their dependents for qualifying injuries to the brain. The HAVANA Act amendments did not require that the qualifying injury occur in the Republic of Cuba, the People's Republic of China, or another foreign country designated by the Secretary of State. Section 9216 of the James M. Inhofe National Defense Authorization Act for Fiscal Year 2023 provided agencies with authority to designate incidents affecting employees or dependents who are not under the security responsibility of the Secretary of State.

The records within DHRA 23 DoD are used to provide human resource information and system support for the DoD civilian workforce worldwide that manages the HR processing and reporting, including position, compensation and benefits, and performance management, as well as create efficiencies in Human Capital Management. The SORN is being updated to cover compensation records and administrative appeals relating to claims filed under the HAVANA Act. This SORN modification expands the Category of Individuals section to cover current and former DoD employees, and dependents of current or former employees who on or after January 1, 2016, experienced a qualifying brain injury.

Subject to public comment, the DoD is adding standard routine use "I" authorizing sharing in the context of Inspector General activities, routine use "J" to allow for disclosures mandated by Federal statute or treaty, and routine use "N" to allow for sharing with the Department of State for the purpose of evaluating whether an incident is an "other incident" for purposes of establishing a qualifying injury. The following sections of this SORN are also being modified: (1) to the System Location section to reflect the various locations in which records may reside; (2) to the Authority for Maintenance of the System section to update citations(s) and add additional authorities; (3) to the Purpose section to provide clarity on how information will be used; (4) to the Categories of Records section to clarify how the records relate to the Category of Individuals; (5) to the Records Source Categories section to update source information; (6) to the Record Access Procedures section to reflect the need for individuals to identify the appropriate DoD office or component to which their request should be directed;

and (7) to the Notification Procedures section to update the appropriate citation for notifications.

DoD SORNs have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT** or at the Office of the Assistant to the Secretary for Defense for Privacy, Civil Liberties, and Transparency (OATSD(PCLT)) website at <https://dpcl.d.defense.gov/privacy>.

II. Privacy Act

Under the Privacy Act, a “system of records” is a group of records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined as a U.S. citizen or lawful permanent resident.

In accordance with 5 U.S.C. 552a(r) and Office of Management and Budget (OMB) Circular No. A-108, OATSD(PCLT) has provided a report of this system of records to the OMB and to Congress.

Dated: September 18, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

SYSTEM NAME AND NUMBER:

Defense Civilian Human Resource Management System (DCHRMS), DHRA 23 DoD.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Department of Defense (Department or DoD), located at 1000 Defense Pentagon, Washington, DC 20301-1000, and other Department installations, offices, or mission locations. Information may also be stored within a government-certified cloud, implemented and overseen by the Department's Chief Information Officer (CIO), 6000 Defense Pentagon, Washington, DC 20301-6000.

SYSTEM MANAGER(S):

Director, Enterprise Solutions and Integration Defense Civilian Personnel Advisory Service, 4800 Mark Center Drive, Suite 06E22, Arlington, VA 22350-6000, dodhra.mc-alex.dcpas.mbx.saco@mail.mil.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. Chapter 11, Office of Personnel Management; 5 U.S.C. Chapter 13, Special Authority; 5 U.S.C. Chapter 29, Commissions, Oaths, Records, and Reports; 5 U.S.C. Chapter 31, Authority for Employment; 5 U.S.C.

Chapter 33, Examination, Selection, and Placement; 5 U.S.C. Chapter 41, Training; 5 U.S.C. Chapter 43, Performance Appraisal; 5 U.S.C. Chapter 51, Classification; 5 U.S.C. Chapter 53, Pay Rates and Systems; 5 U.S.C. Chapter 55, Pay Administration; 5 U.S.C. Chapter 61, Hours of Work; 5 U.S.C. Chapter 63, Leave; 5 U.S.C. Chapter 72, Antidiscrimination; Right to Petition Congress; 5 U.S.C. 7201, Antidiscrimination Policy; Minority Recruitment Program; 5 U.S.C. Chapter 75, Adverse Actions; 5 U.S.C. Chapter 83, Retirement; 5 U.S.C. Chapter 84, Federal Employees' Retirement System, Antidiscrimination Policy; Minority Recruitment Program; 10 U.S.C. 136, Under Secretary of Defense for Personnel and Readiness; HAVANA Act of 2021, Public Law 117-46, 135 Stat. 391 (2021) (codified at 22 U.S.C. 2680b(i)); Executive Order (E.O.) 9830, Amending the Civil Service Rules and Providing for Federal Personnel Administration, as amended; 29 CFR 1614.601, EEO Group Statistics; and E.O. 9397 (SSN), as amended.

PURPOSE(S) OF THE SYSTEM:

Data is used to maintain a system of records that provides human resource information and system support for the Department of Defense (DoD) civilian workforce worldwide that manages the human resources processing and reporting, including position, compensation and benefits, performance management, and in making determinations of qualifications, as well as create efficiencies in Human Capital Management. Data is also used for analysis in order to meet Congressional and Federal reporting requirements.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Civilian employee, prospective applicants, and job applicants selected for civilian appropriated/non-appropriated fund (NAF), local nationals, and National Guard civilian technician positions in the DoD; and past and present DoD Civilian employees and their dependents eligible to submit claims in accordance with the HAVANA Act.

CATEGORIES OF RECORDS IN THE SYSTEM:

Personal information including: Name, date and place of birth, citizenship, gender, marital status, DoD identification number (DoD ID), Social Security Number (SSN), addresses, phone numbers, email addresses, employee number, emergency contact information, dependent and family member information, security clearance information, race and ethnic origin,

disability code, and foreign language capability. Compensation records and administrative appeals relating to claims filed under the HAVANA Act. Position authorization and control information, position data and performance elements, personnel data and projected suspense information for personnel actions, pay, benefits, and entitlements data. Historical information on employees, including job experience, education, training, and training transaction data, performance plans, interim appraisals, final appraisals, closeouts and ratings, professional accounting or other certifications or licenses, awards information and merit promotion information, separation and retirement data, civilian deployment information, and adverse and disciplinary action data. In addition, the Corporate Management Information System data (which is comprised of each employee current and historical record, to include all person, assignment, position, and personnel actions/updates) will be maintained and refreshed for agencies' historical and congressional reporting purposes.

RECORD SOURCE CATEGORIES:

The individual, resumes, applicant record, employee or supervisor generated training requests; human resources generated records; employee generated data recorded as self-certified; and other employee or supervisor generated records. Data is also received from various interfaces with systems including, the Corporate Management Information System, Joint Personnel Adjudication System, Fourth Estate Manpower Tracking System, Defense Civilian Payroll System, the Air Force Manpower Programming and Execution System, NAF Payroll, Thrift Savings Plan hardship, Interactive Voice Recognition System, USA Staffing, and employee completed training data provided by respective Component agencies.

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) of the Privacy Act of 1974, as amended, all or a portion of the records or information contained herein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

A. To contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the Federal Government when necessary to

accomplish an agency function related to this system of records.

B. To the appropriate Federal, State, local, territorial, tribal, foreign, or international law enforcement authority or other appropriate entity where a record, either alone or in conjunction with other information, indicates a violation or potential violation of law, whether criminal, civil, or regulatory in nature.

C. To any component of the Department of Justice for the purpose of representing the DoD, or its components, officers, employees, or members in pending or potential litigation to which the record is pertinent.

D. In an appropriate proceeding before a court, grand jury, or administrative or adjudicative body or official, when the DoD or other Agency representing the DoD determines that the records are relevant and necessary to the proceeding; or in an appropriate proceeding before an administrative or adjudicative body when the adjudicator determines the records to be relevant to the proceeding.

E. To the National Archives and Records Administration for the purpose of records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906.

F. To a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, and at the request of, the individual who is the subject of the record.

G. To appropriate agencies, entities, and persons when (1) the DoD suspects or confirms a breach of the system of records; (2) the DoD determines as a result of the suspected or confirmed breach there is a risk of harm to individuals, the DoD (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the DoD's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

H. To another Federal agency or Federal entity, when the DoD determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs and operations), the Federal Government, or

national security, resulting from a suspected or confirmed breach.

I. To another Federal, State or local agency for the purpose of comparing to the agency's system of records or to non-Federal records, in coordination with an Office of Inspector General in conducting an audit, investigation, inspection, evaluation, or some other review as authorized by the Inspector General Act of 1978, as amended.

J. To such recipients and under such circumstances and procedures as are mandated by Federal statute or treaty.

K. To the Equal Employment Opportunity Commission for the purpose of providing Equal Employment Opportunity group statistics in accordance with 29 CFR 1614.601, EEO Group Statistics.

L. To the Office of Personnel Management (OPM) for the purpose of addressing civilian pay and leave, benefits, retirement deduction, and any other information necessary for the OPM to carry out its legally authorized government-wide personnel management functions and studies.

M. To educational institutions and commercial training providers for the purpose of selecting and registering applicants approved by a DoD component to attend a specified program, and, when applicable, to provide for payment.

N. To the Department of State, as appropriate in evaluating whether an incident is an "other incident" for purposes of establishing a qualifying injury or should be so designated. Other incident is a new onset of physical manifestations that cannot otherwise be readily explained that is designated under 22 U.S.C. 2680b.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records may be stored electronically. The records may be stored on magnetic disc, tape, or digital media; in agency-owned cloud environments; or in vendor Cloud Service Offerings certified under the Federal Risk and Authorization Management Program (FedRAMP).

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records may be retrieved by name, DoD ID, or SSN.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are retained for 25 years after the records are closed—defined as after an individual separates from the Agency for Service members or after final payment is received for dependents; Corporate Management Information

System records are cutoff and destroyed when no longer needed for business use.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Records are accessed and/or maintained in areas accessible only to authorized personnel who are properly screened, cleared, and trained. Common Access Cards (CACs) are employed to ensure access is limited to authorized personnel only. Role based access is used to ensure HR Personnel and system administrators have access to only the records they are entitled to see. Employees are able to access and view only their records and update certain personal information to them via two-factor authentication or CAC. Additional technical controls include encryption of data at rest and in transit, firewall, virtual private network, intrusion detection system, DoD Public Key Infrastructure Certificates, and least privilege access. Security systems and/or security guards protect buildings where records are accessed or maintained. Additional physical access controls include, biometric access systems, multiple layers of locked access control doors and mantraps, closed-circuit television, and physical intrusion alarms.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this system should address written inquiries to the Office of the Secretary of Defense/Joint Staff FOIA Requester Service Center, Office of Freedom of Information, 1155 Defense Pentagon, Washington, DC 20301-1155. Signed written requests should contain name and number of this system of records notice along with full, current address, and email of the individual name, date of birth, DoD ID Number, and dates of employment (or approximate), and last employing agency. In addition, the requester must provide either a notarized statement or an unsworn declaration made in accordance with 28 U.S.C. 1746, in the following format:

If executed outside the United States: "I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date). (Signature)."

If executed within the United States, its territories, possessions, or commonwealths: "I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature)".

CONTESTING RECORD PROCEDURES:

The DoD rules for accessing records, contesting contents, and appealing

initial Component determinations are contained in 32 CFR part 310, or may be obtained from the system manager.

NOTIFICATION PROCEDURES:

Individuals seeking to determine whether information about themselves is contained in this system of records should follow the instructions for Record Access Procedures above.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

January 28, 2020, 85 FR 4949;
November 15, 2010, 75 FR 69642.
[FR Doc. 2024-21715 Filed 9-20-24; 8:45 am]

BILLING CODE 6001-FR-P

DEPARTMENT OF DEFENSE**Office of the Secretary**

[Transmittal No. 23-34]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense (DoD).

ACTION: Arms sales notice.

SUMMARY: The DoD is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT:
Pamela Young at (703) 953-6092,
pamela.a.young14.civ@mail.mil, or

dsca.ncr.rsrcmgmt.list.cns-mbx@mail.mil.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104-164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives with attached Transmittal 23-34, and Policy Justification.

Dated: September 18, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 6001-FR-P



DEFENSE SECURITY COOPERATION AGENCY
2800 Defense Pentagon
Washington, DC 20301-2800

April 26, 2023

The Honorable Kevin McCarthy
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 23-34, concerning the Air Force's proposed Letter(s) of Offer and Acceptance to the Government of Norway for defense articles and services estimated to cost \$166 million. We will issue a news release to notify the public of this proposed sale upon delivery of this letter to your office.

Sincerely,


James A. Hursch
Director

Enclosures:

1. Transmittal
2. Policy Justification

BILLING CODE 6001-FR-C

Transmittal No. 23–34

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser*: Government of Norway

(ii) *Total Estimated Value*:

Major Defense Equipment *	\$ 0 million
Other	\$166 million

TOTAL	\$166 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase*:

Major Defense Equipment (MDE):

None

Non-MDE:

The Government of Norway has requested continued sustainment and associated services for four (4) C–130J aircraft beyond Block 6 through 2028. Included are Joint Mission Planning Systems (JMPS); aircraft components, spare parts, consumables, and accessories; repair and return support; aircraft support and support equipment; unclassified publications and technical documentation; software delivery and support; unclassified Computer Program Identification Number (CPIN) systems; telecommunications support; minor modifications, maintenance and maintenance support; U.S. Government and contractor engineering, technical, and logistics support services; and other related elements of logistical and program support.

(iv) *Military Department*: Air Force (NO–D–QBV)

(v) *Prior Related Cases, if any*: NO–D–QAT

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid*: None known at this time

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold*: None

(viii) *Date Report Delivered to Congress*: April 26, 2023

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Norway—C–130J Sustainment

The Government of Norway has requested continued sustainment and associated services for four (4) C–130J aircraft beyond Block 6 through 2028. Included are Joint Mission Planning Systems (JMPS); aircraft components, spare parts, consumables, and accessories; repair and return support; aircraft support and support equipment;

unclassified publications and technical documentation; software delivery and support; unclassified Computer Program Identification Number (CPIN) systems; telecommunications support; minor modifications, maintenance and maintenance support; U.S. Government and contractor engineering, technical, and logistics support services; and other related elements of logistical and program support. The estimated total cost is \$166 million.

This proposed sale will support the foreign policy goals and national security objectives of the United States by improving the security of a NATO Ally that is a force for political stability and economic progress in Europe.

The proposed sale will improve Norway's capability to meet current and future threats by bolstering operational readiness while enhancing air and defense capabilities with a modernized fleet. Norway already has C–130Js and will have no difficulty absorbing these articles and services into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractor will be Lockheed Martin, Marietta, GA. The purchaser typically requests offsets. Any offset agreement would be defined in negotiations between the purchaser and the contractor.

Implementation of this proposed sale will not require the assignment of any additional U.S. Government or contractor representatives to Norway.

There will be no adverse impact on U.S. defense readiness because of this proposed sale.

[FR Doc. 2024–21697 Filed 9–20–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2024–HA–0068]

Submission for OMB Review; Comment Request

AGENCY: Office of the Assistant Secretary of Defense for Health Affairs (OASD(HA)), Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The DoD has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by October 23, 2024.

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:

Reginald Lucas, (571) 372–7574, whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

SUPPLEMENTARY INFORMATION:

Title: Associated Form; and OMB Number: Defense Health Agency Patient Safety Culture Survey; OMB Control Number 0720–0034.

Type of Request: Extension.

Number of Respondents: 30,965.

Responses per Respondent: 1.

Annual Responses: 30,965.

Average Burden per Response: 10 minutes.

Annual Burden Hours: 5,161.

Needs and Uses: The 2001 National Defense Authorization Act (NDAA) contains specific sections addressing patient safety in military and veterans' health care systems. This legislation states that the Secretary of Defense shall establish a patient care error reporting and management system to study occurrences of errors in patient care and that one purpose of the system should be to “identify systemic factors that are associated with such occurrences” and “to provide for action to be taken to correct the identified systemic factors” (Sec. 754, items b2 and b3). In addition, the legislation states that the Secretary shall “continue research and development investments to improve communication, coordination, and teamwork in the provision of health care” (Sec. 754, item d4). As an ongoing response to this legislation, DHA Headquarters has implemented a web-based patient safety culture survey to obtain DHA staff opinions on patient safety issues. Participation in the DHA Patient Safety Culture Survey also fulfills The Joint Commission (TJC) accreditation requirements related to assessing patient safety culture and using the results to improve. As part of its Leadership Standards, TJC requires facility leaders to regularly evaluate the culture of safety and quality using valid and reliable tools and prioritize and implement changes identified by the evaluation. Additionally, DHA inpatient military treatment facilities (MTFs) recently began participating in The Leapfrog Hospital Safety Grade, an

initiative that provides a letter grade rating of a hospital's patient safety measures through more than 30 national performance indicators. Participation in the DHA Patient Safety Culture Survey provides MTFs with data and information assessed by The Leapfrog Group as part of the Hospital Safety Grade calculation.

Affected Public: Federal government; individuals or households.

Frequency: As required.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Mr. Matt Eliseo.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID 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.

DOD Clearance Officer: Mr. Reginald Lucas.

Requests for copies of the information collection proposal should be sent to Mr. Lucas at whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

Dated: September 17, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024-21627 Filed 9-20-24; 8:45 am]

BILLING CODE 6001-FR-P

ACTION: Arms sales notice.

SUMMARY: The DoD is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT:

Pamela Young at (703) 953-6092, pamela.a.young14.civ@mail.mil, or dsca.ncr.rsrcmgmt.list.cns-mbx@mail.mil.

SUPPLEMENTARY INFORMATION: This 36(b)(5)(C) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104-164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives with attached Transmittal 23-0D.

Dated: September 18, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 6001-FR-P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 23-0D]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense (DoD).



DEFENSE SECURITY COOPERATION AGENCY
2800 Defense Pentagon
Washington, DC 20301-2800

May 2, 2023

The Honorable Kevin McCarthy
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(5)(C) of the Arms Export Control Act (AECA), as amended, we are forwarding Transmittal No. 23-0D. This notification relates to enhancements or upgrades from the level of sensitivity of technology or capability described in the Section 36(b)(1) AECA certification 17-35 of July 10, 2017.

Sincerely,

James A. Hursch
Director

Enclosure:
1. Transmittal

BILLING CODE 6001–FR–C

Transmittal No. 23–0D

REPORT OF ENHANCEMENT OR
UPGRADE OFSENSITIVITY OF TECHNOLOGY OR
CAPABILITY (SEC. 36(B)(5)(C), AECA)

(i) *Purchaser:* Government of Romania
(ii) *Sec. 36(b)(1), AECA Transmittal*
No.: 17–35

Date: July 10, 2017

Military Department: Army

Funding Source: National Funds

(iii) *Description:* On July 10, 2017, Congress was notified by congressional certification transmittal number 17–35 of the possible sale, under Section 36(b)(1) of the Arms Export Control Act, of seven (7) Patriot Configuration-3+ Modernized Fire Units consisting of: seven (7) AN/MPQ–65 radar sets, seven (7) AN/MSQ–132 engagement control stations, thirteen (13) antenna mast groups, twenty-eight (28) M903 launching stations, fifty-six (56) Patriot MIM–104E Guidance Enhanced Missile-TBM (GEM–T) missiles, one hundred and sixty-eight (168) Patriot Advanced Capability-3 (PAC–3) Missile Segment Enhancement (MSE) missiles, and seven (7) Electrical Power Plants (EPP) III. Also included with this request was communications equipment, tools and test equipment; support equipment; prime movers; generators; publications and technical documentation; training equipment; spare and repair parts; personnel training; Technical Assistance Field Team (TAFT), USG and contractor technical, engineering, and logistics support services; Systems Integration and Checkout (SICO); field office support; and other related elements of logistics and program support. The estimated total cost was \$3.9 billion. Major Defense Equipment (MDE) constituted \$1.3 billion of this total.

This transmittal notifies the inclusion of the following additional MDE items: forty (40) Patriot Advanced Capability-2 (PAC–2) Anti-Tactical Missiles (ATM), MIM–104C. The estimated total value of these additional items is \$200 million. The total estimated MDE value will increase by \$200 million, resulting in a new MDE total of \$1.5 billion. The total estimated case value will increase to \$4.1 billion.

(iv) *Significance:* The proposed sale will improve Romania's capacity to counter threats posed by potential attacks. This will contribute to the Romanian Armed Forces' effort to update its capabilities and enhance interoperability with the United States and other allies.

(v) *Justification:* This proposed sale will support the foreign policy goals and national security objectives of the United States by improving the security of a NATO Ally that is a force for political stability and economic progress in Europe.

(vi) *Sensitivity of Technology:* The Sensitivity of Technology statement contained in the original notification applies to items reported here.

The highest level of classification of defense articles, components, and services included in this potential sale is SECRET.

(vii) *Date Report Delivered to Congress:* May 2, 2023

[FR Doc. 2024–21695 Filed 9–20–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2024–SCC–0085]

Agency Information Collection
Activities; Submission to the Office of
Management and Budget for Review
and Approval; Comment Request;
Federal Student Loan Program
Deferment Request Forms

AGENCY: Federal Student Aid (FSA),
Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing a revision of a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before October 23, 2024.

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 Beth Grebeldinger, 202–570–8414.

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: Federal Student Loan Program Deferment Request Forms.

OMB Control Number: 1845–0011.

Type of Review: A revision of a currently approved ICR.

Respondents/Affected Public: Individuals and Households.

Total Estimated Number of Annual Responses: 704,903.

Total Estimated Number of Annual Burden Hours: 112,819.

Abstract: These forms serve as the means by which borrowers in the William D. Ford Federal Direct Loan (Direct Loan), Federal Family Education Loan (FFEL) and the Federal Perkins Loan (Perkins Loan) Programs may request deferment of repayment on their loans if they meet certain statutory and regulatory criteria. The U.S. Department of Education and other loan holders uses the information collected on these forms to determine whether a borrower meets the eligibility requirements for the specific deferment type being submitted. For greater simplicity and to make it easier to maintain consistency among the various forbearance forms, the Department is consolidating all the current forbearance forms into a single collection under OMB No. 1845–0011. This collection is merging the six currently approved deferment forms in 1845–0011 with the military deferment form currently approved under 1845–0080 and the cancer treatment deferment form currently approved under 1845–0154.

The Department is requesting a revision of the currently approved deferment forms. The proposed changes include the following:

Streamlining the forms by eliminating duplicative and obsolete information; reordering items to present information in a more logical order that is consistent between forms; using “plain language”

to present information more clearly and consistently; revising language as necessary to reflect regulatory changes made by the Final Rule published on November 1, 2022 (87 FR 65904) that eliminated the capitalization of unpaid interest following periods of forbearance effective July 1, 2023.

Dated: September 18, 2024.

Kun Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2024-21687 Filed 9-20-24; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF ENERGY

Privacy Act of 1974; System of Records

AGENCY: U.S. Department of Energy.

ACTION: Notice of a modified system of records.

SUMMARY: As required by the Privacy Act of 1974 and the Office of Management and Budget (OMB) Circulars A-108 and A-130, the Department of Energy (DOE or the Department) is publishing notice of a modification to an existing Privacy Act system of records. DOE proposes to amend System of Records DOE-10 Energy Employees Occupational Illness Compensation Program Act Files. This System of Records Notice (SORN) is being modified to align with new formatting requirements, published by OMB, and to ensure appropriate Privacy Act coverage of business processes and Privacy Act information. This notice also incorporates into the "Routine Uses" section changes required by amendments to The Energy Employees Occupational Illness Compensation Program Act (EEOICPA). While there are no substantive changes to the "Categories of Individuals" or "Categories of Records" sections covered by this SORN, substantive changes have been made to the "System Locations," "Routine Uses," and "Administrative, Technical and Physical Safeguards" sections to provide greater transparency. Changes to "Routine Uses" include new provisions related to responding to breaches of information held under a Privacy Act SORN as required by OMB's Memorandum M-17-12, "Preparing for and Responding to a Breach of Personally Identifiable Information" (January 3, 2017). Changes to routine uses pertaining to EEOICPA have been modified to remove two categories of

obsolete users due to the 2004 amendments that repealed the use of physician panels. Three routine uses have been consolidated into one to reduce redundancy. Language throughout the SORN has been updated to align with applicable Federal privacy laws, policies, procedures, and best practices.

DATES: This modified SORN will become applicable following the end of the public comment period on October 23, 2024 unless comments are received that result in a contrary determination.

ADDRESSES: Written comments should be sent to the DOE Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10102, 735 17th Street NW, Washington, DC 20503, and to Ken Hunt, Chief Privacy Officer, U.S. Department of Energy, 1000 Independence Avenue SW, Rm. 8H-085, Washington, DC 20585, by facsimile at (202) 586-8151, or by email at privacy@hq.doe.gov.

FOR FURTHER INFORMATION CONTACT: Ken Hunt, Chief Privacy Officer, U.S. Department of Energy, 1000 Independence Avenue SW, Rm. 8H-085, Washington, DC 20585, or by facsimile at (202) 586-8151, by email at privacy@hq.doe.gov, or by telephone at (240) 686-9485.

SUPPLEMENTARY INFORMATION: On January 9, 2009, DOE published a Compilation of its Privacy Act systems of records, which included System of Records DOE-10 Energy Employees Occupational Illness Compensation Program Act Files. This notice proposes amendments to the system locations section of that system of records by updating, removing, and adding addresses as appropriate. Addresses updated include: John A. Gordon Albuquerque Complex, Office of Science (Chicago and Oak Ridge Offices), Golden Field Offices, Lawrence Livermore National Laboratory, Lockheed Idaho Technical Center, Miamisburg Environmental Management Project, National Energy Technology Laboratory (Pittsburg, Morgantown, and Albany Offices), National Nuclear Security Administration (NNSA) Nevada Field Office, Oak Ridge Institute for Science and Education, Environmental Management Consolidated Business Center, Office of River Protection, Richland Operations Office, Savannah River Office, SLAC National Accelerator Laboratory, and Stanford Synchrotron Radiation Laboratory. Addresses removed include: Bettis Atomic Power Laboratory, Office of Energy, Efficiency and Renewable Energy (Boston and

Denver Offices), Hanford Environmental Health Foundation, Philadelphia Regional Office, Radiological and Environmental Health Laboratory, and Seattle Regional Office. Addresses added include: B&W Pantex, Office of Legacy Management, Technology Engineering Center, and Peek Street Facility. In the "Routine Uses" section, this modified notice deletes a previous routine use concerning efforts responding to a suspected or confirmed loss of confidentiality of information as it appears in DOE's compilation of its Privacy Act systems of records (January 9, 2009) and replaces it with one to assist DOE with responding to a suspected or confirmed breach of its records of Personally Identifiable Information (PII), modeled with language from OMB's Memorandum M-17-12, "Preparing for and Responding to a Breach of Personally Identifiable Information" (January 3, 2017). Further, this notice adds one new routine use to ensure that DOE may assist another agency or entity in responding to the other agency's or entity's confirmed or suspected breach of PII, as appropriate, as aligned with OMB's Memorandum M-17-12. Some changes have been made to the routine uses to accommodate 2004 and 2015 amendments to EEOICPA by Subtitle E of Division C of the Ronald W. Reagan National Defense Authorization Act for Fiscal Year 2005 (Pub. L. 108-375) and Carl Levin and Howard P. "Buck" McKeon National Defense Authorization Act for Fiscal Year 2015 (Pub. L. 113-291). "Categories of Records in the System" now includes individual medical records, payroll information/records, accident reports; badging records; workers' compensation records; security badge records; security records; industrial hygiene records. "Radiological and chemical" has been added to modify "exposure records." An administrative change required by the FOIA Improvement Act of 2016 extends the length of time a requestor is permitted to file an appeal under the Privacy Act from 30 to 90 days. Both the "System Locations" and "Administrative, Technical and Physical Safeguards" sections have been modified to reflect the Department's usage of cloud-based services for records storage. Language throughout the SORN has been updated to align with applicable Federal privacy laws, policies, procedures, and best practices.

SYSTEM NAME AND NUMBER:

DOE-10 Energy Employees Occupational Illness Compensation Program Act Files.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Systems leveraging this SORN may exist in multiple locations. All systems storing records in a cloud-based server are required to use government-approved cloud services and follow National Institute of Standards and Technology (NIST) security and privacy standards for access and data retention. Records maintained in a government-approved cloud server are accessed through secure data centers in the continental United States.

U.S. Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585.

U.S. Department of Energy, 19901 Germantown Road, Germantown, MD 20874–1290.

U.S. Department of Energy, John A. Gordon Albuquerque Complex, 24600 20th Street SE, Albuquerque, NM 87116.

U.S. Department of Energy, NNSA Naval Reactors Field Office, Pittsburgh Naval Reactors, P.O. Box 109, West Mifflin, PA 15122–0109.

U.S. Department of Energy, NNSA Naval Reactors Field Office, Schenectady Naval Reactors, P.O. Box 1069, Schenectady, NY 12301.

U.S. Department of Energy, Amarillo Site Operations, Highway 60, FM2373, Amarillo, TX 79177.

U.S. Department of Energy, Carlsbad Field Office, P.O. Box 3090, Carlsbad, NM 88221.

U.S. Department of Energy, Office of Science, Chicago Office, Consolidated Service Center, 9800 South Cass Avenue, Lemont, IL 60439.

U.S. Department of Energy, Fernald Environmental Management Project, 7400 Wiley Road, Cincinnati, OH 45030.

U.S. Department of Energy, General Atomics Site Office, 3550 General Atomic Court, B–7, Room 119, San Diego, CA 92121.

U.S. Department of Energy, Golden Field Office, 15013 Denver West Parkway, Golden, CO 80401.

U.S. Department of Energy, Idaho Operations Office, 1955 Fremont Avenue, Idaho Falls, ID 83415.

U.S. Department of Energy, Idaho National Engineering and Environmental Laboratory, CF 690 MS 4149, Scoville, ID 83415.

U.S. Department of Energy, Kansas City Site Office, 2000 East 95th Street, Kansas City, MO 64141–3202.

U.S. Department of Energy, NNSA Sandia Site Office, Pennsylvania & H Street, Albuquerque, NM 87185–5400.

U.S. Department of Energy, NNSA Sandia Site Office, 1515 Eubank Blvd. SE, Albuquerque, NM 87123.

U.S. Department of Energy, Knolls Atomic Power Laboratory, 2401 River Road, Niskayuna, NY 12309.

U.S. Department of Energy, Lawrence Berkeley National Laboratory, 1 Cyclotron Road, Berkeley, CA 94720.

U.S. Department of Energy, Lawrence Livermore National Laboratory, 7000 East Avenue, P.O. Box 808, L–1, Livermore, CA 94551–0808.

U.S. Department of Energy, Livermore Site Office, Nevada Test Site, University of California, P.O. Box 45, Mercury, NV 89023.

U.S. Department of Energy, The Office of Site Operations, 528 35th Street, Los Alamos, NM 87545.

U.S. Department of Energy, NNSA Los Alamos National Laboratory, SM #30 Bikini Road, Los Alamos, NM 87545.

U.S. Department of Energy, National Energy Technology Laboratory (Pittsburgh), 626 Cochran Mill Road, Pittsburgh, PA 15236.

U.S. Department of Energy, National Energy Technology Laboratory (Morgantown), 3610 Collins Ferry Road, Morgantown, WV 26505.

U.S. Department of Energy, National Energy Technology Laboratory (Albany), 1450 Queen Avenue SW, Albany, OR 97321.

U.S. Department of Energy, NNSA Nevada Field Office, 232 Energy Way, North Las Vegas, NV 89030.

U.S. Department of Energy, Nevada Test Site Mercury, Nevada, Building 111, P.O. Box 677, Mercury, NV 89023–0677.

Oak Ridge Institute for Science and Education (ORISE), 1299 Bethel Valley Road, Oak Ridge, TN 37830.

U.S. Department of Energy, Office of Science, Consolidated Service Center, P.O. Box 2001, Oak Ridge, TN 37831.

U.S. Department of Energy, Environmental Management Consolidated Business Center (EMCBC), 550 Main Street, Rm. 7–010, Cincinnati, OH 45202.

U.S. Department of Energy, Pacific Northwest National Laboratory, 902 Battelle Blvd., P.O. Box 999, Richland, WA 99352.

U.S. Department of Energy, Paducah Site Office, 5600 Hobbs Road, West Paducah, KY 42086.

U.S. Department of Energy, Portsmouth/Paducah Project Office, 3930 U.S. 23, Perimeter Road, Piketon, OH 45661.

U.S. Department of Energy, Office of River Protection, P.O. Box 450, Richland, WA 99352.

U.S. Department of Energy, Richland Operations Office, P.O. Box 550, Richland, WA 99352.

U.S. Department of Energy, Savannah River Operations Office, P.O. Box A, Aiken, SC 29801.

U.S. Department of Energy, SLAC National Accelerator Laboratory, 2575 Sand Hill Road, Menlo Park, CA 94025.

U.S. Department of Energy, Stanford Site Office, 2575 Sand Hill Road, B–41, MS: 8–A, Menlo Park, CA 94025.

U.S. Department of Energy, Stanford Synchrotron Radiation Lightsource, 2575 Sand Hill Road MS69, Menlo Park, CA 94025.

U.S. Department of Energy, Thomas Jefferson National Accelerator Facility, 12000 Jefferson Avenue, Newport News, VA 23606.

U.S. Department of Energy, Waste Isolation Pilot Project Office, P.O. Box 3090, Carlsbad, NM 88221.

U.S. Department of Energy, West Valley Demonstration Project, 10282 Rock Springs Road, West Valley, NY 14171–9799.

U.S. Department of Energy, B&W Pantex, Hwy. 60 & FM 2373, Bldg. 16–12, Amarillo, TX 79120.

U.S. Department of Energy, Office of Legacy Management, 2597 Legacy Way, Grand Junction, CO 81503.

U.S. Department of Energy, Technology Engineering Center, 4100 Guardian Street, Suite 160, Simi Valley, CA 93603.

U.S. Department of Energy, Peek Street Facility, Code NAVSEA 08U, Navy Sea System Command, 1240 Isaac Hull Avenue SE, Building 104, Washington Navy Yard, DC 20376–8036.

SYSTEM MANAGER(S):

Headquarters: U.S. Department of Energy, Office of Environment, Health, Safety and Security, 1000 Independence Avenue SW, Washington, DC 20585.

Field Offices: The managers of the Office of Environment, Health, Safety and Security of “Systems Locations” listed above are the system managers for their respective portions of this system.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 7101 *et seq.*; 50 U.S.C. 2401 *et seq.*; The Energy Employees Occupational Illness Compensation Program Act of 2000, Public Law 106–398, as amended, and Executive Order 13179, “Providing Compensation to America’s Nuclear Weapons Workers.”

PURPOSE(S) OF THE SYSTEM:

Records in this system are collected and maintained by the Department to facilitate resolution of claims under the EEOICPA and to comply with the provisions of the EEOICPA, specifically the provisions of the Act that govern DOE’s information sharing requirements.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system of records covers individuals or their survivors who claim benefits under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA). These individuals include, but are not limited to, federal employees or survivors of federal employees, employees or survivors of employees of the Department of Energy (including NNSA), its predecessor agencies, and their contractors and subcontractors.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system of records is created by DOE in response to requests from the Department of Labor (DOL), the National Institute for Occupational Safety and Health (NIOSH), and claimants for information for the adjudication of claims. The records are compiled as part of DOE's responsibilities under the EEOICPA. Claim forms filed by or on behalf of claimants or their survivors seeking benefits under the EEOICPA; employment records; radiological and chemical exposure records; medical reports; individual medical records; personnel security questionnaires; payroll information/records; safety records or other incident reports, including but not limited to area sampling data, accidental releases, explosions, spills, etc.; accident reports; badging records; workers' compensation records; security badge records; security records; industrial hygiene records; and correspondence from individuals, DOL, and NIOSH.

RECORD SOURCE CATEGORIES:

Records in this system will be obtained from the individual who is the subject of the records; physicians and other medical professionals; medical institutions; state and federal workers' compensation offices; family members of the subject; attorneys representing the individual; individuals' employers, including DOE and its contractors and subcontractors; medical laboratories; and other state and federal agencies.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

1. A record from this system may be disclosed as a routine use to current or former DOE contractors in performance of their contracts, and their officers and employees who have a need for the record in the performance of their duties. Those provided information under this routine use are subject to the same limitations applicable to Department officers and employees under the Privacy Act.

2. A record from this system may be disclosed as a routine use to DOE financial assistance or cooperative agreement recipients in performance of their financial assistance agreements, and their officers and employees who have a need for the record in the performance of their duties.

3. A record from this system may be disclosed as a routine use to other state and federal agencies or entities whose mission entails reviewing or managing workers' compensation claims or administering other benefits programs.

4. A record from this system may be disclosed as a routine use to members of DOE's Former Worker Medical Screening Program, DOE or DOL advisory board members, and cooperative agreement holders of the Department of Labor, the Department of Health and Human Services, the Department of Justice, and other Federal agencies and their components to implement the Federal compensation program established by the Energy Employees Occupational Illness Compensation Program Act, for the purpose of outreach and assisting in the adjudication or processing of a claim under that Act.

5. A record from this system may be disclosed as a routine use for the purpose of an investigation, settlement of claims, or the preparation and conduct of litigation to (1) persons representing the Department in the investigation, settlement or litigation, and to individuals assisting in such representation; (2) others involved in the investigation, settlement, and litigation, and their representatives and individuals assisting those representatives; (3) witnesses, potential witnesses, or their representatives and assistants; and (4) any other persons who possess information pertaining to the matter when it is necessary to obtain information or testimony relevant to the matter.

6. A record from this system may be disclosed as a routine use to the Department of Justice when DOE determines that an individual may be eligible for compensation under the Radiation Exposure and Compensation Act of 1990 (42 U.S.C. 2210, note, and as further clarified in title 28 Code of Federal Regulations (CFR) part 79), a compensation program administered by the Department of Justice.

7. A record from this system may be disclosed as a routine use to the appropriate local, tribal, state or federal agency when the record alone or in conjunction with other information, indicates a violation or potential violation of law whether civil, criminal, or regulatory in nature.

8. A record from this system may be disclosed as a routine use to a member of Congress submitting a request involving a constituent when the constituent has requested assistance from the member concerning the subject matter of the record. The member of Congress must provide a copy of the constituent's signed request for assistance.

9. A record from this system may be disclosed as a routine use to appropriate agencies, entities, and persons when (1) the Department suspects or has confirmed that there has been a breach of the system of records; (2) the Department has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, DOE (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Department's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

10. A record from this system may be disclosed as a routine use to another Federal agency or Federal entity, when the Department determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records may be stored as paper records, microfilm, or electronic media.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved by the name of the individual, Social Security number, or employee number.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Retention and disposition of these records is in accordance with the National Archives and Records Administration-approved records disposition schedules with a retention of 250 years.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Electronic records may be secured and maintained on a cloud-based

software server and operating system that resides in Federal Risk and Authorization Management Program (FedRAMP) and Federal Information Security Modernization Act (FISMA) hosting environment. Data located in the cloud-based server is firewalled and encrypted at rest and in transit. The security mechanisms for handling data at rest and in transit are in accordance with DOE encryption standards. Records are protected from unauthorized access through the following appropriate safeguards:

- **Administrative:** Access to all records is limited to lawful government purposes only, with access to electronic records based on role and either two-factor authentication or password protection. The system requires passwords to be complex and to be changed frequently. Users accessing system records undergo frequent training in Privacy Act and information security requirements. Security and privacy controls are reviewed on an ongoing basis.

- **Technical:** Computerized records systems are safeguarded on Departmental networks configured for role-based access based on job responsibilities and organizational affiliation. Privacy and security controls are in place for this system and are updated in accordance with applicable requirements as determined by NIST and DOE directives and guidance.

- **Physical:** Computer servers on which electronic records are stored are located in secured Department facilities, which are protected by security guards, identification badges, and cameras. Paper copies of all records are locked in file cabinets, file rooms, or offices and are under the control of authorized personnel. Access to these facilities is granted only to authorized personnel and each person granted access to the system must be an individual authorized to use or administer the system.

RECORD ACCESS PROCEDURES:

The Department follows the procedures outlined in 10 CFR 1008.4. Valid identification of the individual making the request is required before information will be processed, given, access granted, or a correction considered, to ensure that information is processed, given, corrected, or records disclosed or corrected only at the request of the proper person.

CONTESTING RECORD PROCEDURES:

Any individual may submit a request to the System Manager and request a copy of any records relating to them. In accordance with 10 CFR 1008.11, any

individual may appeal the denial of a request made by him or her for information about or for access to or correction or amendment of records. An appeal shall be filed within 90 calendar days after receipt of the denial. When an appeal is filed by mail, the postmark is conclusive as to timeliness. The appeal shall be in writing and must be signed by the individual. The words "PRIVACY ACT APPEAL" should appear in capital letters on the envelope and the letter. Appeals of denials relating to records maintained in government-wide system of records reported by Office of Personnel Management (OPM), shall be filed, as appropriate, with the Assistant Director for Agency Compliance and Evaluation, OPM, 1900 E Street NW, Washington, DC 20415. All other appeals relating to DOE records shall be directed to the Director, Office of Hearings and Appeals (OHA), 1000 Independence Avenue SW, Washington, DC 20585.

NOTIFICATION PROCEDURES:

In accordance with the DOE regulation implementing the Privacy Act, 10 CFR part 1008, a request by an individual to determine if a system of records contains information about themselves should be directed to the U.S. Department of Energy, Headquarters, Privacy Act Officer. The request should include the requester's complete name and the time period for which records are sought.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

This SORN was last published in the **Federal Register**, 74 FR 1008–1011, on January 9, 2009.

Signing Authority

This document of the Department of Energy was signed on September 13, 2024, by Ann Dunkin, Senior Agency Official for Privacy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on September 18, 2024.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2024–21700 Filed 9–20–24; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Agency Information Collection Revision; Correction

AGENCY: U.S. Department of Energy.

ACTION: Notice correction.

SUMMARY: The Department of Energy (DOE) published in the **Federal Register** on August 12, 2024, a notice of a Proposed Agency Information Collection Revision. DOE's Office of the Associate General Counsel for Contactor Human Resources had submitted to the Office of Management and Budget (OMB) for clearance, a proposal for a three-year extension, with changes, of a collection of information under the provisions of the Paperwork Reduction Act of 1995. This document makes a correction to that notice (a miscalculation of the burden hours).

FOR FURTHER INFORMATION CONTACT: Oluwatosin Fadarey, Attorney-Adviser (Labor), GC–63, U.S. Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585.

Email: oluwatosin.fadarey@hq.doe.gov

Phone: (240) 751–3745.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of August 12, 2024, FR Doc. 2024–17889 (89 FR 65617), on page 65617, in the second column, under the **SUPPLEMENTARY INFORMATION** section, the following corrections are made:

- (3) *Type of Review:* Revision;
 - (7) *Annual Estimated Number of Burden Hours:* 300;
 - (8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* \$15,804.
- Statutory Authority:* 29 CFR 5.7(b).

Signing Authority

This document of the Department of Energy was signed on September 17, 2024, by John T. Lucas, Deputy General Counsel for Business Transactions, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been

authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on September 17, 2024.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2024-21657 Filed 9-20-24; 8:45 am]

BILLING CODE 6450-01-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2024-0395; FRL-12083-01-OCSPP]

Agency Information Collection Activities; Proposed Renewal of an Existing ICR Collection and Request for Comment; Pesticide Environmental Stewardship Program Annual Measures Reporting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA), this document announces the availability of and solicits public comment on the following Information Collection Request (ICR) that EPA is planning to submit to the Office of Management and Budget (OMB): “Pesticide Environmental Stewardship Program Annual Measures Reporting,” identified by EPA ICR No. 2415.05 and OMB Control No. 2070-0188. This ICR represents a renewal of an existing ICR that is currently approved through July 31, 2025. Before submitting the ICR to OMB for review and approval under the PRA, EPA is soliciting comments on specific aspects of the information collection that is summarized in this document. The ICR and accompanying material are available in the docket for public review and comment.

DATES: Comments must be received on or before November 22, 2024.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2024-0395, through the Federal eRulemaking Portal at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting or visiting

the docket, along with more information about dockets generally, is available at <https://www.epa.gov/>.

FOR FURTHER INFORMATION CONTACT:

Carolyn Siu, Mission Support Division (7602M), Office of Program Support, Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (703) 347-0159; email address: siu.carolyn@epa.gov.

SUPPLEMENTARY INFORMATION:

I. What information is EPA particularly interested in?

Pursuant to PRA section 3506(c)(2)(A) (44 U.S.C. 3506(c)(2)(A)), EPA specifically solicits comments and information to enable it to:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility.
2. Evaluate the accuracy of the Agency’s estimates of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
3. Enhance the quality, utility, and clarity of the information to be collected.
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

II. What information collection activity or ICR does this action apply to?

Title: Pesticide Environmental Stewardship Program Annual Measures Reporting.

EPA ICR No.: 2415.05.

OMB Control No. 2070-0188.

ICR status: This ICR is currently approved through July 31, 2025. Under the PRA, 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 OMB control numbers for EPA’s regulations in title 40 of the Code of Federal Regulations (CFR), after appearing in the **Federal Register** when approved, are displayed

either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: This information collection request (ICR) collects information to establish partner membership, develop stewardship strategies, measure progress towards stewardship goals, and award incentives. PESP is an EPA partnership program that encourages the use of integrated pest management (IPM) strategies to reduce pests and pesticide risks. IPM is an approach that involves making the best choices from among a series of pest management practices that are both economical and pose the least possible hazard to people, property, and the environment.

Burden statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 51,562 hours. Burden is defined in 5 CFR 1320.3(b).

The ICR, which is available in the docket along with other related materials, provides a detailed explanation of the collection activities and the burden estimate that is only briefly summarized here:

Respondents/affected entities: Entities potentially affected are Pesticide user companies and organizations, or entities that practice IPM or promote the use of IPM through education and training. A list of potentially affected entities with North American Industrial Classification System (NAICS) codes provided to assist in determining potential applicability in question 12.

Respondent’s obligation to respond: Voluntary.

Forms: 9600-1, 9600-02 and 9600-03.

Frequency of response: Annual and on occasion.

Total estimated number of potential respondents: 456.

Total estimated average number of responses for each respondent: 1.

Total estimated annual burden hours: 51,297 hours.

Total estimated annual respondent costs: \$ 3,884,334, which includes \$ 0 for capital investment or maintenance and operational costs.

III. Are there changes in the estimates from the last approval?

EPA expects an increase in the number of potential respondents from 437 to 456, with a corresponding burden increase. This change is based on an anticipated increase in entities participating in the PESP Program. There is also an increase in industry cost by \$382,790, which reflects the

increase in burden and EPA's updated estimates according to the latest wage rates. These changes qualify as adjustments.

IV. What is the next step in the process for this ICR?

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. EPA will issue another **Federal Register** document pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: September 17, 2024.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2024-21711 Filed 9-20-24; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-EPA-HQ-OAR-2024-0345]
[FRL-12128-01-OAR]

Alternative Methods for Calculating Off-Cycle Credits Under the Light-Duty Vehicle Greenhouse Gas Emissions Program: Application From Jaguar Land Rover North America, LLC

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is requesting comment on an application from Jaguar Land Rover North America, LLC ("JLR") for off-cycle carbon dioxide (CO₂) credits under EPA's light-duty vehicle greenhouse gas emissions standards. "Off-cycle" emission reductions can be achieved by employing technologies that result in real-world benefits, but where that benefit is not adequately captured on the test procedures used by manufacturers to demonstrate compliance with emission standards. EPA's light-duty vehicle greenhouse gas program acknowledges these benefits by giving automobile manufacturers several options for generating "off-cycle" CO₂ credits. Under the regulations, a manufacturer may apply for CO₂ credits for off-cycle technologies that result in off-cycle benefits. In these cases, a manufacturer must provide EPA with a

proposed methodology for determining the real-world off-cycle benefit. JLR submitted their application describing a methodology for determining off-cycle credits from the technology described in their application. Pursuant to applicable regulations, EPA is making this off-cycle credit calculation methodology available for public comment.

DATES: Comments must be submitted on or before October 23, 2024.

ADDRESSES: Submit your comments referencing Docket ID No. EPA-HQ-OAR-2024-0345 online using www.regulations.gov (our preferred method), by email to a-and-r-Docket@epa.gov or by mail to: EPA Docket Center, Environmental Protection Agency, Mailcode 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT:

David Wright, Environmental Protection Specialist, Office of Transportation and Air Quality, Implementation, Analysis and Compliance Division, U.S. Environmental Protection Agency, 2000 Traverwood Drive, Ann Arbor, MI 48105. Telephone: (734) 214-4467. Email address: wright.davida@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

EPA's light-duty vehicle greenhouse gas (GHG) program provides three pathways by which a manufacturer may accrue off-cycle carbon dioxide (CO₂) credits for those technologies that achieve CO₂ reductions in the real world but where those reductions are not adequately captured on the test used to determine compliance with the CO₂ standards, and which are not otherwise reflected in the standards' stringency. The first pathway is a predetermined list of credit values for specific off-cycle technologies that may be used beginning in model year 2014.¹ This pathway allows manufacturers to use conservative credit values established by EPA for a wide range of technologies, with minimal data submittal or testing requirements, if the technologies meet EPA regulatory definitions. In cases where the off-cycle technology is not on the menu but additional laboratory testing can demonstrate emission

benefits, a second pathway allows manufacturers to use a broader array of emission tests (known as "5-cycle" testing because the methodology uses five different testing procedures) to demonstrate and justify off-cycle CO₂ credits.² The additional emission tests allow emission benefits to be demonstrated over some elements of real-world driving not adequately captured by the GHG compliance tests, including high speeds, hard accelerations, and cold temperatures. These first two methodologies were completely defined through notice and comment rulemaking and therefore no additional process is necessary for manufacturers to use these methods. The third and last pathway allows manufacturers to seek EPA approval to use an alternative methodology for determining the off-cycle CO₂ credits.³ This option is only available if the benefit of the technology cannot be adequately demonstrated using the 5-cycle methodology. Manufacturers may also use this option to demonstrate reductions that exceed those available via use of the predetermined list.

Under the regulations, a manufacturer seeking to demonstrate off-cycle credits with an alternative methodology (*i.e.*, under the third pathway described above) must describe a methodology that meets the following criteria:

- Use modeling, on-road testing, on-road data collection, or other approved analytical or engineering methods;
- Be robust, verifiable, and capable of demonstrating the real-world emissions benefit with strong statistical significance;
- Result in a demonstration of baseline and controlled emissions over a wide range of driving conditions and number of vehicles such that issues of data uncertainty are minimized;
- Result in data on a model type basis unless the manufacturer demonstrates that another basis is appropriate and adequate.

Further, the regulations specify the following requirements regarding an application for off-cycle CO₂ credits:

- A manufacturer requesting off-cycle credits must develop a methodology for demonstrating and determining the benefit of the off-cycle technology and carry out any necessary testing and analysis required to support that methodology.
- A manufacturer requesting off-cycle credits must conduct testing and/or prepare engineering analyses that demonstrate the in-use durability of the

² See 40 CFR 86.1869-12(c).

³ See 40 CFR 86.1869-12(d).

¹ See 40 CFR 86.1869-12(b).

technology for the full useful life of the vehicle.

- The application must contain a detailed description of the off-cycle technology and how it functions to reduce CO₂ emissions under conditions not represented on the compliance tests.

- The application must contain a list of the vehicle model(s) which will be equipped with the technology.

- The application must contain a detailed description of the test vehicles selected and an engineering analysis that supports the selection of those vehicles for testing.

- The application must contain all testing and/or simulation data required under the regulations, plus any other data the manufacturer has considered in the analysis.

Finally, the alternative methodology must be approved by EPA prior to the manufacturer using it to generate credits. As part of the review process defined by regulation, the alternative methodology submitted to EPA for consideration must be made available for public comment.⁴ EPA will consider public comments as part of its final decision to approve or deny the request for off-cycle credits.

II. Off-Cycle Credit Application

A. 48 Volt Efficient Motor-Generator Combined With a 48 Volt/12 Volt DC/DC Converter

JLR is applying for off-cycle GHG credits for the use of a 48 Volt efficient motor-generator combined with a 48 volt/12 volt DC/DC converter. The JLR technology consists of two components, a 48-volt motor-generator which is either belt driven or connected to the crankshaft of an internal combustion engine, and a 48 volt/12 volt DC/DC converter. The 48 volt motor generator provides a couple of functions, it can operate as a starter motor and crank the engine and it also can operate as a generator converting mechanical energy into electrical energy. The efficiency of the 48 volt generator when belt driven is in the range of 80 to 85% and when connected to the crankshaft of an engine it can be as high as 90 to 95%. Once generated the 48 volt electricity needs to be converted to 12 volts for use by the 12 volt electronics in the vehicle. The conversion of the 48 volt electricity to 12 volt is performed by the second device associated with this technology, a DC-DC converter. Converting 48 volt electricity to 12 volt electricity produces an energy loss which also needs to be measured to determine the overall efficiency of the combined 48 volt

motor-generator and DC-DC converter. This application is only for determining the off-cycle benefit of the generator portion of the technology.

JLR is the first manufacturer to submit a complete alternative method off-cycle GHG application for a 48 volt motor-generator combined with a 48 volt/12 volt DC-DC converter.

JLR is applying for credits for the 2023 and later model years for vehicles sold in the U.S. and equipped with the 48 volt efficient motor-generator combined with a 48 volt/12 volt DC/DC converter. JLR is requesting a credit value of 1.6 grams/mile. Details of the testing and analysis can be found in the manufacturer's application.

III. EPA Decision Process

EPA has reviewed the applications for completeness and is now making the applications available for public review and comment as required by the regulations. The off-cycle credit applications submitted by the manufacturers (with confidential business information redacted) have been placed in the public docket (see **ADDRESSES** section above) and on EPA's website at <https://www.epa.gov/ve-certification/compliance-information-light-duty-greenhouse-gas-ghg-standards>.

EPA is providing a 30-day comment period on this application for off-cycle credits described in this notice, as specified by the regulations. The manufacturer may submit a written rebuttal of comments for EPA's consideration or may revise an application in response to comments. After reviewing any public comments and any rebuttal of comments submitted by manufacturers, EPA will make a final decision regarding the credit request. EPA will make its decision available to the public by placing a decision document (or multiple decision documents) in the docket and on EPA's website at the same manufacturer-specific pages shown above.

Dated: September 18, 2024.

Byron Bunker,

Director, Implementation, Analysis and Compliance Division, Office of Transportation and Air Quality.

[FR Doc. 2024-21713 Filed 9-20-24; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OAR-2024-0350; FRL 12138-02-OAR]

Use of Advanced and Emerging Technologies for Quantification of Annual Facility Methane Emissions Under the Greenhouse Gas Reporting Program

AGENCY: Environmental Protection Agency (EPA)

ACTION: Notice; extension of public comment period.

SUMMARY: On August 29, 2024, the Environmental Protection Agency (EPA) published a request for information (RFI) on the "Use of Advanced and Emerging Technologies for Quantification of Annual Facility Methane Emissions Under the Greenhouse Gas Reporting Program". The EPA is extending the comment period.

DATES: The comment period for the document published on August 29, 2024, at 89 FR 70177, is extended. Comments must be received on or before November 27, 2024.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OAR-2024-0350, to the Federal Portal: <https://www.regulations.gov>. Follow online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. Do not submit electronically any information you consider to be Confidential Business Information (CBI). EPA may publish any comment received to its public docket, submitted, or sent via email. For additional submission methods, the full EPA public comment policy, information about CBI, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT:

Vasco Roma, Environmental Protection Agency, Office of Air and Radiation, Office of Atmospheric Protection, Climate Change Division; telephone number: 202-564-1662; email address: Roma.Vasco@epa.gov.

SUPPLEMENTARY INFORMATION: On August 29, 2024, the EPA published an RFI on the "Use of Advanced and Emerging Technologies for Quantification of Annual Facility Methane Emissions Under the Greenhouse Gas Reporting Program". The public comment for this RFI was scheduled to end on October 28, 2024. In response to multiple extension requests received to date, the EPA is extending that deadline to

⁴ See 40 CFR 86.1869-12(d)(2).

November 27, 2024. This extension will provide the general public with additional time for comment.

Sharyn Lie,

Director, Climate Change Division.

[FR Doc. 2024–21633 Filed 9–20–24; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1265; FR ID 245960]

Information Collection Being Submitted for Review and Approval to Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Pursuant to the Small Business Paperwork Relief Act of 2002, the FCC seeks specific comment on how it might “further reduce the information collection burden for small business concerns with fewer than 25 employees.” The Commission may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments and recommendations for the proposed information collection should be submitted on or before October 23, 2024.

ADDRESSES: Comments should be sent to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. Your comment must be submitted into www.reginfo.gov. per the above instructions for it to be considered. In addition to submitting in www.reginfo.gov also send a copy of your comment on the proposed information collection to Nicole Ongele, FCC, via email to PRA@fcc.gov and to Nicole.Ongele@fcc.gov. Include in the

comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Nicole Ongele at (202) 418–2991. To view a copy of this information collection request (ICR) submitted to OMB: (1) go to the web page <http://www.reginfo.gov/public/do/PRAMain>, (2) look for the section of the web page called “Currently Under Review,” (3) click on the downward-pointing arrow in the “Select Agency” box below the “Currently Under Review” heading, (4) select “Federal Communications Commission” from the list of agencies presented in the “Select Agency” box, (5) click the “Submit” button to the right of the “Select Agency” box, (6) when the list of FCC ICRs currently under review appears, look for the Title of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the FCC invited the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission’s burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology. Pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), the FCC seeks specific comment on how it might “further reduce the information collection burden for small business concerns with fewer than 25 employees.”

OMB Control Number: 3060–1265.

Title: Administrative Order—Performance Testing Measures.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit.

Number of Respondents and Responses: 1,705 unique respondents; 7,681 responses.

Estimated Time per Response: 15–23 hours.

Frequency of Response: Biennial reporting requirements, quarterly reporting requirements and annual reporting requirements.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 151–154, 155, 201–206, 214, 218–220, 251, 252, 254, 256, 303(r), 332, 403, 405, 410, and 1302.

Total Annual Burden: 170,620 hours.

Total Annual Cost: No cost.

Needs and Uses: In the *USF/ICC Transformation Order*, the Commission laid the groundwork for today’s universal service programs providing \$4.5 billion in support for broadband internet deployment in high-cost areas. *Connect America Fund, et al.*, WC Docket No. 10–90, et al., Report and Order and Further Notice of Proposed Rulemaking, 26 FCC Rcd 17663 (2011) (*USF/ICC Transformation Order*). The *USF/ICC Transformation Order* required, among other things, that high-cost universal service recipients “test their broadband networks for compliance with speed and latency metrics and certify to and report the results to the Universal Service Administrative Company (USAC) on an annual basis.” *Id.* at 17705, para. 109. Pursuant to the Commission’s direction in that Order, the Wireline Competition Bureau, the Wireless Telecommunications Bureau, and the Office of Engineering and Technology (the Bureaus and OET) adopted more specific methodologies for such testing in the *Performance Measures Order*. See generally *Performance Measures Order*. See also 47 CFR 54.313(a)(6) (requiring that recipients of high-cost support provide “[t]he results of network performance tests pursuant to the methodology and in the format determined by the Wireline Competition Bureau, Wireless Telecommunications Bureau, and Office of Engineering and Technology”). Addressing petitions for reconsideration, the Bureaus and OET adopted certain modifications and clarifications to the requirements pertaining to high-latency bidders in the Connect America Fund (CAF) Phase II auction, and the Commission refined the general testing requirements further. See generally *Connect America Fund*, WC Docket No. 10–90, Order on Reconsideration, DA 19–911 (WCB/WTB/OET 2019) (*Satellite-Related Performance Measures Order*); *Performance Measures Reconsideration Order*. In the *High Cost Administrative Order*, the Commission adopted a quarterly reporting and certification

schedule, replacing the previous annual requirement, such that all carriers receiving high-cost support are required to report and certify their quarterly performance testing results within two weeks, rather than within one week, after the end of the quarter in which the tests are conducted. *See High Cost Administrative Order*, FCC 25–87, para. 138. Accordingly, this collection includes the requirements for testing speed and latency, and reporting and certifying such performance measures within two weeks after the end of each quarter to ensure that carriers are meeting the public interest obligations associated with their receipt of high-cost universal service support.

Carriers will identify, from among the locations they have already submitted and certified in USAC's High Cost Universal Broadband (HUBB) portal, the locations where they have an active subscriber (deployment locations are reported under OMB Control Number 3060–1228, and active locations will be reported under this control number). From those subscriber locations, USAC will then select a random sample from which the carrier will be required to perform testing for speed and latency. Carriers that do not provide location information in the HUBB will use a randomization tool provided by USAC to select a random sample of locations for testing. Due to the rule changes that the Commission adopted on the *High Cost Administrative Order*, the carrier will then be required to submit to USAC the results of the testing on a quarterly basis. The quarterly filing will include the testing results from the prior quarter. The carrier's sample for each service tier (e.g. 10 Mbps/1 Mbps, 25 Mbps/3 Mbps) shall be regenerated every two years. During the two-year cycle, carriers will have the ability to add and remove subscriber locations if necessary, e.g., as subscribership changes. Also, in July 2023, the Commission adopted the Enhanced Alternative-Connect America Cost Model (E–ACAM) support mechanism, a new model-based offer to existing Alternative-Connect America Cost Model (A–CAM) I, A–CAM II, and Connect America Fund Broadband Loop Support (CAF BLS) carriers. *See Connect America Fund: A National Broadband Plan for Our Future High-Cost Universal Service Support et al.*, WC Docket No. 10–90 et al., Report and Order, Notice of Proposed Rulemaking, and Notice of Inquiry, FCC 23–60, at 23–24, para. 49 (July 24, 2023) (*Enhanced A–CAM Order*). Revisions proposed include (1) a process for E–

ACAM carriers to get a performance measures testing sample from non-HUBB reported locations, and (2) and reporting and certifying such performance measures within two weeks after the end of each quarter. The proposed revisions also include the retitling of this collection from “Connect America Fund—Performance Testing Measures” to “Administrative Order—Performance Testing Measures.” The Commission therefore proposes to revise this information collection to reflect these modified requirements.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2024–21651 Filed 9–20–24; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meetings

FEDERAL REGISTER CITATION NOTICE OF PREVIOUS ANNOUNCEMENT:

89 FR 75540.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING:

Thursday, September 19, 2024 at 10:00 a.m.

Hybrid Meeting: 1050 First Street NE, Washington, DC (12th Floor) and Virtual.

CHANGE IN THE MEETING:

The following item was also discussed:

Proposed Referral of Questions on Dependent Care to Regulations Committee

CONTACT PERSON FOR MORE INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

(Authority: Government in the Sunshine Act, 5 U.S.C. 552b)

Laura E. Sinram,

Secretary and Clerk of the Commission.

[FR Doc. 2024–21846 Filed 9–19–24; 4:15 pm]

BILLING CODE 6715–01–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, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than October 23, 2024.

A. Federal Reserve Bank of Richmond (Brent B. Hassell, Assistant Vice President) P.O. Box 27622, Richmond, Virginia 23261. Comments can also be sent electronically to Comments.applications@rich.frb.org:

1. *Varn Financial Corporation, Ehrhardt, South Carolina*; to become a bank holding company by acquiring Enterprise Bank of South Carolina, also of Ehrhardt, South Carolina.

B. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414. Comments can also be sent electronically to Comments.applications@chi.frb.org:

1. *Security Midwest Bancorp, Inc., Springfield, Illinois*; to become a bank holding company by acquiring Security Bank, S.B. (Bank), Springfield, Illinois, upon the conversion of Bank from mutual to stock form.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2024–21683 Filed 9–20–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Fees for Cruise Ship Operational Sanitation, Construction, and Renovation Inspections

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS) announces fees for vessel sanitation inspections for fiscal year (FY) 2025. These inspections are conducted by HHS/CDC's Vessel Sanitation Program (VSP). VSP helps the cruise line industry fulfill its responsibility for developing and implementing comprehensive sanitation programs to minimize the risk for environmentally associated illnesses and hazards. Every vessel that has a foreign itinerary and carries 13 or more passengers is subject to twice-yearly unannounced operations inspections and, when necessary, reinspection.

DATES: These fees apply to inspections conducted from October 13, 2024, through September 30, 2025.

FOR FURTHER INFORMATION CONTACT: CAPT Luis Rodriguez, Chief, Vessel Sanitation Program, National Center for Environmental Health, Centers for Disease Control and Prevention, 4770 Buford Highway NE, MS 106–6, Atlanta, Georgia 30341–3717; phone: 800–323–2132; email: vsp@cdc.gov.

SUPPLEMENTARY INFORMATION:

Purpose and Background

HHS/CDC established the Vessel Sanitation Program (VSP) in the 1970s as a cooperative activity with the cruise ship industry. VSP helps the cruise ship industry prevent and control the introduction and spread of environmentally associated illnesses and hazards on cruise ships. VSP operates under the authority of the Public Health Service Act (Section 361 of the Public Health Service Act; 42 U.S.C. 264, “Control of Communicable Diseases”). Regulations found at 42 CFR 71.41 (Foreign Quarantine—Requirements Upon Arrival at U.S. Ports: Sanitary Inspection; General Provisions) state that carriers arriving at U.S. ports from foreign areas are subject to sanitary inspections to determine potential rodent, insect, or other vermin infestations; contaminated food or water; or other sanitary conditions requiring measures to prevent introduction or spread of communicable diseases.

The FY 2025 fee schedule reflects increases to cover costs to operate and

improve the program. Travel expenses and other costs have increased, and larger ships and more complex features mean more inspectors are needed for each inspection. Fees charged for inspections also support many additional VSP services beyond inspections (plan reviews, equipment reviews, technical assistance, epidemiological investigations, and outbreak response activities). VSP will continue to enhance customer service to cruise lines and shipyards as well as public health efforts onboard by offering additional value-added services requested by industry partners such as modernization of VSP's data systems to increase functionality and efficiency and updates to VSP training platforms.

Additionally, the fee schedule will be restructured from seven categories to four categories. This new structure addresses comments from industry in July 2019 and more accurately reflects the number of inspectors and inspector-hours needed to perform an inspection.

The fee schedule for sanitation inspections of passenger cruise ships by VSP was first published in the **Federal Register** on November 24, 1987 (52 FR 45019). HHS/CDC began collecting fees on March 1, 1988. The fee schedule was most recently published in the **Federal Register** on August 14, 2023 (88 FR 55048). This notice announces fees for inspections conducted during FY 2025 (beginning on October 13, 2024, through September 30, 2025). The fee schedule for FY 2025 is presented in Appendix A.

The following formula will be used to determine the fees:

$$\text{Average cost per inspection} = \frac{\text{Total cost of VSP}}{\text{Weighted number of annual inspections}}$$

Total cost of VSP = Total cost of operating the program, such as administration, travel, staffing, sanitation inspections, and outbreak response.

Weighted number of annual inspections = Total number of ships and inspections per year accounting for vessel size, number of inspectors

needed for vessel size, travel logistics to conduct inspections, and vessel location and arrivals in U.S. jurisdiction per year.

Fee

The fee schedule (Appendix A) applies to inspections conducted from October 13, 2024, through September 30, 2025.

Applicability

The fees will apply to all passenger cruise vessels for which inspections are conducted as part of HHS/CDC's VSP.

Noah Aleshire,
Chief Regulatory Officer, Centers for Disease Control and Prevention.

Appendix A

FEE SCHEDULE FOR EACH VESSEL SIZE

Vessel size (GT ¹)	Operational inspection ² fee (US\$)	Construction and renovation inspection ³ fee (US\$)
Tier 1 (<30,000 GT)	8,073	16,146
Tier 2 (30,001–110,000 GT)	16,146	32,292
Tier 3 (110,001–180,000 GT)	32,292	64,584

FEE SCHEDULE FOR EACH VESSEL SIZE—Continued

Vessel size (GT ¹)	Operational inspection ² fee (US\$)	Construction and renovation inspection ³ fee (US\$)
Tier 4 (>180,001 GT)	64,584	129,168

¹ Gross tonnage in cubic feet, as shown in *Lloyd's Register of Shipping* (<https://www.lr.org/en/>).

² Operations inspections and re-inspections involve the same procedures and require the same amount of time, so they are charged at the same rates.

³ Construction and renovation inspections require at least twice the amount of time as operations inspections, so they are charged double the rates.

[FR Doc. 2024–21786 Filed 9–20–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10170 and CMS–10156]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by October 23, 2024.

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.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Retiree Drug Subsidy Payment Request and Instructions; *Use:* Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and implementing regulations at 42 CFR part

423 subpart R plan sponsors (e.g., employers, unions) who offer prescription drug coverage meeting specified criteria to their qualified covered retirees are eligible to receive a 28% subsidy for allowable drug costs, through the Retiree Drug Subsidy (RDS) Program. Section 423.886 describes the payment methods, including the provision of necessary information. The information provided in the payment request provides CMS with the information needed to pay RDS sponsors the subsidy.

The application process for the RDS is a completely electronic process (100%). The basis for the decision for adopting this means of collection was to maximize efficiency. The only instance when hard copy/paper applications can be submitted is when the RDS Center is experiencing technical difficulties. The Plan Sponsor completes and submits the RDS application (including the Plan Sponsor's Authorized Representative's electronic signature) on-line, via the secure RDS Secure website, which is accessed at <https://www.rds.cms.hhs.gov>. *Form Number:* CMS–10170 (OMB control number: 0938–0977); *Frequency:* Yearly; *Affected Public:* Private; Business or other for-profits, and Not-for Profits; *Number of Respondents:* 1,245; *Number of Responses:* 1,245; *Total Annual Hours:* 187,995. (For questions regarding this collection, contact Ivan Iveljic at 410–786–3312 or Ivan.iveljic@cms.hhs.gov.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Retiree Drug Subsidy (RDS) Application and Instructions; *Use:* Under § 1860D–22 of the Social Security Act (Act), added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and implementing regulations at 42 CFR part 423 subpart R, Plan Sponsors (e.g., employers or unions) who offer prescription drug coverage to their qualified covered retirees are eligible to receive a 28% subsidy for allowable drug costs.

CMS has contracted with an outside vendor to assist in the administration of the RDS program; this effort is called the RDS Center. Plan Sponsors will apply on-line for the retiree drug subsidy by logging on to the RDS Secure website. 42 CFR 423.844 describes the requirement for qualified retiree prescription drug plans who want to receive the retiree drug subsidy. Once the Plan Sponsor submits the RDS application via the RDS Secure website (and a valid initial retiree list) CMS, using its contractor, will analyze the application to determine whether the Plan Sponsor qualifies for the RDS. To qualify for the subsidy, the Plan Sponsor must show that its coverage is as generous as, or more generous than, the defined standard coverage under the Medicare Part D prescription drug benefit. The information within the application includes sponsor account registration information, plan information, benefit options under the plan, actuary information and actuarial attestation. The RDS center has various checks within each section of the application. Applications can be denied if issues cannot be resolved. *Form Number:* CMS-10170 (OMB control number: 0938-0977); *Frequency:* Yearly; *Affected Public:* Private Sector; Business or other for-profits, and Not-for Profits; *Number of Respondents:* 1,245; *Number of Responses:* 1,245; *Total Annual Hours:* 79,680. (For questions regarding

this collection, contact Ivan Iveljic at 410-786-3312 or Ivan.iveljic@cms.hhs.gov.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024-21631 Filed 9-20-24; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-2219]

Progynon Associates, et al.; Withdrawal of Approval of Four New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of four new drug applications (NDAs) from multiple holders of those NDAs. The basis for the withdrawal is that these NDA holders have repeatedly failed to file required annual reports for the identified NDAs.

DATES: Approval is withdrawn as of September 23, 2024.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug

Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137, Kimberly.Lehrfeld@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The holder of an approved application to market a new drug for human use is required to submit annual reports to FDA concerning its approved application in accordance with § 314.81 (21 CFR 314.81).

In the **Federal Register** of May 28, 2024 (89 FR 46139), FDA published a notice offering an opportunity for a hearing (NOOH) on a proposal to withdraw approval of four NDAs because the holders of those NDAs had repeatedly failed to submit the required annual reports for those NDAs. The holders of those NDAs did not respond to the NOOH. Failure to file a written notice of participation and request for hearing as required by § 314.200 (21 CFR 314.200) constitutes an election by those holders of the NDAs not to make use of the opportunity for a hearing concerning the proposal to withdraw approval of their NDAs and a waiver of any contentions concerning the legal status of the drug products. Therefore, FDA is withdrawing approval of the four applications listed in table 1 of this document.

TABLE 1—APPROVED NDAS FOR WHICH REQUIRED REPORTS HAVE NOT BEEN SUBMITTED

Application No.	Drug	Holder
NDA 004652	ORETON (testosterone) Pellets for Subcutaneous Implantations, 75 milligrams (mg).	Progynon Associates, 9300 Wilshire Blvd., Beverly Hills, CA 90212.
NDA 013268	WINSTEROID (stanozolol) Tablets, 2 mg	Sterling Winthrop Inc., 90 Park Ave., New York, NY 10016.
NDA 017455	Copper T Model TCu 200B (copper) Intrauterine Device	Duramed Research, Inc., 425 Privet Rd., Horsham, PA 19044.
NDA 205003	PRESTALIA (amlodipine besylate/perindopril arginine) Tablets, equivalent to (EQ) 2.5 mg base/3.5mg, EQ 5 mg base/7 mg, and EQ 10 mg base/14 mg.	Adhera Therapeutics, Inc., 224 Holding Ave., Wake Forest, NC 27588.

FDA finds that the holders of the NDAs listed in table 1 have repeatedly failed to submit reports required by § 314.81. In addition, under § 314.200, FDA finds that the holders of the NDAs have waived any contentions concerning the legal status of the drug products. Therefore, under these findings, approval of the NDAs listed in table 1 and all amendments and supplements thereto are hereby withdrawn as of September 23, 2024.

Dated: September 16, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024-21680 Filed 9-20-24; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-3112]

Agency Information Collection Activities; Proposed Collection; Comment Request; Postmarketing Adverse Experience Reporting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public

comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on postmarketing reporting and recordkeeping of adverse experiences for drug and biological products.

DATES: Either electronic or written comments on the collection of information must be submitted by November 22, 2024.

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 November 22, 2024. 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-2024-N-3112 for "Postmarketing Adverse Experience Reporting." 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:

JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Postmarketing Adverse Experience Reporting

OMB Control Number 0910-0230—Revision

This information collection helps support provisions found in sections 201, 502, 505, 701, and 760 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321, 352, 355, 371, and 379aa) governing adverse experience reporting (AER) and associated recordkeeping for FDA-regulated drug products. FDA has

promulgated applicable regulations in part 4 and §§ 310.305, 314.80, 314.81, 314.98, and 329.100 (21 CFR part 4 and 21 CFR 310.305, 314.80, 314.81, 314.98, and 329.100) that implement the statutory requirements, identify specific content and format elements, and establish reporting and retention schedules for the required information. Postmarketing safety data collection and adverse event reporting are critical elements of FDA's monitoring of drugs. For more information, please visit <https://www.fda.gov/drugs/surveillance/postmarketing-adverse-event-reporting-compliance-program>.

Respondents to the information collection are manufacturers, packers, distributors, and applicants of FDA-regulated drug and biologic products marketed with or without an FDA-approved application, including over-the-counter (OTC) drug products marketed without an approved application; OTC drug products marketed under the OTC Drug Monograph Review process (whether subject to a final monograph or not); and drug products marketed outside the monograph system. All reports and followup reports must be submitted to FDA in electronic format, although waivers of the electronic requirements are available for good cause.

Adverse experience reporting for products associated with drug marketing applications are governed by regulations in §§ 314.80, 314.81, and

314.98. The regulations identify required reporting content and format elements, as well as establish followup reporting requirements and mandatory reporting schedules. The regulations also establish associated recordkeeping and require that written procedures be developed for the surveillance, receipt, evaluation, and reporting of postmarketing adverse experiences to FDA. The regulations require reporting in an electronic format that FDA can process, although temporary waivers may be granted on a limited basis for good cause. A final guidance for industry entitled "Providing Submissions in Electronic Format—Postmarketing Safety Reports" (April 2022) is available for general information pertaining to electronic submission of postmarketing safety reports for certain human drugs, biological products, and combination products. The guidance is available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-submissions-electronic-format-postmarketing-safety-reports>.

We have established and maintain the FDA Adverse Event Reporting System (FAERS) at <https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-electronic-submissions>. Information may be submitted via FDA's Electronic Submissions Gateway or utilizing the

"Safety Reporting Portal," developed by FDA and the National Institutes of Health to streamline reporting and review of adverse events.

The primary purpose of FDA's adverse drug experience reporting system is to enable identification of signals for potentially serious safety problems with marketed drugs. Although premarket testing discloses a general safety profile of a new drug's comparatively common adverse effects, the larger and more diverse patient populations exposed to the marketed product provide the opportunity to collect information on rare, latent, and long-term effects. Signals are obtained from a variety of sources, including reports from patients, treating physicians, foreign regulatory agencies, clinical investigators, and literature. Information derived from the adverse drug experience reporting system contributes directly to increased public health protection because the information enables FDA to make important changes to the product's labeling (such as adding a new warning), to make decisions about risk evaluation and mitigation strategies; the need for postmarketing studies or clinical trials; and, when necessary, to initiate removal of a product from the market.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN^{1 2 3}

21 CFR section or guidance; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
310.305(c)(5); AERs for prescription products not the subject of a marketing application	36	88.8	3,197	1	3,197
314.80(c)(1); 15-day alerts for approved products	682	1,832.84	1,250,000	1	1,250,000
314.80(c)(2); periodic reports for approved products	682	1,228.73	838,000	60	50,280,000
329.100; AERs for non-prescription drug products	312	62.522	19,507	6	117,042
ICH E2C(R2) Guidance; Periodic safety updates; Applicants w/waiver for an approved application (section III.A.)	471	8.885	4,185	1	4,185
ICH E2C(R2) Guidance; Periodic safety updates; Applicants w/no waiver for an approved application (section III.B.)	1,115	16.254	18,123	2	36,246
AER During Pandemic Guidance; notifying FDA when normal reporting is not feasible (section III.C.)	1	1	1	8	8
4.103, 4.104, 4.105, 310.305, 314.80, 314.98, 329.100(c); Waiver requests from electronic reporting requirements	1	1	1	24	24
Total	4,2618		2,133,014		51,690,702

¹ There are no capital costs associated with this collection. The operating and maintenance costs associated with this collection of information are approximately \$25,000 annually.

² The reporting burdens for § 310.305(c)(1), (2), and (3), and voluntary reports by healthcare providers received under § 314.80(c)(1)(i) and (ii) are covered under OMB control number 0910–0291.

³ Totals may not sum due to rounding.

⁴ Total of unique respondents.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN^{1 2}

21 CFR section or guidance section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
310.305; AER records—prescription product not the subject of a marketing application.	36	88.8	3,197	16	51,152
314.80(j); AER records—product associated w/marketing application	841	1,814.0606	1,525,625	16	24,410,000

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN^{1 2}—Continued

21 CFR section or guidance section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
<i>Postmarket AER for Nonprescription Drug Products Guidance</i> ; (§ 329.100).	312	62.5224	19,507	8	156,056
<i>AERs During Pandemic Guidance</i> ; Continuity of operations planning (section III.B.).	100	1	100	50	5,000
<i>AERs During Pandemic Guidance</i> ; documenting conditions and resultant high absenteeism (section III.C.2).	350	1	350	8	2,800
<i>AERs During Pandemic Guidance</i> ; documenting AER process (section III.C.1.).	350	1	350	8	2,800
4.105; Postmarketing safety recordkeeping for combination products and constituent parts.	11	18	198	0.1 (6 minutes)	19.8
Total	³ 1,650		1,549,327		24,627,827.8

¹ There are no capital costs associated with this collection of information. There are operating and maintenance costs associated with this collection of information of approximately \$22,000 annually.

² Totals may not sum due to rounding.

³ Total of unique respondents.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN¹

21 CFR section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
4.103; Postmarketing Safety reporting for Combination products—Sharing information with other constituent part applicants.	11	18	198	0.35 (21 minutes)	69.3

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

All applicants who have received marketing approval for drug products (including combination products that are administered as drug products) are required to report serious, unexpected adverse drug experiences (15-day “Alert reports”) (§ 314.80(c)(1)(i)), as well as followup reports (§ 314.80(c)(1)(ii)) to FDA. These include all foreign or domestic AERs as well as AERs based on information from applicable scientific literature and certain reports from post marketing studies. Section 314.80(c)(1)(iii) pertains to AERs submitted by nonapplicants. For operational efficiency, we have adjusted this information collection and burden table to include all 15-day alert reports submitted by applicants, manufacturers, packers, and distributors. Voluntary reports from healthcare providers are included under OMB control number 0910–0291.

Under § 314.80(c)(2), applicants (including combination products that are administered as drug products) must also provide periodic reports of adverse drug experiences. For the reporting interval, a periodic report includes reports of serious, expected adverse drug experiences, all nonserious adverse drug experiences, and an index of these reports; a narrative summary and analysis of adverse drug experiences; an analysis of the 15-day Alert reports submitted during the reporting interval; and a history of actions taken because of adverse drug experiences. Under § 314.80(j), applicants must keep records of all adverse drug experience

reports known to the applicant for 10 years.

For marketed prescription drug products without approved new drug applications (NDAs) or abbreviated new drug applications (ANDAs), manufacturers, packers, and distributors of these products are required to report to FDA serious, unexpected adverse drug experiences as well as followup reports (§ 310.305(c)). Section 310.305(c)(5) pertains to the submission of followup reports to reports forwarded to the manufacturers, packers, and distributors by FDA. Under § 310.305(g), each manufacturer, packer, and distributor shall maintain records of all adverse drug experiences required to be reported for 10 years. All 15-day Alert reports and followup reports must be submitted to FDA in electronic format.

Section 760 of the FD&C Act also provides for mandatory safety reporting for over-the-counter human drug products not subject to applications approved under section 505 of the FD&C Act (NDAs or ANDAs). These requirements apply to all OTC drug products marketed without an approved application, including those marketed under the OTC Drug Monograph Review process (whether or not subject to a final monograph), those marketed outside the monograph system, and including those that have been discontinued from marketing but for which a report of an adverse event was received. Under § 329.100, respondents must submit

reports according to section 760 of the FD&C Act in an electronic format.

To assist respondents with implementation of section 760 of the FD&C Act, FDA developed the guidance for industry entitled “Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application,” (July, 2009) available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarketing-adverse-event-reporting-nonprescription-human-drug-products-marketed-without-approved>. The guidance document discusses what should be included in a serious adverse drug event report submitted under section 760(b)(1) of the FD&C Act, including how to submit these reports and followup reports under section 760(c)(2) of the FD&C Act. Section 760(e) of the FD&C Act also requires that responsible persons maintain records of nonprescription drug adverse event reports, whether the event is serious or not, for a period of 6 years. FDA’s guidance recommends that respondents maintain records of efforts to obtain the minimum data elements for a report of a serious adverse drug event and any followup reports.

In addition, this information collection includes an International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidance for industry entitled “Providing Postmarketing Periodic Safety Reports in the ICH

E2C(R2) Format (Periodic Benefit-Risk Evaluation Report), (November 2016)” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-postmarket-periodic-safety-reports-ich-e2cr2-format-periodic-benefit-risk-evaluation>. The ICH E2C(R2) guidance describes the conditions under which applicants may use the ICH E2C(R2) Periodic Benefit-Risk Evaluation Report format for certain types of adverse event reporting.

FDA regulations in §§ 314.80(c)(2) and 600.80(c)(2) require applicants to submit postmarketing periodic safety reports for each approved application. The reports must be submitted quarterly for the first 3 years following the U.S. approval date and annually thereafter and must contain the information described in §§ 314.80(c)(2)(ii) and 600.80(c)(2)(ii) (the information collection associated with 21 CFR part 600—Biological Products, is approved under OMB control number 0910–0308). The Agency guidance assists respondents with satisfying the regulatory requirements in an alternative format, noting that the process differs depending on whether an applicable periodic safety update report waiver is in place.

Similarly, this information collection accounts for burden that may be applicable to the guidance document, “Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic (May 2020),” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarketing-adverse-event-reporting-medical-products-and-dietary-supplements-during-pandemic>. In response to the Coronavirus Disease 2019 public health emergency, we revised the Agency guidance document to provide recommendations for recordkeeping applicable to any pandemic, not just influenza, including recommendations for planning, notification, and documentation for continuity of operations for firms that report postmarketing adverse events during any pandemic.

For operational efficiency, on March 20, 2023, OMB approved the addition of burden attributable to provisions related to postmarketing safety reporting for combination products as outlined in part 4, subpart B, and previously included in OMB control number 0910–

0834. When information regarding an event that involves a death or serious injury, or an adverse event, associated with the use of a combination product that includes a drug product, is received by the product sponsor, the information must be provided to the other constituent part applicant(s) no later than 5 calendar days after receipt under § 4.103 (21 CFR 4.103). Relatedly, 21 CFR 4.104 explains how and where to submit reports for combination products, and 21 CFR 4.105 provides for associated recordkeeping. For combination products that are administered as drug products with a constituent part, adverse event reports are submitted to the drug application under 21 CFR part 314, and constituent applicants are notified of the AER under § 4.103. These provisions are also described in the guidance document “Postmarketing Safety Reporting for Combination Products” (July 2019), available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarketing-safety-reporting-combination-products>.

Our estimates of the number of respondents and the total annual responses are based on reports submitted to the Agency. This information collection incorporates revisions to include the two guidances for industry regarding submission of adverse event reports (“Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic” and “Providing Submissions in Electronic Format—Postmarketing Safety Reports”) and adjustments to include 15-day alert reports from applicants, manufacturers, distributors, and packers that were not recorded previously in this information collection. We also believe adjustments in the information collection reflect anticipated fluctuations in burden after pandemic conditions, adjustments by reporters’ and changes in electronic reporting methodologies use of updated technology including updates and redefinitions of reporting software, and changes of company business practices over time. All reports and followup reports must be submitted to FDA in electronic format. Waivers of the electronic requirements are available. As a result of these revisions and adjustments, including the additional reports, the inclusion of guidance document recommendations and the

consolidation of the burden from OMB control number 0910–0834 (previously added to this information collection March 2023), the total burden hours of the information collection have increased by 61,615,010.1 hours and 2,546,310 responses as compared to the previous renewal. We invite comment on our assumptions.

Dated: September 18, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21675 Filed 9–20–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–N–2030 and FDA–2024–N–0972]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at <https://www.reginfo.gov/public/do/PRAMain>. 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.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Applications for FDA Approval to Market a New Drug	0910–0001	8/31/2025
Regulations Under the Federal Import Milk Act	0910–0212	8/31/2027

Dated: September 17, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21672 Filed 9–20–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2019–E–1081; FDA–2019–E–1082; FDA–2019–E–1083; FDA–2019–E–1084; FDA–2019–E–1085; and FDA–2019–E–1844]

Determination of Regulatory Review Period for Purposes of Patent Extension; SYMDEKO

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for SYMDEKO and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by November 22, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by March 24, 2025. See “Petitions” in the **SUPPLEMENTARY INFORMATION** section for more information.

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 November 22, 2024. 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 Nos. FDA–2019–E–1081; FDA–2019–E–1082; FDA–2019–E–1083; FDA–2019–E–1084; FDA–2019–E–1085; and FDA–2019–E–1844 for “Determination of Regulatory Review Period for Purposes of Patent Extension; SYMDEKO.” 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 § 10.20 (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: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51,

Rm. 6200, Silver Spring, MD 20993, 301-796-3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biological product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, SYMDEKO (tezacaftor/co-packaged with ivacaftor) indicated for the treatment of patients with cystic fibrosis aged 12 years and older who are homozygous for the F508del mutation or who have at least one mutation in the cystic fibrosis transmembrane conductance regulator gene that is responsive to tezacaftor/ivacaftor based on in vitro data and/or clinical evidence. Subsequent to this approval, the USPTO received patent term restoration applications for SYMDEKO (U.S. Patent Nos. 7,645,789; 7,776,905; 8,415,387; 8,598,181; 8,623,905; and 9,035,072) from Vertex Pharmaceuticals Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated June 12, 2019, FDA advised the USPTO that this human drug product had

undergone a regulatory review period and that the approval of SYMDEKO represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for SYMDEKO is 2,832 days. Of this time, 2,602 days occurred during the testing phase of the regulatory review period, while 230 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* May 15, 2010. The applicant claims May 14, 2010, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 15, 2010, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* June 28, 2017. FDA has verified the applicant's claim that the new drug application (NDA) for SYMDEKO (NDA 210491) was initially submitted on June 28, 2017.

3. *The date the application was approved:* February 12, 2018. FDA has verified the applicant's claim that NDA 210491 was approved on February 12, 2018.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 616 days, 864 days, 882 days, 1,001 days, 1,484 days, or 1,532 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be

filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA-2013-S-0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: September 18, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024-21677 Filed 9-20-24; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-4085]

Advancing Smoking Cessation: Food and Drug Administration and National Institutes of Health Priorities; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting entitled "Advancing Smoking Cessation: FDA and NIH Priorities." Jointly convened by FDA and the National Institutes of Health (NIH), this public meeting will address the need for novel smoking cessation products to help individuals of all ages, including underserved and vulnerable populations, stop smoking. The overall goal of the meeting is to stimulate novel product development to reduce rates of smoking and related chronic illnesses. The meeting format will include presentations and panel discussions.

DATES: The public meeting will be held in person with an option for virtual attendance on October 21, 2024, from 9 a.m. to 4:30 p.m. Eastern Time. Submit requests to make oral presentations at the public meeting by 5 p.m. Eastern Time, October 1, 2024. Either electronic or written comments on this public meeting must be submitted by November 21, 2024. See the

SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public meeting will be held in the White Oak Great Room at the Food and Drug Administration, White Oak Campus, 10903 New Hampshire Ave., Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/about-fda/visitor-information>.

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 November 21, 2024. 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-2024-N-4085 for "Advancing Smoking Cessation: FDA and NIH Priorities." 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:

Laura Chilaka, Center for Tobacco Products, Food and Drug

Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 877-287-1373, TobaccoCessation@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

This public meeting is intended to bring together key people in supporting research on and development of new smoking cessation products in order to stimulate novel product development to reduce the burden of smoking and related chronic illnesses. Participants will hear updates on NIH research and FDA operations.

II. Topics for Discussion at the Public Meeting

Session 1. NIH-supported smoking cessation research and areas of opportunity. This session will provide a brief overview of NIH areas of support and identification of gap areas including focus on underserved and vulnerable populations.

Session 2. Update from FDA. This session will provide a brief overview of relevant FDA operations including focus on underserved and vulnerable populations. The session will discuss the regulatory framework for developing smoking cessation drugs, medical devices and their role in smoking cessation, and tobacco pathways.

Session 3. Clinical and community perspectives. This session will offer a concise introduction to smoking cessation treatment considerations from the clinical viewpoint, with a special emphasis on underserved and diverse communities along with potential access and uptake challenges, through the lens of real-world experiences and diversity considerations.

Session 4. Promising targets for development. This session will highlight selected new and emerging areas for intervention development including pharmacologic agents, brain stimulation, and digital therapeutics. In addition, we will discuss the potential endpoints for use in randomized trials of new interventions.

Session 5. Regulatory paths forward. This session will discuss endpoints for smoking cessation drug development programs, evidence necessary to support their role in drug development, clinical outcome assessments, and innovative clinical trial designs and conduct, including trials integrated in clinical practice and clustering in trial design to increase participation from underserved communities.

Session 6. Public comment. Interested persons may present data, information, or views, orally or in writing, on issues

related to cessation and should address the following questions:

1. How can researchers increase enrollment for traditionally underrepresented populations in clinical trials (e.g., racial and ethnic minority populations, LGBTQ+ populations, rural populations)?
2. Would there be interest in an externally led Patient Focused Drug Development (PFDD) meeting to better understand the challenges and barriers to smoking cessation from individuals trying to quit and what additional endpoints can be evaluated in smoking cessation clinical trials?
3. What are some novel targets that could facilitate cigarette cessation product development?
4. What challenges are researchers and/or drug developers facing in their efforts to identify novel targets for smoking cessation therapies?

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website to register: <https://advancing-smokingcessation.eventbrite.com>. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting in person must register by October 15, 2024, 11:59 p.m. Eastern Time. Persons interested in attending this public meeting virtually must register by October 21, 2024, 9 a.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted.

For special accommodations due to a disability, please visit the registration website: <https://advancing-smokingcessation.eventbrite.com>. Please submit special accommodation requests no later than October 7, 2024.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during the public comment session. We will do our best to accommodate requests to make public comments.

Oral presentations from the public will be scheduled between approximately 3:15 p.m. and 4:15 p.m. Eastern Time on October 21, 2024. Those individuals interested in making formal oral presentations should notify the contact person (see **FOR FURTHER INFORMATION CONTACT**) and submit a brief statement describing the general

nature of the evidence or arguments they wish to present and the names and email addresses of proposed participants, on or before October 1, 2024, by 5 p.m. Eastern Time. Topics should address the questions listed in II., Section 6. Individuals making formal oral presentations will not have the capacity to present slides during the public comment session. Individuals may submit presentation materials to the docket on or before November 21, 2024.

Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. Similarly, room for interested persons to participate in person may be limited. If the number of registrants requesting to speak in person during the open public hearing is greater than can be reasonably accommodated in the venue for the in-person portion of the meeting, FDA may conduct a lottery to determine the speakers who will be invited to participate in person. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin and will select and notify participants as soon as possible to provide speakers with adequate time to prepare. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast. Please visit the following website for more information: <https://advancing-smokingcessation.eventbrite.com>.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see **ADDRESSES**).

(Notice of this meeting is given pursuant to 21 CFR 10.65.)

Dated: September 17, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024-21678 Filed 9-20-24; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-2396]

Chemistry, Manufacturing, and Controls Development and Readiness Pilot Program; Program Announcement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing year three of the Chemistry, Manufacturing, and Controls (CMC) Development and Readiness Pilot (CDRP). This program facilitates the expedited CMC development of products under an investigational new drug application (IND) based on the anticipated clinical benefit of earlier patient access to the products. FDA has implemented this pilot program to assist with CMC readiness for products regulated by both the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER) that have accelerated clinical development timelines. To accelerate CMC development and facilitate CMC readiness, the pilot features increased communication between FDA and sponsors and explores the use of science- and risk-based regulatory approaches, as applicable. This notice outlines the eligibility criteria and process for submitting a request to participate in the pilot.

DATES: Starting October 1, 2024, FDA will accept requests to participate in year three of the CDRP program. See the "Participation" section of this document for eligibility criteria, instructions on how to submit a request to participate, and selection criteria and process.

FOR FURTHER INFORMATION CONTACT:

Tanya Clayton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4506, Silver Spring, MD 20993-0002, 301-796-0871; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

For general questions about the CDRP Program for CBER: industry.biologics@fda.hhs.gov.

For general questions about the CDRP Program for CDER: cdcr-opq-opro-crad-inquiries@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

Development programs for CBER- and CDER-regulated drugs and biologics intended to diagnose, treat, or prevent a serious disease or condition where there is an unmet medical need may have accelerated clinical development timelines. Yet, marketing applications for products in expedited development programs still need to meet FDA's approval standards, including manufacturing facility compliance with current good manufacturing practice (CGMP). Products with accelerated clinical development activities may face challenges in expediting CMC development activities to align with the accelerated clinical timelines. Successfully expediting CMC readiness may require additional interactions with FDA during product development and, if applicable, warrant the use of science- and risk-based regulatory approaches to streamline CMC development activities so that clinical benefits of earlier patient access to these products can be realized.

As described in the FDA Prescription Drug User Fee Act (PDUFA) VII Commitment Letter for fiscal years (FYs) 2023 Through 2027 (Ref. 1), FDA implemented the CDRP program to facilitate CMC readiness for selected CBER- and CDER-regulated products with accelerated clinical development timelines in FY 2023. To accelerate CMC development and facilitate CMC readiness, the pilot features increased communication between FDA and sponsors and explores the use of science- and risk-based regulatory approaches, such as those described in the FDA guidance for industry entitled "Expedited Programs for Serious Conditions—Drugs and Biologics" (May 2014) (Ref. 2), as applicable.

FDA (CBER and CDER) is continuing to administer the CDRP to facilitate the CMC development of selected products under INDs which have expedited clinical development timeframes, based on the anticipated clinical benefits of earlier patient access to the products. For sponsors participating in the pilot, FDA will provide product-specific CMC advice during product development, including two additional CMC-focused Type B meetings, as well as additional CMC-focused discussions. To support these interactions, once a sponsor is admitted to the pilot, FDA will expand the IND quality assessment team so as to ensure it has representation from the full complement of relevant disciplines. The increased communication between FDA review staff and sponsors is intended to ensure a mutual understanding of approaches to

completing CMC activities, including what information should be provided at the appropriate timepoint (*i.e.*, at the time of new drug application (NDA) or biologics license application (BLA) submission, prior to the end of the review cycle, or post-approval) to ensure CMC readiness for a marketing application.

II. Participation

FDA will accept requests to participate in the CDRP program continuously throughout the fiscal year. FDA will select no more than nine proposals per fiscal year, with approximately two-thirds being CBER-regulated products and one-third CDER-regulated products. FDA will renew the CDRP program each fiscal year and announce the opening of the pilot program in the **Federal Register** for the remainder of this PDUFA VII period (until the end of FY 2027). However, once enrolled in the pilot a participating firm will continue to be enrolled in the program until their marketing application is filed. Sponsors who are interested in participating in the pilot program should submit a request to participate in the pilot as an amendment to their IND. The cover letter should state "Request to Participate in the CMC Development and Readiness Pilot."

To promote innovation and understanding in this area, FDA will hold a public workshop and issue a strategy document focused on CMC aspects of expedited development incorporating lessons from the CDRP. At the workshop, sponsors may be asked to present lessons learned from the pilot. FDA may also present summary lessons and case studies. Generally, FDA does not anticipate that the case studies will need to include information, such as the sponsor's name, that can identify a unique product or product-specific manufacturing process information. Case studies will focus on FDA-sponsor interactions and problem solving, and address scientific and technical issues only in general terms. However, as described in the FDA PDUFA VII Commitment Letter for FYs 2023 Through 2027, to be eligible for the pilot, the sponsor must reach agreement with FDA on the information that could be publicly disclosed. FDA will notify a sponsor in advance when it plans to include some aspect of their experience in the program in a public discussion (*e.g.*, a slide presentation, a white paper).

A. Eligibility Criteria

To be considered for the pilot program, participants must meet the following eligibility criteria:

1. Joint CBER and CDER Eligibility Criteria

- Participant must have an active commercial IND (see the definition of commercial IND at <https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/research-investigational-new-drug-applications-what-you-need-know>).

- IND has been submitted in, or converted to, Electronic Common Technical Document (eCTD) format, unless the IND is of a type granted a waiver from eCTD format as per FDA's guidance for industry entitled "Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications" (February 2020) (Ref. 3).

- INDs for combination products (21 CFR 3.2(e)) are eligible; products that require significant cross-Center interactions (*e.g.*, complex combination products) may be less likely to be selected for the pilot.

- In general, there should be enough time remaining before submission of the marketing application to allow the pilot to have an impact on CMC readiness.

- CMC-related information is provided to demonstrate a commitment to pursue a CMC development plan that aligns with the expedited clinical development program (see "CMC Development Plan" in section II.B of this document for details).

Due to the differences in product complexity between CBER- and CDER-regulated products, the following eligibility and selection criteria differ between the Centers.

2. CBER-Specific Eligibility Criteria

- IND is an existing, CBER-regulated IND intended for submission as an application for licensure of a biological product under section 351(a) of the Public Health Service Act (PHS Act) (42 U.S.C. 262(a)) for cellular therapies, gene therapies, and other products regulated by the Office of Therapeutic Products/CBER or vaccines regulated by the Office of Vaccines Research and Review/CBER.

- IND has a Breakthrough Therapy (BT) or Regenerative Medicine Advance Therapy designation.

3. CDER-Specific Eligibility Criteria

- IND is an existing, CDER-regulated IND for a product intended for submission as an application for: (1) approval of a new drug submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)), or (2) licensure of a biological

product under section 351(a) of the PHS Act.

- IND has an expedited clinical timeframe warranted based on anticipated clinical benefits of earlier patient access. This would include INDs with BT or Fast Track designations as well as other INDs that meet this criterion, with eligibility to be determined by FDA.

B. What To Submit in a Request To Participate in the Pilot

To participate in the CDRP, sponsors should submit a written request as an amendment to the IND. In addition to providing a point of contact and noting any expedited program designations the IND has received to date, the request should include the following information.

CMC Development Plan

To focus pilot resources where they will be most useful and have an impact on the timeliness with which CMC readiness is achieved, prospective applicants to the pilot program should include in their Request to Participate a brief description of their CMC development plan, with a prospective timeline for CMC development that would align with when the clinical development program is expected to be complete:

- The plan should list the remaining CMC tasks and activities anticipated to be necessary, with estimated timeframes. This part of the plan should cover the following CMC-related areas:

- Currently available product characterization and preliminary identification of critical quality attributes.

- Summary of the current drug substance and drug product manufacturing process and control strategy (including assays, noting any that are still under development).

- A brief description of the proposed commercial scale manufacturing and control strategy, including any necessary microbial control strategy—focusing on important differences from clinical scale.

- Identification of potential commercial manufacturing facilities, including any contract facilities, or, at least, the type (in house, contract manufacturing organization) of facilities anticipated.

- Plans for ensuring product availability at approval.

- Drug substance and drug product stability assessment plan.

- Strategy for process validation (see FDA's guidance for industry entitled "Process Validation: General Principles and Practices" (Ref. 4)).

- Given the expedited clinical timeframe, mapping out a plan for manufacturing readiness within the same overall timespan may reveal potential challenges in accomplishing CMC readiness. The plan should highlight any anticipated CMC challenges—whether related to the bullets above or otherwise. This will facilitate FDA engagement and collaboration. Participants in the pilot should plan to discuss these challenges with FDA during the pilot. For CDER-regulated products, see MAPP 5015.13, "Quality Assessment for Products in Expedited Programs" (Ref. 5).

- The CMC Development Plan should include proposed timing (*i.e.*, month and year) for the first CMC-specific Type B meeting afforded by the pilot.

C. Selection Criteria and Process

FDA intends to select CBER and CDER INDs based on the criteria outlined below. Requests will be acknowledged and reviewed when received. FDA intends to issue a Proceed to Disclosure Agreement letter, if selected into the pilot, or deny letter within 90 days of receipt.

In selecting INDs for the pilot program, FDA intends to consider factors such as: (1) anticipated clinical benefits of facilitating earlier patient access to the product, (2) novelty of the product, (3) complexity of the product or its manufacturing process, including technology, and (4) anticipated CMC challenges. Overall, FDA intends to seek balance and diversity in product types and therapeutic indications to obtain a variety of relevant experience and learnings from the pilot.

D. FDA-Sponsor Interactions During the Pilot

During this CDRP program, sponsors will have the ability to discuss their product development strategies and goals with FDA review staff during the two dedicated Type B meetings, as well as in additional CMC-focused discussions. Besides additional interactions and collaboration with FDA, for those INDs in the pilot, FDA will assemble a team to support the CMC development and readiness of the IND, *e.g.*, participating in the meetings and other discussions under the pilot.

In preparation for a meeting, sponsors should submit written questions along with a background information package clearly marked as a "PDUFA VII CDRP meeting" as part of the cover letter to enable FDA review staff to address the questions. The briefing package should be submitted to the corresponding IND. Meetings associated with the pilot should be requested by sponsors. For

additional information on meetings and other communications between the sponsors and FDA, see the FDA draft guidance for industry entitled "Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products" (September 2023) (Ref. 6), CDER MAPP 6025.6: "Good Review Practice: Management of Breakthrough Therapy-Designated Drugs and Biologics" (Rev. 1) (February 2024) (Ref. 7), CBER "SOPP 8101.1: Regulatory Meetings With Sponsors and Applicants for Drugs and Biological Products" (March 2023) (Ref. 8), and CBER "SOPP 8212: Breakthrough Therapy Products—Designation and Management" (August 2023) (Ref. 9).

III. Paperwork Reduction Act of 1995

Collections of information from fewer than 10 respondents within any 12-month period are not subject to the Paperwork Reduction Act of 1995 (PRA) (5 CFR 1320.3(c)(4)). To the extent this information collection involves 10 or more respondents within any 12-month period, the collections of information are subject to the PRA. These collections of information are subject to review by the Office of Management and Budget (OMB) under the PRA (44 U.S.C. 3501–3521). The collections of information for NDAs, formal meetings with sponsors and applicants for PDUFA products, and the PDUFA VII Commitment Letter have been approved under OMB control number 0910–0001. The collections of information for INDs have been approved under OMB control number 0910–0014. The collections of information for BLAs have been approved under OMB control number 0910–0338. The collections of information pertaining to CGMP requirements have been approved under OMB control number 0910–0139. The collections of information pertaining to expedited programs for serious conditions for drugs and biologics and breakthrough therapy-designation for drugs and biologics have been approved under OMB control number 0910–0765.

IV. References

The following references are on display at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. “PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027” at <https://www.fda.gov/media/151712/download>.
2. FDA guidance for industry “Expedited Programs for Serious Conditions—Drugs and Biologics” (May 2014): <https://www.fda.gov/media/86377/download>.
3. FDA guidance for industry “Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications” (Rev. 7) (February 2020): <https://www.fda.gov/media/135373/download>.
4. FDA guidance for industry “Process Validation: General Principles and Practices” (Rev. 1) (January 2011): <https://www.fda.gov/files/drugs/published/Process-Validation-General-Principles-and-Practices.pdf>.
5. CDER MAPP 5015.13: “Quality Assessment for Products in Expedited Programs” (December 2022): <https://www.fda.gov/media/162786/download?attachment>.
6. FDA draft guidance for industry “Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products” (Rev. 1) (September 2023): <https://www.fda.gov/media/172311/download>.
7. CDER MAPP 6025.6: “Good Review Practice: Management of Breakthrough Therapy-Designated Drugs and Biologics” (Rev. 1) (February 2024): <https://www.fda.gov/media/89155/download>.
8. CBER “SOPP 8101.1: Regulatory Meetings With Sponsors and Applicants for Drugs and Biological Products” (March 2023).
9. CBER “SOPP 8212: Breakthrough Therapy Products—Designation and Management” (August 2023).

Dated: September 17, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21674 Filed 9–20–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–3805]

The Accreditation Scheme for Conformity Assessment Program; Draft Guidances for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of three draft guidance documents for the Accreditation Scheme for Conformity Assessment Program entitled “The Accreditation Scheme for Conformity Assessment (ASCA) Program; Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff;” “Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment—Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Program; Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff;” and “Biocompatibility Testing of Medical Devices—Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Program; Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff.” In accordance with amendments made by the FDA User Fee Reauthorization Act of 2022 (FUFRA), part of the Medical Device User Fee Amendments of 2022 (MDUFA V), FDA was directed to conclude the Pilot Accreditation Scheme for Conformity Assessment Program by the end of fiscal year 2023 and continue to operate the program (hereafter referred to as the ASCA Program) consistent with the amended FD&C Act. FDA is publishing these draft guidance documents which, when finalized, are intended to provide updates to improve the ASCA Program. These draft guidance documents are not final nor for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by November 22, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2019–D–3805 for “The Accreditation Scheme for Conformity Assessment (ASCA) Program; Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff;” “Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment—Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Program; Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff;” and “Biocompatibility Testing of Medical Devices—Standards Specific Information for the Accreditation

Scheme for Conformity Assessment (ASCA) Program: Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Electronic copies of these three guidance documents are available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidances. Submit written requests for single hard copies of the draft guidance documents entitled “The Accreditation

Scheme for Conformity Assessment (ASCA) Program; Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff”; “Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment—Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Program: Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff”; and “Biocompatibility Testing of Medical Devices—Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Program: Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff” to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Eric Franca, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5500, Silver Spring, MD 20993–0002, 301–796–4505, ASCA@fda.hhs.gov; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has concluded the ASCA pilot phase and is establishing an ongoing ASCA Program, in accordance with amendments made to section 514 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d) by section 2005 of the FDA User Fee Reauthorization Act of 2022, part of the Medical Device User Fee Amendments of 2022. The three final ASCA Pilot guidance documents issued on September 25, 2020, are also being updated to make improvements to the ASCA Program based on lessons learned during ASCA’s pilot phase and to convey the commitments stipulated in MDUFA V. These draft guidance updates incorporate feedback received through public meetings and webinars, the docket, stakeholder meetings, communications with participating accreditation bodies and testing laboratories, and lessons learned internally from review staff and ASCA staff during the pilot phase. The updates will also allow FDA to appropriately

expand ASCA per MDUFA V commitments and expectations.

These draft guidances are being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidances, when finalized, will represent the current thinking of FDA on the ASCA Program. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>. This guidance document is also available at <https://www.regulations.gov>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics>. Persons unable to download an electronic copy of “The Accreditation Scheme for Conformity Assessment (ASCA) Program: Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff”; “Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment—Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Program: Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff”; and “Biocompatibility Testing of Medical Devices—Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Program: Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document numbers GUI00017037, GUI00020011, and/or GUI00020012, respectively, and complete title(s) to identify the guidance(s) you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of

information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part; guidance; or FDA form	Topic	OMB Control No.
"The Accreditation Scheme for Conformity Assessment (ASCA) Program".	ASCA Program	0910–0889
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
860, subpart D	De Novo classification process	0910–0844
"Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program".	Q-submissions	0910–0756
803	Medical Devices; Medical Device Reporting; Manufacturer reporting, importer reporting, user facility reporting, distributor reporting.	0910–0437
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073
58	Good Laboratory Practice (GLP) Regulations for Nonclinical Laboratory Studies.	0910–0119

Dated: September 18, 2024.
Lauren K. Roth,
Associate Commissioner for Policy.
[FR Doc. 2024–21673 Filed 9–20–24; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2024–N–2583]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Human Drug Compounding, Repackaging, and Related Activities Regarding Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.
DATES: Submit written comments (including recommendations) on the collection of information by October 23, 2024.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910–0858. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Human Drug Compounding, Repackaging, and Related Activities Regarding Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act

OMB Control Number 0910–0858—Extension

This information collection helps support implementation of sections

503A and 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353a and 21 U.S.C. 353b), which govern compounding by pharmacies, outsourcing facilities, and other entities. Compounding is generally a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. Although compounded drugs can serve an important medical need for certain patients, they also present risks to patients. FDA’s compounding program aims to protect patients from unsafe, ineffective, and poor-quality compounded drugs, while preserving access to lawfully marketed compounded drugs for patients who have a medical need for them. Respondents to the information collection are pharmacies, outsourcing facilities, and other entities.

To assist respondents in complying with statutory requirements, we have issued the following topic-specific guidance documents:

TABLE 1—PUBLISHED GUIDANCE DOCUMENTS REGARDING SECTIONS 503A AND 503B OF THE FD&C ACT

Title	Notice of availability publication date
Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities (Radiopharmaceutical Compounding and Repackaging Guidance) (available at https://www.fda.gov/media/102615/download).	September 26, 2018 (83 FR 48633).

TABLE 1—PUBLISHED GUIDANCE DOCUMENTS REGARDING SECTIONS 503A AND 503B OF THE FD&C ACT—Continued

Title	Notice of availability publication date
Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities (Radiopharmaceutical Compounding and Repackaging by Outsourcing Facilities Guidance) (available at https://www.fda.gov/media/102637/download).	September 26, 2018 (83 FR 48630).
Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities (Repackaging Guidance) (available at https://www.fda.gov/media/90978/download).	January 13, 2017 (82 FR 4343).
Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application (Biological Products Guidance) (available at https://www.fda.gov/media/90986/download).	January 19, 2018 (83 FR 2787).

The guidance documents also describe conditions under which FDA generally does not intend to take enforcement action for violations of the FD&C Act. These guidance documents were issued consistent with FDA's good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time. The guidance documents communicate FDA's current thinking on the respective topics and include information collection that may result in expenditures of time and effort

by respondents. In FDA's notices of availability for the guidance documents, we also solicited public comment under the PRA on the information collection provisions. FDA has developed and maintains a searchable guidance database available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. Guidance documents covered by this information collection may be found by choosing "Center for Drug Evaluation and Research" from among the FDA

Organizations, and by selecting the term "Compounding" from among the possible filters.¹

In the **Federal Register** of June 12, 2024 (89 FR 49880), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this information collection as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN¹

Recommended activity; guidance section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Radiopharmaceutical Compounding and Repackaging by Outsourcing Facilities Guidance					
Biannual product reports identifying drug products repackaged by the outsourcing facility during the previous 6-month period (section III.B of the Radiopharmaceutical Compounding and Repackaging Guidance by Outsourcing Facilities).	2	2	4	3	12
Repackaging Guidance					
Biannual product reports identifying drug products repackaged by the outsourcing facility during the previous 6-month period (section III.A of the Repackaging Guidance) ..	6	2	12	3	36
Total	8		16		48

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Outsourcing facilities submit their initial and biannual product reports identifying drug products repackaged during the previous 6-month period to FDA via the Agency's electronic Drug

Registration and Listing System as explained in the Radiopharmaceutical Compounding and Repackaging Guidance by Outsourcing Facilities and the Repackaging Guidance. We expect to

receive no waiver requests from the electronic submission process for initial product reports and semiannual reports.

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

Recommended activity; guidance section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Radiopharmaceutical Compounding and Repackaging Guidance					
Consultation between the compounder and prescriber and the notation on the prescription or order documenting the prescriber's determination of clinical difference (section III.A of the Radiopharmaceutical Compounding and Repackaging Guidance).	10	25	250	0.05 (3 minutes)	12.5

¹ Guidance documents applicable to animal drug compounding regulated by the Center for Veterinary Medicine would also be returned if no FDA

Organization is selected; this information collection covers only those compounding guidance documents issued by the Center for Drug Evaluation

and Research and Center for Biologics Evaluation and Research.

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹—Continued

Recommended activity; guidance section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Biological Products Guidance *					
Maintaining records of testing performed in accordance with Appendix A of the Biological Products Guidance (section III.B of the Biological Products Guidance).	5	30	150	0.083 (5 minutes)	12.5
Total	15		400		25

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 4—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE ^{1 2}

Recommended activity; guidance section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Radiopharmaceutical Compounding and Repackaging by Outsourcing Facilities Guidance					
Designing, testing, and producing each label on immediate containers, packages, and/or outer containers (section III.B of the Radiopharmaceutical Compounding and Repackaging Guidance by Outsourcing Facilities).	2	5	10	0.5 (30 minutes)	5
Repackaging Guidance					
Designing, testing, and producing each label on immediate containers, packages, and/or outer containers (section III.A of the Repackaging Guidance).	6	36	216	1	216
Biological Products Guidance					
Designing, testing, and producing the label, container, packages, and/or outer containers for each mixed, diluted, or repackaged biological product (section III.B of the Biological Products Guidance).	15	5	75	0.5 (30 minutes)	37.5
Designing, testing, and producing each label on immediate containers, packages, and/or outer containers for each licensed allergenic extract (section III.C of the Biological Products Guidance).	5	300	1,500	0.5 (30 minutes)	750
Total	28		1,801		1,009

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Totals may not sum due to rounding.

For purposes of our analysis, we characterize the burden associated with the time and effort expended on the information collection recommendations discussed in the respective guidance documents as either reporting, recordkeeping, or third-party disclosure activities. We reconfigured the original table by splitting it into three tables to better differentiate between the estimated annual reporting, recordkeeping, and third-party disclosure burden. At the same time, our findings show that compliance with recordkeeping requirements applicable to compounded and repackaged drug products is standard practice in the compounding and selling of these drug products under States' pharmacy laws and other State laws governing recordkeeping by healthcare professionals and healthcare facilities. Therefore, we excluded from our estimate recordkeeping practices discussed in the respective guidance documents we consider usual and customary.

For the Repackaging Guidance, to correct a clerical error, we have adjusted the number of disclosures per respondent from 21 to 36 because each respondent is estimated to average 6 different products and average 6 different strengths, which requires 36 (6 × 6) unique labels per respondent. The initial narrative reflected that each product would come in six different strengths and thus require six unique labels, but due to a clerical error, this information was not correctly included in the table. We also adjusted the number of respondents to six to match the number of respondents designing, testing, and producing labels. In addition, we adjusted the total number of disclosures per respondent to two given the biannual reporting requirement.

For the Radiopharmaceutical Compounding and Repackaging by Outsourcing Facilities Guidance, a row for biannual product reporting was added to capture product reporting that was inadvertently omitted.

Our estimated burden for the information collection reflects constant respondent numbers. The original numbers were based on the information the program received from product reporting data. We do not have a mechanism in place to determine whether or not these numbers have fluctuated upward or downward; however, based on analogous observations of industry through program experience (some product reports), we believe these numbers are constant. Repackagers who are also registered as outsourcing facilities (OF) are not entity types that are individually regulated as repackagers. They are subsumed in the OF entity type and not easily distinguishable. They may or may not report their repackaging operations.

We are updating the information collection to include burden attendant to reporting and disclosure recommendations found in the Agency guidance documents that was inadvertently omitted in the original information collection due to clerical errors. The burden estimate is adjusted

to reflect a resulting increase of 114 hours and 94 responses annually.

Dated: September 16, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21676 Filed 9–20–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4146]

Agency Information Collection Activities; Proposed Collection; Comment Request; Biosimilars User Fee Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with the Agency's Biosimilars User Fee Program.

DATES: Either electronic or written comments on the collection of information must be submitted by November 22, 2024.

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 November 22, 2024. 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–2024–N–4146 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Biosimilars User Fee Program." 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: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical

utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Biosimilars User Fee Program

OMB Control Number 0910–0718—
Revision

This information collection supports FDA's Biosimilars User Fee Program and implementation of the Biologics Price Competition and Innovation Act of 2009 (BPCI Act). The BPCI Act creates an abbreviated approval pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference biological product. Section 351(k) of the Public Health Service Act (PHS Act) (42 U.S.C. 262(k)), added by the BPCI Act, allows a company to apply for licensure of a biosimilar or interchangeable biological product (351(k) application). The BPCI Act also amended section 735 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379g) to include 351(k) applications as a type of application under "human drug application" for the purposes of the prescription drug user fee provisions. The FD&C Act as amended by the Biosimilar User Fee Amendments of 2022 (BsUFA III), reauthorizes FDA to assess and collect fees for biosimilar biological products from October 2022 through September 2027 to facilitate the development of safe and effective biosimilar products for the American public.

FDA maintains information on our website at <https://www.fda.gov/industry/fda-user-fee-programs/biosimilar-user-fee-amendments> regarding FDA's BsUFA program. Also available on our website is the Biosimilars Action Plan (BAP), which discusses key actions the Agency is taking to encourage innovation and competition among biologics and the development of biosimilars. The BAP builds on progress in implementing the approval pathway for biosimilar and interchangeable products, and provides interested persons with updates on related deliverables and activities.

We have revised the information collection to reflect the currently agreed-upon performance goals established and captured in the latest

reauthorization document entitled, "Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027" (BsUFA Commitment Letter). The BsUFA Commitment Letter is available for download from our website at <https://www.fda.gov/media/152279/download?attachment>. The BsUFA Commitment Letter outlines current program goals, including information technology goals, discusses program effectiveness considerations, and discusses user fee resource management.

The information collection also includes Form FDA 3792, "Biosimilars User Fee Cover Sheet," to be submitted by each new biological product development (BPD) entrant (identified via a new meeting request or investigational new drug (IND) submission) or new biologics license application (BLA) applicant. Form FDA 3792 requests the minimum information necessary to identify the request, to determine the amount of the fee to be assessed, and to account for and track user fees. Form FDA 3792 is completed electronically at https://userfees.fda.gov/OA_HTML/bsufacAcidLogin.jsp, and a notification is emailed to the respondent that includes information regarding annual program fees. We are discontinuing use of the associated annual survey at this time.

Relatedly, Form FDA 3971 (Small Business Waiver and Refund Request), currently approved in OMB control number 0910–0297, may also be utilized. As instructed on our BsUFA web page, respondents should submit Form FDA 3971 by email to CDERCollections@fda.hhs.gov at least 4 months prior to the submission of the application to see if they qualify for a small business waiver. Finally, user fee refund and transfer requests, currently approved in OMB control number 0910–0805, may be submitted to FDA using Forms FDA 3913 and FDA 3914, respectively.

Patent infringement notifications are also included in the scope of collection activity. Section 351(l) of the PHS Act (42 U.S.C. 242(l)) provides for the exchange of patent information and resolution of patent disputes between a 351(k) biosimilar applicant and the holder of the 351(a) BLA reference product. If a biosimilar applicant is served with a complaint in an action for a patent infringement described in section 351(l)(6) of the PHS Act, the biosimilar applicant is required to provide the Secretary of HHS with notice and a copy of the complaint within 30 days of service. FDA is

required to publish notice of a complaint received under section 351(l)(6)(C) of the PHS Act in the **Federal Register**.

Relevant information regarding applicable statutory requirements is discussed in topical guidance documents, issued consistent with our BsUFA Commitment Letter and Agency Good Guidance Practice regulations in 21 CFR 10.115, which provide for public comment at any time. The following draft and final guidance documents include instructional and procedural information on communicating with FDA regarding the BsUFA program:

- "Assessing User Fees Under the Biosimilar User Fee Amendments of 2022" (July 2023), available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/assessing-user-fees-under-biosimilar-user-fee-amendments-2022>. The guidance document instructs respondents on requesting discontinuation from the BPD program, as well as requesting to move products to the discontinued section of the biosimilar list. The guidance document also provides information on the consequences of failing to pay BsUFA III fees as well as processes for submitting reconsideration and appeal requests.

- "Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products" (August 2023), available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/formal-meetings-between-fda-and-sponsors-or-applicants-bsufa-products-guidance-industry>. The guidance document explains standardized procedures for requesting, preparing, scheduling, conducting, and documenting formal meetings with FDA, and discusses good meeting management practices.

- As listed on our CDER 2023 and 2024 Annual Guidance agenda, we are planning to issue a draft guidance for industry entitled "Pediatric Study Plans for Biosimilar Products," to help implement provisions of the Pediatric Research Equity Act, codified in section 505B of the FD&C Act (21 U.S.C. 355c). For more information regarding FDA guidance documents, including ways to participate, please visit <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>.

Description of Respondents: Sponsors and applicants who have or intend to submit an application for a biosimilar product for licensure under section 351(k) of the PHS Act or who intend to submit an initial pediatric study plan (iPSP) as described in section 505B(e)

for those products intended to be licensed under section 351(k) of the PHS Act and being developed as a

proposed biosimilar to a reference product.

FDA estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

FDA form; survey	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Biosimilar User Fee Cover Sheet (Form FDA 3792)	30	2	60	0.5 (30 minutes)	30
Request for discontinuation from BPD program or to move products to discontinued section of Biosimilar List.	6	1	6	1	6
Biosimilar product & interchangeable product applications (351(k)); patent infringement notifications (351(l)).	16	~1.94	31	~610.90	18,938
Formal meeting requests as recommended in FDA guidance.	135	2.30	311	21.42	6,661
Submission of Pediatric Assessment; iPSP template information, including deferrals of pediatric assessments for proposed biosimilar products; iPSP amendments as recommended in FDA guidance.	11	1	11	~38.18	420
Total			419		26,055

Our estimated burden for the information collection reflects an overall increase of 13,069 hours and 105 responses annually. Although part of the increase may be attributed to the inclusion of burden associated with the submission of pediatric study plans, we regard the majority of adjustments as nominal fluctuations consistent with the number of applications and submissions we are receiving.

Dated: September 18, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21671 Filed 9–20–24; 8:45 am]

BILLING CODE 4164–01–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: Biobehavioral and Behavioral Processes Integrated Review

Group; Adult Lifespan Psychopathology Study Section.

Date: October 17–18, 2024.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Benjamin G. Shaper, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3182, MSC 7848, Bethesda, MD 20892, (301) 402–4786, shaperobg@mail.nih.gov.

Name of Committee: Oncology 1—Basic Translational Integrated Review Group; Gene Regulation in Cancer Study Section.

Date: October 21–22, 2024.

Time: 9:30 a.m. to 7:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Manzoor A. Zarger, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6208, MSC 7804, Bethesda, MD 20892, (301) 435–2477, zargerma@csr.nih.gov.

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Biobehavioral Regulation, Learning and Ethology Study Section.

Date: October 21–22, 2024.

Time: 9:30 a.m. to 7:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Sara Louise Hargrave, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 3170,

Bethesda, MD 20892, (301) 443–7193, hargravesl@mail.nih.gov.

Name of Committee: Oncology 1—Basic Translational Integrated Review Group; Basic Cancer Immunobiology Study Section.

Date: October 22–23, 2024.

Time: 8:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Meeting Format: In Person.

Contact Person: Sarita Kandula Sastry, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20782, 301–402–4788, sarita.sastry@nih.gov.

Name of Committee: Applied Therapeutics for Cancer Integrated Review Group; Mechanisms of Cancer Therapeutics C Study Section.

Date: October 22–23, 2024.

Time: 8:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Darcy Hotel, 1515 Rhode Island Ave, NW, Washington, DC 20005.

Meeting Format: In Person.

Contact Person: Gloria Huei-Ting Su, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–496–0465, gloria.su@nih.gov.

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Skeletal Muscle and Exercise Physiology Study Section.

Date: October 22–23, 2024.

Time: 8:00 a.m. to 10:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015.

Meeting Format: In Person.

Contact Person: Carmen Bertoni, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 805B,

Bethesda, MD 20892, (301) 867–5309, bertonic2@csr.nih.gov.

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Macromolecular Structure and Function B Study Section.

Date: October 22–23, 2024.

Time: 8:30 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: In Person and Virtual Meeting.

Contact Person: Alexei A. Yeliseev, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 443–0552, yeliseeva@mail.nih.gov.

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Analytics and Statistics for Population Research Panel; A Study Section.

Date: October 22–23, 2024.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Lisa Steele, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, (301) 257–2638, steeleln@csr.nih.gov.

Name of Committee: Social and Community Influences on Health Integrated Review Group; Social Sciences and Population Studies A Study Section.

Date: October 22–23, 2024.

Time: 9:00 a.m. to 7:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Washington Plaza Hotel, 10 Thomas Circle NW, Washington, DC 20005.

Meeting Format: In Person.

Contact Person: Suzanne Ryan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, (301) 435–1712, ryansj@csr.nih.gov.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Neurodifferentiation, Plasticity, Regeneration and Rhythmicity Study Section.

Date: October 22–23, 2024.

Time: 9:00 a.m. to 8:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Meeting Format: In Person.

Contact Person: Jacek Topczewski, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1002A1, Bethesda, MD 20892, (301) 594–7574, topczewskij2@csr.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: September 17, 2024.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–21617 Filed 9–20–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Eunice Kennedy Shriver National Institute of Child Health and Human Development Initial Review Group, Population Sciences Study Section, October 25, 2024, 09:00 a.m. to 05:00 p.m., Hyatt Regency Bethesda, 7400 Wisconsin Avenue, Bethesda, MD 20814, which was published in the **Federal Register** on June 17, 2024, FR Doc. No. 2024–13310, 89 FR 51537.

This notice is being amended to change the start time of the meeting from 9:00 a.m. to 10:00 a.m. E.T. The meeting is closed to the public.

Dated: September 18, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–21662 Filed 9–20–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which

would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Initial Review Group; Mental Health Services Study Section.

Date: October 21–22, 2024.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency, Bethesda, One Bethesda Metro Center, Bethesda, MD 20814 (Hybrid Meeting).

Contact Person: Aileen Schulte, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, Neuroscience Center, 6001 Executive Blvd., Bethesda, MD 20852, 301–443–1225, email: aschulte@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: September 18, 2024.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–21663 Filed 9–20–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; National Institutes of Health NeuroBioBank Tissue Access Request and Progress Report Forms (National Institute of Mental Health)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request more information on the

proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Andrew Hooper, National Institute of Mental Health (NIMH) Project Clearance Liaison, Science Policy and Evaluation Branch, Office of Science Policy, Planning and Communications, NIMH, Neuroscience Center, 6001 Executive Boulevard, MSC 9667, Bethesda, Maryland 20892, call (301) 480-8433 or Email your request, including your address to: nimhprapubliccomments@mail.nih.gov.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on July 16, 2024, 89 FR 57915, and allowed 60 days for public comment (<https://www.federalregister.gov/d/2024-15588>). No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

The National Institute of Mental Health (NIMH), National Institutes of

Health (NIH), may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the NIH has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: NIH NeuroBioBank Tissue Access Request and Progress Report Forms, REVISION, OMB #0925-0723, exp., date 10/31/2024, National Institute of Mental Health, National Institutes of Health (NIH).

Need and Use of Information Collection: This request serves as notice that the National Institutes of Health (NIH) plans to continue supporting the research community studying

neurological, developmental, and psychiatric disorders by coordinating access to human post-mortem brain tissue and related biospecimens stored by our federation of networked brain and tissue repositories known as the NIH NeuroBioBank. To facilitate this process, researchers wishing to obtain brain tissue and biospecimens stored by the NIH NeuroBioBank must continue completing the NIH NeuroBioBank Tissue Access Request Form. The primary use of the information collected by this instrument is to document, track, monitor, and evaluate the appropriate use of the NIH NeuroBioBank resources, as well as to notify interested recipients of updates, corrections or changes to the system.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 175.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
NBB Tissue Access Request Form (NIH-Funded Research) ..	Researchers	200	1	15/60	50
NBB Tissue Access Request Form (Other US Federal Government-Funded Research).	Researchers	20	1	15/60	5
NBB Tissue Access Request Form (State Government-Funded Research).	Researchers	20	1	15/60	5
NBB Tissue Access Request Form (Foreign Government-Funded Research).	Researchers	20	1	15/60	5
NBB Tissue Access Request Form (Private Industry/Commercial-Funded Research).	Researchers	20	1	15/60	5
NBB Tissue Access Request Form (Other Entity-Funded Research).	Researchers	20	1	15/60	5
NBB Progress Report	Researchers	400	1	15/60	100
Total		700			175

Dated: September 18, 2024.

Andrew A. Hooper,

Project Clearance Liaison, National Institute of Mental Health, National Institutes of Health.

[FR Doc. 2024-21686 Filed 9-20-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; 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: National Eye Institute Special Emphasis Panel; Individual Training Grant (K) Applications.

Date: October 29, 2024.

Time: 9:30 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Eye Institute, 6700 Rockledge Dr., Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Jeanette M Hosseini, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, National Eye Institute, 6700 B Rockledge Drive Bethesda, MD 20817, 301-451-2020, jeanetteh@mail.nih.gov.

Name of Committee: National Eye Institute Special Emphasis Panel; Institutional Training Grants.

Date: October 30, 2024.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Eye Institute, 6700 Rockledge Dr., Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Jennifer C Schiltz, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, National Eye Institute, 6700 B Rockledge

Drive, Bethesda, MD 20817, 240-276-5864, jennifer.schultz@nih.gov.

Name of Committee: National Eye Institute Special Emphasis Panel; Secondary Data Analysis Applications (R21).

Date: November 1, 2024.

Time: 12:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Eye Institute, 6700 Rockledge Dr., Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Brian Hoshaw, Ph.D., Chief, Scientific Review Branch, Division of Extramural Activities, National Eye Institute, National Institutes of Health, 6700 B Rockledge Dr., Rockville, MD 20817, 301-451-2020, hoshawb@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program No. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: September 17, 2024

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-21615 Filed 9-20-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

New Agency Information Collection Activity Under OMB Review: Minimum Standards for Driver's Licenses and Identification Cards Acceptable by Federal Agencies for Official Purposes

AGENCY: Transportation Security Administration, DHS.

ACTION: 30-Day notice.

SUMMARY: This notice announces that the Transportation Security Administration (TSA) has forwarded the new Information Collection Request (ICR) abstracted below to the Office of Management and Budget (OMB) for review and approval under the Paperwork Reduction Act (PRA). The ICR describes the nature of the information collection and its expected burden. The collection involves the requirement that States who seek a temporary waiver of the prohibition on Federal acceptance, for official purposes, of mobile driver's licenses (mDLs) that do not comply with the REAL ID Act and regulations, must submit an application for such waiver to TSA.

DATES: Send your comments by October 23, 2024. A comment to OMB is most effective if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent

within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review—Open for Public Comments" and by using the find function.

FOR FURTHER INFORMATION CONTACT:

Christina A. Walsh, TSA PRA Officer, Information Technology, TSA-11, Transportation Security Administration, 6595 Springfield Center Drive, Springfield, VA 20598-6011; telephone (571) 227-2062; email TSAPRA@tsa.dhs.gov.

SUPPLEMENTARY INFORMATION: TSA

published a Notice of Proposed Rulemaking (NPRM), *Minimum Standards for Driver's Licenses and Identification Cards Acceptable by Federal Agencies for Official Purposes; Waiver for Mobile Driver's Licenses*, soliciting public comments of the following collection of information on August 30, 2023, at 88 FR 60056. TSA received 31 public comments on the NPRM and on this collection. TSA fully considered all comments, including those submitted late.

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The ICR documentation will be available at <https://www.reginfo.gov> upon its submission to OMB. Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

- (1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- (2) Evaluate the accuracy of the agency's estimate of the burden;
- (3) Enhance the quality, utility, and clarity of the information to be collected; and
- (4) Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Information Collection Requirement

Title: Minimum Standards for Driver's Licenses and Identification Cards Acceptable by Federal Agencies for Official Purposes.

Type of Request: New collection.

OMB Control Number: 1652-XXXX.
Form(s): N/A.

Affected Public: States.

Abstract: Beginning May 7, 2025, the REAL ID regulations prohibit Federal agencies from accepting, for official purposes, driver's licenses or identification cards that are not compliant with REAL ID requirements.¹ In December 2020, the REAL ID Modernization Act clarified that mobile or digital driver's licenses or identification cards (collectively "mobile driver's licenses" or "mDLs"), are subject to REAL ID requirements.² This Act also amended the definitions of "driver's license" and "identification card" to specifically include mDLs that have been issued in accordance with regulations prescribed by the Secretary.

The REAL ID Act was enacted, and DHS regulations issued, before the development of mDLs. As a result, many of the current regulation's security requirements for physical cards, such as physical security features to deter fraud and tampering, do not apply to mDLs. In the absence of regulatory requirements to address mDLs, States are unable to issue REAL ID-compliant mDLs. TSA has initiated a two-phased rulemaking to address this gap. The first phase enables States to apply to TSA for a temporary waiver of certain requirements in the regulations. In the second phase, TSA would repeal the waiver provisions established in the first phase and establish comprehensive requirements enabling States to issue mDLs that comply with REAL ID requirements.

In August 2023, TSA published a notice of proposed rulemaking (NPRM)³ to amend the DHS REAL ID regulations as part of the multi-phased approach to address mDLs. The NPRM proposed to waive, on a temporary and State-by-State basis, the regulatory requirement that mDLs must be compliant with REAL ID requirements to be accepted by Federal agencies for official purposes. The NPRM proposed the process and standards for the waiver to permit Federal agencies, at their discretion, to continue accepting for official purposes mDLs after May 7, 2025, if the mDL is issued by a State to whom TSA has issued a waiver.

As the NPRM called for a collection of information under the PRA, TSA invited interested persons to submit written comments, including relevant data about the cost and hour burden of

¹ 6 CFR 37.65(a).

² Sec. 1001 of the REAL ID Modernization Act, Title X of Division U of the Consolidated Appropriations Act, 2021, Public Law 116-260, 134 Stat. 2304.

³ 88 FR 60056 (Aug. 30, 2023).

requirements in the NPRM. TSA is publishing this 30-day notice to provide the public additional opportunity to provide written comments directly to OMB.

Through the NPRM, TSA proposed requiring States that seek a waiver to submit an application and supporting materials to TSA using the procedures in 6 CFR 37.9(a) and 37.10(a)–(b). This collection of the information will enable TSA to issue a waiver to States, and TSA will use all of the submitted documentation to evaluate a State's request for a waiver, if and when the NPRM is made final. States would be required to submit information to TSA as part of their applications for a certificate of waiver for mDLs, as well as to comply with reporting requirements, and in response to TSA notices of suspension and termination. The NPRM also proposed continuing obligations on a State that has been issued a waiver that may require it to submit additional materials to TSA.

Specifically, the NPRM, if finalized, would require the following information collections from States:

- (i) Submission of Initial Application and Audit Report
- (ii) Supplemental Submissions
- (iii) Request for Reconsideration of Denied Application
- (iv) Re-Application
- (v) Reporting of Significant Modifications to mDL Issuance Processes
- (vi) Reporting of Discovery of Significant Cyber Incident or Breach
- (vii) Responses to TSA Notices of Suspension and Termination

Estimated Number of Respondents: 19.

Estimated Annual Burden Hours: An estimated 245 hours annually.

Dated: September 18, 2024.

Christina A. Walsh,

*TSA Paperwork Reduction Act Officer,
Information Technology.*

[FR Doc. 2024–21653 Filed 9–20–24; 8:45 am]

BILLING CODE 9110–05–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7086–N–25]

60-Day Notice of Proposed Information Collection: Project Rental Assistance Program of Section 811 Supportive Housing for Persons With Disabilities; OMB Control No.: 2502–0608

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, 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 comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* November 22, 2024.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection can be sent within 60 days of publication of this notice to www.regulations.gov. Interested persons are also invited to submit comments regarding this proposal by name and/or OMB Control Number and can be sent to: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410–5000; telephone (202) 402–3400. (this is not a toll-free number) or email at Colette.Pollard@hud.gov, for a copy of the proposed forms or other available information.

FOR FURTHER INFORMATION CONTACT:

Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette.Pollard@hud.gov or telephone

(202) 402–3400. 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 and 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. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Project Rental Assistance Program of Section 811 Supportive Housing for Persons with Disabilities.

OMB Approval Number: 2502–0608.

Type of Request: Revision of currently approved collection:

Form Number: HUD–92235, HUD–92236, HUD–92237, HUD–92238, HUD–92239, HUD–92240 & HUD–93205.

Description of the need for the information and proposed use: The collection of this information is necessary to the Department to assist HUD in determining applicant eligibility and capacity to award and administer the HUD PRA funds within statutory and program criteria. A thorough evaluation of an applicant's submission is necessary to protect the Government's financial interest.

Respondents: Business or other for-profit State, local or Tribal government, not-for-profit institutions.

Estimated Number of Respondents: 802.

Estimated Number of Responses: 898.

Frequency of Response: Annually or quarterly.

Average Hours per Response: Varies from 10 minutes to 20 hours.

Total Estimated Burdens: 1584.50.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
	802	9	898	14.5	1584.50	42.55	67,420.47

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 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35.

Jeffrey D. Little,

General Deputy Assistant Secretary, Office of Housing.

[FR Doc. 2024–21668 Filed 9–20–24; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R7–NWRS–2024–0032;
FXRS126107ISLAN–245–FF07R02000]

Notice of Intent To Prepare an Environmental Impact Statement for Rat Eradication From Four Uninhabited Aleutian Islands; Alaska Maritime National Wildlife Refuge, AK

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of intent; request for comments.

SUMMARY: We, the Fish and Wildlife Service, intend to prepare an environmental impact statement (EIS) for a proposed project to eradicate nonnative rats from four uninhabited islands (Amchitka, Attu, Great Sitkin, and Kiska Islands) located in the Alaska Maritime National Wildlife Refuge. The U.S. Department of Agriculture's Animal and Plant Health Inspection Service is a cooperating agency on the EIS. We invite comments for consideration in establishing the scope and content of the EIS from the public and local, State, Tribal, and Federal agencies.

DATES:

Submitting comments: We must receive written data or comments by November 7, 2024.

Public meeting: The Service will hold a public scoping meeting in Anchorage, Alaska. A virtual participation option will also be available. If you wish to participate virtually, contact the person in **FOR FURTHER INFORMATION CONTACT** no later than two days prior to the meeting. The date, time, and location of the meeting will be announced through

local media and social media, and on the project website (<https://www.fws.gov/ratfreealeutians>).

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

- *In-person:* At the public scoping meeting, you may submit written comments to Service personnel or to the court reporter monitoring the meeting and typing up a record.

- *Online:* <https://www.regulations.gov>. Search for and submit comments on Docket No. FWS–R7–NWRS–2024–0032.

- *U.S. mail:* Public Comments Processing, Attn: Docket No. FWS–R7–NWRS–2024–0032; U.S. Fish and Wildlife Service, MS: PRB/3W; 5275 Leesburg Pike; Falls Church, VA 22041–3803.

For more information, see “Public Comment Procedures” under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT:

Steve Delehanty, Refuge Manager, via telephone at 907–226–4627, via email at steve_delehanty@fws.gov, or via U.S. mail at U.S. Fish and Wildlife Service, Alaska Maritime National Wildlife Refuge, 95 Sterling Highway, Homer, AK, 99603. Please also visit the project website at <https://www.fws.gov/aleutianrateis>. 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: We, the Fish and Wildlife Service (Service), intend to prepare an environmental impact statement (EIS) pursuant to the National Environmental Policy Act (NEPA; 42 U.S.C 4321 *et seq.*), the Council on Environmental Quality's regulations for implementing NEPA (40 CFR parts 1500–1508), and the Department of the Interior's NEPA regulations (43 CFR part 46) for a proposed project to eradicate nonnative rats from four uninhabited islands (Amchitka, Attu, Great Sitkin, and Kiska Islands) located in the Alaska Maritime National Wildlife Refuge (Refuge). The U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) is a cooperating agency on the EIS. We invite comments from the public and local, State, Tribal, and Federal agencies on the scope of the analysis, potential alternatives, and identification of relevant information, studies, and analyses.

Purpose and Need for the Proposed Action

The purpose of the proposed action is to eradicate nonnative rats from Amchitka, Attu, Great Sitkin, and Kiska Islands in the Aleutian archipelago, in order to eliminate their impacts on native species and to restore natural island ecosystems. Nonnative rats occur on these four uninhabited islands, where they have impacted native wildlife populations and altered natural ecosystem function.

The Refuge encompasses over 1.9 million hectares and several thousand coastal islands in Alaska. The long-term management strategies for the Refuge are guided by its record of decision for its Final Comprehensive Conservation Plan/Environmental Impact Statement and Wilderness Review (plan) (FWS 1988). The wildlife management goal of the selected management alternative in the plan is to protect existing fish and wildlife populations and habitats, restore endangered and other species to natural levels, and increase opportunities for wildlife viewing and other nonconsumptive uses. One of the strategies identified to meet this goal is the eradication of introduced predators and rodents. Many Refuge islands have had accidental and intentional introductions of nonendemic mammals (*e.g.*, Arctic and red fox, ground squirrel, Norway rat, house mouse, caribou, reindeer, cattle, and Arctic and European hare). Although new introductions are prohibited, accidental introductions, particularly of rodents, are still of great concern.

Action is needed because rats have invaded at least 12 large islands in the Aleutian Island archipelago, including Amchitka, Attu, Great Sitkin, and Kiska Islands, and the diversity and numbers of breeding birds are conspicuously low on islands with established populations of introduced rats, which is consistent with worldwide observations of the devastating direct impacts of introduced rats on seabirds. Most of the Aleutian Islands lying within the Refuge provide important breeding habitat for seabirds, including many bird species for which the Aleutians provide a substantial portion of their worldwide range. Rat-caused modifications to other components of the island ecosystems (*e.g.*, other birds, plants, and invertebrates) are also evident.

The restoration of Aleutian ecosystems through eradications of introduced predators has long been identified as a management priority for the Refuge. Introduced foxes have been removed from over 40 islands in the Aleutians, while Norway rats have been

successfully eradicated from 1. In 2008, the Refuge and partner organizations demonstrated that Norway rats could be successfully eradicated from Hawadax Island, and that the eradication could have a positive impact on native wildlife communities.

Post-eradication monitoring found significant recoveries of terrestrial birds and shorebirds, and the initial recolonization or recovery of marine birds 5 years after eradication. Intertidal ecosystem recovery was also documented 11 years post-eradication.

Proposed Action and Possible Alternatives

The Service intends to eradicate nonnative rats from four uninhabited islands in the Refuge. The islands are remote, and eradication efforts would be undertaken one single island at a time, with years between efforts on each island. The Service is currently considering four preliminary alternatives and a no-action alternative. The Service will identify a preferred alternative in the final EIS. The following alternatives are preliminary and may be revised based on public input and internal considerations.

- *Alternative 1:* The no-action alternative, in which nonnative rats remain on islands.
- *Alternative 2:* This alternative proposes rat eradication primarily using bait pellets containing the rodenticide brodifacoum.
- *Alternative 3:* This alternative proposes rat eradication primarily using bait pellets containing the rodenticide diphacinone.
- *Alternative 4:* This alternative analyzes rat eradication using emerging genetic biocontrol technology to limit propagation or survival.
- *Alternative 5:* This alternative analyzes rat eradication primarily using bait pellets containing the rodenticide norbormide.

Summary of Expected Impacts

The overall impact of the proposed action of eradicating nonnative rats is anticipated to have a beneficial effect on the islands' ecosystems. However, the EIS analysis will focus on the potential significant impacts of each alternative. The Service anticipates impacts to occur to, but not be limited to, the following resources from any or all of the proposed alternatives:

- Access to public lands
- Air quality and climate
- Aquatic and marine environments, including anadromous and non-anadromous fish and invertebrate species
- Cultural and historical resources

- Designated Wilderness
- Endangered Species Act-listed species
- Marine mammals
- Migratory birds, including bald eagles
- Public health and safety
- Socioeconomics, including impacts to subsistence and recreational fisheries
- Water quality

Anticipated Permits and Authorities

The proposed action may require the following permits or approvals:

- Alaska Department of Fish and Game Wildlife Nuisance permit
- Alaska Department of Natural Resources Fish Habitat permit
- Alaska Native Claims Settlement Act section 14(h)(1) private land permission
- Bald and Golden Eagle Protection Act permit
- Clean Water Act permit
- Endangered Species Act section 7 consultation
- Federal Insecticide, Fungicide, and Rodenticide Act section 3 pesticide labels
- Magnuson-Stevens Fisheries Conservation Act consultations for essential fish habitat
- Marine Mammal Protection Act authorization
- Migratory Bird Treaty Act
- Pesticide Use Proposal
- State Historic Preservation Office section 106 consultation under the National Historic Preservation Act
- Water Pollution Control Act of 1948, as amended, National Pollutant Discharge Elimination System permit

Schedule for the Decision-Making Process

The Service will review and consider comments received during scoping and incorporate substantive comments while writing the draft EIS. The Service anticipates completion of the draft EIS in spring 2026, at which time we will publish a **Federal Register** notice of availability requesting public comments. We will also hold a public meeting on the draft EIS. We anticipate making the final EIS available to the public in fall 2026. In accordance with 40 CFR 1506.10, a record of decision shall not be made or issued for a minimum of 30 days after the publication of the final EIS.

Public Comment Procedures

Public Availability of Comments

If you submit a comment at <https://www.regulations.gov>, your entire comment, including any personal identifying information, will be posted on the website. If you submit a hardcopy comment that includes

personal identifying information, such as your address, phone number, or email address, 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 hardcopy comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

How To Request Reasonable Accommodations

For assistance at a scoping meeting, please contact the point of contact in **FOR FURTHER INFORMATION CONTACT**. Information regarding this project will be made available in alternate formats upon request.

Socheata Lor,

Acting Regional Director, Alaska Region.

[FR Doc. 2024–21714 Filed 9–20–24; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_AZ_FRN_MO4500182907]

Notice of Filing of Plats of Survey; Arizona

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of official filing.

SUMMARY: The plats of survey of the following described land were officially filed in the Bureau of Land Management (BLM), Arizona State Office, Phoenix, Arizona on the dates indicated. The surveys announced in this notice are necessary for the management of lands administered by the agency indicated.

ADDRESSES: These plats will be available for inspection in the Arizona State Office, Bureau of Land Management, One North Central Avenue, Suite 800, Phoenix, Arizona 85004–4427. Protests of any of these surveys should be sent to the Arizona State Director at the above address.

FOR FURTHER INFORMATION CONTACT:

Geoffrey A. Graham, Chief Cadastral Surveyor of Arizona; (602) 417–9558; ggraham@blm.gov. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 7–1–1 to leave a message or question for the above individual. The FRS is available 24 hours a day, 7 days a week. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION:

The Gila and Salt River Meridian, Arizona

The plat, in one sheet, representing the dependent resurvey of a portion of the subdivisional lines, the subdivision of sections 4 and 9, and a metes-and-bounds survey of Tract 37, Township 14 North, Range 6 East, accepted May 21, 2024, and officially filed May 23, 2024, for Group 1230, Arizona.

This plat was prepared at the request of the United States Forest Service.

The plat, in one sheet, representing the dependent resurvey of a portion of the subdivisional lines, the subdivision of section 22, and the metes-and-bounds survey of a portion of the Sunset Crater Volcano National Monument boundary, Township 23 North, Range 8 East, accepted June 25, 2024, and officially filed June 28, 2024, for Group 1231, Arizona.

This plat was prepared at the request of the National Park Service.

The plat, in two sheets, representing the dependent resurvey of a portion of the Sixth Standard Parallel North (south boundary of Township 25 North, Range 13 East), the survey of a portion of the Sixth Standard Parallel North (south boundary of township 25 North, Range 12 ½ East), a portion of the Third Guide Meridian East (east boundary Township 25 North, Range 12 ½ East, south boundary, the subdivisional lines and the subdivision of certain sections, Township 24 North, Range 13 East, accepted August 27, 2024, and officially filed August 29, 2024, for Group 1223, Arizona.

This plat was prepared at the request of the Bureau of Indian Affairs.

The plat, in one sheet, representing the survey of the east and north boundaries, the subdivisional lines and the subdivision of certain sections, Township 37 North, Range 26 East, accepted August 27, 2024, and officially filed August 29, 2024, for Group 1227, Arizona.

This plat was prepared at the request of the Bureau of Indian Affairs.

The plat, in one sheet, representing the dependent resurvey of a portion of the subdivisional lines and the subdivision of section 18, Township 25 North, Range 29 East, accepted June 25, 2024, and officially filed June 28, 2024, for Group 1232, Arizona.

This plat was prepared at the request of the Bureau of Indian Affairs.

A person or party who wishes to protest any of these surveys must file a written notice of protest within 30 calendar days from the date of this publication with the Arizona State Director, Bureau of Land Management, stating that they wish to protest.

A statement of reasons for a protest may be filed with the notice of protest to the State Director, or the statement of reasons must be filed with the State Director within 30 days after the protest is filed. Before including your address, or other personal information in your protest, please be aware that your entire protest, including your personal identifying information, may be made publicly available at any time. While

you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

(Authority: 43 U.S.C. chapter 3)

Geoffrey A. Graham,
Chief Cadastral Surveyor of Arizona.

[FR Doc. 2024–21712 Filed 9–20–24; 8:45 am]

BILLING CODE 4331–12–P

DEPARTMENT OF THE INTERIOR**Office of Natural Resources Revenue**

[Docket No. ONRR–2011–0019; DS63644000 DRT000000.CH7000 234D1113RT, OMB Control Number 1012–0001]

Agency Information Collection Activities; Accounts Receivable Confirmations Reporting

AGENCY: Office of Natural Resources Revenue (“ONRR”), Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (“PRA”), ONRR is proposing to renew an information collection. Through this Information Collection Request (“ICR”), ONRR seeks renewed authority to collect information related to the paperwork requirements under the Chief Financial Officers Act of 1990 (“CFO Act”) covering the collection of royalties and other mineral revenues due, which obligations are accounted for as accounts receivables.

DATES: Interested persons are invited to submit comments on or before October 23, 2024.

ADDRESSES: All comment submissions must (1) reference “OMB Control Number 1012–0001” in the subject line; (2) be sent to ONRR before the close of the comment period listed under **DATES**; and (3) be sent through the following method:

Electronically via the Federal eRulemaking Portal: Please visit <https://www.regulations.gov>. In the Search Box, enter the Docket ID Number for this ICR renewal (“ONRR–2011–0019”) to locate the document and click the “Comment Now!” button. Follow the prompts to submit your comment prior to the close of the comment period.

Docket: To access the docket to view ICR publications in the **Federal Register**, go to <https://www.regulations.gov> and search “ONRR–2011–0019”. The docket will display renewal notices recently published in the **Federal Register**, publications associated with prior

renewals, and applicable public comments received for this ICR.

OMB ICR Data: OMB also maintains information on ICR renewals and approvals. You may access this information at <https://www.reginfo.gov/public/do/PRASearch>. Please use the following instructions: Under the “OMB Control Number” heading enter “1012–0001” and click the “Search” button located at the bottom of the page. To view the ICR renewal or OMB approval status, click on the latest entry (based on the most recent date). On the “View ICR—OIRA Conclusion” page, check the box next to “All” to display all available ICR information provided by OMB.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, please contact Thomas Anthony, Financial Services, by email at Thomas.Anthony@onrr.gov or by telephone at (303) 231–3708.

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: Pursuant to the PRA, 44 U.S.C. 3501, *et seq.*, and 5 CFR 1320.5, all information collections as defined in 5 CFR 1320.3, require approval by OMB. ONRR may not conduct or sponsor, and you are not required to respond to, a collection of information unless it displays a currently valid OMB control number.

As part of ONRR’s continuing effort to reduce paperwork and respondent burdens, ONRR is inviting the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information in accordance with the PRA and 5 CFR 1320.8(d)(1). This helps ONRR assess the impact of its information collection requirements and minimize the public’s reporting burden. It also helps the public understand ONRR’s information collection requirements and provide the requested data in the desired format.

ONRR is especially interested in public comments addressing the following:

- (1) 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;
- (2) The accuracy of ONRR’s 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.

ONRR published a notice, with a 60-day public comment period soliciting comment of this collection of information, in the **Federal Register** on April 16, 2024 (89 FR 26915). ONRR did not receive comments from companies regarding the published 60-day **Federal Register** notice. ONRR conducted outreach to industry and did not receive any comments.

Comments that you submit in response to this 30-day notice are a matter of public record. ONRR will include or summarize each comment in its request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask ONRR in your comment to withhold information from public review, ONRR cannot guarantee that it will be able to do so.

Abstract: (a) *General Information:* The Secretary of the United States Department of the Interior (“Secretary”) is responsible for mineral resource development on Federal and Indian lands and the Outer Continental Shelf. Laws pertaining to Federal and Indian mineral leases are posted at <https://onrr.gov/references/statutes>. Pursuant to the Federal Oil and Gas Royalty Management Act of 1982 (“FOGRMA”) and other laws, the Secretary’s responsibilities include maintaining a comprehensive inspection, collection, and fiscal and production accounting and auditing system that: (1) accurately determines mineral royalties, interest, and other payments owed, (2) collects and accounts for such amounts in a timely manner, and (3) disburses the funds collected. See 30 U.S.C. 1701 and 1711. ONRR performs these mineral revenue management responsibilities for the Secretary. See Secretarial Order No. 3306. Royalty payors submit royalty reports to ONRR on a monthly basis by submitting forms ONRR–2014 (Report of Sales and Royalty Remittance) and ONRR–4430 (Solid Minerals Production and Royalty Report). ONRR uses these royalty reports to create accounts

receivables of the mineral revenues that ONRR collects.

The basis for the data that a company submits on forms ONRR–2014 and ONRR–4430 is generally available within the records of the lessee or others involved in developing, transporting, processing, purchasing, or selling such minerals. The information that ONRR collects under this ICR includes data necessary to ensure that ONRR’s accounts receivables are accurately based on the value of the mineral production, as reported to ONRR on forms ONRR–2014 and ONRR–4430.

(b) *Information Collections:* Every year, under the CFO Act, the Office of Inspector General (“OIG”) or its agent audits the accounts receivable portions of the Department of the Interior’s financial statements, which includes accounts receivables based on ONRR forms ONRR–2014 and ONRR–4430. Accounts receivable confirmations are a common practice in the audit business.

As part of CFO Act audits, the OIG or its agent selects a sample of accounts receivable items based on forms ONRR–2014 and ONRR–4430 and provides the sample items to ONRR. ONRR then identifies the company names and addresses for the sample items selected and creates accounts receivable confirmation letters. In order to meet the CFO Act’s requirements, the letters must be on ONRR letterhead and the Deputy Director for ONRR, or his or her designee, must sign the letters. The letters request third-party confirmation responses by a specified date on whether ONRR’s accounts receivable records agree with royalty payor records for the following items: (1) customer identification; (2) royalty invoice number; (3) payor assigned document number; (4) date of ONRR receipt; (5) original amount the payor reported; and (6) remaining balance due to ONRR. The OIG or its agent mails the letters to the payors, instructing them to respond directly to confirm the accuracy and validity of selected royalty receivable items and amounts. In turn, it is the responsibility of the payors to verify, research, and analyze the amounts and balances reported on their respective forms ONRR–2014 and ONRR–4430.

Title of Collection: Accounts Receivable Confirmations.

OMB Control Number: 1012–0001.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Businesses.

Total Estimated Number of Annual Respondents: 24 randomly selected mineral payors from Federal and Indian lands and the OCS.

Total Estimated Number of Annual Responses: 24.

Estimated Completion Time per Response: ONRR estimates that each response will take 15 minutes for payors to complete.

Total Estimated Number of Annual Burden Hours: 6 hours.

Respondent’s Obligation: Voluntary.

Frequency of Collection: Annual.

Total Estimated Annual Non-Hour Burden Cost: ONRR did not identify any “non-hour cost” burden associated with this collection of information.

An agency may not conduct, or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the PRA of 1995 (44 U.S.C. 3501 *et seq.*).

Howard M. Cantor,

Director, Office of Natural Resources Revenue.

[FR Doc. 2024–21613 Filed 9–20–24; 8:45 am]

BILLING CODE 4335–30–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1418]

Certain Cochlear Implant Systems and Components Thereof; Notice of Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on August 16, 2024, under section 337 of the Tariff Act of 1930, as amended, on behalf of Advanced Bionics AG of Switzerland and Advanced Bionics LLC of Valencia, California. Supplements were filed on August 29, and 30, and September 6, 2024. The complaint, as supplemented, alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain cochlear implant systems and components thereof by reason of the infringement of certain claims of U.S. Patent No. 7,317,945 (“the ‘945 patent”) and U.S. Patent No. 8,422,706 (“the ‘706 patent”). The complaint, as supplemented, further alleges that an industry in the United States exists as required by the applicable Federal statute. The complainants request the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email EDIS3Help@usitc.gov. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server at <https://www.usitc.gov>.

FOR FURTHER INFORMATION CONTACT:

Pathenia M. Proctor, The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2560.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2024).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on September 17, 2024, *ordered that—*

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products identified in paragraph (2) by reason of infringement of one or more of claims 1, 3–11, and 13–22 of the '945 patent, and claims 1–20 of the '706 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Pursuant to section 210.10(b)(1) of the Commission's Rules of Practice and Procedure, 19 CFR 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is “cochlear implant systems as a whole, and the individual microphone, sound processor, external headpiece transmitter, implanted receiver and electrode array components of a cochlear implant system”;

(3) Pursuant to Commission Rule 210.50(b)(1), 19 CFR 210.50(b)(1), the presiding administrative law judge shall take evidence or other information and

hear arguments from the parties or other interested persons with respect to the public interest in this investigation, as appropriate, and provide the Commission with findings of fact and a recommended determination on this issue, which shall be limited to the statutory public interest factors set forth in 19 U.S.C. 1337(d)(1), (f)(1), (g)(1);

(4) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainants are:
Advanced Bionics AG, Laubisrütistrasse 28, 8712 Stäfa, Switzerland
Advanced Bionics LLC, 28515 Westinghouse Place, Valencia, CA 91355

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

MED–EL Corporation, USA, 2645 Meridian Parkway, Suite 100, Durham, NC 27713
MED – EL Elektromedizinische Geräte GmbH, Fürstenweg 77a, 6020 Innsbruck, Austria

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street SW, Suite 401, Washington, DC 20436; and

(5) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), as amended in 85 FR 15798 (March 19, 2020), such responses will be considered by the Commission if received not later than 20 days after the date of service by the complainants of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice

and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: September 17, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024–21634 Filed 9–20–24; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 731–TA–929–931 (Fourth Review)]

Silicomanganese From India, Kazakhstan, and Venezuela; Scheduling of Expedited Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of expedited reviews pursuant to the Tariff Act of 1930 (“the Act”) to determine whether revocation of the antidumping duty orders on silicomanganese from India, Kazakhstan, and Venezuela would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time.

DATES: August 5, 2024.

FOR FURTHER INFORMATION CONTACT:

Caitlyn Costello (202) 205–2058, 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 proceeding may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>.

SUPPLEMENTARY INFORMATION:

Background—On August 5, 2024, the Commission determined that the domestic interested party group response to its notice of institution (89 FR 35247, May 1, 2024) of the subject five-year reviews was adequate and that the respondent interested party group response was inadequate. The

Commission did not find any other circumstances that would warrant conducting full reviews.¹ Accordingly, the Commission determined that it would conduct expedited reviews pursuant to section 751(c)(3) of the Act (19 U.S.C. 1675(c)(3)).²

For further information concerning the conduct of these reviews and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Staff report—A staff report containing information concerning the subject matter of the reviews has been placed in the nonpublic record, and will be made available to persons on the Administrative Protective Order service list for these reviews on October 30, 2024. A public version will be issued thereafter, pursuant to § 207.62(d)(4) of the Commission's rules.

Written submissions—As provided in § 207.62(d) of the Commission's rules, interested parties that are parties to the reviews and that have provided individually adequate responses to the notice of institution,³ and any party other than an interested party to the reviews may file written comments with the Secretary on what determination the Commission should reach in the reviews. Comments are due on or before November 7, 2024 and may not contain new factual information. Any person that is neither a party to the five-year reviews nor an interested party may submit a brief written statement (which shall not contain any new factual information) pertinent to the reviews by November 7, 2024. However, should the Department of Commerce ("Commerce") extend the time limit for its completion of the final results of its reviews, the deadline for comments (which may not contain new factual information) on Commerce's final results is three business days after the issuance of Commerce's results. If comments contain business proprietary information (BPI), they must conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on*

Filing Procedures, available on the Commission's website at https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf, elaborates upon the Commission's procedures with respect to filings.

In accordance with §§ 201.16(c) and 207.3 of the rules, each document filed by a party to the reviews must be served on all other parties to the reviews (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Determination—The Commission has determined these reviews are extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: These reviews are being conducted under authority of title VII of the Act; this notice is published pursuant to § 207.62 of the Commission's rules.

By order of the Commission.

Issued: September 17, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024–21618 Filed 9–20–24; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–447 and 731–TA–1116 (Third Review)]

Circular Welded Carbon-Quality Steel Pipe From China; Scheduling of Expedited Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of expedited reviews pursuant to the Tariff Act of 1930 ("the Act") to determine whether revocation of the antidumping duty and countervailing duty orders on circular welded carbon-quality steel pipe from China would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time.

DATES: August 5, 2024.

FOR FURTHER INFORMATION CONTACT: Charles Cummings (202)–708–1666, 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 proceeding may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>.

SUPPLEMENTARY INFORMATION:

Background—On August 5, 2024, the Commission determined that the domestic interested party group response to its notice of institution (89 FR 35244, May 1, 2024) of the subject five-year reviews was adequate and that the respondent interested party group response was inadequate. The Commission did not find any other circumstances that would warrant conducting full reviews.¹ Accordingly, the Commission determined that it would conduct expedited reviews pursuant to section 751(c)(3) of the Act (19 U.S.C. 1675(c)(3)).²

For further information concerning the conduct of these reviews and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Staff report—A staff report containing information concerning the subject matter of the reviews has been placed in the nonpublic record, and will be made available to persons on the Administrative Protective Order service list for these reviews on November 12, 2024. A public version will be issued thereafter, pursuant to § 207.62(d)(4) of the Commission's rules.

Written submissions—As provided in § 207.62(d) of the Commission's rules, interested parties that are parties to the reviews and that have provided individually adequate responses to the notice of institution,³ and any party

¹ A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements will be available from the Office of the Secretary and at the Commission's website.

² Commissioner David S. Johanson determined that, in light of the time that has transpired since the Commission last conducted full investigations in this matter, conducting full reviews is warranted. Commissioner Jason E. Kearns did not participate in this vote.

³ The Commission has found the responses submitted on behalf of Bull Moose Tube Company; Maruichi American Corporation; Nucor Tubular Products, Inc.; and Zekelman Industries to be individually adequate. Comments from other interested parties will not be accepted (*see* 19 CFR 207.62(d)(2)).

¹ A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements will be available from the Office of the Secretary and at the Commission's website.

² Commissioner David S. Johanson voted to conduct full reviews. Commissioner Jason E. Kearns did not participate in this vote.

³ The Commission has found the response submitted on behalf of Eramet Marietta, Inc. to be individually adequate. Comments from other interested parties will not be accepted (*see* 19 CFR 207.62(d)(2)).

other than an interested party to the reviews may file written comments with the Secretary on what determination the Commission should reach in the reviews. Comments are due on or before November 20, 2024 and may not contain new factual information. Any person that is neither a party to the five-year reviews nor an interested party may submit a brief written statement (which shall not contain any new factual information) pertinent to the reviews by November 20, 2024. However, should the Department of Commerce (“Commerce”) extend the time limit for its completion of the final results of its reviews, the deadline for comments (which may not contain new factual information) on Commerce’s final results is three business days after the issuance of Commerce’s results. If comments contain business proprietary information (BPI), they must conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission’s rules. The Commission’s *Handbook on Filing Procedures*, available on the Commission’s website at https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf, elaborates upon the Commission’s procedures with respect to filings.

In accordance with §§ 201.16(c) and 207.3 of the rules, each document filed by a party to the reviews must be served on all other parties to the reviews (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Determination—The Commission has determined these reviews are extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: These reviews are being conducted under authority of title VII of the Act; this notice is published pursuant to § 207.62 of the Commission’s rules.

By order of the Commission.

Issued: September 17, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024–21643 Filed 9–20–24; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–601 and 731–TA–1411 (Review)]

Laminated Woven Sacks From Vietnam; Scheduling of Expedited Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of expedited reviews pursuant to the Tariff Act of 1930 (“the Act”) to determine whether revocation of the antidumping duty order and countervailing duty order on laminated woven sacks from Vietnam would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time.

DATES: August 5, 2024.

FOR FURTHER INFORMATION CONTACT: Kenneth Gatten III 202–708–1447, 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 proceeding may be viewed on the Commission’s electronic docket (EDIS) at <https://edis.usitc.gov>.

SUPPLEMENTARY INFORMATION:

Background—On August 5, 2024, the Commission determined that the domestic interested party group response to its notice of institution (89 FR 35241, May 1, 2024) of the subject five-year reviews was adequate and that the respondent interested party group response was inadequate. The Commission did not find any other circumstances that would warrant conducting full reviews.¹ Accordingly, the Commission determined that it would conduct expedited reviews pursuant to section 751(c)(3) of the Act (19 U.S.C. 1675(c)(3)).²

For further information concerning the conduct of these reviews and rules

of general application, consult the Commission’s Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Staff report—A staff report containing information concerning the subject matter of the reviews has been placed in the nonpublic record, and will be made available to persons on the Administrative Protective Order service list for these reviews on October 16, 2024. A public version will be issued thereafter, pursuant to § 207.62(d)(4) of the Commission’s rules.

Written submissions—As provided in § 207.62(d) of the Commission’s rules, interested parties that are parties to the reviews and that have provided individually adequate responses to the notice of institution,³ and any party other than an interested party to the reviews may file written comments with the Secretary on what determination the Commission should reach in the reviews. Comments are due on or before 5:15 p.m. on October 24, 2024 and may not contain new factual information. Any person that is neither a party to the five-year reviews nor an interested party may submit a brief written statement (which shall not contain any new factual information) pertinent to the reviews by October 24, 2024. However, should the Department of Commerce (“Commerce”) extend the time limit for its completion of the final results of its reviews, the deadline for comments (which may not contain new factual information) on Commerce’s final results is three business days after the issuance of Commerce’s results. If comments contain business proprietary information (BPI), they must conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission’s rules. The Commission’s *Handbook on Filing Procedures*, available on the Commission’s website at https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf, elaborates upon the Commission’s procedures with respect to filings.

In accordance with §§ 201.16(c) and 207.3 of the rules, each document filed by a party to the reviews must be served on all other parties to the reviews (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

¹ A record of the Commissioners’ votes, the Commission’s statement on adequacy, and any individual Commissioner’s statements will be available from the Office of the Secretary and at the Commission’s website.

² Commissioner Jason E. Kearns did not participate in this vote.

³ The Commission has found the response submitted on behalf of the Laminated Woven Sacks Fair Trade Coalition to be adequate. Comments from other interested parties will not be accepted (see 19 CFR 207.62(d)(2)).

Determination—The Commission has determined these reviews are extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: These reviews are being conducted under authority of title VII of the Act; this notice is published pursuant to § 207.62 of the Commission's rules.

By order of the Commission.

Issued: September 17, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024–21620 Filed 9–20–24; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

[OMB Number 1121–0339]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of a Currently Approved Collection; Comments Requested: Generic Clearance for Cognitive, Pilot and Field Studies for Bureau of Justice Statistics Data Collection Activities

AGENCY: Bureau of Justice Statistics, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Bureau of Justice Statistics (BJS), 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 November 22, 2024.

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 Devon Adams, Bureau of Justice Statistics, 999 N Capitol St. NE, Washington, DC 20531 (email: Devon.Adams@usdoj.gov; telephone: 202–307–0765).

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: Over the next three years, BJS anticipates undertaking a variety of new surveys and data collections, as well as reassessing ongoing statistical projects, across a number of areas of criminal justice, including law enforcement, courts, corrections, and victimization. This work will entail development of new survey instruments, redesigning and/or modifying existing surveys, procuring administrative data from state and local government entities, and creating or modifying establishment surveys. In order to inform BJS data collection protocols, to develop accurate estimates of respondent burden, and to minimize respondent burden associated with each new or modified data collection, BJS will engage in cognitive, pilot and field test activities to refine instrumentation and data collection methodologies. BJS envisions using a variety of techniques, including but not limited to tests of different types of survey and data collection operations, sample frame development, focus groups, cognitive testing, pilot testing, exploratory interviews, experiments with questionnaire design, and usability testing of electronic data collection instruments.

Following standard Office of Management and Budget (OMB) requirements, BJS will submit a change request to OMB individually for every group of data collection activities undertaken under this generic clearance. BJS will provide OMB with a copy of the individual instruments or questionnaires (if one is used), as well as other materials describing the project.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a currently approved collection.

2. *The Title of the Form/Collection:* Generic Clearance for cognitive, pilot and field studies for Bureau of Justice Statistics data collection Activities.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form numbers not available for generic clearance. The applicable component within the Department of Justice is the Bureau of Justice Statistics, in the Office of Justice Programs.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Administrators or staff of state and local agencies or programs in the relevant fields; administrators or staff of non-government agencies or programs in the relevant fields; individuals; policymakers at various levels of government.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* We estimate that approximately 30,000 respondents will be involved in exploratory, field test, pilot, cognitive, and focus group work conducted under this clearance over the requested 3-year clearance period. The average response time per respondent will be specific to each project covered under the clearance. Specific estimates of the number of respondents and the average response time are not known for each pilot study or development project covered under a generic clearance at this time. Project specific estimates will be submitted to OMB separately for each project conducted under this clearance. An estimate of the overall number of burden hours for activities under this generic

6. *An estimate of the total public burden (in hours) associated with the collection:* The total respondent burden for identified and future projects covered under this generic clearance over the 3-year clearance period is approximately 20,000 hours.

7. *An estimate of the total annual cost burden associated with the collection, if applicable:* N/A.

If additional information is required, contact: Darwin Arceo, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 4W–218, Washington, DC.

Dated: September 17, 2024.
Darwin Arceo,
*Department Clearance Officer for PRA, U.S.
Department of Justice.*
[FR Doc. 2024–21614 Filed 9–20–24; 8:45 am]
BILLING CODE 4410–18–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed
Consent Decree Under the Clean Air
Act

On September 16, 2024, the Department of Justice lodged a proposed consent decree with the United States District Court for the Western District of Texas in the lawsuit entitled *United States v. Cobb Tuning Products, LLC*, Civil Action No. 1:24–cv–01091–RP. The United States filed a complaint against Cobb Tuning Products, LLC (“Cobb Tuning”) alleging violations of the Clean Air Act related to Cobb Tuning’s manufacture, offer for sale, and sale of devices that defeat emission controls in automobiles. The proposed consent decree resolves the claims alleged in the complaint. The proposed consent decree requires Cobb Tuning to pay a penalty of \$2,914,000 over three years based on its ability to pay and to perform injunctive relief. The publication of this notice opens a period for public comment on the proposed consent decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States v. Cobb Tuning Products, LLC*, D.J. Ref. No. 90–5–2–1–12096. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	Send them to:
By email	<i>pubcomment-ees.enrd@ usdoj.gov.</i>
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 may be examined and downloaded at this Justice Department website: <https://www.justice.gov/enrd/consent-decrees>. If you require assistance accessing the proposed consent decree, you may request assistance by email or by mail

to the addresses provided above for submitting comments.
Scott Bauer,
*Assistant Section Chief, Environmental
Enforcement Section, Environment and
Natural Resources Division.*
[FR Doc. 2024–21659 Filed 9–20–24; 8:45 am]
BILLING CODE 4410–15–P

NATIONAL SCIENCE FOUNDATION

Committee on Equal Opportunities in
Science & Engineering; Notice of
Meeting

In accordance with the Federal Advisory Committee Act (Pub., L. 92–463, as amended), the National Science Foundation (NSF) announces the following meeting:
Name And Committee Code: Committee on Equal Opportunities in Science & Engineering (#1173) (Virtual)
Date And Time: October 21, 2024; 10:00 a.m.–4:30 p.m. (Eastern)
Place: National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314 (Virtual). Meeting Registration: Virtual attendance information will be forthcoming on the CEOSE website at <http://www.nsf.gov/od/oia/activities/ceose/index.jsp>.
Type Of Meeting: Open
Contact Persons: Dr. Bernice Anderson, Senior Advisor and CEOSE Executive Secretary, Office of Integrative Activities (OIA); National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314. Contact Information: Phone: 703–292–8040, Email: banderso@nsf.gov.
Minutes: Meeting minutes and other information may be obtained from the CEOSE Executive Secretary at the above address or the website at <http://www.nsf.gov/od/oia/activities/ceose/index.jsp>.
Purpose Of Meeting: To study data, programs, policies, and other information pertinent to the National Science Foundation and to provide advice and recommendations concerning broadening participation in science and engineering.

Agenda
CEOSE Agenda-at-a-Glance (October 21, 2024)
10:00 a.m.–10:30 a.m. Welcome, Introductions, Opening Remarks
10:30 a.m.–11:00 a.m. Presentation: Report of the NSF CEOSE Executive Liaison
11:00 a.m.–12:00 p.m. Presentation: NSF Efforts focused on BP Data Collection and Analyses
12:00 p.m.–12:45 p.m. Lunch Break

12:45 p.m.–1:30 p.m. Discussion: Reports of the CEOSE AC Liaisons
1:30 p.m.–2:45 p.m. Discussion: Draft 2023–2024 CEOSE Report
2:45 p.m.–3:00 p.m. Break
3:00 p.m.–4:15 p.m. Discussion: 2023–2024 Report Recommendations
4:15 p.m.–4:30 p.m. Announcements and Final Remarks
Dated: September 17, 2024.
Crystal Robinson,
Committee Management Officer.
[FR Doc. 2024–21647 Filed 9–20–24; 8:45 am]
BILLING CODE 7555–01–P

NUCLEAR REGULATORY
COMMISSION

[Docket No. 50–255–LA–3]
ASLBP No. 24–986–01–LA–BD01

Establishment of Atomic Safety and
Licensing Board; Holtec
Decommissioning International, LLC,
and Holtec Palisades, LLC

Pursuant to the Commission’s regulations, see, e.g., 10 CFR 2.104, 2.105, 2.300, 2.309, 2.313, 2.318, 2.321, notice is hereby given that an Atomic Safety and Licensing Board (Board) is being established to preside over the following proceeding:
Holtec Decommissioning International, LLC, and Holtec Palisades, LLC (Palisades Nuclear Plant)
Holtec Decommissioning International, LLC and Holtec Palisades, LLC seek four amendments to Renewed Facility Operating License No. DPR–20 to support the potential reauthorization of power operations at the Palisades Nuclear Plant, located in Covert Township, Michigan. In response to a notice filed in the **Federal Register** announcing the opportunity to request a hearing, see 89 FR 64,486 (Aug. 7, 2024), Alan Blind filed a hearing request on September 9, 2024. The Board is comprised of the following Administrative Judges: Emily I. Krause, Chair, Atomic Safety and Licensing Board Panel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001
Dr. Gary S. Arnold, Atomic Safety and Licensing Board Panel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001
Dr. Arielle J. Miller, Atomic Safety and Licensing Board Panel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001
All correspondence, documents, and other materials shall be filed in accordance with the NRC E-Filing rule. See 10 CFR 2.302.

Dated: September 17, 2024.

Edward R. Hawkens,

Chief Administrative Judge, Atomic Safety and Licensing Board Panel, Rockville, Maryland.

[FR Doc. 2024–21648 Filed 9–20–24; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–360, OMB Control No. 3235–0409]

Submission for OMB Review; Comment Request; Extension Rule 17Ad–15

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 (“PRA”) (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (“Commission”) has submitted to the Office of Management and Budget (“OMB”) a request for approval of extension of the previously approved collection of information provided for in Rule 17Ad–15 (17 CFR 240.17Ad–15) (“Rule 17Ad–15”) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) (“Exchange Act”).

Rule 17Ad–15 requires every registered transfer agent to establish written standards for the acceptance of guarantees of securities transfers from eligible guarantor institutions. Every registered transfer agent is also required to establish procedures, including written guidelines where appropriate, to make certain that the transfer agent uses those standards to determine whether to accept or reject guarantees from eligible guarantor institutions. In implementing these requirements, the Commission aims to ensure that registered transfer agents treat eligible guarantor institutions equitably.

Additionally, Rule 17Ad–15 requires every registered transfer agent to make and maintain records in the event the transfer agent determines to reject signature guarantees from eligible guarantor institutions. Registered transfer agents’ records must include, following the date of rejection, a record of the rejected transfer, along with the reason for rejection, the identification of the guarantor, and an indication whether the guarantor failed to meet the transfer agent’s guarantee standards. Rule 17Ad–15 requires registered transfer agents to maintain these records for a period of three years. The

Commission designed these mandatory recordkeeping requirements to assist the Commission and other regulatory agencies with monitoring registered transfer agents and ensuring compliance with the rule. This rule does not involve the collection of confidential information.

The Commission estimates that approximately 315 registered transfer agents will spend a total of approximately 12,600 burden hours per year complying with recordkeeping requirements of Rules 17Ad–15 (based on approximately 40 burden hours per year per registered transfer agent). The Commission also estimates the aggregate annual internal cost of compliance for the approximately 315 registered transfer agents is approximately \$4,019,400 (based on 40 hours annual burden × \$319 hourly wage × 315 respondents). This reflects a decline in aggregate annual internal cost of compliance of \$650,760 due to the decrease in the number of registered transfer agents from 366 to 315.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following website: www.reginfo.gov. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to: (i) www.reginfo.gov/public/do/PRAMain and (ii) Austin Gerig, Director/Chief Data Officer, Securities and Exchange Commission, c/o Oluwaseun Ajayi, 100 F Street NE, Washington, DC 20549, or by sending an email to: PRA_Mailbox@sec.gov.

Dated: September 18, 2024.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2024–21685 Filed 9–20–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101065; File No. SR–FINRA–2024–001]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Order Approving a Proposed Rule Change To Amend FINRA Rule 3240 (Borrowing From or Lending to Customers) To Strengthen the General Prohibition Against Borrowing and Lending Arrangements

September 17, 2024.

I. Introduction

On January 2, 2024, the Financial Industry Regulatory Authority, Inc. (“FINRA”) 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 (SR–FINRA–2024–001) to amend FINRA Rule 3240 (Borrowing From or Lending to Customers). ³ As stated in the Notice, the proposed rule change would strengthen the general prohibition against borrowing and lending arrangements, narrow some of the existing exceptions to that general prohibition, amend the immediate family exception, ⁴ and enhance the requirements for notifying and obtaining member firms’ approval of such arrangements. ⁵

The proposed rule change was published for public comment in the **Federal Register** on January 22, 2024. ⁶ The public comment period closed on February 12, 2024. The Commission received comment letters related to this filing. ⁷ On February 21, 2024, FINRA consented to an extension of the time period in which the Commission must approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to approve or disapprove the proposed rule change to April 19, 2024. ⁸

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ See Exchange Act Release No. 99351 (Jan. 16, 2024), 89 FR 3968 (Jan. 22, 2024) (File No. SR–FINRA–2024–001) (“Notice”), <https://www.govinfo.gov/content/pkg/FR-2024-01-22/pdf/2024-01068.pdf>.

⁴ See *infra* note 28 and accompanying text.

⁵ See Notice.

⁶ *Id.*

⁷ The comment letters are available at <https://www.sec.gov/comments/sr-finra-2024-001/srfinra2024001.htm>.

⁸ See letter from Ilana Reid, Associate General Counsel, FINRA, to Daniel Fisher, Branch Chief, Division of Trading and Markets, Commission, filed with the Commission on February 21, 2024. This letter is available at <https://www.finra.org/sites/>

Continued

On April 18, 2024, the Commission published an order instituting proceedings to determine whether to approve or disapprove the proposed rule change.⁹ On April 26, 2024, FINRA responded to the comment letters received in response to the Notice.¹⁰ On July 15, 2024, FINRA consented to an extension of the time period in which the Commission must approve or disapprove the proposed rule change to September 18, 2024.¹¹ This order approves the proposed rule change.

II. Description of the Proposed Rule Change

A. Background

FINRA Rule 3240 generally prohibits, with exceptions, registered persons from borrowing money from, or lending money to, their customers. The rule has five tailored exceptions,¹² available only when the registered person's member firm has written procedures allowing the borrowing and lending of money between such registered persons and customers of the member firm,¹³ the borrowing or lending arrangements meet the conditions applicable to the relevant exception¹⁴ and, when required, the registered person notifies the member firm prior to entering into a borrowing or lending arrangement and obtains the member firm's pre-approval in writing.¹⁵

B. Proposed Rule Change

1. The General Prohibition on Borrowing From or Lending to Customers

The proposed rule change would amend the title of FINRA Rule 3240 from "Borrowing From or Lending to Customers" to "Prohibition on

[default/files/2024-02/SR-FINRA-2024-001-Extension1.pdf](https://www.sec.gov/default/files/2024-02/SR-FINRA-2024-001-Extension1.pdf).

⁹ See Exchange Act Release No. 99988 (Apr. 18, 2024), 89 FR 31242 (Apr. 24, 2024) (File No. SR-FINRA-2024-001) ("Order Instituting Proceedings").

¹⁰ See letter from Ilana Reid, Associate General Counsel, Office of General Counsel, FINRA, dated April 26, 2024, <https://www.sec.gov/comments/sr-finra-2024-001/srfinra2024001-463852-1226394.pdf> ("FINRA Comment Response").

¹¹ See letter from Ilana Reid, Associate General Counsel, Office of General Counsel, FINRA, to Dan Fisher, Division of Trading and Markets, Commission, dated July 15, 2024, <https://www.finra.org/sites/default/files/2024-07/SR-FINRA-2024-001-Extension2.pdf>.

¹² See Rule 3240(a)(2)(A) (the "immediate family exception"); Rule 3240(a)(2)(B) (the "financial institution exception"); Rule 3240(a)(2)(C) (the "registered person exception"); Rule 3240(a)(2)(D) (the "personal relationship exception"); Rule 3240(a)(2)(E) (the "business relationship exception").

¹³ See Rule 3240(a)(1).

¹⁴ See Rule 3240(a)(2).

¹⁵ See Rules 3240(a)(3) and 3240(b).

Borrowing From or Lending to Customers," and change the title of Rule 3240(a) from "Permissible Lending Arrangements; Conditions" to "General Prohibition; Permissible Borrowing or Lending Arrangements; Conditions."¹⁶ FINRA stated that the proposed rule change would make the regulatory purpose more prominent by emphasizing that the rule is "first and foremost" a general prohibition against borrowing or lending arrangements between registered persons and their customers (a "broker-customer relationship").¹⁷

The proposed rule change would also make substantive changes to FINRA Rule 3240 to extend the application of the rule to: (1) borrowing or lending arrangements that pre-exist the initiation of a broker-customer relationship;¹⁸ (2) borrowing or lending arrangements entered into within six months after a broker-customer relationship ends by defining a "customer" to include "any customer that has, or in the previous six months had, a securities account assigned to the registered person at any member;"¹⁹ (3) indirect borrowing or lending arrangements with related parties of the registered person or customer;²⁰ and (4) owner-financing arrangements.²¹ The Commission describes each aspect of the proposed rule changes in turn.

a. Pre-Existing Borrowing and Lending Arrangements

Currently, Rule 3240(a) states "[n]o person associated with a member in any registered capacity may borrow money from or lend money to any customer of such person. . . ." The proposed rule change would amend Rule 3240(a) to extend the rule's general requirements concerning borrowing and lending arrangements—including the general prohibition—to borrowing and lending arrangements that pre-exist a new broker-customer relationship.²² Specifically, the proposed rule change would amend Rule 3240(a) to prohibit registered persons from initiating a broker-customer relationship with a person with whom the registered person has an existing borrowing or lending arrangement unless the conditions of the proposed rule are met.²³

¹⁶ Proposed Rule 3240 and proposed Rule 3240(a).

¹⁷ See Notice at 3969.

¹⁸ Proposed Rule 3240(a).

¹⁹ Proposed Rule 3240.02.

²⁰ Proposed Rule 3240.05.

²¹ Proposed Rule 3240.03.

²² See Notice at 3969.

²³ Proposed Rule 3240(a).

b. Expansion of the Definition of Customer

The proposed rule change would similarly extend the application of the rule to borrowing or lending arrangements entered into within six months after a broker-customer relationship ends.²⁴ Specifically, the proposed rule change would add new FINRA Rule 3240.02 (Customer) to define "customer," for purposes of Rule 3240, as including "any customer that has, or in the previous six months had, a securities account assigned to the registered person at any member."²⁵

c. Borrowing and Lending Arrangements With Related Parties of the Registered Person or Customer

The proposed rule change would add new FINRA Rule 3240.05 (Arrangements with Persons Related to Either the Registered Person or the Customer) to extend Rule 3240 to indirect borrowing or lending arrangements involving related parties of the customer or registered person. Specifically, the proposed rule change would provide that a registered person instructing or asking a customer to enter into a borrowing or lending arrangement with a person related to the registered person (e.g., the registered person's immediate family member or outside business) or to have a person related to the customer (e.g., the customer's immediate family member or business) enter into a borrowing or lending arrangement with the registered person would present similar conflict of interest concerns as borrowing or lending arrangements directly between the registered person and the customer.²⁶ Accordingly, the proposed rule change would expressly state that such arrangements would not be consistent with Rule 3240 unless the conditions set forth in Rule 3240 are satisfied.²⁷ FINRA stated that the proposed rule change would address the potential for customer abuse that arises in these more indirect borrowing and lending arrangements.²⁸

d. Owner-Financing Arrangements

The proposed rule change would add Rule 3240.03 (Owner-Financing Arrangements) to expressly state that, for purposes of Rule 3240, borrowing or lending arrangements include owner-financing arrangements.²⁹ For example, Rule 3240 would apply to situations

²⁴ See Notice at 3969.

²⁵ Proposed Rule 3240.02.

²⁶ Proposed Rule 3240.05.

²⁷ *Id.*

²⁸ Notice at 3969.

²⁹ Proposed Rule 3240.03.

where a registered person purchases real estate from their customer, the customer agrees to finance the purchase, and the registered person provides a promissory note for the entire purchase price or arranges to pay in installments.³⁰ Accordingly, such owner-financing arrangements would not be consistent with Rule 3240 unless the conditions set forth in Rule 3240 are satisfied.

2. The “Immediate Family” Definition

Currently, Rule 3240 has an exception from the general prohibition for borrowing or lending arrangements with a customer who is a member of the registered person’s immediate family.³¹ Rule 3240(c) defines “immediate family” to mean “parents, grandparents, mother-in-law or father-in-law, husband or wife, brother or sister, brother-in-law or sister-in-law, son-in-law or daughter-in-law, children, grandchildren, cousin, aunt or uncle, or niece or nephew, and any other person whom the registered person supports, directly or indirectly, to a material extent.”³²

FINRA stated that, in order to “modernize” the “immediate family” definition,³³ the proposed rule change would amend the definition to make it consistent with the definition in FINRA Rule 3241,³⁴ which addresses similar potential conflicts of interest to Rule 3240.³⁵ Specifically, the proposed rule change would amend Rule 3240(c) to replace “husband or wife” with “spouse or domestic partner” and include “step and adoptive relationships.”³⁶ In addition, the proposed rule change would amend the “any other person” clause to limit it to “any other person who resides in the same household as the registered person” and who the registered person “financially supports, directly or indirectly, to a material extent.”³⁷

3. The Close Personal Relationship and Business Relationship Exceptions

Currently, Rule 3240 has an exception from the general prohibition for borrowing or lending arrangements based on a “personal relationship with the customer, such that the loan would

not have been solicited, offered, or given had the customer and the registered person not maintained a relationship outside of the broker-customer relationship” (the “personal relationship exception”).³⁸ Similarly, the rule’s general prohibition currently does not apply to borrowing or lending arrangements based on a “business relationship outside of the broker-customer relationship” (the “business relationship exception”).³⁹

The proposed rule change would narrow the personal relationship exception to apply only to personal relationships that are “bona fide” and “close,” and maintained outside of, and formed prior to, the broker-customer relationship.⁴⁰ The proposed rule change would also narrow the business relationship exception to borrowing and lending arrangements that are based on a “bona fide business relationship” maintained outside of the broker-customer relationship.⁴¹

In addition to narrowing the personal relationship and business relationship exceptions, the proposed rule change would add new Rule 3240.04 (Close Personal Relationships; Business Relationships), which would provide a list of non-exhaustive factors⁴² to help firms evaluate whether a borrowing or lending arrangement is based on a bona fide close personal relationship or a bona fide business relationship. The non-exhaustive factors in proposed Rule 3240.04 are: “when the relationship began, its duration and nature, and any facts suggesting that the relationship is not bona fide or was formed with the purpose of circumventing the purpose of Rule 3240.”⁴³ Proposed Rule 3240.04 would also provide examples of “close personal relationships,” including, “a childhood or long-term friend or a godparent, and other similarly close personal relationships.”⁴⁴ Additionally, proposed Rule 3240.04 would provide an example of a “business relationship” to include “a loan from a registered person to a small outside business that the registered person co-owned for years for the sole purpose of providing the business with additional operating capital.”⁴⁵

FINRA stated that the proposed rule change would “help establish the scope of the close personal relationship and business relationship exceptions, focus

on the most relevant factors when evaluating whether a close personal relationship or business relationship exists, and ensure that members consider meaningfully the potential issues involved in the proposed arrangement.”⁴⁶

4. Notification and Approval Requirements

Currently, Rule 3240(b) requires notification and approval for certain of the excepted borrowing or lending arrangements.⁴⁷ Generally, the exceptions for borrowing or lending arrangements involving personal relationships, business relationships, and registered persons require member firm notification and approval. In contrast, the exceptions for borrowing or lending arrangements with immediate family members and financial institutions do not require member firm notification and approval. The proposed rule change would make the following changes to the notification and approval requirements.

a. Approval Requirements for the Close Personal Relationship, Business Relationship, and Registered Persons Exceptions

Current Rule 3240(b)(1)(A) provides that a registered person shall notify the member firm of borrowing or lending arrangements made within the personal relationship exception,⁴⁸ business relationship exception,⁴⁹ or the registered persons exception⁵⁰ prior to entering into such arrangements, and that the member firm shall pre-approve in writing such arrangements.⁵¹ The proposed rule change would amend Rule 3240(b)(1) to make clear that, while registered persons cannot proceed with such arrangements without their member firm’s prior approval, the member firm is not required to approve the arrangement.⁵² Specifically, the proposed rule change would delete the “shall pre-approve” language and instead require the registered person to provide notice “prior to entering into such arrangements” or “prior to the modification of such arrangements” and “obtain the member’s approval.”⁵³

Further, the proposed rule change would amend the notification and approval requirements in Rule 3240(b)(1) to cover borrowing or lending arrangements that pre-exist the broker-

³⁰ See Notice at 3969.

³¹ See Rule 3240(a)(2)(A).

³² Rule 3240(c).

³³ See Notice at 3970; see also FINRA Rule 3241.

³⁴ See Notice at 3970.

³⁵ See Notice at 3977. FINRA Rule 3241 governs registered persons who are named a customer’s beneficiary or hold a position of trust for a customer. FINRA Rule 3241 and FINRA Rule 3240 are both designed to prevent harm to customers due to registered persons being in a position of power and responsibility in their lives. See Notice at 3977 n.56.

³⁶ Proposed Rule 3240(c).

³⁷ *Id.*

³⁸ Rule 3240(a)(2)(D).

³⁹ Rule 3240(a)(2)(E).

⁴⁰ Proposed Rule 3240(a)(2)(D).

⁴¹ Proposed Rule 3240(a)(2)(E).

⁴² See *infra* Section II.B.4.e.

⁴³ Proposed Rule 3240.04.

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ See Notice at 3970.

⁴⁷ *Id.*

⁴⁸ Rule 3240(a)(2)(D).

⁴⁹ Rule 3240(a)(2)(E).

⁵⁰ Rule 3240(a)(2)(C).

⁵¹ Rule 3240(b)(1)(A).

⁵² See Notice at 3970.

⁵³ See proposed Rule 3240(b)(1)(A).

customer relationship. Specifically, proposed Rule 3240(b)(1)(B) would require registered persons, prior to the initiation of a broker-customer relationship at the member firm with a person with whom the registered person has an existing borrowing or lending arrangement, to notify the member firm in writing of any existing borrowing or lending arrangements within the close personal relationship, business relationship, and registered persons exceptions and obtain the member firm's approval in writing of the broker-customer relationship.⁵⁴

b. Notification and Approval Requirements for the Immediate Family Member Exception

Current Rule 3240(b)(2) provides, in pertinent part, that a member firm's written procedures may indicate that registered persons are not required to notify the member firm or receive member firm approval of borrowing or lending arrangements within the immediate family exception.⁵⁵ The proposed rule change would amend Rule 3240(b)(2) to apply the same approach to borrowing or lending arrangements within the immediate family exception that pre-exist the broker-customer relationship.⁵⁶ Specifically, the proposed rule change would amend Rule 3240(b)(2) to provide that the member firm's procedures may indicate that registered persons are not required to notify the member firm or receive member firm approval of such arrangements either prior to or subsequent to initiating a broker-customer relationship.⁵⁷ FINRA stated, however, that Rule 3240(b)(2) implies that member firms may choose to require such notice and approval of those arrangements.⁵⁸

c. Notification and Approval Requirements for the Financial Institution Exception

Current Rule 3240(b)(3) provides, in pertinent part, that a member firm's written procedures may indicate that registered persons are not required to notify the member firm or receive the member firm's approval of borrowing or lending arrangements within the financial institution exception,⁵⁹

provided that "the loan has been made on commercial terms that the customer generally makes available to members of the general public similarly situated as to need, purpose and creditworthiness."⁶⁰ The proposed rule change would amend Rule 3240(b)(3) to also cover borrowing or lending arrangements within the financial institution exception that pre-exist the broker-customer relationship.⁶¹ Specifically, the proposed rule change would amend Rule 3240(b)(3) to provide that the member firm's written procedures may also indicate that registered persons are not required to notify the member firm or receive the member firm's approval of borrowing or lending arrangements within the financial institution exception entered into either prior to or subsequent to initiating a broker-customer relationship, provided that the loan has been made on commercial terms that the customer generally makes available to members of the general public similarly situated as to need, purpose and creditworthiness.⁶² FINRA stated, however, that Rule 3240(b)(3) implies that member firms may choose to require such notice and approval of those arrangements.⁶³

d. Notifications in Writing and Record Retention

Currently, Rule 3240 does not require that registered persons who must notify their member firms of borrowing and lending arrangements to do so in writing.⁶⁴ Furthermore, the current rule does not require member firms to retain any notices of borrowing and lending arrangements that they may receive from registered persons; it only requires member firms to retain written approvals.⁶⁵ The proposed rule change would require registered persons to notify their member firms in writing of those borrowing and lending arrangements under Rule 3240 that require notification and approval (*i.e.*, the exceptions involving registered persons, close personal relationships, and business relationships).⁶⁶

The proposed rule change would also amend Rule 3240.01 to require member firms to retain the written notifications

and approvals records for at least three years after the date that the borrowing or lending arrangement has terminated, or for at least three years after the registered person's association with the member has terminated.⁶⁷ The proposed rule change would also require record retention of notices and approvals related to the immediate family and financial institution exceptions, unless the member firm's procedures indicate that registered persons are not required to notify the member firm and/or receive member firm approval.⁶⁸

e. Reasonable Assessment by Member of the Risks Created by the Borrowing or Lending Arrangement

The proposed rule change also would add new Rule 3240.06 (Obligations of Member Receiving Notice). Proposed Rule 3240.06 would require a member firm, upon receiving written notice under Rule 3240, to "perform a reasonable assessment of the risks created by the borrowing or lending arrangement with a customer, modification to the borrowing or lending arrangement with a customer, or existing borrowing or lending arrangement with a person who seeks to be a customer of the registered person."⁶⁹ It would further provide that the member firm make a "reasonable determination of whether to approve the borrowing or lending arrangement, modification to the borrowing or lending arrangement, or, where there is an existing borrowing or lending arrangement with a person who seeks to be a customer of the registered person, the broker-customer relationship."⁷⁰ In the Notice, FINRA stated that a member firm's "reasonable assessment" should consider several non-exhaustive factors, such as:

- (1) any potential conflicts of interest in the registered person being in a borrowing or lending arrangement with a customer;
- (2) the length and type of relationship between the customer and registered person;

⁵⁴ See proposed Rule 3240(b)(1)(B).

⁵⁵ Rule 3240(b)(2).

⁵⁶ See Notice at 3971.

⁵⁷ See proposed Rule 3240(b)(2).

⁵⁸ See Notice at 3971 n.21.

⁵⁹ The "financial institution exception" states that no person associated with a member firm in any registered capacity may borrow money from or lend money to any customer of such person, unless the customer (i) is a financial institution regularly engaged in the business of providing credit,

financing, or loans, or other entity or person that regularly arranges or extends credit in the ordinary course of business and (ii) is acting in the course of such business. See Rule 3240(a)(2)(B).

⁶⁰ See Rule 3240(b)(3).

⁶¹ See Notice at 3971.

⁶² See proposed Rule 3240(b)(3).

⁶³ See Notice at 3971 n.21.

⁶⁴ See *id.* at 3971.

⁶⁵ *Id.*

⁶⁶ *Id.*; see proposed Rules 3240(b)(1)(A) and (b)(1)(B) and proposed Rule 3240.01.

⁶⁷ See proposed Rule 3240.01.

⁶⁸ See Notice at 3971 n.21 (stating that "Rule 3240.01 would also be amended to provide that the record-retention requirements are for purposes of Rule 3240(b), not just Rule 3240(b)(1). As explained above, Rule 3240(b)(1) requires notice and approval of arrangements that are within the personal relationship, business relationship, and registered persons exceptions. While Rule 3240(b)(2) and (3) do not expressly require notice and approval of arrangements within the immediate family member and financial institution exceptions, those subparagraphs imply that members may choose to require such notice and approval of those arrangements.").

⁶⁹ Proposed Rule 3240.06.

⁷⁰ *Id.*

(3) the material terms of the borrowing or lending arrangement;

(4) the customer's or the registered person's ability to repay the loan;

(5) the customer's age;

(6) whether the registered person has been a party to other borrowing or lending arrangements with customers;

(7) whether, based on the facts and circumstances observed in the member's business relationship with the customer, the customer has a mental or physical impairment that renders the customer unable to protect his or her own interests;

(8) any disciplinary history or indicia of improper activity or conduct with respect to the customer or the customer's account (e.g., excessive trading); and

(9) any indicia of customer vulnerability or undue influence of the registered person over the customer.⁷¹

Moreover, the factors that a member firm considers "should allow for a reasonable assessment of the associated risks so that the member can make a reasonable determination of whether to approve the borrowing or lending arrangement, modification to the borrowing or lending arrangement, or, where there is an existing borrowing or lending arrangement with a person who seeks to be a customer of the registered person, the broker-customer relationship."⁷² FINRA also stated in the Notice that it "would expect a member to try to discuss the arrangement with the customer[.]" as part of the member firm's reasonable assessment of the risks.⁷³

III. Discussion and Commission Findings

After careful review of the proposed rule change and the comment letters, and FINRA's response to comments, the Commission finds that the proposed rule change is consistent with the requirements of the Exchange Act and the rules and regulations thereunder that are applicable to a national securities association.⁷⁴ Specifically, as explained in more detail below, the Commission finds that the proposed rule change is consistent with Section 15A(b)(6) of the Exchange Act, 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.⁷⁵

The proposed rule change would strengthen the general prohibition against borrowing and lending arrangements between registered persons and their customers. Specifically, it would narrow the types of permissible borrowing and lending arrangements by covering relationships that pre-exist a new broker-customer relationship, as well as borrowing or lending arrangements entered into within six months after a broker-customer relationship ends. The proposed rule change would also extend the application of the rule to indirect borrowing and lending arrangements involving related parties of the customer or registered person and to owner-financing arrangements. In addition, the proposed rule change would modify the relationship categories in the immediate family exception. Furthermore, it would require borrowing and lending arrangements based on the close personal relationship and business relationship exceptions be "bona fide." It also would require: registered persons to notify their member firms in writing and obtain member firms' approval of certain borrowing and lending arrangements; member firms to retain records of notices and approvals; and member firms to conduct a reasonable assessment of the risks associated with certain arrangements. Accordingly, and as explained in more detail below, the Commission finds that the proposed rule change is consistent with Section 15A(b)(6) of the Exchange Act. The Commission addresses the proposed rule change's specific provisions, and any related comments, in turn.

A. The General Prohibition on Borrowing From or Lending to Customers

FINRA is proposing to amend the title of FINRA Rule 3240 to "Prohibition on Borrowing From or Lending to Customers," and change the title of Rule 3240(a) to "General Prohibition; Permissible Borrowing or Lending Arrangements; Conditions." Commenters did not specifically comment on this proposed rule change. By emphasizing that FINRA Rule 3240 imposes a general prohibition on registered persons borrowing from or lending to their customers, the proposed rule change highlights the regulatory purpose of the rule to generally prohibit borrowing and lending arrangements.

The proposed rule change would also make several substantive changes to the general prohibition on borrowing from

or lending to customers, including extending the rule to cover borrowing and lending arrangements that pre-exist the broker-customer relationship; extending the rule's limitations to borrowing or lending arrangements entered into within six months after a broker-customer relationship ends; and, specifying that certain borrowing and lending arrangements are covered by the general prohibition. The Commission addresses those changes below.

1. Pre-Existing Borrowing and Lending Arrangements

The proposed rule change would amend Rule 3240(a) to provide that the rule's general requirements concerning borrowing and lending arrangements—including the general prohibition—apply to borrowing and lending arrangements that pre-exist a new broker-customer relationship. The proposed rule change would prohibit registered persons from initiating a broker-customer relationship with a person with whom the registered person has an existing borrowing or lending arrangement unless the conditions of the proposed rule are met.⁷⁶

Two commenters supported this change.⁷⁷ One of these commenters stated that conflicts of interest would exist in the relationship irrespective of whether or not a borrowing or lending arrangement existed before or after the broker-customer relationship is established.⁷⁸ Thus, the commenter noted, broadening and applying the general prohibition to borrowing or lending arrangements that pre-exist the broker-customer relationship will protect investors.⁷⁹ Another commenter supported covering borrowing or lending arrangements that pre-exist broker-customer relationship to the extent the proposed rule change would continue to permit any borrowing or lending arrangements.⁸⁰ To the extent

⁷⁶ See *id.* at 3969.

⁷⁷ See letter from William Jacobson, Clinical Professor of Law and Director, Cornell Securities Law Clinic, dated February 12, 2024, at 2, <https://www.sec.gov/comments/sr-finra-2024-001/srfinra2024001-428040-1059142.pdf> ("CSLC") (emphasizing that by extending the prohibition to situations where financial arrangements pre-date the formal establishment of a broker-customer relationship, "the amendment aims to prevent potential conflicts of interest or abuses."); see also letter from Joseph C. Pfeiffer, President, Public Investor Advocate Bar Association, dated February 12, 2024, at 1, <https://www.sec.gov/comments/sr-finra-2024-001/srfinra2024001-426619-1057382.pdf> ("PIABA").

⁷⁸ PIABA at 1–2.

⁷⁹ PIABA at 1.

⁸⁰ See letter from Claire McHenry, President, North American Securities Administrators Association, Inc., dated February 12, 2024, at 4,

⁷¹ See Notice at 3971.

⁷² See *id.*

⁷³ See *id.* at 3972.

⁷⁴ In approving this rule change, the Commission has considered the rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

⁷⁵ 15 U.S.C. 78o–3(b)(6).

that any borrowing or lending arrangements are permitted, this commenter called for strong safeguards to protect investors from “predatory lending or undue influence in a broker-customer relationship.”⁸¹

FINRA stated that the proposed rule change would strengthen the general prohibition against borrowing and lending arrangements by extending the scope of arrangements to which the rule would apply to pre-existing arrangements.⁸² In addition, FINRA stated that the proposed rule change would strengthen the notice and approval requirements by, among other things, requiring member firms, upon receiving notice under the proposed rule, to conduct a reasonable assessments of the risks created by a borrowing or lending arrangement and make a reasonable determination of whether to approve it, as described more fully below.⁸³

The proposed rule change reasonably extends the general prohibition against borrowing and lending arrangements to cover borrowing or lending arrangements that pre-exist a new

broker-customer relationship. By extending this general prohibition to such arrangements, the proposed rule change reasonably extends the scope of the rule while preserving the opportunity for parties to enter into such arrangements in limited circumstances and subject to procedural protections (as discussed below) designed to minimize the impact of the potential conflict. For these reasons, the proposed rule change is reasonably 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.

2. Expansion of the Definition of Customer

The proposed rule change would add new FINRA Rule 3240.02 (Customer) to define “customer,” for purposes of Rule 3240, to include any customer who has, or in the previous six months had, a securities account assigned to the registered person at any member firm. FINRA stated that the proposed rule change would extend the rule’s limitations to borrowing or lending arrangements entered into within six months after a broker-customer relationship terminates.⁸⁴

One commenter supported this proposed extension of the rule’s limitations to borrowing or lending arrangements, but favored extending the covered time period to one year as a stronger anti-evasion measure instead of the proposed six months.⁸⁵ The commenter stated that a one-year “lookback” time period would curtail attempts to evade this rule and therefore “enhance investor protection to a greater degree than the proposed six month time period.”⁸⁶ The commenter further stated that FINRA Rule 4111 (Restricted Firm Obligations) uses a one-year “lookback” time period.⁸⁷

In response, FINRA stated that it proposed to align the new Rule 3240 time period with the six-month time period in the definition of “customer” in Rule 3241, because Rule 3241 addresses similar potential conflicts of interest,⁸⁸ whereas Rule 4111’s one-year

“lookback” time period relates to the identification of firms with a significant history of misconduct.⁸⁹ FINRA stated that there are costs associated with extending the general prohibition after the broker-customer relationship ends.⁹⁰ Such costs relate to evaluating and making reasonable determinations on a host of arrangements about which the member firm was not previously notified, as well as costs associated with continued monitoring for prohibited borrowing and lending arrangements with every customer who transfers an account away from the member firms’ registered persons.⁹¹ FINRA stated also that the six-month time period “strikes an appropriate balance between achieving the regulatory objective of addressing circumvention of the proposed rule change and imposing requirements that are reasonable and appropriate, including reasonable requirements on member firms in tracking transfers of customers’ accounts.”⁹²

The proposed rule change reasonably extends the rule’s coverage to borrowing and lending arrangements involving customers who in the previous six months had a securities account assigned to a registered person. As a result, the proposed rule change protects investors by broadening the scope of customer relationships covered by the rule’s general prohibition and limited exceptions. Further, the six-month limit on how long a broker-dealer must monitor terminated customer accounts reasonably balances the benefits of the rule’s protections with the burden of complying with the rule’s requirements for an extended period after the termination of the broker-customer relationship. For these reasons, the proposed rule change is reasonably 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.

persons being in a position of power and responsibility in their lives. See Notice 3977 n.56.

⁸⁹ See FINRA Comment Response at 14. FINRA Rule 4111 addresses risks from broker-dealers with a significant history of misconduct, including firms with a high concentration of individuals with a significant history of misconduct (“Restricted Firms”). For purposes of calculating concentration, the rule covers persons registered with the member firm for one or more days within the one year prior to the date of the annual calculation used for determining Restricted Firm status. See Regulatory Notice 21–34 (Sep. 28, 2021), <https://www.finra.org/rules-guidance/notices/21-34>.

⁹⁰ See FINRA Comment Response at 15.

⁹¹ See *id.*

⁹² See *id.* at 14 (citing FINRA Regulatory Notice 20–38 (Oct. 2020)).

<https://www.sec.gov/comments/sr-finra-2024-001/srfinra2024001-428019-1058522.pdf> (“NASAA”).

⁸¹ See *id.* Specifically, two commenters who provided comments on specific provisions of the proposed rule change stated a preference for a broad prohibition on all borrowing and lending arrangements. See NASAA at 3–4 (identifying a complete ban with no exceptions as the most efficient and effective way to address “the serious conflicts inherent in such a relationship and the potential for investor harm”); see also letter from Jenice Malecki, Jacqueline Candela, and Adam Schreck of Malecki Law, dated February 12, 2024, at 1, <https://www.sec.gov/comments/sr-finra-2024-001/srfinra2024001-428039-1058683.pdf> (“Malecki”) (stating that “lending arrangements between registered representatives and their customers should be strictly prohibited. Transactions amongst registered representatives and customers inherently involve parties negotiating from disparate bargaining positions.”). In response, FINRA stated that it considered prohibiting all such arrangements but rejected the approach because such arrangements may be mutually beneficial to the contracting parties. See FINRA Comment Response at 1–2. FINRA stated also that the proposed rule change would strengthen the general prohibition against such arrangements by extending the scope of arrangements to which the rule would apply and by narrowing some exceptions. See FINRA Comment Response at 4. In addition, FINRA stated that the proposed rule change would strengthen the notice and approval requirements, as discussed more fully below. See *id.* As discussed herein, FINRA Rule 3240 generally prohibits registered persons from borrowing money from, or lending money to, their customers but permits such arrangements under limited circumstances designed to minimize the impact of conflicts of interest. The proposed rule change would strengthen the general prohibition against borrowing and lending arrangements between registered persons and their customers. Accordingly, for the reasons discussed in detail below, we find that the proposed rule change is consistent with the public interest and the protection of investors.

⁸² See FINRA Comment Response at 4.

⁸³ *Id.*

⁸⁴ See Notice at 3969.

⁸⁵ PIABA at 2.

⁸⁶ *Id.*

⁸⁷ *Id.*

⁸⁸ See FINRA Comment Response at 14. Rule 3241.01 defines “customer” as “any customer that has, or in the previous six months had, a securities account assigned to the registered person at any member.” FINRA Rule 3241 governs registered persons who are named a customer’s beneficiary or hold a position of trust for a customer. FINRA Rule 3241 and FINRA Rule 3240 are both designed to prevent harm to customers due to registered

3. Borrowing and Lending Arrangements With Related Parties of the Registered Person or Customer

The proposed rule change would extend the rule's general prohibition to borrowing or lending arrangements with related parties of the customer or registered person that involve conflicts similar to those presented by borrowing or lending arrangements directly between registered persons and their customers. Specifically, proposed new FINRA Rule 3240.05 would provide that a registered person instructing or asking a customer to enter into a borrowing or lending arrangement with a person related to the registered person or to have a person related to the customer enter into a borrowing or lending arrangement with the registered person would present similar conflict of interest concerns as borrowing or lending arrangements between the registered person and the customer and would be inconsistent with Rule 3240 unless the conditions set forth in Rule 3240(a) are satisfied. FINRA stated that the proposed rule change would address the potential for customer abuse that arises when a registered person: (1) "induces a customer to enter into a borrowing or lending arrangement with a person or entity related to the registered person" or (2) "induces a customer to have a person or entity related to the customer enter into an arrangement with the registered person."⁹³

Two commenters supported the proposed rule change.⁹⁴ One stated that it is a "good idea" because "[t]he same or very similar conflict of interest is present if a registered representative's close family member obtains a loan from a registered representative's client just as if the registered representative obtained it themselves."⁹⁵ The other commenter stated that the proposed rule change would close "potential loopholes" and safeguard against abuses that may occur "when a registered person induces a customer to enter into financial arrangements with related individuals."⁹⁶

The proposed addition of FINRA Rule 3240.05 reasonably extends the rule to cover indirect borrowing or lending arrangements involving parties related to either the registered person or the customer, and thus prevents a registered person from evading the restrictions of Rule 3240. As such, the proposed rule change appropriately addresses conflicts of interest between registered persons

and customers that may arise from certain borrowing or lending arrangements with related persons and entities. For these reasons, the proposed rule change is reasonably 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.

4. Owner-Financing Arrangements

Proposed Rule 3240.03 would include owner-financing arrangements as borrowing or lending arrangements that are covered by Rule 3240.⁹⁷ For example, the proposed rule change would cover situations where a registered person purchases real estate from their customer, the customer agrees to finance the purchase, and the registered person provides a promissory note for the entire purchase price or arranges to pay in installments.⁹⁸ Commenters did not specifically comment on this proposed rule change.

By extending Rule 3240 to cover owner-financing arrangements, the proposed rule change protects investors by addressing financing arrangements that present similar conflicts of interest and a similar potential for abuse as other borrowing and lending arrangements covered by Rule 3240. Generally prohibiting such financing arrangements, unless the conditions of the rule are met, is a reasonable approach to address the potential risk of harm associated with this type of borrowing or lending arrangement. For these reasons, the proposed rule change is reasonably 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.

B. The "Immediate Family" Definition

Rule 3240's general prohibition on borrowing or lending arrangements provides an exception for arrangements between a registered person and a customer who is a member of the registered person's immediate family.⁹⁹ The proposed rule change would update the "immediate family" definition to include new relationship categories.¹⁰⁰ Specifically, the proposed rule change would amend Rule 3240(c) to replace "husband or wife" with "spouse or

domestic partner" and amend the definition to include "step and adoptive relationships."¹⁰¹ In addition, the proposed rule change would amend the "any other person" clause to state that it only applies to "any other person who resides in the same household as the registered person" and who the registered person "financially supports, directly or indirectly, to a material extent."¹⁰² Commenters supported the proposed rule change.¹⁰³

By amending the definition of "immediate family," the proposed rule change updates the rule to encompass a broader set of familial relationships, while at the same time retaining a reasonably narrow and clear scope, which provides more compliance certainty. In addition, amending the "any other person" clause to restrict the definition to those individuals who live with, and are financially supported by, the registered person is a reasonable approach to reducing the potential for the exception to be misused. For these reasons, the proposed rule change is reasonably 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.

C. The Close Personal Relationship and Business Relationship Exceptions

Rule 3240 currently includes a personal relationship exception¹⁰⁴ and a business relationship exception¹⁰⁵ to the general prohibition against registered persons borrowing or lending to their customers. The proposed rule change would narrow the personal relationship exception to apply only to personal relationships that are "bona fide" and "close," and maintained outside of, and formed prior to, the broker-customer relationship. The proposed rule change would also narrow the business relationship exception to borrowing and lending arrangements that are based on a "bona fide business relationship" outside of the broker-customer relationship.¹⁰⁶

In addition, proposed Rule 3240.04 would provide factors for evaluating

¹⁰¹ Proposed Rule 3240(c).

¹⁰² *Id.*

¹⁰³ See, e.g., CSLC at 3 (stating that amending the "any other person" clause would align the definition with "practical considerations" that would reduce the potential for misuse. Also stating that "[t]he modernization of this definition showcases a dedication to inclusivity and adaptability. It also works to strengthen the rule, making sure it stays relevant to contemporary society and prevents individuals from exploiting technicalities."); see also PIABA at 2.

¹⁰⁴ Rule 3240(a)(2)(D).

¹⁰⁵ Rule 3240(a)(2)(E).

¹⁰⁶ Proposed Rule 3240(a)(2)(E).

⁹³ Notice at 3969.

⁹⁴ See CSLC; PIABA.

⁹⁵ PIABA at 2.

⁹⁶ CSLC at 2.

⁹⁷ Proposed Rule 3240.03.

⁹⁸ See Notice at 3969 (referencing James K. Breeze, Letter of Acknowledgment, Waiver and Consent, Case ID 2008012846501 (June 30, 2009); Vincenzo G. Covino, Letter of Acknowledgment, Waiver and Consent, Case ID 2009020793901 (Feb. 9, 2012)).

⁹⁹ See Rule 3240(a)(2)(A).

¹⁰⁰ See Notice at 3970.

whether a borrowing or lending arrangement is based on a bona fide, close personal relationship or a bona fide business relationship, including “when the relationship began, its duration and nature, and any facts suggesting that the relationship is not bona fide or was formed with the purpose of circumventing the purpose of Rule 3240.”¹⁰⁷ Proposed Rule 3240.04 would also provide examples of “close personal relationships,” including, “a childhood or long-term friend or a godparent.”¹⁰⁸ Finally, proposed Rule 3240.04 would provide as an example of a “business relationship,” “a loan from a registered person to a small outside business that the registered person co-owned for years for the sole purpose of providing the business with additional operating capital.”¹⁰⁹

One commenter supported the proposed rule change, stating that replacing the current requirement with the bona fide relationship requirement for both the close personal relationship and business relationship exceptions “eliminates subjectivity and ambiguity”¹¹⁰ and “emphasizes the genuine and sincere nature of the relationship, focusing on authenticity and legitimacy.”¹¹¹ This commenter also stated that the factors test introduced by proposed Rule 3240.04 offer “clear criteria for evaluation, emphasizing specific aspects such as the duration and nature of the relationship . . . , providing a structured framework for assessing relationship legitimacy.”¹¹²

Two other commenters opposed the proposed rule change.¹¹³ One stated that close personal relationships do not “confer any additional protections from the kinds of conflicted, exploitative, and abusive practices that the rules should be designed to prevent.”¹¹⁴ The other commenter stated the proposed amendments to the exceptions would result in the exceptions being too subjectively applied because it asks firms to make judgments of legitimacy and would be difficult to implement.¹¹⁵ Specifically, the commenter stated that the term “bona fide” is vague and ambiguous and that the lack of an explanation or test to discern what

constitutes a relationship as legitimate would make it difficult to interpret the application of the exceptions.¹¹⁶ To address this issue, the commenter requested that FINRA provide more examples of relationships that would qualify for the close personal relationship and business relationship exceptions.¹¹⁷ In addition, this commenter stated that if the rule’s intent is to prohibit arrangements when the personal relationship is formed after the commencement of the broker-customer relationship, it should explicitly say so.¹¹⁸

In response, FINRA stated that it proposed to narrow the exception and provide factors that are relevant to assessing whether a relationship falls within the scope of either the close personal or business relationship exception precisely because it shared concerns about the scope of these exceptions. In particular, FINRA stated that limiting the personal relationship exception to relationships that are (1) bona fide, (2) close, and (3) maintained outside of, and formed prior to, the broker-customer relationship, “would reduce the risk that a registered person would concoct a personal relationship with a customer for the purpose of borrowing from or lending to the customer, and . . . address concerns that this exception could be exploited.”¹¹⁹ In response to the commenter’s request for clarification regarding whether the proposed rule change would cover personal relationships developed after the formation of the broker-customer relationship, FINRA reiterated that relationships formed after the establishment of the broker-customer relationship would not fall within the proposed close personal relationship exception, which would only apply to bona fide, close personal relationships maintained outside of, and formed prior to, the broker-customer relationship.¹²⁰ According to FINRA, the close personal relationship exception is designed only to apply where the borrowing or lending arrangement is less likely to have resulted from the broker-customer relationship because the close personal relationship existed prior to the broker-customer relationship and does not involve the two parties being introduced through the broker-customer

relationship that may involve conflicts of interest.¹²¹

In response to commenter requests for more examples of close personal and business relationships, FINRA stated that the examples described in the proposed rule change “add helpful clarity while giving members the flexibility to consider factors relevant to whether these exceptions apply.”¹²² In declining to provide additional examples, FINRA stated that, ultimately, the applicability of the exceptions depends on the facts and circumstances.¹²³ However, to the extent any particular scenario raises questions regarding the application of the rule, FINRA would consider issuing additional guidance on a case-by-case basis.¹²⁴

The proposed rule change reasonably limits the personal relationship exception to bona fide, close relationships maintained outside of, and formed prior to, the broker-customer relationship and the business relationship exception to borrowing and lending arrangements that are based on a bona fide business relationship maintained outside of the broker-customer relationship. By narrowing these exceptions in this manner, the proposed rule change would help ensure that these exceptions to the general prohibition are limited to the types of relationships where the risk to investors should be reduced. Similarly, by providing factors for evaluating whether a borrowing or lending arrangement is based on a bona fide, close personal relationship or a bona fide business relationship, as well as examples of close personal relationships and business relationships, the proposed rule change would help parties comply with the terms of these exceptions. For these reasons, the proposed rule change is reasonably 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.

D. Notification and Approval Requirements

As stated above, Rule 3240(b) requires notification and approval for certain borrowing or lending arrangements.

¹²¹ See *id.* at 9–10 (stating that the situation where an older or vulnerable customer loans money to a registered person who had befriended them after they already formed a broker-customer relationship, would be outside the scope of the proposed close personal relationship exception, and thus, would be prohibited).

¹²² See *id.* at 10.

¹²³ See *id.*

¹²⁴ See *id.*

¹⁰⁷ Proposed Rule 3240.04.

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*

¹¹⁰ CSLC at 3.

¹¹¹ *Id.*; see also PIABA at 2 (commending “any effort to limit the exceptions and make very clear that this conduct is not allowed.”).

¹¹² CSLC at 3.

¹¹³ Malecki; NASAA.

¹¹⁴ See NASAA at 4.

¹¹⁵ See Malecki at 5.

¹¹⁶ See *id.* at 5–6.

¹¹⁷ See *id.* at 5–6 (expressing the view that the existing examples are limited and very specific and may not be relatable to most broker-customer relationships).

¹¹⁸ See *id.* at 5.

¹¹⁹ See FINRA Comment Response at 9.

¹²⁰ *Id.*

Generally, the exceptions for borrowing and lending arrangements involving personal relationships, business relationships, and registered persons, require member firm notice and approval. The exceptions for borrowing and lending arrangements with immediate family members and financial institutions do not require member firm notification and approval. The proposed rule change would amend the notification and approval requirements of Rule 3240. We discuss the proposed changes separately below.

1. Approval Requirements for the Close Personal Relationship, Business Relationship, and Registered Persons Exceptions

The proposed rule change would amend Rule 3240(b)(1) to clarify that, although registered persons are required to obtain the member firm's prior approval of borrowing or lending arrangements within the close personal relationship, business relationship, or registered persons exceptions, the member firm is not required to approve such arrangements.¹²⁵ Specifically, the proposed rule change would delete "shall pre-approve" from the current rule and instead require the registered person to provide notice "prior to entering into such arrangements" or "prior to the modification of such arrangements" and to "obtain the member's approval." Two commenters supported the proposed rule change.¹²⁶

The proposed rule change would clarify that a member firm is not required to pre-approve borrowing or lending arrangements within the close personal relationship, business relationship, or registered persons exceptions. As such, the proposed rule change would strengthen an important existing control on such arrangements, by explicitly making clear that a member firm is not required to approve any such arrangement simply because a registered person notified the member firm. For these reasons, the proposed rule change is reasonably 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.

2. Notification and Approval Requirements for the Immediate Family Member Exception and the Financial Institution Exception

Current Rule 3240(b)(2) provides, in pertinent part, that a member firm's written procedures may indicate that that registered persons are not required to notify the member firm or receive member firm approval either prior to or subsequent to entering into borrowing or lending arrangements with immediate family members.¹²⁷ Similarly, current Rule 3240(b)(3) provides, in pertinent part, that a member firm's written procedures may indicate that registered persons are not required to notify the member firm or receive member firm approval of borrowing or lending arrangements within the financial institution exception, provided that "the loan has been made on commercial terms that the customer generally makes available to members of the general public similarly situated as to need, purpose and creditworthiness."¹²⁸

The proposed rule change would amend Rule 3240(b)(2) and Rule 3240(b)(3) to apply the same approach to borrowing or lending arrangements within the immediate family exception and the financial institution exception, respectively, to such arrangements that pre-exist the broker-customer relationship.¹²⁹ These changes are intended to correspond to and account for the fact that, under the proposed rule change, the general prohibition applies to borrowing or lending arrangements that pre-exist the broker-customer relationship.¹³⁰

Specifically, to extend these provisions to pre-existing arrangements, the proposed rule change would amend Rule 3240(b)(2) to provide that the member firm's written procedures may indicate that registered persons are not required to notify the member firm or receive the member firm's approval of pre-existing borrowing or lending arrangements that would fall within the immediate family exception prior to initiating a broker-customer relationship.¹³¹ Similarly, the proposed rule change would amend Rule 3240(b)(3) to provide that the member firm's written procedures may also indicate that registered persons are not

required to notify the member firm or receive member firm approval of pre-existing arrangements that would fall within the financial institution exception prior to initiating a broker-customer relationship, provided the borrowing or lending arrangements meet the restrictions of the exception set forth above.¹³²

Two commenters expressed concern that the proposed rule change would not require notice and approval of borrowing or lending arrangements with immediate family members or financial institutions.¹³³ One of these commenters stated that given the risk of financial exploitation in familial relationships, FINRA should require "at least the same notification and approval for arrangements with immediate family as it requires for other registered persons and 'close personal' and business relationships."¹³⁴ The other commenter concurred, stating that the proposed rule change disregards "important considerations about the perpetrators of financial fraud."¹³⁵

In response, FINRA stated that, other than extending the Rule 3240(b)(2) obligations to borrowing and lending arrangements established prior to initiating a broker-customer relationship, the proposed rule change would not amend the existing immediate family exception or require notice or approval of borrowing and lending arrangements with immediate family members.¹³⁶ FINRA further stated that Rule 3240 is not intended to encourage registered persons to avoid traditional financing arrangements, but rather to continue to allow for tailored exceptions to the general prohibition on borrowing or lending arrangements in limited situations where FINRA believes the likelihood that the registered person has borrowed from or lent money to a customer by virtue of the broker-customer relationship is reduced (*e.g.*, certain borrowing or lending arrangements with immediate family members and financial institutions).¹³⁷ FINRA also identified "examples of

¹³² See proposed Rule 3240(b)(3).

¹³³ See NASAA at 4–5; *see also* Malecki at 6.

¹³⁴ See NASAA at 5; *see also* Malecki at 6 (stating that "member firms should not be able to 'opt-out' of reviewing and/or approving these types of lending/borrowing transactions with customers, through their own firm procedures, as it defeats the purpose of and intent behind Rule 3240 itself").

¹³⁵ Malecki at 3 (stating that "an 'immediate' familial relationship is not a barrier to committing fraud generally, and it should not be used as an exception for allowing lending arrangements between registered representatives and their customers.").

¹³⁶ See FINRA Comment Response at 7; *see also* Notice at 3976.

¹³⁷ See FINRA Comment Response at 6–7.

¹²⁵ See Notice at 3970.

¹²⁶ See CSLC at 4 (stating that the proposed rule change "mitigate the risk of a conflict of interest by clarifying that member firms are empowered to approve or disapprove a proposed arrangement."); *see also* Malecki at 6 (stating that "member firms should not be able to 'opt-out' of reviewing and/or approving these types of lending/borrowing transactions with customers.").

¹²⁷ Rule 3240(b)(2). However, as noted above, the current rule allows a member to require such notification and approval for borrowing and lending arrangements with immediate family or financial institutions if the member firm so chooses. *See* Notice at 3971 n.21.

¹²⁸ Rule 3240(b)(3).

¹²⁹ See Notice at 3971.

¹³⁰ *See id.*

¹³¹ See proposed Rule 3240(b)(2).

mutually beneficial borrowing or lending arrangements between immediate family members, including senior family members (e.g., loans to cover medical expenses, dependent care, home repairs, etc.).”¹³⁸ FINRA recognized that “[p]ermitting family members to privately lend with each other, may also allow family members to obtain small or short-term loans, including at an interest rate lower than commercially available.”¹³⁹ Further, FINRA reiterated that a registered person is prohibited from entering into a borrowing or lending arrangement with a customer who is an immediate family member, including one who is a senior investor, unless the member firm adopts written procedures permitting such arrangements.¹⁴⁰ FINRA noted that members firms may choose to prohibit all borrowing and lending arrangements, allow only some of the exceptions, or impose limitations on the exceptions.¹⁴¹ Finally, FINRA stated that requiring notice and approval for borrowing and lending arrangements with immediate family members “may invade legitimate privacy interests because such a requirement could interfere with or intrude upon personal or private family matters.”¹⁴² According to FINRA, by strengthening the general prohibition and narrowing its exceptions, the proposed rule change would further protect all investors, including senior investors.¹⁴³

The proposed rule change is not imposing new obligations on borrowing and lending arrangements within the immediate family exception or within the financial institution exception but would extend the existing regime to situations where such financial arrangements pre-exist the formal establishment of a broker-customer relationship. As with all the exceptions under the rule, a registered person can only enter into a borrowing or lending arrangement pursuant to the immediate family exception or financial institution exception if the member firm has adopted written procedures permitting such an arrangement. A member firm’s procedures may prohibit all such arrangements, allow only some of the excepted arrangements, or impose limits

on the exceptions, as the member firm deems appropriate to be reasonably designed to achieve compliance with the proposed rule change.¹⁴⁴ Accordingly, while not explicitly required, as part of establishing a reasonably designed supervisory system as required under FINRA rules,¹⁴⁵ member firms may nevertheless require notification and approval of arrangements that fall under the immediate family exception and financial institution exception as part of their written procedures based on their assessment of the risks associated with such arrangements.¹⁴⁶ By providing member firms the flexibility to determine whether or not to allow such arrangements, and if so, whether to require notice and approval for such arrangements, and in particular for arrangements within the immediate family exception, FINRA reasonably balances the potential risk of harm associated with such arrangements with the potential benefits of such arrangements and the potential associated privacy concerns. Moreover, as discussed above, the proposed rule change broadens and strengthens the application of the rule by, among other things, covering relationships that pre-exist a new broker-customer relationship, as well as borrowing or lending arrangements entered into within six months after a broker-customer relationship ends, which will add protections to investors, including those whose arrangements fall within the immediate family exception. For these reasons, the proposed rule change is reasonably 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.

3. Notifications in Writing and Record Retention

As stated above, Rule 3240 does not require that registered persons who must notify their member firms of borrowing and lending arrangements do so in writing.¹⁴⁷ Furthermore, the current rule does not require member firms to retain any notices of borrowing and lending arrangements that they may receive from registered persons; it only requires member firms to retain written approvals.¹⁴⁸

The proposed rule change would require registered persons to notify their member firms in writing of those

borrowing and lending arrangements under Rule 3240 that require notification and approval (i.e., the exceptions involving registered persons, close personal relationships, and business relationships).¹⁴⁹ The proposed rule change would also amend Rule 3240.01 to require member firms to retain the written notifications and approvals records for at least three years after the date that the borrowing or lending arrangement has terminated, or for at least three years after the registered person’s association with the member has terminated.¹⁵⁰ The proposed rule change would also require record retention of notices and approvals related to the immediate family and financial institution exceptions, unless the member firm’s procedures indicate that registered persons are not required to notify the member firm and/or receive member firm approval.¹⁵¹

One commenter supported the proposed rule change.¹⁵²

By requiring registered persons to give written notice and requiring member firms to preserve records of such written notice—whether required specifically by the rule or by the member firm’s written procedures—for at least three years, the proposed rule change is reasonably designed to help ensure compliance with the amended Rule 3240 and its exceptions. For these reasons, the proposed rule change is reasonably 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.

4. Reasonable Assessment by Member of the Risks Created by the Borrowing or Lending Arrangement

The proposed rule change would add proposed Rule 3240.06, which would require a member firm, after receiving a written notice under Rule 3240, to “perform a reasonable assessment of the risks created by the borrowing or lending arrangement with a customer, modification to the borrowing or lending arrangement with a customer, or existing borrowing or lending arrangement with a person who seeks to be a customer of the registered person.”¹⁵³ The proposed rule change would also require that the member firm make a “reasonable determination of whether to approve the borrowing or

¹³⁸ *Id.* at 8.

¹³⁹ *Id.*

¹⁴⁰ *See id.*

¹⁴¹ *Id.*

¹⁴² *Id.*

¹⁴³ *Id.* FINRA further stated that Rule 2010 (Standards of Commercial Honor and Principles of Trade)—which provides that a member, in the conduct of its business, shall observe high standards of commercial honor and just and equitable principles of trade—protects investors from unethical behavior and is broad enough to cover a wide range of unethical conduct. *See id.*

¹⁴⁴ *See* Rule 3110(b)(1).

¹⁴⁵ *See* Rule 3110(a).

¹⁴⁶ *See infra* Section III.D.4.

¹⁴⁷ *See* Notice at 3971.

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*; *see* proposed Rules 3240(b)(1)(A) and (b)(1)(B) and proposed Rule 3240.01.

¹⁵⁰ *See* proposed Rule 3240.01.

¹⁵¹ *See supra* note 68.

¹⁵² *See* CSLC at 4.

¹⁵³ Proposed Rule 3240.06.

lending arrangement, modification to the borrowing or lending arrangement, or, where there is an existing borrowing or lending arrangement with a person who seeks to be a customer of the registered person, the broker-customer relationship.”¹⁵⁴ FINRA stated that it expects a member firm’s reasonable assessment to take into consideration a non-exhaustive list of factors that may lead to undue harm to the customer as a result of a borrowing or lending arrangement with a registered person.¹⁵⁵

One commenter supported the proposed rule change, stating that a reasonable assessment could result in “more questionable arrangements being scrutinized, leading to improved investor protection.”¹⁵⁶ Two commenters suggested modifications to the reasonable assessment requirement.¹⁵⁷ To help regulators assess and compare approval and supervision practices across firms, one of these commenters suggested that the reasonable assessment provisions should require a minimum amount of disclosure and include documentation of the steps the member firm took to assess the risk ahead of approving the loan agreement, the steps the member firm took to minimize the conflict of interest, how the member firm communicated the risk to the customer, and an outline of supervisory measures the member firm will take.¹⁵⁸ In addition, this commenter suggested that a “reasonable assessment and determination process should include an interview (preferably by a compliance officer) with the customer outside the presence of the registered person” or, where that is not possible, a requirement that the member firm verify that the customer benefits from the loan and was not pressured into

it.¹⁵⁹ Furthermore, this commenter recommended that the proposed rule change require the member firm to apply heightened scrutiny to the underlying accounts or impose other appropriate conditions where a firm approves a borrowing or lending arrangement, or approves a new broker-customer relationship where there is a pre-existing borrowing or lending arrangement.¹⁶⁰ Finally, this commenter called for the list of factors FINRA provided in the Notice to be included in the rule text.¹⁶¹ The other commenter suggested that a registered person be “required to disclose to a customer, in writing, that such arrangements are presumptively prohibited and to document the exception under which the lending arrangement falls” and that member firms should be required to consult with the customer before approving a borrowing or lending arrangement to ensure the customer receives a full and fair disclosure about the terms of the arrangement.¹⁶² In addition, this second commenter recommended that the proposed rule change require member firms that allow registered persons to enter lending arrangements with their customers to collateralize any such loans that such member firms approve.¹⁶³

In response, FINRA stated that FINRA Rule 3110 (Supervision) requires each member firm to “establish and maintain a system to supervise the activities of each associated person that is reasonably designed to achieve compliance with applicable securities laws and regulations, and with applicable FINRA rules.” FINRA stated that member firms could consider incorporating the commenter’s suggested supervisory and disclosure requirements into their systems for supervising for compliance with Rule 3240, but FINRA is not requiring them here.¹⁶⁴ FINRA did not include the list

of factors in the rule text, explaining that given the flexibility firms have to develop their own supervisory systems under Rule 3110, “it is not necessary or appropriate to prescribe specific supervisory procedures in Rule 3240.”¹⁶⁵ FINRA did, however, highlight guidance regarding “the minimum that should be included in written supervisory procedures, including: (1) the specific identification of the individual(s) responsible for supervision; (2) the supervisory steps and reviews to be taken by the appropriate supervisor; (3) the frequency of such reviews; and (4) how such reviews shall be documented.”¹⁶⁶ With respect to the suggestion that the terms of the arrangement should be discussed with, and disclosed to, the customer, FINRA reiterated that it expects a member to consider the reasonable assessment factors noted earlier—several of which pertain to the terms of the arrangement and the nature of the parties—and to try to discuss the arrangement with the customer.¹⁶⁷ FINRA also stated that regardless of the terms of a member firm’s supervisory system, Rule 3110 requires member firms to follow-up on red flags related to borrowing or lending arrangements between registered persons and their customers.¹⁶⁸

Requiring a member firm, after receiving written notice under Rule 3240, to perform a reasonable assessment of the risks created by the borrowing or lending arrangement with

consideration of: (1) any potential conflicts of interest in the registered person being in a borrowing or lending arrangement with a customer; (2) the material terms of the borrowing or lending arrangement; (3) the customer’s or the registered person’s ability to repay the loan; (4) the customer’s age; (5) whether, based on the facts and circumstances observed in the member’s business relationship with the customer, the customer has a mental or physical impairment that renders the customer unable to protect his or her own interests; and (6) any indicia of customer vulnerability or undue influence of the registered person over the customer. *See id.* at 13. FINRA further stated that those factors along with the guidance in FINRA Regulatory Notice 21–43 (Dec. 2021) would “help members evaluate the key risks and conflicts while giving members appropriate flexibility in evaluating which factors may apply to a particular situation.” *See id.* at 14.

¹⁶⁵ FINRA Comment Response at 12–13 (stating that “FINRA rules concerning duties, conflicts and responsibilities related to associated persons generally do not set forth specific supervisory procedures that member firms must adopt to satisfy the requirements of FINRA’s supervision rule. *See generally* Rule 2000 Series (Duties and Conflicts); Rule 3000 Series (Supervision and Responsibilities Related to Associated Persons)”).

¹⁶⁶ *Id.* at 12 (referencing guidance from Notice to Members 98–96 and Notice to Members 99–45 regarding tailoring the supervisory system to the member firm’s business).

¹⁶⁷ *See id.* at 14.

¹⁶⁸ *See id.* at 12–13.

¹⁵⁴ *Id.*

¹⁵⁵ *See* Notice at 3971 (listing the following factors: (1) any potential conflicts of interest in the registered person being in a borrowing or lending arrangement with a customer; (2) the length and type of relationship between the customer and registered person; (3) the material terms of the borrowing or lending arrangement; (4) the customer’s or the registered person’s ability to repay the loan; (5) the customer’s age; (6) whether the registered person has been a party to other borrowing or lending arrangements with customers; (7) whether, based on the facts and circumstances observed in the member firm’s business relationship with the customer, the customer has a mental or physical impairment that renders the customer unable to protect his or her own interests; (8) any disciplinary history or indicia of improper activity or conduct with respect to the customer or the customer’s account (e.g., excessive trading); and (9) any indicia of customer vulnerability or undue influence of the registered person over the customer).

¹⁵⁶ CSLC at 6.

¹⁵⁷ NASAA at 5–6; Malecki at 2.

¹⁵⁸ *See* NASAA at 5–6.

¹⁵⁹ *See id.* at 6 (stating that an interview would help ensure the borrowing or lending arrangement does not put the customer at risk of undue influence).

¹⁶⁰ *Id.* at 6 (stating that heightened supervision would guard against the conflicts of interest that come with these relationships, and that an enhanced review of trades and transactions in the account should at least be required when the customer is elderly or otherwise vulnerable to exploitation).

¹⁶¹ *See* NASAA at 5.

¹⁶² *See* Malecki at 7.

¹⁶³ *See id.* at 2–3 (stating that other than prohibiting borrowing and lending arrangements, the only way to ensure that a customer is not harmed is to require member firms to have “‘skin’ in such arrangements.”).

¹⁶⁴ *See* FINRA Comment Response at 12. FINRA also stated that the non-exhaustive list of factors FINRA expects members to consider address “many of the commenters’ concerns,” including

a customer and, based on that assessment, to make a reasonable determination of whether to approve the borrowing or lending arrangement, is reasonably designed to protect investors. Whether a specific borrowing or lending arrangement creates the potential for a conflict or other abuse that could harm an investor requires analysis of the facts and circumstances. Because of its supervisory obligations, a broker-dealer is both obligated and best positioned to analyze the facts and circumstances related to a borrowing or lending arrangements between one of its registered persons and a customer. In addition, consistent with the flexibility firms have to develop their own supervisory systems under Rule 3110, the member firm is also best positioned to determine reasonable controls to supervise for compliance with the proposed rule change based on its assessment of the risks involved with a borrowing or lending arrangement that falls within one of the five exceptions to Rule 3240. While not required, reasonably designed controls could include the supervisory, disclosure or other requirements suggested by commenters (such as providing disclosure, collateralizing loans between one of its registered persons and a customer, interviewing customers, and applying heightened scrutiny as it perceives higher risks). As such, the proposed rule change represents an important safeguard for protecting investors from conflicts or other abuses that could harm them in such arrangements. Moreover, in exercising its supervisory obligations under FINRA Rule 3110, a member firm may always choose to prohibit or restrict borrowing and lending arrangements as it sees fit and in light of the risks presented by an arrangement. For example, if the broker-dealer determines that the risks to the customer of lending money to a registered person cannot be effectively managed, the proposed rule change would allow the firm to disapprove or further restrict the arrangement. For these reasons, the proposed rule change is reasonably 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.

IV. Conclusion

For the reasons set forth above, the Commission finds that the proposed rule change is consistent with Section 15A(b)(6) of the Exchange Act, which requires, among other things, that FINRA rules be designed to prevent fraudulent and manipulative acts and practices, promote just and equitable

principles of trade, and, in general, protect investors and the public interest.¹⁶⁹

It is therefore ordered pursuant to Section 19(b)(2) of the Exchange Act¹⁷⁰ that the proposal (SR-FINRA-2024-001), be and hereby is approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁷¹

Sherry R. Haywood,

Assistant Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-101064; File No. SR-FINRA-2024-014]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend FINRA Rule 6897(b) (CAT Cost Recovery Fees) To Implement a Historical Consolidated Audit Trail Recovery Assessment

September 17, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”)¹ and Rule 19b-4 thereunder,² notice is hereby given that on September 5, 2024, 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 and II below, which Items have been prepared by FINRA. FINRA has designated the proposed rule change as “establishing or changing a due, fee or other charge” under Section 19(b)(3)(A)(ii) of the Act³ and Rule 19b-4(f)(2) thereunder,⁴ which renders the proposal effective upon receipt of this filing by the Commission. 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

FINRA is proposing to amend FINRA Rule 6897(b) (CAT Cost Recovery Fees) to implement a historical Consolidated Audit Trail (“CAT”) recovery

assessment designed to permit FINRA to recoup its contributions to recoverable historical costs of the National Market System Plan Governing the Consolidated Audit Trail incurred prior to January 1, 2022.⁵

The text of the proposed rule change is available on FINRA’s website at <http://www.finra.org>, at the principal office of FINRA and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, 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

On July 11, 2012, the Commission adopted Rule 613 of Regulation NMS, which required the self-regulatory organizations to submit a national market system (“NMS”) plan to create, implement and maintain a consolidated audit trail that would capture customer and order event information for orders in NMS securities across all markets, from the time of order inception through routing, cancellation, modification, or execution.⁶ On November 15, 2016, the Commission approved the CAT NMS Plan (“Plan” or “CAT NMS Plan”).⁷ Under the CAT NMS Plan, the Operating Committee has the discretion to establish funding for Consolidated Audit Trail, LLC (“CAT LLC”) to operate the CAT, including establishing fees for Industry Members to be assessed by CAT LLC that would be implemented

⁵ Pursuant to Section 11.3(b) of the CAT NMS Plan, FINRA filed a separate proposed rule change to establish fees assessed to Industry Members, payable to Consolidated Audit Trail, LLC, related to recoverable historical CAT costs incurred prior to January 1, 2022. See File No. SR-FINRA-2024-013. Unless otherwise specified, capitalized terms used in this rule filing are defined as set forth in the CAT NMS Plan and FINRA Rule 6800 Series (Consolidated Audit Trail Compliance Rule).

⁶ See Securities Exchange Act Release No. 67457 (July 18, 2012), 77 FR 45722 (August 1, 2012).

⁷ See Securities Exchange Act Release No. 79318 (November 15, 2016), 81 FR 84696 (November 23, 2016) (“CAT NMS Plan Approval Order”).

¹⁶⁹ 15 U.S.C. 78o-3(b)(6).

¹⁷⁰ 15 U.S.C. 78s(b)(2).

¹⁷¹ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 78s(b)(3)(A)(ii).

⁴ 17 CFR 240.19b-4(f)(2).

on behalf of CAT LLC by the Participants.⁸ The Operating Committee adopted a revised funding model to fund the CAT (“CAT Funding Model”) and, on September 6, 2023, the Commission approved the CAT Funding Model, after concluding that the model was reasonable and that it satisfied the requirements of Section 11A of the Exchange Act and Rule 608 thereunder.⁹

The CAT Funding Model provides a framework for the recovery of the costs to create, develop, and maintain the CAT, including providing a method for allocating costs to fund the CAT among Participants and Industry Members. The CAT Funding Model establishes two categories of fees: (1) CAT fees assessed by CAT LLC and payable by certain Industry Members to recover a portion of historical CAT costs previously paid by the Participants (“Historical CAT Assessment” fees);¹⁰ and (2) CAT fees assessed by CAT LLC and payable by Participants and Industry Members to fund prospective CAT costs.¹¹ With respect to Historical CAT Assessment fees, to date, the CAT Operating Committee has established Historical CAT Assessment 1 with regard to historical CAT costs incurred prior to January 1, 2022 (“Historical CAT Costs 1”).¹²

In light of the filing of File No. SR–FINRA–2024–013, which implements Historical CAT Assessment 1 with regard to Industry Members, FINRA is

filing the instant proposed rule change to establish a fee to allow FINRA to recoup its contributions to the Participants’ assessed share of Historical CAT Costs 1 (“Historical CAT Cost Recovery Assessment 1”). Historical CAT Cost Recovery Assessment 1 is designed to allow FINRA to recover its designated portion of Historical CAT Costs 1—amounting to \$4,391,414—in a manner consistent with the Exchange Act and the CAT Funding Model Approval Order. In the Approval Order, the Commission acknowledged that “the Exchange Act expressly contemplates the ability of the Participants to recoup their costs to fulfill their statutory obligations under the Exchange Act.”¹³ The Commission also noted FINRA’s statement “that it would file a rule change to increase its member fees with the filing of any proposed rule change to effectuate the Funding Model.”¹⁴ Given the approval of the CAT Funding Model and FINRA’s proposed rule change to establish Historical CAT Assessment 1 in accordance with the CAT Funding Model,¹⁵ FINRA is submitting this filing to implement Historical CAT Cost Recovery Assessment 1.¹⁶

FINRA’s Designated Portion of Historical CAT Costs 1

As discussed in File No. SR–FINRA–2024–013, which seeks to implement Historical CAT Assessment 1,¹⁷ to date,

FINRA and the other Participants have agreed to pay all Past CAT Costs via loans to CAT LLC. Specifically, in the absence of an SEC-approved model establishing how the Participants were to fund the creation, implementation, and maintenance of the CAT, in 2017, FINRA and the other Participants unanimously agreed to apportion all CAT operational costs amongst the group and to fund the CAT through a series of interest-free loans. Through these loans, FINRA contributed \$13,174,243 or roughly 4.14% toward the \$318,059,819 in operating expenses composing Historical CAT Costs 1. Of that approximately \$13 million expenditure, FINRA expects to recover \$8,782,829 in loan repayments from CAT LLC following implementation of Historical CAT Assessment 1, and, under the CAT Funding Model, will forgive the remaining \$4,391,414 in loan repayments, which FINRA now seeks to recover through the implementation of Historical CAT Cost Recovery Assessment 1.¹⁸

The following table illustrates FINRA’s approximate contributions to the Plan Participants’ collective one-third share of Historical CAT Costs 1 during each of the relevant periods.¹⁹

Period	Participants’ collective share of historical CAT costs 1	FINRA’s share of historical CAT costs 1
Pre-FAM Period (Prior to June 22, 2020)	\$41,430,243	\$1,716,067

⁸ See Section 11.1(b) of the CAT NMS Plan.

⁹ See Securities Exchange Act Release No. 98290 (September 6, 2023), 88 FR 62628 (September 12, 2023) (“CAT Funding Model Approval Order”).

¹⁰ See Section 11.3(b) of the CAT NMS Plan.

¹¹ See Section 11.3(a) of the CAT NMS Plan.

¹² See File No. SR–FINRA–2024–013.

¹³ CAT Funding Model Approval Order, 88 FR 62628, 62636–37.

¹⁴ FINRA has consistently made clear its intention to file a rule change to implement member CAT fees simultaneous with the filing of any proposed rule change to effectuate the CAT Funding Model. See Letter from Marcia E. Asquith, Corporate Secretary, EVP, Board and External Relations, FINRA, to Vanessa Countryman, Secretary, SEC, dated April 11, 2023 (“FINRA April 2023 Letter”) at 7 (“If the Funding Model is approved by the Commission, FINRA intends to file a rule change to increase member fees simultaneous with the filing of any proposed rule change to effectuate the Funding Model.”); see also Letter from Marcia E. Asquith, Corporate Secretary, EVP, Board and External Relations, FINRA, to Vanessa Countryman, Secretary, SEC, dated June 22, 2022 (“FINRA June 2022 Letter”) at 6 (“[G]iven FINRA’s unique nature, FINRA necessarily must seek recovery in turn for the costs it is allocated.”). FINRA also requested that, if the Commission were to approve the CAT

Funding Model, it acknowledge “FINRA’s need and ability to cover CAT costs that are not recovered through contractual arrangements through member fee increases, so as not to jeopardize FINRA’s ability to carry out its critical regulatory mission.” See CAT Funding Model Approval Order, 88 FR 62628, 62645.

¹⁵ See File No. SR–FINRA–2024–013.

¹⁶ The CAT NMS Plan states that “[n]o Participant will make a filing with the SEC pursuant to Section 19(b) of the Exchange Act regarding any Historical CAT Assessment until any applicable Financial Accountability Milestone described in Section 11.6 has been satisfied.” See Section 11.3(b)(iii)(B)(III) of the CAT NMS Plan. The CAT NMS Plan further states that “in all filings submitted by the Participants to the Commission under Section 19(b) of the Exchange Act, to establish or implement Post-Amendment Industry Member Fees pursuant to this Article, . . . the Participants shall clearly indicate whether such fees are related to Post-Amendment Expenses incurred during Period 1, Period 2, Period 3, or Period 4.” See Section 11.6(b) of the CAT NMS Plan. As discussed in File No. SR–FINRA–2024–013, all applicable Financial Accountability Milestones for Historical CAT Assessment 1 and, by extension, Historical CAT Cost Recovery Assessment 1—that is, Period 1, Period 2, and Period 3 of the Financial Accountability Milestones—have been satisfied. Furthermore, the

costs sought to be recovered via both Historical CAT Assessment 1 and Historical CAT Cost Recovery Assessment 1 relate to Post-Amendment Expenses incurred during Periods 1, 2 and 3 of the Financial Accountability Milestones.

¹⁷ Historical CAT Assessment 1 seeks to recover from CAT Executing Brokers two-thirds of Historical CAT Costs 1—the \$318,059,819 in recoverable costs incurred by CAT LLC prior to January 1, 2022.

¹⁸ FINRA notes that, as is the case with respect to Historical CAT Assessment 1 discussed in File No. SR–FINRA–2024–013, FINRA’s recovery under the instant proposed rule change also would not include any portion of Excluded Costs, i.e., \$48,874,937 in CAT costs incurred from November 15, 2017 through November 15, 2018, \$19,628,791 of costs paid to the the [sic] Initial Plan Processor from November 16, 2018 through February 2019 when the relationship with the Initial Plan Processor was concluded, and \$14,749,362 of costs related to the termination of the relationship with the Initial Plan Processor.

¹⁹ A detailed description (including the amounts) of all costs incurred by the Participants during the pre-FAM period (prior to June 22, 2020) and during each relevant FAM period, i.e., FAM Period 1, FAM Period 2, and FAM Period 3, is provided in File No. SR–FINRA–2024–013.

Period	Participants' collective share of historical CAT costs 1	FINRA's share of historical CAT costs 1
FAM Period 1	2,125,781	88,051
FAM Period 2	14,325,493	593,371
FAM Period 3	48,138,423	1,993,925
Total (through January 1, 2022)	106,019,940	4,391,414

FINRA's recovery of these approximately \$4.4 million in Historical CAT Costs is reasonable and consistent with the Exchange Act. As discussed herein and in File No. SR-FINRA-2024-013, these costs were reasonable, appropriate and necessary for the creation, implementation and maintenance of the CAT. As stated by FINRA and permitted under the Exchange Act, FINRA will seek to recover its portion of the Participants' share of CAT costs to ensure that FINRA can fulfill its regulatory mandate and responsibilities.²⁰

Historical CAT Cost Recovery Assessment 1

FINRA is proposing to amend Rule 6897(b) (CAT Cost Recovery Fees) to

implement Historical CAT Cost Recovery Assessment 1 at this time to allow FINRA to recover its contributions to the Participants' designated one-third share of Historical CAT Costs 1.²¹ FINRA intends that the fee framework for the Historical CAT Cost Recovery Assessment 1 would generally correspond to the framework put in place by CAT LLC with respect to Historical CAT Assessment 1, as provided for in File No. SR-FINRA-2024-013. FINRA also intends that the timing and commencement of payment for Historical CAT Cost Recovery Assessment 1 generally would correspond with that established by CAT LLC with respect to Historical CAT Assessment 1, as provided for in File

No. SR-FINRA-2024-013. Thus, as with Historical CAT Assessment 1, FINRA proposes that each member CAT Executing Broker shall receive its first invoice from FINRA for Historical CAT Cost Recovery Assessment 1 in November 2024, setting forth fees calculated based on October 2024 transactions in Eligible Securities executed otherwise than on an exchange, as reflected in CAT Data.

The following fields of the Participant Technical Specifications indicate the CAT Executing Brokers for transactions executed otherwise than on an exchange.²²

TRF/ORF/ADF Transaction Data Event²³

No.	Field name	Data type	Description	Include key
26	reporting Executing Mpid	Member Alias	MPID of the executing party	R.
28	contra Executing Mpid	Member Alias	MPID of the contra-side executing party.	C.

As discussed in File No. SR-FINRA-2024-013, the Operating Committee has determined that Historical Fee Rate 1 is \$0.00003994969693072937 per executed equivalent share, and, under the CAT Funding Model, each of the CAT Executing Broker for the Buyer ("CEBB"), CAT Executing Broker for the Seller ("CEBS"), and relevant Participant for a given transaction in an

Eligible Security would be responsible for one-third of that rate, or \$0.00001331656564357646 per executed equivalent share.²⁴ In line with this approach, with respect to FINRA's portion of the Participants' one-third share, FINRA is proposing that, for Historical CAT Cost Recovery Assessment 1, the Participants' assessed fee rate would be split evenly between

the CEBB and CEBS to establish a Historical CAT Cost Recovery Fee Rate 1 of \$0.000007 per executed equivalent share²⁵ for transactions where FINRA is the relevant Participant.²⁶

FINRA proposes to amend Rule 6897(b)(1)(A) to implement Historical CAT Cost Recovery Assessment 1. Proposed Rule 6897(b)(1)(A)(i) would provide that each member CAT Executing Broker shall receive its first

²⁰ See *supra* note 14.

²¹ In approving the CAT Funding Model, the Commission noted that it "believe[d] that FINRA's allocation of CAT fees likely will be passed through to Industry Members." See CAT Funding Model Approval Order, 88 FR 62628, 62684.

²² As per Section 1.1 of the Plan, for a transaction in an Eligible Security executed otherwise than on an exchange and required to be reported to an equity trade reporting facility of a registered national securities association, *i.e.*, one of FINRA's Trade Reporting Facilities (each a "TRF"), OTC Reporting Facility ("ORF") or Alternative Display Facility ("ADF"), the CEBB and CEBS are the Industry Members identified as the executing broker and the contra-side executing broker in the TRF/ORF/ADF transaction data event in CAT Data. In those circumstances where there is a non-Industry Member identified as the contra-side executing broker in the TRF/ORF/ADF transaction data event or no contra-side executing broker is identified in the TRF/ORF/ADF transaction data

event, then the Industry Member identified as the executing broker in the TRF/ORF/ADF transaction data event would be treated as, and be required to pay the fee assessed to, both the CEBB and CEBS.

²³ See Table 61, Section 6.1 (TRF/ORF/ADF Transaction Data Event) of the CAT Reporting Technical Specifications for Plan Participants.

²⁴ Dividing \$0.00003994969693072937 by three equals \$0.00001331656564357646. As noted in File No. SR-FINRA-2024-013, CAT LLC determined to use six decimal places for Historical CAT Assessment 1 (*i.e.*, \$0.000013 per executed equivalent share) to balance the accuracy of the calculation with the potential systems and other impracticalities of using additional decimal places in the calculation.

²⁵ In approving the CAT Funding Model, the Commission concluded that "the use of executed equivalent share volume as the basis of the proposed cost allocation methodology is reasonable and consistent with the approach taken by the funding principles of the CAT NMS Plan." See CAT

Funding Model Approval Order, 88 FR 62628, 62640. Under the CAT NMS Plan, executed equivalent shares in a transaction in Eligible Securities are reasonably counted as follows: (1) each executed share for a transaction in NMS Stocks will be counted as one executed equivalent share; (2) each executed contract for a transaction in Listed Options will be counted based on the multiplier applicable to the specific Listed Options (*i.e.*, 100 executed equivalent shares or such other applicable multiplier); and (3) each executed share for a transaction in OTC Equity Securities shall be counted as 0.01 executed equivalent share. See Section 11.3(a)(i)(B) and 11.3(b)(i)(B) of the CAT NMS Plan.

²⁶ Dividing \$0.00001331656564357646 by two and rounding to six decimal places equals \$0.000007. FINRA believes that it is appropriate at this time to use six decimal places to maintain consistency with the approach determined by CAT LLC.

invoice from FINRA in November 2024, setting forth the Historical CAT Cost Recovery Assessment 1 fees calculated based on transactions in October 2024, and shall receive similar invoices from FINRA for Historical CAT Cost Recovery Assessment 1 for each month thereafter in which Historical CAT Cost Recovery Assessment 1 is in effect. As provided in proposed Rule 6897(b)(1)(A)(ii), FINRA shall provide each member CAT Executing Broker with an invoice for Historical CAT Cost Recovery Assessment 1 on a monthly basis. Each monthly invoice from FINRA (separate from the invoice provided by CAT LLC with respect to Historical CAT Assessment 1) shall set forth a fee for each transaction in Eligible Securities executed by the CAT Executing Broker in its capacity as the CEBB and/or the CEBS (as applicable) otherwise than on an exchange as set forth in CAT Data. The fee assessed to each CEBB and CEBS for each such transaction will be calculated by multiplying the number of executed equivalent shares in the transaction by the Historical CAT Cost Recovery Fee Rate 1 of \$0.000007 per executed equivalent share.

Further, as provided in proposed Rule 6897(b)(1)(A)(iii), Historical CAT Cost Recovery Assessment 1 will remain in effect until \$4,391,414 (FINRA's contribution to the one-third share of Historical CAT Costs 1 assessed to the Plan Participants) is collected from member CAT Executing Brokers collectively, which is estimated to be four months, but could be for a longer or shorter period of time.²⁷ FINRA will provide notice when Historical CAT Cost Recovery Assessment 1 will no longer be in effect. Proposed Rule 6897(b)(1)(A)(iv) provides that each member CAT Executing broker shall be required to pay each invoice for Historical CAT Cost Recovery Assessment 1 within 30 days of receipt of such invoice or other notice indicating payment is due (unless a longer payment period is otherwise indicated) and such payment must be made in the manner prescribed by FINRA, as set forth in Rule 6897(b)(2).

As with Historical CAT Assessment 1, since Historical CAT Cost Recovery Assessment 1 is a monthly fee based on transaction volume from the prior month, Historical CAT Cost Recovery

Assessment 1 may result in the collection of more than FINRA's approximately \$4.4 million contribution to Historical CAT Costs 1. To the extent that occurs, any excess money collected during the final month in which Historical CAT Cost Recovery Assessment 1 is in effect will be used to offset future member fees assessed by FINRA in connection with FINRA's designated CAT costs as a Plan Participant.²⁸

Beginning with the initial invoice for Historical CAT Cost Recovery Assessment 1 in November 2024, FINRA will make available to each member CAT Executing Broker a copy of the relevant details for fee liable transactions executed each month otherwise than on an exchange. Similar to the information that would be provided by CAT LLC to CAT Executing Brokers in assessing the off-exchange portion of Historical CAT Assessment 1 each month,²⁹ such information would provide member CAT Executing Brokers with the ability to understand the details regarding the calculation of their Historical CAT Cost Recovery Assessment 1 fees. To assist Industry Members in complying with Historical CAT Assessment 1, in November 2023 CAT LLC began making mock invoices with details for any fee liable transactions, including those executed otherwise than on an exchange, available to CAT Executing Brokers.³⁰ FINRA intends to likewise provide these same trade elements in the trade billing details accompanying FINRA invoices each month that Historical CAT Cost Recovery Assessment 1 is in effect.³¹

²⁸ A similar approach will be taken by CAT LLC with respect to any excess money collected pursuant to Historical CAT Assessment 1 during its final month. See File No. SR-FINRA-2024-013.

²⁹ See File No. SR-FINRA-2024-013.

³⁰ As detailed in File No. SR-FINRA-2024-013, in addition to providing mock invoices, CAT LLC has worked to address Industry Member concerns regarding reconciliation of invoices for Historical CAT Assessment 1, including providing guidance and processes to assist firms in their efforts to perform reconciliations in connection with CAT invoice data. Specifically, FCAT is providing certain key elements of the trade to CAT Reporters, such as the tradeID and branch sequence, in the trade billing details accompanying CAT invoices to provide CAT Executing Brokers with alternative methods for matching fee-liable transactions with their internal books and records. See File No. SR-FINRA-2024-013.

See also CAT Technical Specifications for Billing Trade Details; Trade Details Schema, <https://catnmsplan.com/sites/default/files/2024-02/02.05.24-Billing-Trade-Details-Schema.json>; CAT Billing Scenarios, Version 1.0 (November 30, 2023), <https://www.catnmsplan.com/sites/default/files/2024-01/01.12.2024-CAT-Billing-Scenarios-v1.0.pdf>.

³¹ FINRA billing methodology for Historical CAT Cost Recovery Assessment 1 is aligned with the billing methodology for CAT LLC's Historical CAT Assessment 1 under the SEC-approved CAT

FINRA will also make publicly available on its website: (i) the total amount invoiced each month that Historical CAT Cost Recovery Assessment 1 is in effect, (ii) the total amount invoiced for Historical CAT Cost Recovery Assessment 1 for all months since its commencement, and (iii) the total costs remaining to be collected from members in aggregate for Historical CAT Cost Recovery Assessment 1. By reviewing statistics regarding how much has been invoiced and how much remains to be invoiced for Historical CAT Cost Recovery Assessment 1, members would have sufficient information to reasonably track how much longer Historical CAT Cost Recovery Assessment 1 is likely to be in place.

FINRA has filed the proposed rule change for immediate effectiveness. The effective date and the implementation date will be the date of filing.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,³² which requires, among other things, that FINRA rules must 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; and must not be designed to permit unfair discrimination between customers, issuers, brokers or dealers. FINRA also believes that the proposed rule change is consistent with the provisions of Section 15A(b)(5) of the Act,³³ which requires, among other things, that FINRA rules provide for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system that FINRA operates or controls. FINRA further believes that the proposed rule change is consistent with Section 15A(b)(9) of the Act, which

Funding Model. As with the Historical CAT Assessment 1 invoices to be provided by CAT LLC to Industry Members, the invoices that FINRA would provide in connection with Historical CAT Cost Recovery Assessment 1 are designed to allow member CEBBs and CEBSs to reconcile the invoiced amounts with the included underlying fee-liable transaction details each month. As noted in File No. SR-FINRA-2024-013, the CAT NMS Plan does not address the manner or extent to which CAT Executing Brokers may seek to pass on any CAT fees to their customers, and, as such, facilitating CEBBs' and CEBSs' ability to pass through Historical CAT Assessment 1 fees to their clients is outside the scope of the proposal. Likewise, facilitating CEBBs' and CEBSs' ability to pass through their Historical CAT Cost Recovery Assessment 1 fees to their clients is also outside the scope of the instant proposal.

³² 15 U.S.C. 78o-3(b)(6).

³³ 15 U.S.C. 78o-3(b)(5).

²⁷ From June 1, 2023, through May 31, 2024, the average monthly executed equivalent share volume in Eligible Securities where FINRA is the relevant Participant was approximately 104.7 billion shares. Assuming similar 2024 trading volumes, FINRA would recover its approximately \$4.4 million portion of the Participants' assessed share of Historical CAT Costs 1 within four months. Given the fee rate and total amount to be recovered, the proposed four-month recovery period is reasonable.

requires that FINRA rules not impose any burden on competition that is not necessary or appropriate in furtherance of the purpose of the Exchange Act.³⁴ Section 15A(b)(2) of the Act also requires that FINRA be “so organized and [have] the capacity to be able to carry out the purposes” of the Act and “to comply, and . . . to enforce compliance by its members, and persons associated with its members,” with the provisions of the Exchange Act.³⁵

FINRA believes that this proposed rule change is consistent with the Act because it is designed to assist FINRA in meeting regulatory obligations pursuant to the Plan. In approving the Plan, the SEC noted that the Plan “is necessary and appropriate in the public interest, for the protection of investors and the maintenance of fair and orderly markets, to remove impediments to, and perfect the mechanism of a national market system, or is otherwise in furtherance of the purposes of the Act.”³⁶ To the extent that this proposed rule change implements a requirement that facilitates FINRA’s achievement of its regulatory obligations under the Plan and applies specific requirements to FINRA members in this regard, FINRA believes that this proposed rule change furthers the objectives of the Plan, as identified by the SEC, and is therefore consistent with the Act.

As discussed in detail in File No. SR-FINRA-2024-013, FINRA believes that the proposed fees paid by the CEBBs and CEBSS in connection with Historical CAT Assessment 1 are reasonable, equitably allocated and not unfairly discriminatory. Historical CAT Cost Recovery Assessment 1 would similarly allow FINRA to recover its designated portion of Historical CAT Costs 1 from member CAT Executing Brokers in a fair and reasonable manner, as contemplated by the Exchange Act and consistent with the CAT Funding Model Approval Order.

Proposed Historical CAT Cost Recovery Assessment 1 would be charged to member CAT Executing Brokers in support of the maintenance of a consolidated audit trail for regulatory purposes. The proposed fees, therefore, are consistent with the Commission’s view that regulatory fees be used for regulatory purposes. The proposed fees would not cover FINRA services unrelated to the CAT, and any surplus would be used as a reserve to offset future member fees assessed by FINRA to recover its contributions, as a

Plan Participant, to CAT costs.³⁷ Accordingly, FINRA believes that the proposed fees are reasonable, equitable and not unfairly discriminatory.

The reasonableness of Historical CAT Cost Recovery Assessment 1 and its consistency with the Exchange Act likewise is grounded in the facts described above and detailed in File No. SR-FINRA-2024-013. Specifically, the expenses that compose the portion of Historical CAT Costs 1 sought to be recovered through Historical CAT Cost Recovery Assessment 1 were recognized by the SEC as appropriate for recovery pursuant to the formula approved in the CAT Funding Model (*i.e.*, technology, legal, consulting, insurance, professional administration, and public relations costs). FINRA has determined that these costs, which are described in detail in File No. SR-FINRA-2024-013, are reasonable and it is appropriate that FINRA recover its Participant contribution to such costs through Historical CAT Cost Recovery Assessment 1. FINRA also has determined that Historical CAT Cost Recovery Assessment 1 provides for the equitable allocation of fees among FINRA members and is not unfairly discriminatory, as discussed herein.

Historical CAT Cost Recovery Assessment 1 is designed to allow FINRA to recover its designated portion of Historical CAT Costs 1, consistent with the Exchange Act and the CAT Funding Model Approval Order.³⁸ In approving the CAT Funding Model, the Commission noted FINRA’s request that it acknowledge “FINRA’s need and ability to cover CAT costs that are not recovered through contractual arrangements through member fee increases, so as not to jeopardize FINRA’s ability to carry out its critical regulatory mission.”³⁹ The Commission also recognized that “the Exchange Act expressly contemplates the ability of the Participants to recoup their costs to fulfill their statutory obligations under the Exchange Act.”⁴⁰ The Commission further noted FINRA’s statement “that it would file a rule change to increase its member fees with the filing of any proposed rule change to effectuate the Funding Model.”⁴¹ The instant proposed rule change to adopt Historical CAT Cost Recovery Assessment 1 represents such a fee with respect to Historical CAT Costs 1.

Without a mechanism to recover its CAT costs, FINRA, which is unique among the Participants as a not-for-profit, national securities association, would not be able to effectively sustain its regulatory mission. Thus, consistent with the cost allocation framework put in place by the SEC-approved CAT Funding Model, whereby CEBBs and CEBSS share equal responsibility for the costs assessed directly to Industry Members based on their transactions in Eligible Securities, FINRA is seeking to recoup its designated portion of Historical CAT Costs 1 in a like manner that is fair, reasonable, and equitably allocated among FINRA’s member firms in their capacity as CAT Executing Brokers.

Historical CAT Cost Recovery Assessment 1 is designed to recover FINRA’s portion of Historical CAT Costs 1 incurred by CAT LLC associated with the development, implementation, and operation of the CAT system under the CAT NMS Plan. Thus, Historical CAT Cost Recovery Assessment 1 also is designed to support FINRA’s efforts to align its operating expenses with its operating revenues, target break-even cash flows, and continue to responsibly manage expenses driven by mandatory initiatives, like the CAT NMS Plan, in a manner consistent with FINRA’s public Financial Guiding Principles.⁴²

FINRA’s approach in determining Historical CAT Cost Recovery Fee Rate 1, which is generally consistent with the approach provided for under the SEC-approved CAT Funding Model, is also reasonable and consistent with the Exchange Act. Specifically, similar to the CAT cost assessment methodology approved by the Commission, FINRA proposes to allocate equally among member CEBBs and CEBSS the portion of Participants’ one-third share of Historical CAT Costs 1 previously paid by FINRA.⁴³ FINRA proposes to

⁴² See FINRA’s Financial Guiding Principles, https://www.finra.org/sites/default/files/finra_financial_guiding_principles_0.pdf. See also Securities Exchange Act Release No. 90176 (October 14, 2020), 85 FR 66592, 66602–03 (October 20, 2020) (Notice of Filing and Immediate Effectiveness of File No. SR-FINRA-2020-032).

⁴³ In its approval of the CAT Funding Model, the Commission determined that charging CAT fees to CAT Executing Brokers was reasonable. In reaching this conclusion the Commission noted that the use of CAT Executing Brokers is appropriate because the CAT Funding Model is based upon the calculation of executed equivalent shares, and, therefore, charging CAT Executing Brokers would reflect their executing role in each transaction. Furthermore, the Commission noted that, because CAT Executing Brokers are already identified in transaction reports from FINRA’s equity trade reporting facilities recorded in CAT Data, charging CAT Executing Brokers could streamline the billing process. See CAT Funding Model Approval Order, 88 FR 62628, 62629.

³⁷ See *supra* note 28 and accompanying text.

³⁸ See *supra* note 14 and 27 and accompanying text.

³⁹ See CAT Funding Model Approval Order, 88 FR 62628, 62645.

⁴⁰ See *supra* note 39 at 62636–37.

⁴¹ See *supra* note 39.

³⁴ 15 U.S.C. 78o-3(b)(9).

³⁵ See 15 U.S.C. 78o-3(b)(2).

³⁶ CAT NMS Plan Approval Order, 81 FR 84696, 84697.

determine Historical CAT Cost Recovery Fee Rate 1 by dividing the portion of Historical Fee Rate 1 assessed to the Participants under the CAT Funding Model, *i.e.*, \$0.00001331656564357646 per executed equivalent share, by two and rounding to six decimal places such that member CEBBs and CEBBs would each be subject to an equal fee, *i.e.*, \$0.000007 per executed equivalent share, for each transaction in Eligible Securities executed otherwise than on an exchange. Therefore, for each month that Historical CAT Cost Recovery Assessment 1 is in effect, member CEBBs and CEBBs will pay a fee to FINRA based on the same transactions used to determine fees payable by CEBBs and CEBBs to CAT LLC under Historical CAT Assessment 1 for off-exchange transactions. FINRA believes that this approach is reasonable in that, as is the case with the SEC-approved CAT Funding Model, it apportions the assessed fee for members equally between the CAT Executing Broker for the buyer and the seller.⁴⁴

FINRA believes that it is reasonable, appropriate, and consistent with the Exchange Act to determine Historical CAT Cost Recovery Assessment 1 by dividing Historical CAT Assessment 1, *i.e.*, \$0.000013 per executed equivalent share, by two and round to six decimal places which equals \$0.000007 such that member CEBBs and CEBBs would each be subject to an equal fee of \$0.000007 per executed equivalent share.⁴⁵ As discussed above, equally apportioning the fee between the CEBBs and CEBBs is consistent with the approach to apportioning costs between Executing Brokers under the SEC-approved CAT Funding Model. In addition, FINRA believes it is reasonable and appropriate at this time to divide Historical CAT Assessment 1 by two and round the Historical CAT Cost Recovery Assessment 1 fee rate to six decimal places. As noted above and in File No. SR-FINRA-2024-013, CAT LLC determined to use six decimal places for the Historical CAT Assessment 1 fee rate to balance the accuracy of the calculation with the potential systems and other impracticalities of using additional decimal places in the calculation. FINRA likewise believes that it is appropriate at this time to use six decimal places to maintain consistency with the approach determined by CAT LLC, to which members have been testing since earlier this year, which should reduce potential complexity in connection with the fee and billing

structure for Historical CAT Cost Recovery Assessment 1.

From June 2023 through May 2024, the average monthly executed equivalent share volume in Eligible Securities where FINRA is the relevant Participant was approximately 104.7 billion shares. Assuming similar trading volumes, under Historical CAT Cost Recovery Assessment 1, FINRA would recover its portion of the Participants' assessed share of Historical CAT Costs 1 within approximately four months.⁴⁶ Given the relatively modest fee rate and amount to be recovered, the expected four-month recovery period is fair, reasonable, and equitable, and will allow FINRA to recover its costs in a relatively short timeframe without imposing significant additional financial or compliance burdens on members.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Section 15A(b)(9) of the Act⁴⁷ requires that FINRA's rules not impose any burden on competition that is not necessary or appropriate in furtherance of the purpose of the Exchange Act. FINRA notes that Historical CAT Cost Recovery Assessment 1 is designed to assist FINRA in meeting its regulatory obligations pursuant to the Plan.

Furthermore, in approving the CAT Funding Model, the SEC analyzed the potential competitive impact of the CAT Funding Model, including competitive issues related to market services, trading services and regulatory services, efficiency concerns, and capital formation.⁴⁸ The SEC also analyzed the potential effect of CAT fees calculated pursuant to the CAT Funding Model on affected categories of market participants, including Participants (including exchanges and FINRA), Industry Members (including subcategories of Industry Members, such as alternative trading systems, CAT Executing Brokers and market makers), and investors generally, and considered market effects related to equities and options, among other things.⁴⁹ Based on this analysis, the SEC approved the CAT Funding Model as compliant with the Exchange Act. The Historical CAT Cost Recovery Assessment 1 fee framework is

generally consistent with the fee framework of the CAT Funding Model, as approved by the SEC.

As discussed in File No. SR-FINRA-2024-013, each of the inputs into the calculation of Historical CAT Assessment 1 is reasonable and the resulting fee rate for Historical CAT Assessment 1 is reasonable. Therefore, Historical CAT Cost Recovery Assessment 1, for these same reasons, is reasonable and would not impose any burden on competition that is not necessary or appropriate in furtherance of the purpose of the Exchange Act.

Economic Impact Assessment

Based on the regulatory need discussed above, FINRA has undertaken an economic impact assessment, as set forth below, to analyze the potential economic impacts of the proposed rule change, including potential costs, benefits, and distributional and competitive effects, relative to the current baseline.

Regulatory Need

As discussed above under the "FINRA's Designated Portion of Historical CAT Costs 1" section, FINRA is filing a proposed rule change to establish Historical CAT Cost Recovery Assessment 1 to recover its designated portion of the Participants' share of Historical CAT Costs 1. FINRA intends that the fee framework and timeline for Historical CAT Cost Recovery Assessment 1 generally correspond to the fee framework and timeline put in place by CAT LLC with respect to Historical CAT Costs 1, as provided for in File No. SR-FINRA-2024-013 and as discussed above.

Economic Baseline

Also, as discussed above under the "FINRA's Designated Portion of Historical CAT Costs 1" section, FINRA arrived at the fee rate for Historical CAT Cost Recovery Assessment 1 by dividing by two the fee rate assessed to the Participants in connection with the implementation of Historical CAT Costs 1, *i.e.*, \$0.000013 per executed equivalent share, and rounding the result to six decimal places.⁵⁰

For the twelve months from June 1, 2023, through May 31, 2024, based on transactions reported to a FINRA TRF or to the ORF, there were 896 firm MPIDs that executed at least one purchase or sale of an equivalent share of an Eligible Security.⁵¹ The top 50 MPIDs by

⁴⁶ See *supra* note 27.

⁴⁷ 15 U.S.C. 78o-3(b)(9).

⁴⁸ See CAT Funding Model Approval Order, 88 FR 62628, 62678-86.

⁴⁹ See *supra* note 48.

⁵⁰ See also File No. SR-FINRA-2024-013.

⁵¹ For the twelve months from June 1, 2023, through May 31, 2024, approximately 1.25 trillion shares of NMS stocks were reported to the TRF, and

Continued

⁴⁴ See *supra* note 43.

⁴⁵ See *supra* note 26 and accompanying text.

reported executed equivalent share volume bought and/or sold 2,161,308,428,108 equivalent shares, or 85.08% of total shares bought and/or sold.

Economic Impacts

FINRA's proposal to recover its designated portion of the Participants' share of Historical CAT Costs 1 applies an approach generally consistent with the CAT Funding Model as approved by the SEC in that it assesses half of the fee rate that is assessed to FINRA under Historical CAT Assessment 1 (rounded to six decimal places) to each of the CEBB and CEBS for transactions where FINRA is the relevant Participant.⁵² With regard to off-exchange transactions in Eligible Securities, generally the same members that will be assessed Historical CAT Cost Recovery Assessment 1 will also be assessed Historical CAT Assessment 1. Therefore, FINRA's proposed approach in recovering its designated portion of Historical CAT Costs 1 should reduce potential complexity in connection with the fee and billing structure for Historical CAT Cost Recovery Assessment 1. The recovery period for FINRA's portion of the share of Historical CAT Costs 1 is expected to be four months, which is shorter than the Historical Recovery Period for the two-thirds portion of Historical CAT Costs 1 assessed to Industry Members.⁵³

Where CEBBs and CEBSs choose to pass Historical CAT Cost Recovery Assessment 1 on to customers, some customers could attempt to avoid incurring this temporary cost by delaying trades until after FINRA's contribution to the Participants' share of Historical CAT Costs 1 is paid. FINRA believes this is an unlikely outcome because this fee is only one part of a trader's decision regarding whether and where to trade. In addition, as the Historical CAT Cost Recovery Assessment 1 recovery period is dependent on the level of trading activity, delaying trading may only serve to lengthen the recovery period. However, traders that do trade during the recovery period may incur relatively

approximately 1.16 trillion shares of OTC Equity Securities were reported to ORF. Given that each executed share for a transaction in an OTC Equity Security is counted as 0.01 equivalent share, FINRA estimates that the executed equivalent share volume for NMS stocks and OTC Equity Securities reported to a FINRA equity trade reporting facility in that twelve-month period is approximately 1.26 trillion shares. Dividing that figure by twelve provides the average monthly executed equivalent share volume of approximately 104.7 billion shares.

⁵² See CAT Funding Model Approval Order, 88 FR 62628; See also File No. SR-FINRA-2024-013.

⁵³ See File No. SR-FINRA-2024-013.

more costs than those that trade after the recovery period has ended.

As the SEC noted in approving the revised CAT Funding Model, if FINRA passes on its portion of the CAT fee allocation to its member firms and exchanges choose not to pass through their CAT fee allocations to their members, the cost to transact off-exchange may increase relative to executing on an exchange, potentially giving exchanges a competitive advantage.⁵⁴ However, we do not know whether or to what extent (or how) the exchanges may seek to recover their portion of the Historical CAT Costs 1, and we do not know whether or to what extent member firms will choose to pass through exchange-incurred CAT fees to customers. We also note that FINRA members remain subject to regulatory obligations, such as best execution obligations, with respect to their order routing decisions.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Exchange Act⁵⁵ and Rule 19b-4(f)(2) thereunder,⁵⁶ because it establishes or changes a due, or fee.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend the rule change if it appears to the Commission that the action is necessary or appropriate in the public interest, for the protection of investors, or would otherwise further the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

⁵⁴ See *supra* note 52 at 62684.

⁵⁵ 15 U.S.C. 78s(b)(3)(A)(ii).

⁵⁶ 17 CFR 240.19b-4(f)(2).

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-2024-014 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-2024-014. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also 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-2024-014 and should be submitted on or before October 15, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁵⁷

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024-21625 Filed 9-20-24; 8:45 am]

BILLING CODE 8011-01-P

⁵⁷ 17 CFR 200.30-3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–028, OMB Control No. 3235–0032]

Proposed Collection; Comment Request; Extension: Rule 17f–1(b)*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 (“PRA”) (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (“Commission”) is soliciting comments on the existing collection of information provided for in Rule 17f–1(b) (17 CFR 240.17f–1(b)), under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget (“OMB”) for extension and approval.

Under Rule 17f–1(b) under the Exchange Act, approximately 9,500 entities in the securities industry are registered in the Lost and Stolen Securities Program (“Program”). Registration fulfills a statutory requirement that entities report and inquire about missing, lost, counterfeit, or stolen securities. Registration also allows entities in the securities industry to gain access to a confidential database that stores information for the Program.

The Commission staff estimates that 4 new entities will register in the Program each year. The staff estimates that the average number of hours necessary to comply with Rule 17f–1(b) is one-half hour. Accordingly, the staff estimates that total annual burden for all participants is 2 hours (4 × one-half hour). The Commission staff estimates that compliance staff work at subject entities results in an internal cost of compliance, at an estimated hourly wage of \$344, of \$172 per year per entity (.5 hours × \$344 per hour = \$172 per year). Therefore, the aggregate annual internal cost of compliance is approximately \$688 (\$172 × 4 = \$688).

Written comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission’s estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on

respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted by November 22, 2024.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: Austin Gerig, Director/Chief Data Officer, Securities and Exchange Commission, c/o Oluwaseun Ajayi, 100 F Street NE, Washington, DC 20549, or send an email to: PRA_Mailbox@sec.gov.

Dated: September 18, 2024.

Vanessa A. Countryman,
Secretary.

[FR Doc. 2024–21656 Filed 9–20–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101050; File No. SR–NYSE–2024–56]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 7.31

September 17, 2024.

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 September 9, 2024, New York Stock Exchange LLC (“NYSE” or the “Exchange”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the 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 Rule 7.31 regarding the Minimum Trade Size Modifier. The proposed rule change is available on the Exchange’s website at www.nyse.com, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

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 Rule 7.31 regarding the Minimum Trade Size (“MTS”) Modifier.

Rule 7.31(i)(3) provides that a Limit IOC Order, Non-Displayed Limit Order, Non-Displayed Primary Pegged Order, or MPL Order may be designated with an MTS Modifier. Rule 7.31(i)(3)(A) currently provides that an MTS must be a minimum of a round lot and that an order with an MTS Modifier will be rejected if the MTS is less than a round lot or if the MTS is larger than the size of the order. The Exchange proposes to amend Rule 7.31(i)(3)(A) to provide that an MTS may be an odd lot quantity and thus proposes to eliminate rule text currently providing that an MTS must be a minimum of a round lot and that an order with an MTS of less than one round lot would be rejected. The Exchange believes that restricting the use of the MTS Modifier to round lot sizes only is unnecessary and that providing member organizations with the option to use the MTS Modifier with an odd lot quantity could increase liquidity and enhance opportunities for order execution on the Exchange. The Exchange notes that permitting odd-lot order quantities is not novel on the Exchange or other equity exchanges and believes that this proposed change is consistent with other equity exchanges’ approaches to the use of instructions similar to the MTS Modifier.⁴

⁴ The rules of Cboe EDGA Exchange, Inc. (“EDGA”), Cboe EDGX Exchange, Inc. (“EDGX”), and Members Exchange (“MEMX”) appear to permit the use of instructions comparable to the MTS Modifier in any size. *See* EDGA Rules 11.2 (providing that orders are eligible for odd-lot, round-lot, and mixed-lot executions unless otherwise indicated) and 11.6(h) (defining Minimum Execution Quantity instruction); EDGX Rules 11.2 and 11.6(h) (same); MEMX Rules 11.2

The Exchange also proposes to amend Rule 7.31(i)(3) to include the non-displayed ALO Order as an order type that could be designated with an MTS Modifier. This clarifying change is intended only to reflect current behavior, by providing a complete list of the order types that may be designated with an MTS Modifier. The Exchange notes that the inclusion of the non-displayed ALO Order⁵ as an order type that may be designated with an MTS Modifier is consistent with the existing use of the MTS Modifier with non-displayed order types such as Non-Displayed Limit Orders and MPL Orders (including MPL–ALO Orders). Moreover, although the non-displayed ALO Order is a Limit Order that is non-displayed, the Exchange believes that specifically including the non-displayed ALO Order in the text of Rule 7.31(i)(3) would reduce ambiguity as to the order types that may be designated with an MTS Modifier.

Because of the technology changes associated with this proposed rule change, the Exchange will announce the implementation date by Trader Update, which, subject to effectiveness of this proposed rule change, will be no later than in the fourth quarter of 2024.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,⁶ in general, and furthers the objectives of Section 6(b)(5),⁷ in particular, because 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.

The Exchange believes that the proposed change would remove impediments to, and perfect the mechanism of, a free and open market and a national market system, and protect investors and the public interest because it would provide member organizations with the option to use the MTS Modifier with odd lot quantities, which could encourage order flow to the

Exchange and promote opportunities for order execution on the Exchange, to the benefit of all market participants. The proposed change would also clarify that the MTS Modifier may be used in conjunction with non-displayed ALO Orders, thereby removing impediments to, and perfecting the mechanism of, a free and open market and a national market system by updating Exchange rules to ensure that they reflect the current availability of the MTS Modifier and promoting consistency and specificity in Exchange rules as to the use of such modifier with non-displayed order types. The Exchange notes that the proposed change would not otherwise impact the operation of the MTS Modifier as provided under current Exchange rules. The Exchange also believes that the proposed change would align Exchange rules with the use of instructions similar to the MTS Modifier on other equity exchanges, thereby removing impediments to, and perfecting the mechanism of, a free and open market and a national market system.⁸

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change would allow the optional MTS Modifier to be used with an odd lot quantity and accurately reflect the order types that may be designated with an MTS Modifier. The Exchange believes that the proposed change would promote competition among exchanges by offering member organizations options available on other equity exchanges and, to the extent the proposed change would increase opportunities for order execution, promote competition by making the Exchange a more attractive venue for order flow and enhancing market quality for all market participants.

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 Act⁹ and Rule 19b–4(f)(6) thereunder.¹⁰ 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)(iii) of the Act¹¹ and Rule 19b–4(f)(6)(iii) thereunder.¹²

A proposed rule change filed under Rule 19b–4(f)(6)¹³ normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),¹⁴ 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 take effect as soon as the technology associated with the proposed change is available, which is anticipated to be less than 30 days from the date of this filing. The Commission believes that waiver of the operative delay is consistent with the protection of investors and the public interest because the proposal raises no novel issues and would allow use of the MTS Modifier with odd lot quantities without delay and promote clarity in Exchange rules as to the order types that may be designated with an MTS Modifier. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.¹⁵

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

⁹ 15 U.S.C. 78s(b)(3)(A)(iii).

¹⁰ 17 CFR 240.19b–4(f)(6).

¹¹ 15 U.S.C. 78s(b)(3)(A)(iii).

¹² 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has fulfilled this requirement.

¹³ 17 CFR 240.19b–4(f)(6).

¹⁴ 17 CFR 240.19b–4(f)(6)(iii).

¹⁵ For purposes only of accelerating the operative date of this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

and 11.6(f) (same). See also, e.g., IEX Rule 1190(b)(3) (providing that a non-displayed order may be a Minimum Quantity Order and may be an odd lot order).

⁵ An ALO Order is a Non-Routable Limit Order that, unless it receives price improvement, will not remove liquidity from the Exchange Book; an ALO Order may be designated as non-displayed. See Rule 7.31(e)(2).

⁶ 15 U.S.C. 78f(b).

⁷ 15 U.S.C. 78f(b)(5).

⁸ See note 4, *supra*.

the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) ¹⁶ 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-NYSE-2024-56 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-NYSE-2024-56. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All

submissions should refer to file number SR-NYSE-2024-56 and should be submitted on or before October 15, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁷

Vanessa A. Countryman,

Secretary.

[FR Doc. 2024-21624 Filed 9-20-24; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-101052; File No. SR-FINRA-2024-015]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Amend Form U4 and FINRA Rule 3110.19(d) (Obligation To Provide List of RSLs to FINRA) for New RSL Question

September 17, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") ¹ and Rule 19b-4 thereunder,² notice is hereby given that on September 13, 2024, 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. FINRA has designated the proposed rule change as constituting a "non-controversial" rule change under paragraph (f)(6) of Rule 19b-4 under the Act,³ which renders the proposal effective upon receipt of this filing by the Commission. 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

FINRA is proposing to (1) amend Section 1 (General Information) of the Uniform Application for Securities Industry Registration or Transfer ("Form U4") to add a new question eliciting information to identify locations as residential supervisory locations ("RSLs"); (2) amend FINRA Rule 3110.19(d) (Obligation to Provide List of RSLs to FINRA) to remove the reference to a list of RSLs and the quarterly

timeframe for member firms to provide the list to FINRA and replace it with the requirement that member firms provide current information identifying all locations designated as RSLs in the frequency, manner and format as FINRA may prescribe; and (3) make conforming changes to Section 6 (Registration Requests with Affiliated Firms) of the Form U4 and amend the Form U4 Instructions to account for the new question soliciting RSL information ("RSL Question").

The text of the proposed rule change is available on FINRA's website at <http://www.finra.org>, at the principal office of FINRA and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, 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

Proposed Amendment to Section 1 (General Information) of Form U4 To Add a New RSL Question

Effective June 1, 2024, FINRA Rule 3110.19 permits a member firm to designate a private residence at which an associated person engages in specified supervisory activities, subject to certain safeguards and limitations, as an RSL, a non-registered location.⁴

Currently, Rule 3110.19(d) requires a member firm that elects to designate any of its offices or locations as an RSL to provide FINRA with a current list of those offices or locations by the 15th day of the month following each calendar quarter in the manner and format (e.g., through an electronic process or such other process) as FINRA may prescribe.⁵ As part of FINRA's

⁴ See Securities Exchange Act Release No. 98980 (November 17, 2023), 88 FR 82447 (November 24, 2023) (Notice of Filing of Amendment No. 2 and Order Granting Accelerated Approval of File No. SR-FINRA-2023-006); see also *Regulatory Notice* 24-02 (January 2024).

⁵ See *supra* note 4.

¹⁷ 17 CFR 200.30-3(a)(12).

¹⁵ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 17 CFR 240.19b-4(f)(6).

¹⁶ 15 U.S.C. 78s(b)(2)(B).

proposal to adopt Rule 3110.19, FINRA committed to exploring ways for member firms to provide information identifying their RSLs to FINRA and other securities regulators in an efficient and timely manner, including by identifying RSLs to the Central Registration Depository (“CRD®”) using FINRA Gateway⁶ as a possible option.⁷ In general, commenters to the proposal suggested that FINRA consider leveraging the CRD system to identify and track RSLs,⁸ and FINRA received similar suggestions from engagement with members of its advisory committees and other interested parties. Noted benefits of this approach included an increase in the timeliness and accuracy of the RSL information and enhanced efficiency of providing the information to FINRA in an automated fashion rather than manually created lists of RSLs.

Following a thorough review of the various options for member firms to identify their RSLs to FINRA, and in consideration of the comment letters submitted to the SEC in connection with the proposal to adopt Rule 3110.19 and other feedback FINRA has received, FINRA has determined that amending Form U4 to add the proposed new RSL Question would be the most appropriate manner for member firms to indicate a non-registered location that is identified on Form U4 a private residence is an RSL by responding “Yes” or “No.” Therefore, FINRA is prescribing that member firms must comply with Rule

3110.19(d), as proposed to be amended, by submitting such information to FINRA via the proposed RSL Question on Form U4.

As noted, the CRD system includes information reported on the uniform registration forms that member firms and regulatory authorities complete and maintain as part of the securities industry registration and licensing process.⁹ Member firms use Form U4 to register associated persons with FINRA, other self-regulatory organizations (“SROs”), and jurisdictions as appropriate.¹⁰ The Form U4 elicits registration information, which consists of, among other things, administrative, employment, criminal, regulatory, customer complaint, and financial information about associated persons.¹¹ The administrative information elicited on Form U4 includes work and residential location information about a member firm’s associated persons, including the offices and locations (registered and unregistered) to which those persons are assigned.¹²

FINRA believes that the most efficient, timely, and useful means for member firms to provide information identifying RSLs to FINRA is through the Form U4. Because member firms currently provide work and residential information about their associated persons through the Form U4 and keep such information up-to-date on an ongoing basis, FINRA believes that the proposed RSL Question on Form U4 would leverage existing processes to access and update Form U4 information to the CRD system and provide member firms with a uniform way to submit information to identify their RSLs in a manner with which they are familiar. FINRA believes that prescribing the Form U4 as the method of providing information identifying RSLs to FINRA would also allow member firms using FINRA’s API Platform to respond to the proposed RSL Question for multiple locations simultaneously through an efficient machine-to-machine upload process.¹³ In addition, the RSL information would be readily accessible to securities regulators because it would be available in the CRD system, which FINRA, state, and other regulatory

authorities use in connection with their licensing and regulatory activities.¹⁴

For these reasons, FINRA is proposing to amend Section 1 (General Information) of the Form U4 to add a RSL Question that, when a member firm has indicated that an associated person’s office of employment address is a non-registered location that is identified on Form U4 as a private residence, would ask, “Is this Office of Employment address an RSL?” and prompt the member firm to answer either “Yes” or “No.” The proposed RSL Question would also state that if “Yes” is selected to the RSL Question, the member firm confirms that the location is designated as an RSL as defined in FINRA Rule 3110.¹⁵ While FINRA acknowledges that the RSL reporting process would result in a slight extension of the previously announced October 15, 2024 initial RSL reporting deadline, FINRA believes the later reporting start date would ultimately result in a more timely and efficient process going forward that would yield many benefits that promote investor protection and are in the public interest. As noted above, FINRA believes that by changing the RSL reporting mechanism to the Form U4 rather than a quarterly list, the proposed rule change would: (1) leverage existing reporting processes to increase the timeliness and accuracy of RSL information; (2) enhance the efficiency of providing RSL information to FINRA in an automated fashion; and (3) make the RSL information more readily accessible to securities regulators.

Proposed Amendment to Rule 3110.19(d)

Currently, Rule 3110.19(d) provides that a member firm that elects to designate any of its offices or locations as an RSL is required to provide FINRA

⁶ FINRA Gateway is an electronic compliance portal designed to streamline the compliance and reporting experience for member firms and provide consolidated access to, among other things, uniform registration forms, which includes Form U4 (“FINRA Gateway”). See <https://www.finra.org/filing-reporting/finra-gateway>. Member firms use FINRA Gateway or other platforms to file both initial and amendments to Form U4 in the CRD system, the central licensing and registration system used by the U.S. securities industry and its regulators. In general, the CRD system includes information reported on the uniform registration forms that member firms and regulatory authorities complete and maintain as part of the securities industry registration and licensing process. FINRA, state, and other regulatory authorities use the information in the CRD system in connection with their licensing and regulatory activities.

⁷ See Letter from Kosha Dalal, Vice President and Associate General Counsel, FINRA, to Vanessa Countryman, Secretary, SEC, dated September 14, 2023, <https://www.finra.org/sites/default/files/2023-09/FINRA-2023-006-Response-to-Comments-09-14-2023.pdf>.

⁸ See, e.g., Letter from David T. Bellaire, Executive Vice President & General Counsel, Financial Services Institute, to Secretary, SEC, dated April 27, 2023, <https://www.sec.gov/comments/sr-finra-2023-006/srfinra2023006-20165189-334506.pdf>; Letter from Andrew Hartnett, NASAA President and Deputy Commissioner, Iowa Insurance Division, to Sherry R. Haywood, Assistant Secretary, SEC, dated April 27, 2023, <https://www.sec.gov/comments/sr-finra-2023-006/srfinra2023006-20165163-334468.pdf>.

⁹ See *supra* note 6.

¹⁰ See Form U4, Sections 4 (SRO Registrations) and 5 (Jurisdiction Registrations) for available registrations.

¹¹ See Form U4.

¹² See Form U4, Sections 1 (General Information), 6 (Registration Requests with Affiliated Firms), and 11 (Residential History).

¹³ FINRA’s API Platform is an application programming interface that allows subscribers to make automated data transfers with FINRA.

¹⁴ The reporting of RSL designations to the CRD system through the Form U4 would allow FINRA and other securities regulators to easily use the information for regulatory purposes. RSL data would be fully integrated into the existing customizable reporting capability available to securities regulators and would allow, for example, a state securities regulator to generate reports of the designated RSLs in its state by various criteria such as city or zip code. The creation of such custom reports would not be possible if, for example, member firms provided RSL information to FINRA in a Portable Document Format (“PDF”) document.

¹⁵ Complete and accurate reporting on Form U4 is the joint responsibility of the member firm and the associated person. By identifying a location or office as an RSL on Form U4, however, the member firm is confirming the location or office is an RSL as defined in Rule 3110. As such, the member firm is confirming that the requirements set forth in Rule 3110.19 have been met for designation of the RSL (e.g., the firm has conducted a risk assessment prior to designating the office or location as an RSL as set forth in Rule 3110.19(e)).

with a list of the RSLs by the 15th day of the month following each calendar quarter in the manner and format (e.g., through an electronic process or such other process) as FINRA may prescribe. However, the FINRA By-Laws impose a 30-day timeframe upon firms to keep Form U4 current at all times, and because the proposed RSL Question would be part of the Form U4, the 30-day updating requirement makes unnecessary the quarterly timeframe for firms to provide FINRA a list of RSLs as currently required under Rule 3110.19(d). As such, FINRA is proposing to make a conforming change to Rule 3110.19(d) to replace the requirement for member firms to provide to FINRA a quarterly list of RSLs in the manner and format prescribed by FINRA with the requirement for member firms to provide to FINRA current information identifying their RSLs in the frequency, manner and format prescribed.¹⁶

Under the proposed rule change, the requirement for member firms to provide a list of RSLs to FINRA would no longer be necessary since they would be reporting information identifying their RSLs via Form U4 and such information would be available to FINRA in the CRD system. Because FINRA and other securities regulators have access to the information in the CRD system in connection with their licensing and regulatory activities, they would be able to view the most current information about a member firm's RSLs at any time. Accordingly, this proposed amendment to remove the quarterly RSL list requirement is appropriate to align with the proposed amendment to Form U4 to include the RSL Question.

Also, in light of the proposed amendment to Form U4 to include the RSL Question, the quarterly timeframe currently provided in Rule 3110.19(d) does not align with the timing requirements for Form U4 amendments. Therefore, the proposed rule change would conform the timeframe pursuant to which member firms would be required to provide to FINRA information identifying their RSLs by removing the reference to the quarterly basis currently set forth in Rule 3110.19(d). Under the FINRA By-Laws, member firms and associated persons have a continuing obligation to ensure that a Form U4 is timely updated when

an event or proceeding occurs that renders a prior response on the form inaccurate or incomplete; specifically, not later than 30 days after learning of the facts and circumstances giving rise to the change.¹⁷

While FINRA acknowledges that the RSL reporting process would result in a slight extension of the previously announced October 15, 2024 initial RSL reporting deadline to December 26, 2024, FINRA believes that, under most circumstances, the reporting of RSL designations via the Form U4 would provide FINRA and other securities regulators this information on a more timely basis than the quarterly cadence currently set forth under Rule 3110.19(d) and would make the information more readily accessible to FINRA and other securities regulators.¹⁸ In this regard, the locations or offices that member firms have designated as RSLs would be reported to FINRA on a rolling basis, consistent with the requirements to keep information current on the Form U4, rather than only four times per year. As a result, FINRA and other securities regulators may receive more current information going forward for use in connection with their licensing and regulatory activities than they would have received if the RSL information was first provided through a quarterly RSL list on October 15, 2024, as previously announced in *Regulatory Notice* 24–02. FINRA believes that, on balance, the slight extension in the deadline for initial RSL reporting would be offset by the benefits from the efficiencies and timeliness resulting from the use of the ongoing reporting processes associated with Form U4 reporting.¹⁹

Other Proposed Conforming Amendments

FINRA is proposing to add the same RSL Question in Section 1 (General Information) to Section 6 (Registration Requests with Affiliated Firms) of Form U4. Section 6 (Registration Requests with Affiliated Firms) of the Form U4 is similar to Section 1 (General Information) and is used by a member firm to request registration for an associated person with an affiliate of the

member firm. As in Section 1 (General Information), the RSL Question in Section 6 (Registration Requests with Affiliated Firms) would also prompt the member firm, when it has indicated that an associated person's office of employment address is a non-registered location that is identified on Form U4 as a private residence, to answer either "Yes" or "No," and state that if "Yes" is selected, the member firm confirms that the location is designated as an RSL as defined in FINRA Rule 3110.

FINRA also is proposing to amend the Form U4 Instructions to account for the new RSL Question. The proposed conforming update to the instructions would provide: "If the Office of Employment address is a non-registered location and designated as a private residence, enter 'yes' or 'no' to indicate whether the Office of Employment address is a residential supervisory location as defined in FINRA Rule 3110. (Note: this question can be answered only if the Private Residence Check Box has been checked.) If 'yes' is selected, the firm confirms that this location is designated as an RSL as defined in FINRA Rule 3110."

Implementation Procedures

The implementation date of the proposed rule change will be November 26, 2024. An implementation date that is 30 days prior to the date by which member firms must provide FINRA information identifying their RSLs under amended Rule 3110.19(d) would also align with the requirements of the FINRA By-Laws for member firms and registered persons to keep information disclosed on registration forms current at all times and that amendments to such forms must be filed with FINRA and other applicable regulators not later than 30 days after learning of the facts and circumstances giving rise to the change.²⁰

FINRA is proposing to prescribe, for member firms that have indicated on Form U4 that an associated person's office of employment address is a non-registered location that is a private residence, the following procedures for responding to the proposed RSL Question. The proposed RSL Question would prompt member firms to answer the question as either "Yes" or "No" within the timeframes set forth in the following chart:

²⁰ See *supra* note 17.

¹⁶ FINRA is also proposing to amend the header to paragraph (d) to read as "Obligation to Provide Information Identifying RSLs to FINRA."

¹⁷ See FINRA By-Laws, Article V, Section 2(c).

¹⁸ See *supra* note 14.

¹⁹ FINRA also notes that during the transition period between the effective date of the proposed rule change and the November 26, 2024 implementation date, member firms may begin responding to the RSL Question on Form U4 on a voluntary basis.

Date member firm determines whether non-registered private residence location is or is not an RSL *	Date member firm response to the RSL question on form U4 as “Yes” or “No” is due
From June 1, 2024 (effective date of Rule 3110.19) through November 25, 2024.	Required by December 26, 2024 **.
On or After November 26, 2024	Required within 30 days of RSL designation in accordance with FINRA By-Laws.

* The member firm must first have indicated on the associated person’s Form U4 that the Office of Employment address is a non-registered location and a private residence by checking the “Private Residence Check Box.” See Form U4 Instructions, Section 1 (General Information) (directing a filer to “Check this [Private Residence Check Box] if the Office of Employment address is a private residence.”).

** Prior to the implementation date,²¹ member firms may begin responding to the RSL Question on Form U4 on a voluntary basis from the date the RSL Question becomes available on Form U4 (“transition period”).²²

As of the November 26, 2024 implementation date, for any associated person’s office of employment address that is a non-registered location and has been identified as a private residence through the “Private Residence Checkbox” on Form U4, member firms would have until December 26, 2024 to amend Form U4 to respond “Yes” or “No” to the RSL Question (if they have not already done so during the transition period) to identify whether such private residence location has or has not been designated by the member firm as an RSL on or after the June 1, 2024 effective date of Rule 3110.19.²³ Also, as of the November 26, 2024 implementation date, member firms filing a Form U4 to report, for the first time, that an associated person’s office of employment address that is a non-registered location and has been identified as a private residence through the “Private Residence Checkbox” on Form U4 would have until December 26, 2024 to respond to the RSL Question to indicate whether that location has or has not been designated by the member firm as an RSL on or after the June 1, 2024 effective date of Rule 3110.19.²⁴

²¹ FINRA expects to deploy the RSL Question on Form U4 on or before September 30, 2024. FINRA will announce when the RSL Question has been deployed on Form U4.

²² While member firms may respond to the RSL Question on a voluntary basis during the transition period, the RSL Question information that is voluntarily reported on Form U4 must nonetheless be accurate, as is the case with any other information provided through Form U4.

²³ Prior to the November 26, 2024 implementation date, FINRA is proposing to permit member firms to transition into their RSL reporting requirement. During this transition period, member firms may voluntarily begin responding to the proposed RSL Question on Form U4. FINRA believes this transition period for compliance is appropriate given the potentially significant number of private residence locations that member firms may need to review to determine whether or not to identify them on Form U4 as RSLs and report this information to FINRA by December 26, 2024. While member firms may respond to the RSL Question on a voluntary basis during the transition period, the RSL Question information that is voluntarily reported on the Form U4 must nonetheless be accurate, as is the case with any other information provided through Form U4. See Form U4, Section 15 (Signatures).

²⁴ For example, if an associated person begins working from their home on November 1, 2024 and

On and after the November 26, 2024 implementation date, member firms must keep the response to the RSL Question current at all times by supplementary amendments to the initial (or original) Form U4 and such amendments must be filed with FINRA no later than 30 days after a member firm designates or no longer designates a private residence location as an RSL.²⁵

FINRA has filed the proposed rule change for immediate effectiveness. The implementation date for the proposed rule change will be November 26, 2024.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,²⁶ which requires, among other things, that FINRA rules must 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. FINRA believes that the proposed rule change would provide the most efficient, timely, and useful manner for member firms to provide their RSL information to FINRA. In this regard, the proposed RSL Question would allow member firms to leverage existing processes to access and update Form U4 information to the CRD system using FINRA Gateway and, for machine-to-machine uploads, FINRA’s API Platform, without the need to develop or implement a new method for providing the RSL information. In addition, member firms would, in most circumstances, provide more current information to FINRA about their RSL designations because they would be required to amend the Form U4 to report any changes to their RSL designations no later than 30 days after

their firm files an amended Form U4 on November 30, 2024 to report the associated person’s new office of employment address is a non-registered location that is a private residence, the firm would have until December 26, 2024 to respond “Yes” or “No” to the RSL Question to indicate whether the firm has or has not designated that private residence location as an RSL.

²⁵ See *supra* note 17.

²⁶ 15 U.S.C. 78o–3(b)(6).

the change. Specifically, member firms would be required to update their RSL information on an ongoing basis rather than only four times per year. Furthermore, by member firms reporting their RSL designations to FINRA through the Form U4, FINRA and other securities regulators would be able to readily access this information and easily use it for regulatory purposes.

B. Self-Regulatory Organization’s Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. As discussed above, a member firm that elects to designate any of its offices or locations as an RSL is required to provide information identifying such offices to FINRA. FINRA believes that doing so through an RSL Question on the Form U4 within the implementation timeframes described in this filing would provide the most efficient, timely, and useful manner for member firms to do so.

The proposed rule change would amend the Form U4 to add a new RSL Question to facilitate the reporting of offices or locations designated by member firms as RSLs to FINRA. The proposed new RSL Question would require member firms to indicate whether a non-registered location that is identified on Form U4 as a private residence is an RSL by responding “Yes” or “No.” As described above, this proposed rule change would require member firms to amend such forms for all their associated persons whose office of employment address is a non-registered location that is identified on Form U4 as a private residence within the implementation timeframe described in this proposed rule change, which may place an administrative and operational burden on member firms. FINRA notes that amendments to Form U4 are relatively frequent over the course of a year, so member firms may be able to comply with this requirement going forward when they update the Form U4 for other reasons, subject to the

requirement in the FINRA By-Laws to ensure that a Form U4 is timely updated not later than 30 days after learning of the facts and circumstances giving rise to the change.²⁷ In addition, FINRA believes the transition period would help mitigate potential administrative and operational burdens on member firms as it would provide more time and flexibility to member firms in responding to the proposed new RSL Question. Longer term, following the initial December 26, 2024 deadline, FINRA believes that the time it would take a member firm to respond to the proposed new RSL Question for the subset of associated persons whose office of employment address is identified on Form U4 as a non-registered location that is a private residence would be minimal.

Moreover, FINRA believes the administrative and operational burdens on member firms and associated persons as a result of the proposed rule change would be mitigated because member firms and associated persons already must use Form U4 for associated persons to become registered with appropriate SROs, and both member firms and applicants for membership file initial, transfer and amended Forms U4 for their associated persons electronically to the CRD system using the FINRA Gateway or FINRA's API Platform (for machine-to-machine uploads of Form U4 filings). The CRD system includes reporting and record keeping capabilities that are familiar to member firms, and it may expedite the submission and timely maintenance of accurate information regarding a member firm's RSLs and the storage of historic Form U4 filings. Further, FINRA, the SEC and other securities regulators have ready access to Form U4 filings submitted to the CRD system using FINRA Gateway or FINRA's API Platform.

FINRA considered alternative methods to collect RSL information from member firms, including a custom electronic information request or submission of simple lists of locations through the FINRA Gateway. Either option would be costlier for member firms because they would need to develop an infrastructure to create, maintain and report such information, as well as to ensure the accuracy of the information. In addition, because the RSL information would not be submitted through Form U4, such information would not be easily

aggregated, analyzed, or made readily available to securities regulators.

FINRA also considered staggered due dates for responses to the RSL Question on Form U4, whereby member firms would be required to provide a "Yes" response to the RSL Question to indicate all of the non-registered locations that are identified on Form U4 as private residences that the member firm designated as RSLs by a specified date, after which member firms would be required to provide a "No" response to the RSL Question for those non-registered locations that are identified on Form U4 as private residences that the member firm did not designate as RSLs. However, such staggered responses are unnecessary because the announced October 15, 2024 initial deadline for the first quarterly list has been replaced with the December 26, 2024 deadline and, as noted above, FINRA believes that the length of the transition period sufficiently mitigates the potential administrative and operational burdens on member firms by leveraging current operational processes already used by member firms. In addition, FINRA believes that a single implementation date is simpler and less likely to lead to confusion regarding the deadlines for compliance by member firms.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act²⁸ and Rule 19b-4(f)(6) thereunder.²⁹

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the

Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-FINRA-2024-015 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to File Number SR-FINRA-2024-015. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also 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-2024-015 and should be submitted on or before October 15, 2024.

²⁷ For example, in 2023, member firms filed Form U4 amendments for almost 480,000 registered individuals, which is approximately 75% of the individuals who were registered as of December 31, 2023.

²⁸ 15 U.S.C. 78s(b)(3)(A).

²⁹ 17 CFR 240.19b-4(f)(6).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.³⁰

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–21623 Filed 9–20–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101051; File No. SR–NYSEAMER–2024–57]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Change To Amend Rule 7.31E

September 17, 2024.

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 September 9, 2024, 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 amend Rule 7.31E regarding the Minimum Trade Size Modifier. The proposed rule change is available on the Exchange’s website at www.nyse.com, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

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 Rule 7.31E regarding the Minimum Trade Size (“MTS”) Modifier.

Rule 7.31E(i)(3) provides that a Limit IOC Order, Non-Displayed Limit Order, MPL Order, Tracking Order, Non-Displayed Primary Pegged Order, or Discretionary Pegged Order may be designated with an MTS Modifier. Rule 7.31E(i)(3)(A) currently provides that an MTS must be a minimum of a round lot and that an order with an MTS Modifier will be rejected if the MTS is less than a round lot or if the MTS is larger than the size of the order. The Exchange proposes to amend Rule 7.31E(i)(3)(A) to provide that an MTS may be an odd lot quantity and thus proposes to eliminate rule text currently providing that an MTS must be a minimum of a round lot and that an order with an MTS of less than one round lot would be rejected. The Exchange believes that restricting the use of the MTS Modifier to round lot sizes only is unnecessary and that providing ETP Holders with the option to use the MTS Modifier with an odd lot quantity could increase liquidity and enhance opportunities for order execution on the Exchange. The Exchange notes that permitting odd-lot order quantities is not novel on the Exchange or other equity exchanges and believes that this proposed change is consistent with other equity exchanges’ approaches to the use of instructions similar to the MTS Modifier.⁴

The Exchange also proposes to amend Rule 7.31E(i)(3) to include the non-displayed ALO Order as an order type that could be designated with an MTS Modifier. This clarifying change is intended only to reflect current behavior, by providing a complete list of the order types that may be designated with an MTS Modifier. The Exchange notes that the inclusion of the non-displayed ALO Order ⁵ as an order type

that may be designated with an MTS Modifier is consistent with the existing use of the MTS Modifier with non-displayed order types such as Non-Displayed Limit Orders and MPL Orders (including MPL–ALO Orders).

Moreover, although the non-displayed ALO Order is a Limit Order that is non-displayed, the Exchange believes that specifically including the non-displayed ALO Order in the text of Rule 7.31E(i)(3) would reduce ambiguity as to the order types that may be designated with an MTS Modifier.

Because of the technology changes associated with this proposed rule change, the Exchange will announce the implementation date by Trader Update, which, subject to effectiveness of this proposed rule change, will be no later than in the fourth quarter of 2024.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,⁶ in general, and furthers the objectives of Section 6(b)(5),⁷ in particular, because 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.

The Exchange believes that the proposed change would remove impediments to, and perfect the mechanism of, a free and open market and a national market system, and protect investors and the public interest because it would provide ETP Holders with the option to use the MTS Modifier with odd lot quantities, which could encourage order flow to the Exchange and promote opportunities for order execution on the Exchange, to the benefit of all market participants. The proposed change would also clarify that the MTS Modifier may be used in conjunction with non-displayed ALO Orders, thereby removing impediments to, and perfecting the mechanism of, a free and open market and a national market system by updating Exchange rules to ensure that they reflect the current availability of the MTS Modifier and promoting consistency and specificity in Exchange rules as to the use of such modifier with non-displayed order types. The Exchange notes that the

Order may be designated as non-displayed. See Rule 7.31E(e)(2).

⁶ 15 U.S.C. 78f(b).

⁷ 15 U.S.C. 78f(b)(5).

³⁰ 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.

⁴ The rules of Cboe EDGA Exchange, Inc. (“EDGA”), Cboe EDGX Exchange, Inc. (“EDGX”), and Members Exchange (“MEMX”) appear to permit the use of instructions comparable to the MTS Modifier in any size. See EDGA Rules 11.2 (providing that orders are eligible for odd-lot, round-lot, and mixed-lot executions unless otherwise indicated) and 11.6(h) (defining Minimum Execution Quantity instruction); EDGX Rules 11.2 and 11.6(h) (same); MEMX Rules 11.2 and 11.6(f) (same). See also, e.g., IEX Rule 1190(b)(3) (providing that a non-displayed order may be a Minimum Quantity Order and may be an odd lot order).

⁵ An ALO Order is a Non-Routable Limit Order that, unless it receives price improvement, will not remove liquidity from the Exchange Book; an ALO

proposed change would not otherwise impact the operation of the MTS Modifier as provided under current Exchange rules. The Exchange also believes that the proposed change would align Exchange rules with the use of instructions similar to the MTS Modifier on other equity exchanges, thereby removing impediments to, and perfecting the mechanism of, a free and open market and a national market system.⁸

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change would allow the optional MTS Modifier to be used with an odd lot quantity and accurately reflect the order types that may be designated with an MTS Modifier. The Exchange believes that the proposed change would promote competition among exchanges by offering ETP Holders options available on other equity exchanges and, to the extent the proposed change would increase opportunities for order execution, promote competition by making the Exchange a more attractive venue for order flow and enhancing market quality for all market participants.

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 Act⁹ and Rule 19b-4(f)(6) thereunder.¹⁰ 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)(iii) of the Act¹¹ and Rule 19b-4(f)(6)(iii) thereunder.¹²

A proposed rule change filed under Rule 19b-4(f)(6)¹³ normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b-4(f)(6)(iii),¹⁴ 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 take effect as soon as the technology associated with the proposed change is available, which is anticipated to be less than 30 days from the date of this filing. The Commission believes that waiver of the operative delay is consistent with the protection of investors and the public interest because the proposal raises no novel issues and would allow use of the MTS Modifier with odd lot quantities without delay and promote clarity in Exchange rules as to the order types that may be designated with an MTS Modifier. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.¹⁵

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)¹⁶ 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.

¹¹ 15 U.S.C. 78s(b)(3)(A)(iii).

¹² 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has fulfilled this requirement.

¹³ 17 CFR 240.19b-4(f)(6).

¹⁴ 17 CFR 240.19b-4(f)(6)(iii).

¹⁵ For purposes only of accelerating the operative date of this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

¹⁶ 15 U.S.C. 78s(b)(2)(B).

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-2024-57 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-2024-57. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-NYSEAMER-2024-57 and should be submitted on or before October 15, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁷

Vanessa A. Countryman,
Secretary.

[FR Doc. 2024-21621 Filed 9-20-24; 8:45 am]

BILLING CODE 8011-01-P

¹⁷ 17 CFR 200.30-3(a)(12).

⁸ See note 4, *supra*.

⁹ 15 U.S.C. 78s(b)(3)(A)(iii).

¹⁰ 17 CFR 240.19b-4(f)(6).

**SECURITIES AND EXCHANGE
COMMISSION****Sunshine Act Meetings**

TIME AND DATE: 2:00 p.m. on Thursday, September 26, 2024.

PLACE: The meeting will be held via remote means and/or at the Commission's headquarters, 100 F Street NE, Washington, DC 20549.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED:

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters also may be present.

In the event that the time, date, or location of this meeting changes, an announcement of the change, along with the new time, date, and/or place of the meeting will be posted on the Commission's website at <https://www.sec.gov>.

The General Counsel of the Commission, or her designee, has certified that, in her opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (6), (7), (8), 9(B) and (10) and 17 CFR 200.402(a)(3), (a)(5), (a)(6), (a)(7), (a)(8), (a)(9)(ii) and (a)(10), permit consideration of the scheduled matters at the closed meeting.

The subject matter of the closed meeting will consist of the following topics:

- Institution and settlement of injunctive actions;
- Institution and settlement of administrative proceedings;
- Resolution of litigation claims; and
- Other matters relating to examinations and enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting agenda items that may consist of adjudicatory, examination, litigation, or regulatory matters.

CONTACT PERSON FOR MORE INFORMATION:

For further information, please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551-5400.

Authority: 5 U.S.C. 552b.

Dated: September 19, 2024.

Vanessa A. Countryman,
Secretary.

[FR Doc. 2024-21808 Filed 9-19-24; 4:15 pm]

BILLING CODE 8011-01-P

SMALL BUSINESS ADMINISTRATION

**[Disaster Declaration #20407 and #20408;
NEW MEXICO Disaster Number NM-20004]**

**Presidential Declaration Amendment of
a Major Disaster for the State of New
Mexico**

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 4.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of New Mexico (FEMA-4795-DR), dated June 20, 2024.

DATES: Issued on August 26, 2024.

Physical Loan Application Deadline Date: October 19, 2024.

Economic Injury (EIDL) Loan Application Deadline Date: March 20, 2025.

ADDRESSES: Visit the MySBA Loan Portal at <https://lending.sba.gov> to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Vanessa Morgan, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205-6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for the State of New Mexico, dated June 20, 2024, is hereby amended to update the incident period for this disaster as beginning June 17, 2024 and continuing through August 20, 2024.

Incident: South Fork Fire, Salt Fire, and Flooding.

Incident Period: June 17, 2024 through August 20, 2024.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Francisco Sánchez, Jr.,

Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024-21666 Filed 9-20-24; 8:45 am]

BILLING CODE 8026-09-P

SMALL BUSINESS ADMINISTRATION

**[Disaster Declaration #20568 and #20569;
TEXAS Disaster Number TX-20023]**

**Presidential Declaration Amendment of
a Major Disaster for Public Assistance
Only for the State of Texas**

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 2.

SUMMARY: This is an amendment of the Presidential declaration of a major

disaster for Public Assistance Only for the State of Texas (FEMA-4798-DR), dated August 21, 2024.

DATES: Issued on September 17, 2024.

Physical Loan Application Deadline Date: October 21, 2024.

Economic Injury (EIDL) Loan Application Deadline Date: May 21, 2025.

ADDRESSES: Visit the MySBA Loan Portal at <https://lending.sba.gov> to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205-6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of Texas, dated August 21, 2024, is hereby amended to include the following areas as adversely affected by the disaster.

Incident: Hurricane Beryl.

Incident Period: July 5, 2024 through July 9, 2024.

Primary Counties: Chambers.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Francisco Sánchez, Jr.,

Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024-21669 Filed 9-20-24; 8:45 am]

BILLING CODE 8026-09-P

SMALL BUSINESS ADMINISTRATION

**[Disaster Declaration #20451 and #20452;
NEW MEXICO Disaster Number NM-20006]**

**Presidential Declaration Amendment of
a Major Disaster for Public Assistance
Only for the State of New Mexico**

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of New Mexico (FEMA-4795-DR), dated July 11, 2024.

DATES: Issued on August 26, 2024.

Physical Loan Application Deadline Date: September 9, 2024.

Economic Injury (EIDL) Loan Application Deadline Date: April 11, 2025.

ADDRESSES: Visit the MySBA Loan Portal at <https://lending.sba.gov> to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT:

Vanessa Morgan, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205-6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of New Mexico, dated June 11, 2024 is hereby amended to update the incident period for this disaster as beginning June 17, 2024 and continuing through August 20, 2024.

Incident: South Fork Fire, Salt Fire, and Flooding.

Incident Period: June 17, 2024 through August 20, 2024.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Francisco Sánchez, Jr.,

Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024-21667 Filed 9-20-24; 8:45 am]

BILLING CODE 8026-09-P

DEPARTMENT OF STATE

[Public Notice: 12549]

Notice of Determinations; Culturally Significant Objects Being Imported for Exhibition—Determinations: “Egon Schiele: Living Landscapes” Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects being imported from abroad pursuant to agreements with their foreign owners or custodians for temporary display in the exhibition “Egon Schiele: Living Landscapes” at the Neue Galerie New York, in New York, New York, and at possible additional exhibitions or venues yet to be determined, are of cultural significance, and, further, that their temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT:

Reed Liriano, Program Coordinator, Office of the Legal Adviser, U.S. Department of State (telephone: 202-632-6471; email: section2459@state.gov). The mailing address is U.S. Department of State, L/PD, 2200 C Street NW (SA-5), Suite 5H03, Washington, DC 20522-0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made

pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236-3 of August 28, 2000, and Delegation of Authority No. 523 of December 22, 2021.

Nicole L. Elkon,

Deputy Assistant Secretary for Professional and Cultural Exchanges, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2024-21636 Filed 9-20-24; 8:45 am]

BILLING CODE 4710-05-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2022-0242]

Parts and Accessories Necessary for Safe Operation; Application for an Exemption From Encore Flooring & Building Products, USDOT #2329419

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of final disposition; grant of exemption.

SUMMARY: The Federal Motor Carrier Safety Administration (FMCSA) announces its decision to grant an application from Encore Flooring & Building Products (Encore, USDOT #2329419) for an exemption to allow it to operate commercial motor vehicles (CMVs) equipped with a module manufactured by Intellistop, Inc. (Intellistop). The Intellistop module is designed to pulse the required rear clearance, identification, and brake lamps from a lower-level lighting intensity 4 times in 2 seconds when the brakes are applied and then return the lights to a steady-burning state while the brakes remain engaged. The Agency has determined that granting the exemption to Encore would likely achieve a level of safety equivalent to, or greater than, the level of safety achieved by the regulation.

DATES: This exemption is effective September 23, 2024 and ending September 24, 2029.

FOR FURTHER INFORMATION CONTACT: Mr. David Sutula, Vehicle and Roadside Operations Division, Office of Carrier, Driver, and Vehicle Safety, MC-PSV,

Federal Motor Carrier Safety Administration; 1200 New Jersey Avenue SE, Washington, DC 20590-0001; (202) 366-9209; MCPSV@dot.gov.

SUPPLEMENTARY INFORMATION:**I. Viewing Comments and Documents**

To view comments, go to www.regulations.gov, insert the docket number “FMCSA-2022-0242” in the keyword box, and click “Search.” Next, sort the results by “Posted (Newer-Older),” choose the first notice listed, click “Browse Comments.”

To view documents mentioned in this notice as being available in the docket, go to www.regulations.gov, insert the docket number “FMCSA-2022-0242” in the keyword box, click “Search,” and chose the document to review.

If you do not have access to the internet, you may view the docket online by visiting Dockets Operations on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366-9317 or (202) 366-9826 before visiting Dockets Operations.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b) to grant exemptions from the Federal Motor Carrier Safety Regulations (FMCSRs). FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including the applicant's safety analysis. The Agency must provide an opportunity for public comment on the request.

The Agency reviews safety analyses and public comments submitted and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305(a)). The Agency must publish its decision in the **Federal Register** (49 CFR 381.315(b)). If granted, the notice will identify the regulatory provision from which the applicant will be exempt, the effective period, and all terms and conditions of the exemption (49 CFR 381.315(c)(1)). If the exemption is denied, the notice will explain the reason for the denial (49 CFR 381.315(c)(2)). The exemption may be renewed (49 CFR 381.300(b)).

III. Background

A. Current Regulatory Requirements

Section 393.25(e) of the FMCSRs requires all exterior lamps (both required lamps and any additional lamps) to be steady burning, with certain exceptions not relevant here. Two other provisions of the FMCSRs—section 393.11(a) and section 393.25(c)—mandate that required lamps on CMVs meet the requirements of Federal Motor Vehicle Safety Standard (FMVSS) No. 108 in effect at the time of manufacture. FMVSS No. 108, issued by the U.S. Department of Transportation's National Highway Traffic Safety Administration (NHTSA), includes a requirement that installed brake lamps, whether original or replacement equipment, be steady burning.

B. Applicant's Request

Encore applied for an exemption from 49 CFR 393.25(e) to allow it to operate CMVs equipped with Intellistop's module. When the brakes are applied, the Intellistop module is designed to pulse the rear clearance, identification, and brake lamps from a lower-level lighting intensity to a higher-level lighting intensity 4 times in 2 seconds and then maintain the original equipment manufacturer's (OEM) level of illumination for those lamps until the brakes are released and reapplied. Intellistop asserts that its module is designed to ensure that if the module ever fails, the clearance, identification, and brake lamps will default to normal OEM function and illumination.

Encore's application followed the Agency's October 7, 2022 (87 FR 61133), denial of Intellistop's application for an industry-wide exemption to allow all interstate motor carriers to operate CMVs equipped with the Intellistop module. While the Agency determined that the scope of the exemption Intellistop sought was too broad to ensure that an equivalent level of safety would be achieved, the Agency explained that individual motor carrier applications for exemption may be more closely aligned with FMCSA authorities. Exemptions more limited in scope would allow the Agency to ensure compliance with all relevant FMCSA regulations because the individual exemptee would be easily identifiable and its compliance with applicable regulations could be monitored, thus providing a level of safety equivalent to compliance with 49 CFR 393.25(e).

Encore stated that previous research demonstrated that the use of pulsating brake-activated lamps increases the visibility of vehicles and should lead to a significant decrease in rear-end

crashes. In support of its application, Encore submitted several reports of research conducted by NHTSA on the issues of rear-end crashes, distracted driving, and braking signals.^{1 2 3} This same body of research was also referenced in Intellistop's industry-wide exemption application. Relying on these studies, Encore stated that the addition of brake-activated pulsating lamp(s) will not have an adverse impact on safety and would likely maintain a level of safety equivalent to or greater than the level of safety achieved without the exemption.

A copy of the application is included in the docket referenced at the beginning of this notice.

IV. Comments

FMCSA published a notice of the Encore application in the **Federal Register** on January 27, 2023, and asked for public comment (88 FR 5399). The Agency received 20 comments from organizations and individuals, including Intellistop, Inc.; Pi-Lit, Inc.; Meiborg Brothers, Inc.; the Truck Safety Coalition (TSC); the Transportation Safety Equipment Institute (TSEI); and 15 other commenters. Fifteen of the commenters favored the exemption application, and five commenters (TSEI and 4 anonymous commenters) expressed concerns.

TSEI reiterated comments it had previously made in support of the safety benefits of brake-activated warning lamps when used in conjunction with steady burning red brake lamps as well as its prior support of the exemption requests from Groendyke Transport, National Tank Truck Carriers (NTTC), and Grote Industries. Despite these previous expressions of support for the potential benefits of some brake warning lamp configurations, TSEI stated that it is concerned about any exemption permitting the pulsing of lamps that are currently required to be steady burning without a thorough consideration of

safety data and research. TSEI stated that the aim of future rulemaking should be to ensure consistent application across all vehicles equipped with such pulsating lamps and recommended that the Agency engage in a formal rulemaking to amend part 393 to allow for pulsating brake lamps.

Four anonymous commenters cited various reasons for opposing the application, mainly contending that Agency resources should be focused on other areas. One commenter stated that the flashing lamps may be more distracting to other motorists.

TSC supported Encore's request and stated that enhanced rear signaling (ERS) can provide functionality beyond what traditional CMV lighting and reflective devices offer, including: drawing attention to CMVs stopped ahead; increasing awareness of roadside breakdowns; notification of emergency braking; and improving driver confidence both in ERS-equipped CMVs and in the following vehicle. TSC also stated that, in addition to these safety benefits, ERS performance is superior to that of steady burning brake lamps in conditions of severe weather, taillight glare, and around infrastructure obstacles.

Intellistop supported the applicant's request for exemption. It commented that for over 20 years multiple States have allowed pulsing or flashing of brake lamps. Many State driver training schools recommend tapping brakes when a CMV is slowing or stopping to warn other drivers. Intellistop stated that it is unlikely that other motorists would confuse the use of their module with the recommendation to tap brakes when a CMV is slowing or stopping.

Twelve additional commenters supported granting the exemption. These commenters believe that any technology that has been shown to reduce rear-end crashes should be allowed and cited various benefits of brake activated pulsating lamps, including (1) enhanced awareness that the vehicle is making a stop, especially at railroad crossings, and (2) increased visibility in severe weather conditions. Several commenters noted that 37 States currently allow brake lamps to flash. In addition, three commenters noted that the guidelines developed by the American Driver and Traffic Safety Education Association advise driving instructors to teach new drivers to pulse brake lamps when stopping to improve visibility.

V. Equivalent Level of Safety Analysis

Encore requested that FMCSA grant an exemption from 49 CFR 393.25(e)—requiring certain exterior lamps to be

¹ See NHTSA Study—Evaluation of Enhanced Brake Lights Using Surrogate Safety Metrics <https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/811127.pdf>; As part of the General Findings the NHTSA study report concluded that "rear lighting continues to look promising as a means of reducing the number and severity of rear-end crashes."

² See also NHTSA Study—Enhanced Rear Lighting and Signaling Systems <https://tinyurl.com/y2romx76> or https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/task_3_results_0.pdf; As part of the conclusions NHTSA found that enhanced, flashing brake lighting "demonstrated improvements in brake response times and other related performance measures."

³ See also NHTSA—Traffic Safety Facts <https://tinyurl.com/yxglsdax> or <https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/tsf811128.pdf>; which concluded that flashing brake lights were a promising signal for improving attention-getting during brake applications.

steady burning—to allow it to operate CMVs equipped with Intellistop's module. FMCSA has determined that in order for Encore to operate vehicles in compliance with the FMCSRs, an exemption from 49 CFR 393.25(e) must be accompanied by limited exemptions from 49 CFR 393.11(a) and 393.25(c), both of which mandate that required lamps on CMVs operated in interstate commerce must, “at a minimum, meet the applicable requirements of 49 CFR 571.108 (FMVSS No. 108) in effect at the time of manufacture of the vehicle.” FMCSA grants exemptions only when it determines “such exemption[s] would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent the exemption[s].”

Rear-end crashes generally account for approximately 30 percent of all crashes. They often result from a failure to respond (or delays in responding) to a stopped or decelerating lead vehicle. Data on crashes that occurred between 2010 and 2016 show that large trucks are consistently three times more likely than other vehicles to be struck in the rear in two-vehicle fatal crashes.^{4,5} FMCSA is deeply interested in the development and deployment of technologies that can reduce the frequency, severity, and risk of rear-end crashes.

Both FMCSA and NHTSA have examined alternative rear-signaling systems to reduce the incidence of rear-end crashes. While research efforts concluded that improvements in the incidence of rear-end crashes could be realized through certain rear-lighting systems that flash,⁶ the FMCSRs do not currently permit the use of pulsating, brake-activated lamps on the rear of CMVs. FMCSA believes that the two agencies' previous research programs demonstrate that rear-signaling systems may be able to “improve attention getting” to reduce the frequency and severity of rear-end crashes. Any possible benefit must be balanced against a possible risk of increased driver distraction and confusion. In

balancing these interests, the Agency was compelled to deny the Intellistop application for exemption because the industry-wide scope of the request was too broad for the Agency to effectively monitor for the potential risk of driver distraction or confusion.

The Agency acknowledges the limitations of the research studies completed to date and the overall data deficiencies in this area. Nonetheless, as noted in its Intellistop decision, the Agency recognizes that existing data do suggest a potential safety value in the use of alternative rear-signaling systems, generally. Specifically, FMCSA considered NHTSA's research concerning the development and evaluation of rear-signaling applications designed to reduce the frequency and severity of rear-end crashes via enhancements to rear-brake lighting. The study examined enhancements for (1) redirecting drivers' visual attention to the forward roadway (for cases involving a distracted driver) and (2) increasing the saliency or meaningfulness of the brake signal (for inattentive drivers).⁷ The research considered the attention-getting capability and discomfort glare of a set of candidate rear brake lighting configurations using driver judgments and eye-drawing metrics. The results of this research served to narrow the set of candidate lighting configurations to those that would most likely be carried forward for additional on-road study. Based on subjective participant responses, this research indicates some form of flashing or variation in brake light brightness may be more than two times more attention-getting than the baseline, steady-burning brake lights for distracted drivers.⁸

While some of the data collected in the study may not be statistically significant, the study results nonetheless indicate that additional efforts to get drivers' attention when they are approaching the rear of a CMV that is stopping may be helpful to reduce driver distraction and, ultimately, rear-end crashes. This was

among several reasons why researchers concluded that the promising nature of enhanced brake lighting systems warranted additional work and research. FMCSA believes the acquisition of relevant data through real-world monitoring is of critical importance as the Agency continues to seek new and innovative options for reducing crashes. This is particularly true given the data limitations noted in previous studies.

Despite finding a potential safety value in the use of alternative rear-signaling technology, in the Intellistop decision the Agency determined that the data presently available did not justify an exemption to allow all interstate motor carriers to alter the performance of an FMVSS-required lighting device (*i.e.*, stop lamps) on any CMV. In contrast, however, Encore's application requests an exemption from the steady-burning brake lamp requirement for CMV operations by only one interstate motor carrier. As FMCSA noted in its denial of Intellistop's industry-wide exemption application, individual motor carrier exemption requests more closely align with FMCSA and NHTSA authorities to ensure compliance with all other applicable regulations and with the safety performance of the smaller population of affected motor carriers. With an individual motor carrier exemption, the Agency can also more easily monitor compliance with terms and conditions intended to ensure operations conducted under the exemption do in fact provide an equivalent level of safety. Encore's application demonstrates why this is particularly true, since the vehicles operated by Encore under the exemption would be easily identifiable, and compliance with NHTSA's “make inoperative” prohibition and other related regulations could be readily checked.

The Agency's decision to grant this exemption is based on the data suggesting enhanced rear signal systems, such as pulsing brake lights, may help reduce the frequency and severity of rear-end crashes, as well as on the limited number of vehicles operating under the exemption. Encore currently operates a nationwide fleet of approximately 223 vehicles. The installation of the module on CMVs operated by a single motor carrier provides the opportunity for the Agency to collect data on the effects of pulsing brake lights in real-world conditions. The terms and conditions FMCSA imposes through this exemption will ensure appropriate Federal oversight in the use of these devices on a finite number of CMVs utilizing a phased-in approach.

⁴ U.S. Department of Transportation, National Highway Traffic Safety Administration (2012), Traffic Safety Facts—2010 Data; Large Trucks, Report No. DOT HS 811 628, Washington, DC (June 2012), available at: <https://crashstats.nhtsa.dot.gov/Api/Public/ViewPublication/811628>.

⁵ U.S. Department of Transportation, National Highway Traffic Safety Administration (2018), Traffic Safety Facts—2016 Data; Large Trucks, Report No. DOT HS 812 497, Washington, DC (May 2018), available at: <https://crashstats.nhtsa.dot.gov/Api/Public/ViewPublication/812497>.

⁶ Expanded Research and Development of an Enhanced Rear Signaling System for Commercial Motor Vehicles: Final Report, William A. Schaudt *et al.* (Apr. 2014) (Report No. FMCSA–RRT–13–009).

⁷ See NHTSA Study—Evaluation of Enhanced Brake Lights Using Surrogate Safety Metrics <https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/811127.pdf>.

⁸ *Ibid.* While data demonstrated that brighter flashing lights were the most attention-getting combination for distracted drivers in this study, flashing lights with no increase in brightness were still more effective at capturing a distracted driver's attention than the baseline steady-burning brake lamps. Both look-up (eye drawing) data and interview data supported the hypothesis that simultaneous flashing of all rear lighting combined with increased brightness would be effective in redirecting the driver's eyes to the lead vehicle when the driver is looking away with tasks that involve visual load.

Initially restricting the application of this exemption to a limited portion of Encore's fleet will allow for a comparison between the crash involvement of Encore CMVs equipped with the Intellistop device, those without the device, and the overall crash involvement of CMVs operated by similarly sized motor carriers with similar operations and overall safety performance. Data collected through this exemption and any other similar exemptions the Agency may grant in the future will allow for an evaluation of how the Intellistop module may improve following-vehicle driver responses to CMV braking. Consideration of the scope of any particular carrier's operation and the number and types of vehicles the carrier operates are critical to ensuring FMCSA gathers the most relevant data as the Agency considers safety benefits gained by the deployment of these rear brake lamp systems in CMV operations. The Agency's incremental approach in granting this limited exemption will also allow FMCSA to investigate and respond as appropriate to any incidents of alleged driver confusion attributable to use of the brake lamp systems in CMV operations, which some commenters have raised as a potential concern.

FMCSA acknowledges that, until recently, all pulsating rear lamp exemptions the Agency granted involved the addition of non-mandatory auxiliary lights while the Intellistop module that Encore seeks to install alters the functionality of original equipment manufacturers' lamps. Nonetheless, those previous exemptions are instructive, most notably Groendyke. The Groendyke exemption involved auxiliary lamps rather than required lighting, but, like the Intellistop module, the modulation of the auxiliary lamps in the Groendyke exemption occurs during braking. More importantly, Groendyke also involved a technology installed on a number of one carrier's CMVs, which allowed the Agency more realistically to monitor the exemptee's compliance with other applicable regulations. When granting the exemption, FMCSA found Groendyke's experience with brake-activated pulsating warning lamps, which resulted in a 33.7 percent reduction in rear-end crashes, to be compelling. Through the granting of the Groendyke exemption, the Agency was able to collect additional real-world data about the operation of the module at issue. Similarly, limited exemptions with narrowly tailored terms and conditions permitting the use of the Intellistop module will allow the

Agency to collect data about the reliability and safety benefits of an integrated alternative rear-signaling system.

FMCSA notes that Encore failed to provide any evidence beyond what is publicly available about the integration of the Intellistop module with its CMVs' existing systems or to support the claim that a malfunction of the device would result in the brake lights returning to OEM functionality. Nonetheless, based on the Agency's understanding of the device's design and assertions made in publicly available materials, FMCSA believes concerns about both the reliability and integration of the device are sufficiently alleviated in this instance because of the narrow scope of the exemption and the stringent requirements imposed by the Agency in the terms and conditions. Any evidence that module failure results in anything less than a return to brake light OEM functionality will result in revocation of the exemption.

Likewise, granting this exemption to an easily identifiable carrier alleviates concerns the Agency previously articulated about its inability to monitor compliance with NHTSA's "make inoperative" prohibition. FMCSA can monitor compliance with this exemption and ensure that only Encore installs the module on its own CMVs.

Notwithstanding the promise the Agency sees in this technology, exemptions are warranted only if the applicant can demonstrate that an equivalent level of safety likely will be maintained. For this reason, the Agency believes it is important to consider the safety record of the applicant motor carrier. The Agency carefully considered Encore's existing on-road safety performance record prior to granting this exemption. While Encore's out-of-service (OOS) rate exceeds the national average, with a vehicle out-of-service (VOOS) rate of 33.3 percent (national average—21.4 percent), FMCSA believes this to be a statistical aberration based on a small sample size. Encore's relatively small fleet had few inspections during the sampling period. Thus, Encore's VOOS rate scored abnormally high. When compared to their VOOS when Encore initially applied (66.6%), it is clear that one or two inspections of the small fleet are affecting their VOOS rate. In addition, Encore had no driver OOS incidents (national average 6 percent) and no hazardous materials OOS incidents (national average 4.5 percent). Encore maintains a Satisfactory safety rating.

FMCSA has authority to grant temporary exemptions to the FMCSRs only to motor carriers and not to CMV

manufacturers or vehicle alterers. FMCSA acknowledges that the research described above did not fully address all of the implications of allowing pulsating stop lamps, especially by automobiles where stop lamp design is stylized and often brand-specific, and that it remains unclear whether deviation from the uniform brake-light patterns of CMVs may cause confusion among highway users when the lamps are pulsed during braking. When Intellistop sought an industry-wide exemption, FMCSA concluded that the potential risks of widespread adoption outweighed the potential benefits. But FMCSA reaches a different conclusion here, where any risks will be more limited and easier to monitor. FMCSA notes, moreover, that the research suggests that the use of rear-signaling systems may be a means to reduce the frequency and severity of rear-end crashes involving CMVs, as do the reductions in rear-end crashes reported by Groendyke (84 FR 17910, April 26, 2019) utilizing an auxiliary flashing rear-signaling system. These facts and the specific safety record of the applicant motor carrier support the conclusion that permitting the use of Intellistop's pulsating-lamp module among a limited and known population of vehicles of a single motor carrier, subject to terms and conditions for monitoring, is likely to achieve a level of safety that is equivalent to, or greater than, the level of safety achieved without the exemption.

VI. Exemption Decision

a. Grant of Exemption

FMCSA has evaluated Encore's exemption application and the comments received. The Agency believes that granting a temporary exemption to section 393.25(e), and temporary limited exemptions to the requirements of 49 CFR 393.11(a) and 393.25(c) to allow Encore to operate a limited number of CMVs equipped with Intellistop's pulsating-brake module will likely achieve a level of safety that is equivalent to, or greater than, the level of safety achieved without the exemption.

This exemption is restricted to vehicles in Encore's fleet and provides relief from the steady burning requirement for rear clearance, identification, and brake lamp activation for 2 seconds following brake activation. All other FMVSS No. 108 requirements cross-referenced or incorporated within the FMCSRs remain in effect, with a limited exception to the requirement exempted here in sections 393.11(a) and 393.25(c) for only the first two seconds of brake engagement. In

addition, through the terms and conditions, FMCSA will be able to monitor to performance of these CMVs to determine whether they were involved in a crash and whether they appear to be overrepresented in crashes compared to a control group (Encore vehicles that are not equipped with the Intellistop unit but are operating on similar routes with similar schedules, etc.).

The Agency has evaluated the application and hereby grants the exemption for a 5-year period, beginning September 23, 2024 and ending September 24, 2029. During the temporary exemption period, Encore (Applicant) may operate CMVs, equipped with Intellistop's module that pulses the rear brake, clearance, and identification lamps from a lower-level lighting intensity to a higher-level lighting intensity 4 times in 2 seconds. This grant applies only to the "steady-burning" requirement as specified in FMVSS 108 S7.3, and Tables I-a, I-b, and I-c. All other photometric and requirements for stop lamps specified in FMVSS 108 must still be met.

b. Terms and Conditions of the Exemption

(i). *Installation of the Intellistop module.* The Applicant is responsible for installing the Intellistop module. This exemption applies only to CMVs owned and operated by the Applicant. **THE PRODUCT MUST BE INSTALLED ONLY BY THE OWNER OF THE VEHICLE. IN ACCORDANCE WITH FEDERAL LAW (49 U.S.C. 30112(a)(1) AND 49 U.S.C. 30122), THE PRODUCT MAY NOT BE INSTALLED BY ANY MANUFACTURER, DISTRIBUTOR, DEALER, RENTAL COMPANY, OR MOTOR VEHICLE REPAIR BUSINESS.**

The Applicant may not install the Intellistop module on more than 50% of its power units, and 50% of its trailers during the first year of operation under the exemption. The Applicant shall provide the vehicle identification numbers for the power units and trailers that will be operating under the exemption.

The Applicant must maintain a control group of equal size to the group of power units and trailers equipped with the Intellistop unit during the first year of the exemption. And the CMVs in the control group must operate on routes with schedules that are similar to those of the Intellistop-equipped vehicles.

Installed modules may be used only to modulate rear clearance, identification, and stop lamps.

Within 30 business days of its first installation of the Intellistop module,

the Applicant must notify the Agency via email at MCPSV@dot.gov of the number and type of CMVs it is operating, or intends to operate, with the Intellistop module installed; the module type and/or sub-type; and any trouble-shooting, repair, or other use of an Intellistop module covered by this exemption. Amended installation information, including CMVs on which the device is installed or uninstalled, may then be submitted via the quarterly submission specified in sub-paragraph (iv) *Recurring Reporting Requirements* below.

If the Applicant sells or transfers ownership of any CMV equipped with an Intellistop module under this exemption, or if the exemption is terminated for any reason, the Applicant must remove the module and restore the CMV to full compliance with the FMCSRs and FMVSSs prior to the transfer of ownership, or upon termination of the exemption. The Applicant must also certify in writing to the purchaser/transferee and FMCSA that the CMV has been restored to compliance with the FMCSRs and FMVSSs.

(ii). *Driver Pre-Trip Vehicle Inspections.* The Applicant must ensure that each driver of an Intellistop-equipped CMV performs a pre-trip inspection to confirm that the Intellistop module operates only for 2 seconds and does not interfere with the normal operation of lamps after 2 seconds. If the lamps are not steady burning after 2 seconds, the CMV must not be dispatched until repairs are made. At the end of each work shift, drivers must note any problems observed by or reported to them concerning the Intellistop module on a driver vehicle inspection report (see 49 CFR 396.11), and the motor carrier must correct the problem before the vehicle is dispatched again.

(iii). *Safety Notification to FMCSA.* The Applicant must notify FMCSA within 5 business days after it becomes aware, or otherwise determines, that the continued use of a module or entire type or subtype of module covered by this exemption is no longer likely to maintain a level of safety that is at least equivalent to the level that would be achieved absent this exemption. Notification must be made by sending an email to FMCSA at MCPSD@dot.gov.

(iv). *Recurring Reporting Requirements.* During the exemption period, the Applicant must provide quarterly submissions to FMCSA of the data described below. The Applicant's first quarterly submission is due on December 23, 2024, and thereafter will be due every 3 months, on the first

business day of the month. The first quarterly submission must include the required data beginning 60 days prior to the date of module installation. All quarterly submissions must include data through at least the 14th day (inclusive) of the month immediately preceding the submission. Unless otherwise agreed to by FMCSA, quarterly submissions must be sent via email to FMCSA at MCPSD@dot.gov. If the Applicant does not have one or more categories of information described below, it must, within 20 days of the effective date of this exemption, discuss with FMCSA other available information. If the Agency accepts such alternative information, the Applicant must submit that data in lieu of the information specified below.

In the quarterly submission, the Applicant must provide FMCSA the following information known to the Applicant regarding all crashes and other incidents ("crash or incident") involving a CMV equipped with an Intellistop module covered by this exemption where the Intellistop module is potentially implicated. Crashes involving a CMV equipped with an Intellistop module that are "head-on" or otherwise involve only the front of the Intellistop-equipped CMV impacting some other object (such that the Intellistop module, without question, could not be implicated) are not subject to this condition. For the first quarterly submission, data must include any crash or incident occurring in the 60 days prior to installation of the Intellistop module that would have been contained in this reporting category had the module been installed at the time of the crash or incident. The Applicant's knowledge includes, but is not limited to: (1) outreach from a consumer, lawyer, or any other person or organization (via letter, email, fax, telephone call, social media, or any other medium); (2) lawsuits to which the Applicant is a party, or otherwise knows exist where an Intellistop module covered by this exemption is an issue in the litigation; and (3) insurance claims against the Applicant related to use of the Intellistop module. When in the Applicant's possession, information provided to FMCSA shall include:

1. The date of first contact regarding, or the Applicant's first awareness of, the crash or incident;
2. The date of the most recent follow-up contact, if any, between the Applicant and the other party;
3. The date, time, and location of the crash or incident;
4. A brief description of the crash or incident; and

5. The Intellistop module type and/or subtype(s) involved in the crash or incident.

6. Information, if any, indicating that the Intellistop module is, or was, not working as intended, or caused confusion or a roadway hazard for either the consumer or other motorists.

Annual data. At the end of each 12-month period this exemption is in effect, the Applicant shall, within 60 days, submit a report detailing all information in its possession regarding crash rates and vehicle miles traveled by CMVs equipped with a module covered by this exemption. Additionally, the report shall specify the number and type of CMVs the Applicant is operating under the exemption, the module type or sub-type installed on each CMV, the affected lamps (rear clearance, identification, and/or brake lamps), the number of covered vehicles sold or transferred in ownership during the 12-month reporting period, and a statement certifying that any sold/transferred vehicle(s) have been restored to compliance with applicable FMVSSs and FMCSRs.

Meetings. The Applicant shall, at FMCSA's request, meet with FMCSA to answer questions regarding data and information provided by the Applicant under this exemption.

(v). **Early Termination.** The exemption is valid for 5 years from the date of issuance unless rescinded earlier by FMCSA. FMCSA will terminate the exemption if: (1) the Applicant fails to comply with the terms and conditions; (2) the exemption results in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b).

(vi). **Notification from the Public.** Interested parties possessing information that would demonstrate that Encore's CMVs equipped with Intellistop's pulsating rear-light module may not be achieving the requisite statutory level of safety should immediately notify FMCSA. The Agency will evaluate any such information and, if safety is being compromised or if the continuation of the exemption is not consistent with 49 U.S.C. 31136(e) and 31315(b), will take immediate steps to revoke the exemption.

(vii). **Non-Endorsement.** This limited and conditional exemption does not constitute an endorsement of the Intellistop product by FMCSA, NHTSA, the U.S. DOT, or any of their components, or by any of these agencies' employees or agents. As a

condition of the continued effectiveness of this exemption, Intellistop is expressly prohibited from describing its product as approved by, endorsed by, or otherwise authorized by FMCSA, NHTSA, or U.S. DOT, or as compliant with Federal safety regulations.

VII. Preemption

In accordance with 49 U.S.C. 31315(d), as implemented by 49 CFR 381.600, during the period this exemption is in effect, no State shall enforce any law or regulation applicable to interstate commerce that conflicts with or is inconsistent with this exemption. States may, but are not required to, adopt the same exemption with respect to operations in intrastate commerce.

Vincent G. White,

Deputy Administrator.

[FR Doc. 2024-21681 Filed 9-20-24; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Quarterly Reports of Positive Train Control System Performance

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: The purpose of this notice is to inform the public that FRA has determined it is in the public interest for railroads to continue submitting reports of their positive train control (PTC) systems' performance to FRA on a quarterly basis as the Infrastructure Investment and Jobs Act currently requires, and as the Office of Management and Budget (OMB) has approved through March 31, 2027.

FOR FURTHER INFORMATION CONTACT: Gabe Neal, Staff Director, Signal, Train Control, and Crossings Division, telephone: 816-516-7168, email: Gabe.Neal@dot.gov.

SUPPLEMENTARY INFORMATION: On November 15, 2021, President Joseph R. Biden signed into law the Infrastructure Investment and Jobs Act, which included the Passenger Rail Expansion and Rail Safety Act of 2021.¹ Section 22414 of the Passenger Rail Expansion and Rail Safety Act of 2021 requires PTC-mandated host railroads² and other railroads subject to FRA's PTC

regulations³ to submit Reports of PTC System Performance on Form FRA F 6180.152⁴ to FRA on a quarterly basis, instead of biannually as otherwise required by FRA's regulations at 49 CFR 236.1029(h).⁵

Section 22414 of the Passenger Rail Expansion and Rail Safety Act of 2021 requires FRA, by November 15, 2024, to reduce the frequency with which host railroads must submit Reports of PTC System Performance (Form FRA F 6180.152) to not less frequently than twice per year, unless FRA determines that quarterly reporting is in the public interest and publishes a justification for such determination in the **Federal Register**. 49 U.S.C. 20157(m)(3)(B); 49 CFR 1.89. FRA has determined that it is in the public interest for host railroads to continue submitting Reports of PTC System Performance (Form FRA F 6180.152) to FRA on a quarterly basis, rather than reverting to a lesser or biannual frequency, and the purpose of this notice is to provide the necessary justification under Section 22414. *See* 49 U.S.C. 20157(m)(3)(B).

As background, 49 U.S.C. 20157(m) and 49 CFR 236.1029(h) require each applicable host railroad to submit certain metrics about PTC system performance to FRA on behalf of the host railroad itself and each of its applicable tenant railroads. The metrics include, for example, the number of PTC system initialization failures, cut outs, and malfunctions during the reporting period, with subtotals that identify whether the source or cause of the initialization failures, cut outs, and malfunctions was the onboard subsystem, the wayside subsystem, the communications subsystem, the back office subsystem, or a non-PTC component.⁶

In addition, railroads' Reports of PTC System Performance (Form FRA F 6180.152) must encompass positive performance-related information in addition to failure-related information. For example, railroads report the number of enforcements by the PTC system in which it is reasonable to assume an accident or incident was prevented.⁷ These statistics enable FRA to evaluate PTC technology's positive impact on rail safety and the extent to

³ Title 49 Code of Federal Regulations (CFR) part 236, subpart I.

⁴ OMB Control No. 2130-0553. The Quarterly Report of PTC System Performance (Form FRA F 6180.152) is available in FRA's eLibrary at <https://railroads.dot.gov/elibrary/quarterly-report-ptc-system-performance-form-fra-f-6180152>.

⁵ 49 U.S.C. 20157(m).

⁶ 49 U.S.C. 20157(m)(2)(A)-(C); 49 CFR 236.1029(h)(1)(i)-(iii).

⁷ 49 U.S.C. 20157(m)(2)(E); 49 CFR 236.1029(h)(1)(v).

¹ Infrastructure Investment and Jobs Act, Public Law 117-58, 135 Stat. 429 (Nov. 15, 2021).

² *I.e.*, host railroads subject to Title 49 United States Code (U.S.C.) 20157.

which PTC systems are meeting their desired objectives.

In October 2021, OMB initially approved Form FRA F 6180.152 when it was a biannual reporting requirement under FRA's regulations, 49 CFR 236.1029(h), *Biannual Report of PTC System Performance*. In October 2022, OMB approved Form FRA F 6180.152, as modified by 49 U.S.C. 20157(m), simply to shift to a quarterly frequency as required. Most recently, in March 2024, OMB re-approved Form FRA F 6180.152 for a three-year period through March 31, 2027, in its current form, the Quarterly Report of PTC System Performance.

FRA has had the benefit of receiving railroads' Reports of PTC System Performance (Form FRA F 6180.152) on a quarterly basis for the last six quarters. FRA has found that the quarterly frequency has improved FRA's ability to oversee the performance and reliability of PTC systems effectively. For example, FRA has been able to monitor more closely industry-wide and system-by-system trends in PTC system reliability, without needing to wait six months for the next set of performance-related statistics. FRA also utilizes the data it receives in railroads' Quarterly Reports of PTC System Performance to inform and perform other necessary oversight, including inspections, targeted audits, and program reviews. The quarterly frequency enables FRA to direct its resources to areas, including specific PTC-governed track segments, that show the potential for a possible unsafe condition or where PTC system failures are occurring at a relatively high rate or trending upwards. The quarterly frequency enables FRA to intervene more promptly than it would be able to with less frequent reporting.

Also, railroads' Quarterly Reports of PTC System Performance must contain a summary of any actions the host railroad and its tenant railroads are taking to reduce the frequency and rate of initialization failures, cut outs, and malfunctions, such as any actions to correct or eliminate systemic issues and specific problems.⁸ Requiring railroads to provide this data to FRA on a quarterly basis, rather than a biannual basis, helps ensure that both host railroads and tenant railroads are regularly taking actions to improve the performance of their PTC systems and enables FRA to monitor and track railroads' corrective actions regularly throughout the year.

As noted above, OMB has approved the Quarterly Report of PTC System

Performance (Form FRA F 6180.152) through March 31, 2027. Before that expiration date, FRA will issue the requisite 60-day and 30-day notices in the **Federal Register** to solicit public comment pursuant to the Paperwork Reduction Act.

Issued in Washington, DC.

John Karl Alexy,

*Associate Administrator for Railroad Safety,
Chief Safety Officer.*

[FR Doc. 2024-21654 Filed 9-20-24; 8:45 am]

BILLING CODE 4910-06-P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA-2022-0114; Notice 2]

Winnebago Industries, Inc., Denial of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Denial of petition.

SUMMARY: Winnebago Industries, Inc., (Winnebago or petitioner), has determined that certain model year (MY) 2013–2023 Winnebago motorhomes do not fully comply with Federal Motor Vehicle Safety Standard (FMVSS) No. 108, *Lamps, Reflective Devices, and Associated Equipment*. Winnebago filed a noncompliance report dated November 11, 2022, and amended the report on December 2, 2022, and May 17, 2023. Winnebago petitioned NHTSA on December 2, 2022, and amended the petition on May 17, 2023, for a decision that the subject noncompliance is inconsequential as it relates to motor vehicle safety. This document announces the denial of Winnebago's petition.

FOR FURTHER INFORMATION CONTACT: Leroy Angeles, Office of Vehicle Safety Compliance, NHTSA, (202) 366-5304.

SUPPLEMENTARY INFORMATION:

I. Overview: Winnebago determined that certain MY 2013–2023 Winnebago motorhomes do not fully comply with paragraph S6.4.1 and Table IV-a of FMVSS No. 108, *Lamps, Reflective Devices, and Associated Equipment* (49 CFR 571.108).

Winnebago filed a noncompliance report dated November 11, 2022, and amended the report on December 2, 2022, and May 17, 2023, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports*. Winnebago petitioned NHTSA on December 2, 2022, and amended its

petition on May 17, 2023, for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential as it relates to motor vehicle safety, pursuant to 49 U.S.C. 30118(d) and 30120(h) and 49 CFR part 556, *Exemption for Inconsequential Defect or Noncompliance*.

Notice of receipt of Winnebago's petition was published with a 30-day public comment period, on August 1, 2023, in the **Federal Register** (88 FR 50276). No comments were received. To view the petition and all supporting documents log onto the Federal Docket Management System (FDMS) website at <https://www.regulations.gov/>. Then follow the online search instructions to locate docket number "NHTSA-2022-0114."

II. Vehicles Involved: Winnebago reported that 13,126 of the following motorhomes, manufactured between April 5, 2012, and November 4, 2022, are potentially involved:

- 2015–2021 Winnebago Vista
- 2015–2021 Winnebago Sunstar
- 2013–2019 Winnebago Horizon
- 2014–2023 Winnebago Forza
- 2018–2021 Winnebago Intent
- 2015–2016 Winnebago Brave
- 2015–2016 Itasca Tribute

III. Rule Requirements: Paragraphs S6.4.1 and S7.1.1.6 and Table IV-a of FMVSS No. 108 include the requirements relevant to this petition.¹ Each turn signal lamp, stop lamp, high-mounted stop lamp, and school bus signal lamp must meet the applicable effective projected luminous lens area requirement specified in Tables IV-a, IV-b, and IV-c of FMVSS No. 108. For the subject vehicles, the luminous lens area of the turn signals shall be no smaller than 7,500 square millimeters.

IV. Noncompliance: Winnebago explains that the subject vehicles are equipped with front turn signal lamps that do not meet the luminous lens area requirements specified by S7.1.1.6 and Table IV-a of FMVSS No. 108. Specifically, the luminous lens area of the turn signals equipped in the subject vehicles is 6,361 square millimeters, thus, 1,139 square millimeters smaller than the minimum area required by the standard.

V. Summary of Winnebago's Petition: The following views and arguments presented in this section, "V. Summary of Winnebago's Petition," are the views

¹ In an email dated April 9, 2024, Winnebago clarified that the front turn signal is affected by the subject noncompliance, therefore paragraph S7.1.1.6 of FMVSS No. 108 also include the requirement relevant to Winnebago's petition.

⁸ 49 U.S.C. 20157(m)(2)(H); 49 CFR 236.1029(h)(2).

and arguments provided by Winnebago. They do not reflect the views of NHTSA. Winnebago describes the subject noncompliance and contends that the noncompliance is inconsequential as it relates to motor vehicle safety.

Winnebago submits that NHTSA has previously explained that the purpose of FMVSS No. 108 is to reduce traffic accidents by, among other things, “enhancing the conspicuity of motor vehicles on the public roads so that their presence is perceived, and their signals understood, both in daylight and in darkness or other conditions of reduced visibility.” Winnebago further adds that in a 1990 final rule notice that increased the minimum lens area for wide vehicles from 8 square inches (*i.e.*, 5,161.28 sq mm) to 12 square inches (*i.e.*, 7,741 sq mm), NHTSA explained that the increase in lens area is necessary because wide vehicles “are susceptible to build up of grime” and “an increase in lens area would enhance vehicle conspicuity and contribute to safety.”

Winnebago says that around July 2022, it was informed by a lamp supplier that there “was concern about the compliance of turn signals installed in certain Winnebago vehicles . . .” Specifically, with the “minimum effective projected luminous area requirements of FMVSS No. 108.” Winnebago says it investigated the turn signals in the subject vehicles and confirmed that the “effective projected luminous lens area” is 6,361 square millimeters and thus, approximately 1,139 square millimeters smaller than the required minimum lens area.

Winnebago says that other than the size of the effective projected luminous lens area for the turn signals in the subject vehicles, the turn signals are fully compliant with all applicable performance requirements. Winnebago states that the turn signals at issue “have been in use for more than 15 years” and “is not aware of any crashes, injuries, customer complaints or field reports in connection with this noncompliance.” Winnebago states its belief that although the turn signal lens area is slightly smaller than the required minimum, the difference in size is “likely to be imperceptible to both vehicle occupants and approaching drivers, and do not have an effect on the conspicuity of the motorhomes on which they are installed.”

Winnebago states its belief that NHTSA increased the required minimum lens area for turn signals in wide vehicles due to the concern of buildup of grime and dirt. Winnebago claims that the turn signals on

motorhomes “are generally well maintained by their owners compared to other classes of wide vehicles. Thus, a slightly smaller turn signal would not reasonably result in a buildup of dirt and grime on turn signals . . .”

Winnebago concludes by reiterating the subject noncompliance is inconsequential as it relates to motor vehicle safety and that its petition for exemption from providing notice and remedy for the noncompliance be granted.

VI. NHTSA’s Analysis: The burden of establishing the inconsequentiality of a failure to comply with a *performance requirement* in an FMVSS is substantial and difficult to meet. Accordingly, the Agency has not found many such noncompliances inconsequential.²

In determining inconsequentiality of a noncompliance, NHTSA focuses on the safety risk to individuals who experience the type of event against which a recall would otherwise protect.³ In general, NHTSA does not consider the absence of complaints or injuries when determining if a noncompliance is inconsequential to safety. The absence of complaints does not mean vehicle occupants have not experienced a safety issue, nor does it mean that there will not be safety issues in the future.⁴ Further, because each inconsequential noncompliance petition must be evaluated on its own facts and determinations are highly fact-dependent, NHTSA does not consider prior determinations as binding precedent. Petitioners are reminded that they have the burden of persuading NHTSA that the noncompliance is inconsequential to safety.

NHTSA has evaluated the merits of Winnebago’s petition and determined

² Cf. *Gen. Motors Corporation; Ruling on Petition for Determination of Inconsequential Noncompliance*, 69 FR 19897, 19899 (Apr. 14, 2004) (citing prior cases where noncompliance was expected to be imperceptible, or nearly so, to vehicle occupants or approaching drivers).

³ See *Gen. Motors, LLC; Grant of Petition for Decision of Inconsequential Noncompliance*, 78 FR 35355 (June 12, 2013) (finding noncompliance had no effect on occupant safety because it had no effect on the proper operation of the occupant classification system and the correct deployment of an air bag); *Osram Sylvania Prods. Inc.; Grant of Petition for Decision of Inconsequential Noncompliance*, 78 FR 46000 (July 30, 2013) (finding occupant using noncompliant light source would not be exposed to significantly greater risk than occupant using similar compliant light source).

⁴ See *Morgan 3 Wheeler Limited; Denial of Petition for Decision of Inconsequential Noncompliance*, 81 FR 21663, 21666 (Apr. 12, 2016); see also *United States v. Gen. Motors Corp.*, 565 F.2d 754, 759 (D.C. Cir. 1977) (finding defect poses an unreasonable risk when it “results in hazards as potentially dangerous as sudden engine fire, and where there is no dispute that at least some such hazards, in this case fires, can definitely be expected to occur in the future”).

Winnebago has not met its burden of persuasion that the subject noncompliance is inconsequential to motor vehicle safety.

The subject vehicles’ failure to be equipped with turn signals compliant with the minimum lens area requirement reduces other road users’ visibility of the signal lamps. Reduced visibility may lead other roadway users to lack understanding of the subject vehicle’s intent to turn or make lane changes. This may, in turn, increase the risk of a crash. The effective projected luminous lens area (EPLLA) requirement serves other safety purposes, including but not limited to, minimizing glare by keeping intrinsic brightness within reason and increases visibility and conspicuity of the lamps. Further, NHTSA disagrees with Winnebago’s statement that the lenses are “slightly smaller” than the required minimum of 7,500 square millimeters. The lamps at issue have an area 15 percent smaller than the required minimum area. Thus, NHTSA is not persuaded that the noncompliant lenses “do not have an effect on the conspicuity of the vehicles” at issue here.

Additionally, although Winnebago claims the lamps are otherwise compliant, Winnebago provided no rationale explaining why meeting other non-related requirements compensates for meeting the subject requirements. Therefore, NHTSA did not find this argument persuasive.

Concerning Winnebago’s claims about the buildup of dirt and grime, Winnebago did not provide any data to support their statement that motorhome owners “keep their vehicles clean.” Regardless, NHTSA can identify multiple likely scenarios where vehicles get dirty during normal use as well as in extreme weather events such as while driving in the snow or on salted roads. Furthermore, as NHTSA stated in the preamble to the 1990 final rule referenced by the petitioner, the masking effects of road grime, dirt and winter slush are even greater on lamps with smaller lens areas. Since Winnebago’s lamps are less than the required lens area, NHTSA continues to be concerned about this masking effect on the lamps subject to this petition.

VII. NHTSA’s Decision: In consideration of the foregoing, NHTSA has decided that Winnebago has not met its burden of persuasion that the subject FMVSS No. 108 noncompliance is inconsequential to motor vehicle safety. Accordingly, Winnebago’s petition is hereby denied and Winnebago is consequently obligated to provide notification of and free remedy for that

noncompliance under 49 U.S.C. 30118 and 30120.

(Authority: 49 U.S.C. 30118, 30120; 49 CFR part 556; delegations of authority at 49 CFR 1.95 and 501.8)

Eileen Sullivan,

Associate Administrator for Enforcement.

[FR Doc. 2024–21707 Filed 9–20–24; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0897]

Agency Information Collection Activity: Statement of Assurance of Compliance With 85 Percent Enrollment Ratios; Statement of Assurance of Compliance With 85 Percent Enrollment Ratios Continuation Sheet

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Benefits Administration, Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Comments must be received on or before November 22, 2024.

ADDRESSES: Comments must be submitted through www.regulations.gov.

FOR FURTHER INFORMATION CONTACT:

Program-Specific information: Nancy Kessinger, 202–632–8924, nancy.kessinger@va.gov.

VA PRA information: Maribel Aponte, 202–461–8900, vacopaperworkreduct@va.gov.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Statement of Assurance of Compliance with 85 Percent Enrollment Ratios; Statement of Assurance of Compliance with 85 Percent Enrollment Ratios Continuation Sheet, VA Form 22–10215; VA Form 22–10215a.

OMB Control Number: 2900–0897.

Type of Review: Revision of a currently approved collection.

Abstract: The VA uses data from the VA Form 22–10215 and VA Form 22–10215a for this information collection to ensure the compliance of IHLs and NCD training institutions that are approved by the VA to ensure that no more than 85% of students in any approved program are students in receipt of financial support from the educational

institution or by VA under title 38, U.S.C., or under title 10, U.S.C. Without this information, VA might pay benefits in error. Except as otherwise provided by regulation, VA shall not approve an enrollment in any course for an eligible Veteran, not already enrolled, for any period during which more than 85 percent of the students enrolled in the course are having all or part of their tuition, fees or other charges paid for them by the educational institution or by VA under title 38, U.S.C., or under title 10, U.S.C. This is known as the 85/15 Rule and is applicable to Institutions of Higher Learning (IHLs) and Non-College Degree postsecondary schools (NCDs). The requirements apply to all courses, not otherwise exempt, or waived, offered by all educational institutions, regardless of whether the institution is degree-granting, proprietary profit, proprietary nonprofit, eleemosynary, public and/or tax-supported. These schools are required to submit information necessary to determine if their programs of training are approved for the payment of VA educational assistance. This specified information is submitted either to VA or to the State Approving Agency (SAA) having jurisdiction over that school.

Affected Public: Educational Institutions.

Estimated Annual Burden: 1,814 hours.

Estimated Average Burden per Respondent: 60 minutes.

Frequency of Response: Quarterly.

Estimated Number of Respondents: 1,814.

(Authority: 44 U.S.C. 3501 *et seq.*)

Dorothy Glasgow,

VA PRA Clearance Officer, (Alt.), Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2024–21704 Filed 9–20–24; 8:45 am]

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Part II

Department of the Treasury

Internal Revenue Service

Department of Labor

Employee Benefits Security Administration

Department of Health and Human Services

26 CFR Part 54

29 CFR Part 2590

45 CFR Parts 146 and 147

Requirements Related to the Mental Health Parity and Addiction Equity Act; Final Rule

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 54**

[TD 10006]

RIN 1545–BQ29

DEPARTMENT OF LABOR**Employee Benefits Security Administration****29 CFR Part 2590**

RIN 1210–AC11

DEPARTMENT OF HEALTH AND HUMAN SERVICES**45 CFR Parts 146 and 147**

[CMS–9902–F]

RIN 0938–AU93

Requirements Related to the Mental Health Parity and Addiction Equity Act

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Final rules.

SUMMARY: This document sets forth final rules amending regulations implementing the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) and adding new regulations implementing the nonquantitative treatment limitation (NQTL) comparative analyses requirements under MHPAEA, as amended by the Consolidated Appropriations Act, 2021 (CAA, 2021). Specifically, these final rules amend the existing NQTL standard to prohibit group health plans and health insurance issuers offering group or individual health insurance coverage from using NQTLs that place greater restrictions on access to mental health and substance use disorder benefits as compared to medical/surgical benefits. As part of these changes, these final rules require plans and issuers to collect and evaluate relevant data in a manner reasonably designed to assess the impact of NQTLs on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits and to take reasonable action, as necessary, to address material differences in access to mental health or substance use disorder benefits as compared to medical/

surgical benefits. These final rules also amend existing examples and add new examples on the application of the rules for NQTLs to clarify and illustrate the requirements of MHPAEA.

Additionally, these final rules set forth the content requirements for NQTL comparative analyses and specify how plans and issuers must make these comparative analyses available to the Department of the Treasury (Treasury), the Department of Labor (DOL), and the Department of Health and Human Services (HHS) (collectively, the Departments), as well as to an applicable State authority, and to participants, beneficiaries, and enrollees. Finally, HHS finalizes regulatory amendments to implement the sunset provision for self-funded non-Federal governmental plan elections to opt out of compliance with MHPAEA, as adopted in the Consolidated Appropriations Act, 2023 (CAA, 2023).

DATES:

Effective date: These regulations are effective on November 22, 2024.

Applicability date: See the **SUPPLEMENTARY INFORMATION** section for information on the applicability dates.

FOR FURTHER INFORMATION CONTACT:

William Fischer, Internal Revenue Service, Department of the Treasury, at 202–317–5500; Beth Baum or David Sydlík, Employee Benefits Security Administration, Department of Labor, at 202–693–8335; David Mlawsky, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at 410–786–6851.

SUPPLEMENTARY INFORMATION:**I. Background**

America continues to experience a mental health and substance use disorder crisis affecting people across all demographics, with marginalized communities disproportionately impacted.¹ The COVID–19 pandemic exacerbated the crisis, but its effects have continued post-pandemic.² From August 19, 2020, to February 1, 2021, the percentage of adults exhibiting symptoms of an anxiety or a depressive disorder rose from 36.4 percent to 41.5 percent.³ In 2022, there were an

estimated 15.4 million adults aged 18 or older in the United States with a serious mental illness and nearly one in four adults (59.3 million) living with any mental illness.⁴

Additionally, in 2022, nearly 54.6 million people aged 12 or older were classified as needing treatment for substance use, but only about 24 percent of those people received any treatment, according to the Substance Abuse and Mental Health Services Administration's (SAMHSA) National Survey on Drug Use and Health (NSDUH).⁵ The unmet need for treatment for substance use disorders has been even greater among racial minorities and other marginalized communities. Between 2019 and 2021, median monthly overdose deaths among persons aged 10–19 years increased 109 percent; and deaths involving illicitly manufactured fentanyl increased 182 percent.⁶ In 2021, American Indian and Alaskan Native men aged 15–34 had an age-adjusted death rate caused by drug overdoses of 42 per 100,000 people, compared to 20.5 age-adjusted deaths per 100,000 people during the same time period in 2018.⁷ Non-Hispanic Black or African American men aged 35–64 had an age-adjusted death rate caused by drug overdoses of 61.2 per 100,000 people; an increase from 30.6 deaths per 100,000 people during the same time period in 2018.⁸

Following the COVID–19 pandemic, employers highlighted that they have responded to the impact of the pandemic on the mental health and substance use disorder crisis by offering more comprehensive benefits, including

Depressive Disorder and Use of Mental Health Care Among Adults During the COVID–19 Pandemic—United States, Aug. 2020–Feb. 2021, *MMWR Morb Mortal Wkly Rep* 2021;70:490–494, <https://www.cdc.gov/mmwr/volumes/70/wr/mm7013e2.htm>.

⁴ SAMHSA (2023), Key substance use and mental health indicators in the United States: Results from the 2022 National Survey on Drug Use and Health (HHS Publication No. PEP23–07–01–006, NSDUH Series H–58), <https://www.samhsa.gov/data/report/2022-nsduh-annual-national-report>.

⁵ *Ibid.*

⁶ Tanz, L.J., Dinwiddie, A.T., Mattson, C.L., O'Donnell, J., Davis, N.L. (2022), Drug Overdose Deaths Among Persons Aged 10–19 Years—United States, July 2019–Dec. 2021, *MMWR Morb Mortal Wkly Rep* 2022;71:1576–1582, <https://www.cdc.gov/mmwr/volumes/71/wr/mm7150a2.htm>.

⁷ Han, B., Einstein, E.B., Jones, C.M., Cotto, J., Compton, W.M., Volkow, N.D. (2022), Racial and Ethnic Disparities in Drug Overdose Deaths in the US During the COVID–19 Pandemic, *JAMA Netw Open*, 5(9):e2232314, DOI:10.1001/jamanetworkopen.2022.32314, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9490498/>. Age-adjusted death rates are death rates that control for the effects of differences in population age distributions.

⁸ *Ibid.*

¹ Kaiser Family Foundation (2022), Five key findings on mental health and substance use disorders by race/ethnicity, <https://www.kff.org/mental-health/issue-brief/five-key-findings-on-mental-health-and-substance-use-disorders-by-race-ethnicity/>.

² American Psychological Association (2023), Stress in America™ 2023: A nation grappling with psychological impacts of collective trauma, <https://www.apa.org/news/press/releases/2023/11/psychological-impacts-collective-trauma>.

³ Vahratian, A., Blumberg, S.J., Terlizzi, E.P., Schiller, J.S. (2021), Symptoms of Anxiety or

mental health support. According to a report published in 2021, “about three in four large employers and two in four small/medium employers report that they offer at least one type of mental health support for employees.”⁹ In a recent survey, 87 percent of large employers stated that access to mental health care was a top priority, and another survey found that “the number of in-network behavioral health providers has increased by an average of 48 percent in 3 years among commercial health plans.”¹⁰ Group health plans and health insurance issuers have taken steps to ensure mental health parity is reflected in their benefit designs and to educate participants, beneficiaries, and enrollees¹¹ about MHPAEA’s requirements, by reaching out to members, expanding telehealth availability, expanding behavioral health provider networks, integrating behavioral health with physical health care, and working to reduce stigmatization of seeking treatment.

Despite these efforts, disparities in coverage between mental health and substance use disorder benefits and medical/surgical benefits have grown. In the preamble to the proposed rules,¹² the Departments cited a 2019 Milliman report¹³ that found a growing disparity

in the utilization of out-of-network behavioral health care providers relative to out-of-network medical/surgical care providers. A recent study by RTI International¹⁴ found that out-of-network use was 3.5 times higher for all behavioral health clinician office visits than for all out-of-network medical/surgical clinician office visits; in addition, the study noted that these disparities in out-of-network use for behavioral health office visits compared to medical/surgical office visits have remained large and, according to the study, are not fully attributable to behavioral health provider shortages. The study concluded that these results demonstrate the need for more robust parity enforcement.

RTI concluded that its analyses of the most recent, comprehensive private insurance claims data

reveal material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, as reflected in much greater use of out-of-network providers. . . . These disparities indicate that behavioral health networks are clearly inadequate and signal potential noncompliance with the NQTL requirements of MHPAEA.¹⁵

These final rules aim to strengthen consumer protections consistent with MHPAEA’s fundamental purpose—to ensure that individuals in group health plans or with group or individual health insurance coverage who seek treatment for covered mental health conditions or substance use disorders do not face greater burdens on access to benefits for those conditions or disorders than they would face when seeking coverage for the treatment of a medical condition or a surgical procedure.¹⁶ As highlighted

in the preamble to the proposed rules,¹⁷ such barriers are particularly problematic when the benefits that the plan or issuer purports to make available and that individuals reasonably expect to be covered are not in fact covered. To the extent these barriers disproportionately limit access to mental health or substance use disorder benefits, such practices contravene MHPAEA’s statutory language, which requires that the financial requirements and treatment limitations applicable to mental health or substance use disorder benefits be “no more restrictive” than the predominant requirements and limitations applicable to substantially all medical/surgical benefits.¹⁸ The Departments’ enforcement efforts have shown that such barriers persist more than 15 years after MHPAEA’s enactment.¹⁹ These final rules are critical to addressing barriers to access to mental health and substance use disorder benefits.

The problems persist notwithstanding the Departments’ unprecedented commitment to advance parity for mental health and substance use disorder benefits in recent years, as reflected through increased enforcement efforts and the Departments’ work with interested parties to help them understand and comply with MHPAEA’s requirements.²⁰ To promote compliance, the Departments have provided extensive guidance and compliance assistance materials, especially with respect to NQTLs,²¹ yet disparities still persist.

In 1996, Congress enacted the Mental Health Parity Act of 1996 (MHPA 1996), which required parity in aggregate

⁹ Coe, E., Cordina, J., Enomoto, K., Mandel, A., Stueland, J. (2021), National Surveys Reveal Disconnect Between Employees and Employers Around Mental Health Need, McKinsey & Company, <https://www.mckinsey.com/industries/healthcare/our-insights/national-surveys-reveal-disconnect-between-employees-and-employers-around-mental-health-need>.

¹⁰ America’s Health Insurance Plans (AHIP), Health Insurance Providers Facilitate Broad Access to Mental Health Support (Aug. 2022), <https://ahiporg-production.s3.amazonaws.com/documents/Mental-Health-Survey-July-2022-FINAL.pdf>.

¹¹ Consistent with the proposed rules, these final rules apply directly to group health plans or health insurance coverage offered by an issuer in connection with a group health plan, and apply to individual health insurance coverage by cross-reference through 45 CFR 147.160, which currently provides that the requirements of 45 CFR 146.136 apply to health insurance coverage offered by a health insurance issuer in the individual market in the same manner and to the same extent as to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the large group market. As noted later in this preamble, HHS is finalizing an amendment to 45 CFR 147.160 to also include a cross-reference to 45 CFR 146.137 to similarly extend the new comparative analysis requirements to individual health insurance coverage in the same manner and to the same extent as group health insurance coverage. For simplicity, this preamble generally refers only to the applicability to group health plans and health insurance coverage offered in connection with a group health plan and to participants and beneficiaries enrolled in such a plan or coverage, but references to participants and beneficiaries should also be considered to include enrollees in the individual market, unless otherwise specified.

¹² 88 FR 51552, 51554 (Aug. 3, 2023).

¹³ Melek, S., Davenport, S., Gray, T.J. (2019), *Addiction and mental health vs. physical health:*

Widening disparities in network use and provider reimbursement, Milliman, 6, https://assets.milliman.com/ektron/Addiction_and_mental_health_vs_physical_health_Widening_disparities_in_network_use_and_provider_reimbursement.pdf.

¹⁴ Mark, T.L., Parish, W. (2024), *Behavioral health parity—Pervasive disparities in access to in-network care continue*, RTI International, <https://dpjh8al9zd3a4.cloudfront.net/publication/behavioral-health-parity-pervasive-disparities-access-network-care-continue/fulltext.pdf>.

¹⁵ *Id.* at 46.

¹⁶ In a floor statement, Representative Patrick Kennedy (D-RI), one of the chief architects of MHPAEA, made the case for its passage on the grounds that “access to mental health services is one of the most important and most neglected civil rights issues facing the Nation. For too long, persons living with mental disorders have suffered from discriminatory treatment at all levels of society.” 153 Cong. Rec. S1864–5 (daily ed. Feb. 12, 2007). Cf. H. Rept. 110–374, part 3 (Mar. 4, 2008), <https://www.congress.gov/congressional-report/110th-congress/house-report/374> (“The purpose of H.R. 1424, the ‘Paul Wellstone Mental Health and Addiction Equity Act of 2007’ is to have fairness and equity in the coverage of mental health and substance-related disorders vis-a-vis coverage for medical and surgical disorders.”).

¹⁷ 88 FR 51552 (Aug. 3, 2023).

¹⁸ Internal Revenue Code (Code) section 9812(a)(3)(A), Employee Retirement Income Security Act of 1974 (ERISA) section 712(a)(3)(A), and Public Health Service Act (PHS Act) section 2726(a)(3)(A).

¹⁹ See, e.g., 2022 MHPAEA Report to Congress (Jan. 2022), <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2022-realizing-parity-reducing-stigma-and-raising-awareness.pdf>; 2023 MHPAEA Comparative Analysis Report to Congress (July 2023), <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2023-mhpaea-comparative-analysis.pdf>.

²⁰ More information on the Departments’ enforcement efforts and guidance issued under MHPAEA is available at <https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/mental-health-and-substance-use-disorder-parity/tools-and-resources> and <https://www.cms.gov/marketplace/private-health-insurance/mental-health-parity-addiction-equity>.

²¹ As discussed in more detail later in this preamble, NQTLs are generally non-numerical limits on the scope or duration of treatment, such as prior authorization requirements, step therapy, and standards related to network composition.

lifetime and annual dollar limits for mental health benefits and medical/surgical benefits for group health plans and health insurance coverage offered in connection with such plans.²² These mental health parity provisions were codified in Code section 9812, ERISA section 712, and PHS Act section 2705.²³ Congress expanded on these efforts in 2008 with the enactment of MHPAEA,²⁴ which amended Code section 9812, ERISA section 712, and PHS Act section 2705 by adding requirements for plans and issuers related to financial requirements and treatment limitations and made further amendments to the existing mental health parity provisions, including provisions to apply the mental health parity requirements to substance use disorder benefits.

The Affordable Care Act (ACA)²⁵ reorganized, amended, and added to the provisions of part A of title XXVII of the PHS Act relating to group health plans and health insurance issuers in the group and individual markets. The ACA added section 715(a)(1) to ERISA and section 9815(a)(1) to the Code to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and to make them applicable to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans. The PHS Act sections included by these references are sections 2701 through 2728. The ACA extended MHPAEA to apply to individual health insurance coverage and redesignated MHPAEA in the PHS Act as section 2726.²⁶ Additionally,

section 1311(j) of the ACA applies PHS Act section 2726 to qualified health plans²⁷ in the same manner and to the same extent as it applies to health insurance issuers and group health plans. The ACA also included a requirement for coverage of mental health and substance use disorder services, including behavioral health treatment, as a category of essential health benefits (EHB).²⁸ HHS' EHB regulations require health insurance issuers offering non-grandfathered health insurance coverage in the individual and small group markets to comply with MHPAEA and its implementing regulations to satisfy the requirement to cover "mental health and substance use disorder services, including behavioral health treatment," as part of EHB.²⁹

The Departments published a request for information soliciting comments on issues under MHPAEA³⁰ and subsequently issued interim final regulations to implement the requirements of MHPAEA.³¹ After considering the comments, the Departments published the 2013 final regulations.³² As detailed in the preamble to the proposed rules, in the years after the 2013 final regulations were published, the Departments provided extensive guidance and compliance assistance materials to the regulated community, State regulators, and other interested parties to facilitate the implementation and enforcement of MHPAEA, including the 2020 MHPAEA Self-Compliance Tool,³³ which

small group market only through the requirement to provide EHB, which does not apply to grandfathered health plans, the requirements of MHPAEA do not apply to grandfathered health plans offered in the small group market.

²⁷ A qualified health plan is a health insurance plan that is certified by a health insurance exchange that it meets certain minimum standards established under the ACA and described in subpart C of 45 CFR part 156. See 45 CFR 155.20.

²⁸ Section 1302 of the ACA requires non-grandfathered health plans in the individual and small group markets to cover EHB, which include items and services in the following ten benefit categories: (1) ambulatory patient services; (2) emergency services; (3) hospitalization; (4) maternity and newborn care; (5) mental health and substance use disorder services, including behavioral health treatment; (6) prescription drugs; (7) rehabilitative and habilitative services and devices; (8) laboratory services; (9) preventive and wellness services and chronic disease management; and (10) pediatric services, including oral and vision care. See 45 CFR 156.115 for description of the benefits a health plan must provide to provide EHB.

²⁹ Section 1302(b)(1)(E) of the ACA; 45 CFR 156.115(a)(3).

³⁰ 74 FR 19155 (Apr. 28, 2009).

³¹ 75 FR 5410 (Feb. 2, 2010).

³² 78 FR 68240 (Nov. 13, 2013).

³³ See Self-Compliance Tool for the Mental Health Parity and Addiction Equity Act (MHPAEA)

provided a basic framework for plans and issuers to assess whether their NQTLs satisfy MHPAEA's parity requirements.³⁴

The CAA, 2021 was enacted by Congress on December 27, 2020,³⁵ and amended MHPAEA, in part, by expressly requiring group health plans and health insurance issuers that provide both medical/surgical benefits and mental health or substance use disorder benefits to perform and document comparative analyses of the design and application of NQTLs that apply to mental health or substance use disorder benefits. The statute also requires plans and issuers to make their analyses available to the Departments or applicable State authorities, upon request, effective February 10, 2021. Additionally, the CAA, 2021 sets forth a process by which the Departments must evaluate the requested NQTL comparative analyses and enforce the comparative analyses requirements and requires the Departments to submit annually to Congress and make publicly available a report summarizing the comparative analyses requested for review by the Departments.³⁶

To help plans and issuers comply with the amendments to MHPAEA made by the CAA, 2021, the Departments issued Frequently Asked Questions (FAQs) About Mental Health and Substance Use Disorder Parity Implementation and the Consolidated Appropriations Act, 2021 Part 45 (FAQs Part 45).³⁷ As detailed in the preamble to the proposed rules, these FAQs provided initial guidance to plans and issuers on these amendments to MHPAEA.³⁸ Additionally, as required

(2020), <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/self-compliance-tool.pdf>.

³⁴ 88 FR 51552, 51555–56 (Aug. 2, 2023).

³⁵ Section 203 of title II of Division BB of the CAA, 2021, Public Law 116–260, 134 Stat. 1182 (Dec. 27, 2020).

³⁶ The report must state, in part, whether each plan or issuer that submitted a comparative analysis upon request submitted sufficient information to permit review; whether and why the Departments determined the plan or issuer is in compliance with MHPAEA; the specific information each plan or issuer needed to submit to allow for a review of its comparative analysis; and, for each plan or issuer the Departments determined not to be in compliance, specifications of the actions that the plan or issuer must take to come into compliance. See Code section 9812(a)(8)(B)(iv), ERISA section 712(a)(8)(B)(iv), and PHS Act section 2726(a)(8)(B)(iv).

³⁷ FAQs about Mental Health and Substance Use Disorder Parity Implementation and the Consolidated Appropriations Act, 2021 Part 45 (Apr. 2, 2021), <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-45.pdf> and <https://www.cms.gov/ccio/resources/fact-sheets-and-faqs/downloads/mhpaea-faqs-part-45.pdf>.

³⁸ 88 FR 51552, 51562 (Aug. 3, 2023).

²² Public Law 104–204, 110 Stat. 2874 (Sept. 26, 1996). The Departments published interim final rules implementing MHPA 1996 at 62 FR 66932 (Dec. 22, 1997).

²³ The Departments published interim final rules implementing MHPA 1996 at 62 FR 66932 (Dec. 22, 1997).

²⁴ Sections 511 and 512 of the Tax Extenders and Alternative Minimum Tax Relief Act of 2008 (Division C of Pub. L. 110–343, 122 Stat. 3765 (Oct. 3, 2008)).

²⁵ References to the Affordable Care Act or ACA include the Patient Protection and Affordable Care Act (Pub. L. 111–148, 123 Stat. 3028) enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, 124 Stat. 1029) enacted on March 30, 2010.

²⁶ The requirements of MHPAEA generally apply to both grandfathered and non-grandfathered health plans. See section 1251 of the ACA and its implementing regulations at 26 CFR 54.9815–1251, 29 CFR 2590.715–1251, and 45 CFR 147.140. Under section 1251 of the ACA, grandfathered health plans are exempted only from certain ACA requirements enacted in Subtitles A and C of Title I of the ACA. The provisions extending MHPAEA requirements to individual health insurance coverage and requiring that qualified health plans comply with MHPAEA are not included in these sections. However, because MHPAEA requirements apply to health insurance coverage offered in the

by the CAA, 2021, the Departments provided reports to Congress on the NQTL comparative analyses reviews conducted by the Departments.³⁹ These reports highlighted that nearly all of the comparative analyses reviewed by the Departments during the relevant time periods contained insufficient information to support a finding of compliance upon initial receipt and reflected common insufficiencies.

Building on the lessons learned from implementing and enforcing MHPAEA, as well as the guidance provided in FAQs Part 45, on August 3, 2023, the Departments published proposed rules to amend existing MHPAEA regulations at 26 CFR 54.9812–1, 29 CFR 2590.712, and 45 CFR 146.136;⁴⁰ to add a proposed new regulation at 26 CFR 54.9812–2, 29 CFR 2590.712–1, and 45 CFR 146.137 in order to codify minimum standards for developing NQTL comparative analyses; and to codify HHS-only amendments to implement the sunset provision for self-funded non-Federal governmental plan elections to opt out of compliance with MHPAEA. On September 28, 2023, the Departments extended the comment period that was set to expire on October 2, 2023, by 15 days to October 17, 2023, to give interested parties additional time to review the proposed rules and submit comments.⁴¹

The Departments received 9,503 comments that were submitted during the comment period⁴² in response to the proposed rules from a wide variety of interested parties, including private citizens; consumer and advocacy organizations; employers, employee organizations, and other plan sponsors; Federal, State, and local officials; health care providers and facilities and health

systems; health insurance issuers; service providers, including managed behavioral health organizations (MBHOs), third-party administrators (TPAs), and pharmacy benefit managers (PBMs); trade and professional associations; and researchers. Many commenters provided detailed feedback on multiple aspects of the proposed rules and in response to various specific comment solicitations included in the preamble to the proposed rules and the request for information.

In general, many commenters supported the proposed rules, because they would formalize and, according to these commenters, provide greater clarity on what health plans and issuers must do to comply with MHPAEA. Some commenters highlighted that the existing rules were insufficient and that the proposed rules were timely and necessary to strengthen MHPAEA and ensure fair access to mental health and substance use disorder care. Commenters highlighted the importance of the proposed rules to participants, beneficiaries, and enrollees, including children, teens, young adults, and others living with mental health conditions and substance use disorders. Several other commenters, however, expressed either opposition or concern regarding the proposed rules. Several commenters stated that the proposed rules would increase health plan and issuer costs and reduce treatment quality. A few commenters recommended the Departments withdraw the proposed rules and initiate a new rulemaking process after additional input from interested parties.

After reviewing the comments received during the comment period, the Departments are finalizing the proposed rules, with some changes in response to comments as described in more detail later in this preamble, to ensure that participants, beneficiaries, and enrollees can access the mental health and substance use disorder care they need without facing greater restrictions than when accessing medical and surgical care, consistent with the fundamental purpose of MHPAEA. These final rules provide additional clarity to plans and issuers on how to comply with MHPAEA's requirements and, as a result, will strengthen the protections of MHPAEA. As highlighted earlier in this preamble, since the 2013 final regulations, the Departments repeatedly sought input from interested parties on MHPAEA's requirements; therefore, the Departments decline to withdraw the proposed rules or initiate a new rulemaking process after soliciting additional input from interested parties.

As explained throughout this preamble, the amendments made by these final rules are faithful to MHPAEA's parity requirements and sensitive to the flexibility plans and issuers have in designing benefits for group health plans and health insurance coverage.⁴³

Among other things, these final rules:

- Make clear that MHPAEA requires that individuals will not face greater restrictions on access to mental health and substance use disorder benefits as compared to medical/surgical benefits.

- Reinforce that health plans and issuers cannot use NQTLs, such as prior authorization and other medical management techniques, standards related to network composition, or methodologies to determine out-of-network reimbursement rates, for mental health and substance use disorder benefits, that are more restrictive than the predominant NQTLs applied to substantially all medical/surgical benefits in the same classification.

- Require plans and issuers to collect and evaluate data and take reasonable action, as necessary, to address material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, where the relevant data suggest that the NQTL contributes to material differences in access.

- Codify the requirement in MHPAEA, as amended by the CAA, 2021, that health plans and issuers conduct comparative analyses to measure the impact of NQTLs. This includes evaluating standards related to network composition, out-of-network reimbursement rates, and medical management and prior authorization NQTLs.

- Prohibit plans and issuers from using discriminatory information, evidence, sources, or standards that systematically disfavor or are specifically designed to disfavor access to mental health and substance use disorder benefits when designing NQTLs.

- Implement the sunset provision for self-funded non-Federal governmental plan elections to opt out of compliance with MHPAEA.

As a result, the Departments anticipate that these final rules will result in changes in network composition and medical management techniques related to mental health and substance use disorder care, more robust mental health and substance use disorder provider networks, and fewer

³⁹ *Ibid.*

⁴⁰ 88 FR 51552 (Aug. 3, 2023). On July 25, 2023, DOL, in collaboration with HHS and the Treasury, also issued Technical Release 2023–01P. The Technical Release set out principles and sought public comment to inform future guidance with respect to the application of the proposed data collection and evaluation requirements to NQTLs related to network composition and a potential time-limited enforcement safe harbor for plans and issuers that include data in their comparative analyses that demonstrate they meet or exceed all the thresholds identified in future guidance with respect to NQTLs related to network composition. The Departments encouraged interested parties to submit their comments consistent with the instructions contained in it separate from any comments they submitted in response to the proposed rules. The Departments are considering these comments separately and these final rules do not respond to those comments. Plans and issuers would be allowed adequate time to conform to any future guidance on the type, form, and manner of collection and evaluation for the relevant data required under the final rules.

⁴¹ 88 FR 66728 (Sept. 28, 2023).

⁴² The comment period for the proposed rules was extended by 15 days to October 17, 2023.

⁴³ The Departments note that impacts on plan and issuer costs are discussed in more detail in the regulatory impact analysis, later in this preamble.

and less restrictive prior authorization requirements for individuals seeking mental health and substance use disorder care, as well as provide additional clarity and information needed for plans and issuers to meet their obligations under MHPAEA and for the Departments and States to enforce those obligations.

II. Overview of the Final Rules—Departments of the Treasury, Labor, and HHS

The Departments are issuing these final rules to ensure that individuals with mental health conditions and substance use disorders can benefit from the full protections afforded to them under MHPAEA, while offering clear guidance to plans and issuers on how to comply with MHPAEA's requirements. These final rules amend certain provisions of existing MHPAEA regulations at 26 CFR 54.9812–1, 29 CFR 2590.712, and 45 CFR 146.136 to incorporate new and revised definitions of key terms, as well as to specify the steps that plans and issuers must take to meet their obligations under MHPAEA. These final rules also add new regulations at 26 CFR 54.9812–2, 29 CFR 2590.712–1, and 45 CFR 146.137 codifying minimum standards for developing NQTL comparative analyses to assess whether an NQTL, as written and in operation, complies with MHPAEA's requirements and setting forth the content elements of comparative analyses and the period for plans and issuers to respond to a request from the Departments to submit their comparative analyses. Additionally, in these final rules, HHS finalizes an amendment to 45 CFR 147.160 to specify that the final regulations at 45 CFR 146.137 apply to individual health insurance coverage offered by a health insurance issuer in the same manner and to the same extent that the regulations apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the large group market.⁴⁴ Consistent with the existing text at 45 CFR 147.160(a), HHS is also extending the same requirements and framework outlined in the amendments to 45 CFR 146.136 in these final rules to individual health insurance coverage in

the same manner and to the same extent as the amendments that apply to group health insurance coverage. Finally, HHS is finalizing amendments to 45 CFR 146.180 to reflect the sunset of the election option for self-funded non-Federal governmental plans to opt out of compliance with MHPAEA, consistent with changes made by the CAA, 2023 to PHS Act section 2722(a)(2).⁴⁵

A. Amendments to Existing Regulations at 26 CFR 54.9812–1, 29 CFR 2590.712, and 45 CFR 146.136

1. Purpose Section—26 CFR 54.9812–1(a)(1), 29 CFR 2590.712(a)(1), and 45 CFR 146.136(a)(1)

In the preamble to the proposed rules, the Departments stated that the fundamental purpose of the MHPAEA statute, the 2013 final regulations, and the proposed rules is to ensure that participants and beneficiaries in a group health plan or in group health insurance coverage offered by a health insurance issuer that offers mental health or substance use disorder benefits are not subject to greater restrictions when seeking those benefits than when seeking medical/surgical benefits under the terms of the plan or coverage. The Departments also stated that the fundamental purpose of MHPAEA should serve as the guiding principle for plans and issuers as they work to comply with the requirements of the law and its implementing regulations. Accordingly, the Departments proposed to add a purpose section to the regulations, specifying this fundamental purpose, and that MHPAEA and its implementing regulations should be interpreted in a manner that is consistent with this purpose.

Many commenters supported the addition of the purpose section and the principles it addressed, including the goal of increasing access to mental health and substance use disorder benefits, to ensure equal treatment for mental health and substance use disorder benefits and medical/surgical benefits. A few commenters expressed opposition to the proposed purpose section, arguing that its language goes beyond the intent of MHPAEA (as Congress did not direct the Departments to provide a purpose in regulations, either initially or in later amendments).

The purpose section is important to highlight the overall goals of MHPAEA and to emphasize that the provisions of the 2013 final regulations, as amended by these final rules, should be interpreted in light of these goals.

Congress provided authority to the Departments to “promulgate such regulations as may be necessary or appropriate to carry out the provisions of” chapter 100 of the Code, part 7 of ERISA, and title XXVII of the PHS Act, including MHPAEA.⁴⁶ MHPAEA was enacted to address barriers to access to mental health and substance use disorder benefits as compared to medical/surgical benefits. These final rules implement MHPAEA's requirements and provide clarifying text to promote compliance with the law. The Departments are finalizing the purpose section as proposed, with minor changes in response to comments.

Several commenters requested that the reference to “generally comparable” medical/surgical benefits in the proposed purpose section be revised to refer to the classification of benefits. These commenters noted that, consistent with the 2013 final regulations, evaluation of a plan's or issuer's MHPAEA compliance is assessed within the relevant classification of benefits, and that use of the term “comparable,” which is used in the 2013 final regulations and amendments made to MHPAEA by the CAA, 2021 with respect to requirements for NQTLs, is confusing and should be revised.

The Departments agree with commenters who noted that use of the term “comparable” can be confusing when used in this context, because compliance with the requirements for financial requirements, quantitative treatment limitations, and NQTLs has historically been determined within one of the six classifications of benefits.⁴⁷ Therefore, these final rules remove the reference to “generally comparable” medical/surgical benefits and instead specify that plans and issuers must not design or apply financial requirements and treatment limitations that impose a greater burden on access (that is, are more restrictive) to mental health or substance use disorder benefits under the plan or coverage than they impose on access to medical/surgical benefits in the same classification of benefits. The

⁴⁶ See Code section 9833, ERISA section 734, and PHS Act section 2792.

⁴⁷ The six classifications of benefits listed at 26 CFR 54.9812–1(c)(2)(ii)(A), 29 CFR 2590.712(c)(2)(ii)(A), and 45 CFR 146.136(c)(2)(ii)(A) include inpatient, in-network; inpatient, out-of-network; outpatient, in-network; outpatient, out-of-network; emergency care, and prescription drugs. Special rules for multi-tiered prescription drug benefits, multiple network tiers, and permissible sub-classifications for office visits, separate from other outpatient services, are addressed at 26 CFR 54.9812–1(c)(3)(iii), 29 CFR 2590.712(c)(3)(iii), and 45 CFR 146.136(c)(3)(iii).

⁴⁴ Non-grandfathered health insurance coverage offered by a health insurance issuer in connection with a group health plan in the small group market is required to comply with the requirements under PHS Act section 2726 to satisfy the requirement to provide coverage for mental health and substance use disorder services, including behavioral health treatment, as part of EHB, and as such will also be required to comply with the comparative analysis requirements finalized under 45 CFR 146.137. See 45 CFR 156.115(a)(3).

⁴⁵ Division FF, title I, subtitle C, chapter 3, section 1321, Public Law 117–328, 136 Stat. 4459 (Dec. 29, 2022).

Departments are finalizing the purpose section without any other substantive changes, but with a few minor clarifications to ensure that terms are used consistently with and accurately describe other parts of these final rules.

2. Meaning of Terms—26 CFR 54.9812–1(a)(2), 29 CFR 2590.712(a)(2), and 45 CFR 146.136(a)(2)

a. Medical/Surgical Benefits, Mental Health Benefits, and Substance Use Disorder Benefits

Under the statute and the 2013 final regulations, the term “medical/surgical benefits” means benefits for medical or surgical services as defined under the terms of the plan or health insurance coverage but does not include mental health or substance use disorder benefits. The 2013 final regulations further provide that the term must be defined in accordance with applicable Federal and State law, and that any condition defined by the plan or coverage as being or as not being a medical/surgical condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the International Classification of Diseases (ICD) or State guidelines).

The proposed rules generally retained the first sentence of the 2013 final regulations’ definition of “medical/surgical benefits,”⁴⁸ but amended the definition to provide that, notwithstanding this first sentence, any condition or procedure defined by the plan or coverage as being or not being a medical condition or surgical procedure must be defined consistent with generally recognized independent standards of current medical practice (for example, the most current version of the ICD). Further, the proposed rules stated that, to the extent that generally recognized independent standards of current medical practice do not address whether a condition or procedure is a medical condition or surgical procedure, plans and issuers may define the condition or procedure as medical/surgical benefits, as long as such definitions are in accordance with applicable Federal and State law. The Departments also proposed to remove the reference to State guidelines in the definition of the term in the 2013 final

regulations, both to make the definitions more consistent with the statute, and to minimize situations where differences between generally recognized independent standards of current medical practice and State guidelines create conflicts and improperly limit protections under MHPAEA.

The Departments also proposed to make similar changes to the definitions of “mental health benefits” and “substance use disorder benefits” by amending the first sentence of each definition and removing the references to State guidelines, consistent with the changes described above for “medical/surgical benefits.”⁴⁹ For purposes of the requirement that any condition or disorder defined by the plan or coverage as being or not being a mental health condition must be defined to be consistent with generally recognized independent standards of current medical practice, the proposed rules stated that the plan’s or coverage’s definition must include all conditions covered under the plan or coverage, except for substance use disorders, that fall under any of the diagnostic categories listed in the mental, behavioral, and neurodevelopmental disorders chapter (or equivalent chapter) of the most current version of the ICD or that are listed in the most current version of the American Psychiatric Association (APA) Diagnostic and Statistical Manual of Mental Disorders (DSM). Similarly, the proposed rules stated that the plan’s or coverage’s definition of “substance use disorder benefits” must include all disorders covered under the plan or coverage that fall under any of the diagnostic categories listed as a mental or behavioral disorder due to psychoactive substance use (or equivalent category) in the mental, behavioral, and neurodevelopmental disorders chapter (or equivalent chapter) of the most current version of the ICD or that are listed as a Substance-Related and Addictive Disorder (or equivalent category) in the most current version of the DSM. The proposed rules solicited comments on whether any additional clarification is needed on how State law may interact with the proposed amended definitions of “medical/surgical benefits,” “mental

health benefits” and “substance use disorder benefits.”

In general, many commenters supported modifying these key definitions in existing MHPAEA regulations by specifying that, to be consistent with generally recognized independent standards of current medical practice, the terms of the plan or coverage must accord with appropriate chapters of the ICD or DSM. Many commenters generally supported requiring plans and issuers to follow the ICD or DSM, reasoning that both are generally accepted, peer-reviewed, nonprofit professional standards for diagnosis and descriptions of medical conditions, mental health conditions, and substance use disorders, and that following these authoritative and comprehensive diagnostic tools promotes uniform and standard application of MHPAEA to mental health conditions and substance use disorders. Several commenters noted that these changes would significantly improve clarity and would increase access to care, especially for intellectual and neurodevelopmental disorders, including dementia and autism spectrum disorder (ASD). Another commenter recommended clarifying whether plans and issuers are required to consider both the ICD and the DSM in categorizing benefits for the purposes of the proposed rules. One commenter added that the Departments’ proposal to align and clarify the definitions of “mental health benefits” and “substance use disorder benefits” would ensure parity between the relevant terms and protect the application of MHPAEA for conditions and disorders recognized under independent standards of current medical practice. Another commenter expressing support reasoned that the proposed amendments would clearly specify how mental health conditions and substance use disorders must be defined for MHPAEA compliance purposes and minimize contradictions with State guidelines that now limit MHPAEA protections. The commenter also remarked that self-insured plans frequently include language from State-level mandated benefit requirements prevalent in the plan’s geographic area that may not be MHPAEA-compliant.

Several commenters supported the removal of any reference to State guidelines to prevent situations in which contradictions between Federal and State guidelines would result in a loss of protections under MHPAEA. One commenter wrote that State law definitions often predate MHPAEA, may conflict with ICD and DSM standards, and should not be the operable standard, while others stated that State

⁴⁸ Under the 2013 final regulations, the term “medical/surgical benefits” means benefits with respect to items or services for medical conditions or surgical procedures, as defined under the terms of the plan or health insurance coverage and in accordance with applicable Federal and State law, but does not include mental health or substance use disorder benefits. 26 CFR 54.9812–1(a), 29 CFR 2590.712(a), and 45 CFR 146.136(a).

⁴⁹ Consistent with the statute and the 2013 final regulations, the Departments note that references to “mental health and substance use disorder benefits” and “mental health or substance use disorder benefits” throughout these final rules are intended to have the same meaning as the terms “mental health benefits” and “substance use disorder benefits” in combination.

guidelines should not be given precedence over Federal regulations to ensure that MHPAEA's protections are not subverted. However, one commenter urged that the Departments continue allowing plans and issuers to use State guidelines to inform the definitions of "medical/surgical benefits," "mental health benefits," and "substance use disorder benefits," regardless of whether State law is consistent with generally recognized independent standards of current medical practice. The commenter noted that independent standards of medical practice vary and change over time and are not established with the same intents and purposes as State laws. The commenter also stated that States have been the traditional regulators of health insurance issuers when it comes to interpretive and enforcement matters, even for coverage issues subject to Federal law (such as the ACA and MHPAEA). Another commenter supported the clarification that, when the DSM or ICD does not indicate whether a condition or disorder is a mental health condition or substance use disorder, plans and issuers may define the condition or disorder in accordance with applicable Federal and State law.

In the proposed rules, the Departments noted that, to the extent applicable State law or generally recognized independent standards of current medical practice define a condition or disorder as a mental health condition or substance use disorder, plans and issuers must treat all benefits for the condition or disorder as mental health benefits or substance use disorder benefits, respectively, for purposes of analyzing parity and ensuring compliance with MHPAEA. To better understand interested parties' concerns in implementing this requirement, the Departments solicited comments on potential challenges in applying MHPAEA to all benefits for a mental health condition or substance use disorder where a specific item or service can be furnished for both medical conditions or surgical procedures and mental health conditions or substance use disorders, and whether additional clarifications or modifications to the proposed definitions are necessary.

In response to this comment solicitation, commenters identified several instances in which an individual with a mental health or substance use disorder diagnosis may need a particular treatment for that condition or disorder that may also be provided to treat a medical condition. For example,

ASD⁵⁰ might be treated with speech and occupational therapy, which is also used to treat some medical conditions. Additionally, an eating disorder might require medical nutrition therapy, which could also be used to treat a medical condition (such as for the treatment of obesity or diabetes). Moreover, with respect to benefits for prescription drugs, a commenter noted that claims for reimbursement generally do not include diagnosis information. Some commenters explained that many specific prescription drugs are prescribed for mental health conditions and substance use disorders, as well as for medical/surgical conditions, and including diagnosis information would require a range of different entities and interested parties to change their current practice. Commenters also recommended several methods under which the rules could allow plans and issuers to characterize items and services as medical/surgical benefits, mental health benefits, or substance use disorder benefits. One commenter suggested items and services be characterized as either mental health benefits, substance use disorder benefits, or medical/surgical benefits based on the condition or disorder being treated. Similarly, another commenter suggested that items and services be characterized as mental health benefits or substance use disorder benefits when a claim's primary diagnosis is a mental health condition or substance use disorder, respectively, as that diagnosis is driving the treatment provided. Alternatively, several commenters suggested the rules could be aligned with existing Centers for Medicare & Medicaid Services (CMS) guidance on MHPAEA compliance for Medicaid and the Children's Health Insurance Program (CHIP) so that plans and issuers could use a "reasonable method" for defining services commonly used to treat both medical conditions and mental health conditions or substance use disorders, for example, by using the plan's or issuer's annual claims experience to determine its spending on the service in question.⁵¹

After reviewing comments received from interested parties, the Departments are finalizing the definitions of "medical/surgical benefits," "mental health benefits" and "substance use

disorder benefits" as proposed. While plans and issuers have some discretion in defining mental health benefits and substance use disorder benefits, this discretion must be exercised in a manner that comports with generally recognized independent standards of current medical practice, and the definitions in these final rules include sufficient safeguards to protect against defining a benefit in a manner that could result in limitations on access to mental health or substance use disorder benefits that are more restrictive than those applicable to medical/surgical benefits. Further, while the Departments acknowledge the concern that independent standards of current medical practice change over time and may not have been established with the same intents and purposes as State law or State guidelines, such standards better ensure that plans and issuers define mental health conditions and substance use disorders in a manner consistent with the purposes of MHPAEA. The Departments agree with one commenter's concern that some State laws, in particular, might predate MHPAEA. As a result, such State laws might not offer the same safeguards to access to mental health or substance use disorder benefits as MHPAEA. The Departments also note that plans and issuers are required to ensure that the definitions used in the plan or coverage are consistent with the appropriate chapters of the most current version of either the ICD or the DSM.

Additionally, while States generally are the traditional regulators of health insurance issuers, with respect to MHPAEA, the Departments are not persuaded that this necessitates permitting plans and issuers to use definitions of "medical/surgical benefits," "mental health benefits" and "substance use disorder benefits" that are solely tied to applicable State law or guidelines. The definitions of "medical/surgical benefits," "mental health benefits," and "substance use disorder benefits" in these final rules preserve the ability of plans and issuers to use applicable Federal and State law to inform their definitions, but only to the extent that those laws are consistent with generally recognized independent standards of current medical practice.⁵²

These final rules do not make any changes to the proposed definitions to specifically address how plans and

⁵⁰ As discussed later in this preamble, the Departments stated in the proposed rules and reiterate in these final rules that ASD is a mental health condition for purposes of MHPAEA.

⁵¹ CMS, Frequently Asked Questions: Mental Health and Substance Use Disorder Parity Final Rule for Medicaid and CHIP (Oct. 11, 2017), Q4, <https://www.medicaid.gov/federal-policy-guidance/downloads/faq101117.pdf>.

⁵² The final rules also permit plans and issuers to use applicable Federal and State law to inform their definitions to the extent generally recognized independent standards of current medical practice do not address whether a condition or disorder is a medical condition, surgical procedure, mental health condition, or substance use disorder.

issuers should apply MHPAEA where a specific item or service may be used to treat both medical conditions or surgical procedures as well as mental health conditions or substance use disorders. These final rules, like the proposed rules and the 2013 final regulations, require plans and issuers to continue to characterize items and services as medical/surgical benefits, mental health benefits, or substance use disorder benefits based on the condition or disorder being treated. This interpretation is the most appropriate reading of the definitions of medical/surgical benefits, mental health benefits, and substance use disorder benefits, consistent with the statute and the purpose of MHPAEA. The Departments note that the existing CMS mental health and substance use disorder parity guidance for Medicaid and CHIP identified by several commenters addresses long-term services and supports provided through Medicaid and CHIP, not items and services covered by group health plans and health insurance coverage. The Departments reiterate that, if a plan (or coverage) defines a condition or disorder as a mental health condition or substance use disorder, plans and issuers subject to these final rules must treat all benefits for the condition or disorder as mental health benefits or substance use disorder benefits, respectively, for purposes of compliance with MHPAEA. The Departments decline to adopt the alternative methods suggested by commenters that plans and issuers might use to characterize items and services as medical/surgical benefits, mental health benefits, or substance use disorder benefits, as they may be insufficient to ensure consistency with generally recognized independent standards of current medical practice and in accordance with applicable State and Federal law. Furthermore, while the Departments acknowledge the particular challenges with respect to prescription drug benefits due to the lack of diagnostic information on claims for reimbursement, these final rules, similar to the 2013 final regulations, provide plans and issuers enough flexibility to make decisions about how to classify items and services, including prescription drugs, as either mental health benefits, substance use disorder benefits, or medical/surgical benefits.

To provide guidance to plans and issuers on how to ensure that they define benefits consistent with generally recognized independent standards of current medical practice, the proposed rules proposed separate definitions of

the ICD and DSM. Specifically, the Departments proposed that the ICD would be defined as the World Health Organization's International Classification of Diseases adopted by HHS through 45 CFR 162.1002 or successor regulations, and the DSM would be defined as the APA's Diagnostic and Statistical Manual of Mental Disorders. The proposed definitions also specified, for purposes of the definition, which version of the ICD or DSM is the most current as of a particular date. This was intended to provide clarity on when a plan or issuer would be required to begin to rely on a new version of the ICD or DSM after it is released and allow sufficient time after the adoption of an updated version of the ICD or DSM for a plan or issuer to update the terms of its plan or coverage to be consistent with any changes made from the previous version. The proposed definitions stated that the most current version of the ICD or DSM, respectively, would be the version applicable no earlier than the date that is 1 year before the first day of the applicable plan year; however, the proposed rules would permit the use of an updated version before the plan or issuer is required to use it. Finally, in recognition of the fact that future versions of the ICD or DSM may include revisions to the categories of conditions or disorders or chapters listed in the proposed amended definitions for "mental health benefits" and "substance use disorder benefits," the proposed amended definitions referred to "equivalent categories" and "equivalent chapters."

The Departments received several comments on the proposed definitions of the terms "ICD" and "DSM," with some commenters suggesting alternatives to the language identifying the most current versions of the DSM and ICD. One commenter suggested specifying that if a new version of the DSM or ICD is published in the middle of a plan year, then plans and issuers must use the updated version by the start of the next plan year. One commenter suggested that the most current version of an independent standard should encompass any version commonly in use among providers, and any version used in the most recent claims experience available to plans and issuers.

The Departments are finalizing the definition of "ICD" as proposed, with clarifications with respect to the most current version of the ICD. Specifically, under these final rules, the most current version of the ICD as of November 22, 2024, the effective date of these final rules, is the International Classification

of Diseases, 10th Revision, Clinical Modification adopted for the period beginning on October 1, 2015, through HHS regulations at 45 CFR 162.1002 (or successor regulations).⁵³ Any subsequent version of the ICD adopted through 45 CFR 162.1002 (or successor regulations) after November 22, 2024, will be considered the most current version beginning on the first day of the plan year that is one year after the date the subsequent version is adopted.

The Departments are also finalizing the definition of "DSM" as proposed, with similar clarifications, which note that the most current version as of November 22, 2024, the effective date of these final rules, is the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision published in March 2022. A subsequent version of the DSM published after November 22, 2024, will be considered the most current version beginning on the first day of the plan year that is one year after the date the subsequent version is published (as the DSM is published, rather than made applicable). Consistent with this clarification, if a new version of the DSM is published in the middle of a plan year, plans and issuers will have at least one full year before they are required to use the updated version with respect to a plan year. For example, if a new version of the DSM is published on August 1, 2025, for a calendar year plan, that version of the DSM would be the most current version with respect to the plan year beginning on January 1, 2027.

It is important to provide specificity with regard to the relevant versions of the ICD and DSM instead of allowing the use of multiple versions, as suggested by commenters, to ensure that plans and issuers do not select a version that restricts access to mental health and substance use disorder benefits in a manner that is more restrictive than access to medical/surgical benefits. Because the Departments understand that the ICD and DSM are both broadly utilized by providers and facilities, as well as plans and issuers, and were referenced in the 2013 final regulations, these final rules continue to rely on such standards.

Finally, the preamble to the proposed rules noted that interested parties requested that the Departments confirm whether specific conditions are mental health conditions for purposes of MHPAEA. Consistent with the 2013 final regulations and section 13007 of

⁵³ These HHS regulations implement section 212 of the Protecting Access to Medicare Act of 2014 by setting compliance dates for the 10th Revision of the ICD for diagnosis and procedure coding.

the 21st Century Cures Act (Cures Act),⁵⁴ the Departments confirmed in the proposed rules that eating disorders, such as anorexia nervosa, bulimia nervosa, and binge-eating disorder, are mental health conditions under generally recognized independent standards of current medical practice.⁵⁵ Similarly, the proposed rules made clear that, for purposes of MHPAEA, ASD is a mental health condition under generally recognized independent standards of current medical practice.⁵⁶ Therefore, benefits for these disorders are considered mental health benefits, and subject to the protections of MHPAEA and its implementing regulations, including these final rules.

The Departments also solicited comments on other specific mental health conditions or substance use disorders that may warrant additional clarification for purposes of analyzing parity and ensuring compliance with MHPAEA. The Departments received only a few comments in response, including a request to clarify whether gender dysphoria is a mental health condition. Because the most current versions of both the ICD and DSM include gender dysphoria as a mental health condition as of the time of the issuance of these final rules, benefits for this condition are currently subject to the protections of MHPAEA and its implementing regulations, consistent with the framework described earlier in this preamble.⁵⁷

b. Processes, Strategies, Evidentiary Standards, and Factors

The proposed rules included proposed new definitions of terms used in paragraph (c)(4)(i) of the 2013 final regulations, which states that a plan or issuer may not impose an NQTL with respect to mental health or substance use disorder benefits in any classification unless, under the terms of the plan (or health insurance coverage) as written and in operation, any “processes,” “strategies,” “evidentiary standards,” or other “factors” used in

applying the NQTL to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, those used in applying the limitation with respect to medical/surgical benefits in the same classification. These terms and the corresponding standard were incorporated into MHPAEA’s statutory language in the amendments made by the CAA, 2021.⁵⁸ Because the Departments heard from interested parties prior to the issuance of the proposed rules that it can be difficult to determine what constitute relevant processes, strategies, evidentiary standards, and other factors, the Departments proposed definitions of these terms and included an illustration of the interaction of the definitions of these terms in the preamble to the proposed rules. The illustration described how a plan might rely on various combinations of processes, strategies, evidentiary standards, and other factors in designing and applying an NQTL, and gave examples of each term. The Departments also solicited comments on the proposed definitions, including any alternate definitions or additional clarifications that should be considered.

In general, many commenters supported the proposed definitions of these key terms, which they described as foundational to the development of sufficient comparative analyses and necessary to hold plans and issuers accountable for discriminatory NQTLs. Several commenters described widespread misinterpretation by plans and issuers of the meaning of these key terms. Other commenters wrote that the proposed definitions would help clarify the difference between “factors” and “evidentiary standards,” and draw a clear distinction between “strategies” and “processes,” which relate, respectively, to plans’ and issuers’ approaches to the design of an NQTL, and to their application of an NQTL. Other commenters stated that the definitions of these terms should clearly distinguish between each component of a plan’s or issuer’s required comparative analysis and assign each step of the analysis to a particular component of the comparative analysis. Additionally, a commenter requested more specific examples of processes and evidentiary standards, and the differences between factors and evidentiary standards. One commenter stated that the proposed definitions are not coherent as applied to network contracting activities, development of reimbursement

methodologies, or most other network composition NQTLs. This commenter claimed that there is no algorithmic approach to decision making that can be documented and requested the Departments to provide guidance on how the many activities involved in constructing provider networks and provider reimbursements across different plan types, service settings, and reimbursement methodologies should be categorized.

As stated in the preamble to the proposed rules, the proposed definitions for the terms “processes,” “strategies,” “evidentiary standards,” and “factors” are intended to further clarify how to properly apply and distinguish between these terms, and to help facilitate proper comparisons between the design and application of NQTLs to medical/surgical benefits and mental health and substance use disorder benefits in the same classification, compliance with the requirements related to NQTLs, and the development of sufficient comparative analyses, as required under the CAA, 2021 and these final rules. The definitions in these final rules improve clarity and add specificity to the terms used in MHPAEA, as amended by the CAA, 2021, to reduce misinterpretations, and are consistent with the requirements in these final rules that set forth the manner in which plans and issuers are required to perform and document comparative analyses, discussed later in this preamble. The Departments also provide additional guidance on how plans and issuers must comply with the provisions of these final rules with respect to NQTLs related to network composition,⁵⁹ later in this preamble.

The Departments note that nothing in these final rules requires an “algorithmic” decision making process; however, plans and issuers must perform and document their comparative analyses as required under 26 CFR 54.9812–2, 29 CFR 2590.712–1, and 45 CFR 146.137 to show that the processes, strategies, evidentiary standards, and other factors used in designing or applying an NQTL to mental health and substance use

⁵⁴ Public Law 114–255, 130 Stat. 1033 (Dec. 13, 2016). Section 13007 of the Cures Act states that, if a plan or an issuer offering group or individual health insurance coverage provides coverage for eating disorder benefits, including residential treatment, such group health plan or health insurance issuer shall provide such benefits consistent with the requirements of MHPAEA.

⁵⁵ See, e.g., DSM Disorders (5th ed.), Section II: Diagnostic Criteria and Codes, Feeding and Eating Disorders; ICD–10, Chapter V: Mental and behavioral disorders, Code F50: Eating disorders.

⁵⁶ DSM (5th ed.), Section II: Diagnostic Criteria and Codes, Autism Spectrum Disorder.

⁵⁷ DSM (5th ed.), Section II: Diagnostic Criteria and Codes, Gender Dysphoria; ICD–10, Chapter V: Mental and behavioural disorders, Code F64: Gender identity disorders.

⁵⁸ Code section 9812(a)(8)(A), ERISA section 712(a)(8)(A), and PHS Act section 2726(a)(8)(A).

⁵⁹ The term “NQTLs related to network composition” generally refers to the NQTLs listed in 26 CFR 54.9812–1(c)(4)(ii)(D), 29 CFR 2590.712(c)(4)(ii)(D), and 45 CFR 146.136(c)(4)(ii)(D) of these final rules: standards related to network composition, including but not limited to standards for provider and facility admission to participate in a network or for continued network participation, including methods for determining reimbursement rates, credentialing standards, and procedures for ensuring the network includes an adequate number of each category of provider and facility to provide services under the plan or coverage.

disorder benefits, as written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing or applying the NQTL to medical/surgical benefits in the relevant classification. Additionally, anything used by a plan or issuer to design or apply an NQTL should be considered a process, strategy, evidentiary standard, or factor (or information, evidence, sources, or standards on which a factor or evidentiary standard is based), consistent with the Departments' broad interpretation of these terms.

Under the proposed rules, the Departments proposed that evidentiary standards generally would not be considered factors, but instead would be considered or relied upon in designing or applying a factor. The Departments noted that, although the framework established in the 2013 final regulations treated the terms within the phrase "processes, strategies, evidentiary standards, and other factors" as having overlapping meanings (and the term "other factors" was utilized as a catch-all), the CAA, 2021 added to MHPAEA other references to factors and evidentiary standards that indicate Congress meant to distinguish between them.⁶⁰ The Departments requested comments on this approach to defining evidentiary standards separately from factors, including whether there are any circumstances under which an evidentiary standard should also be considered a factor under the framework outlined in the proposed rules, but did not receive any specific comments on this issue. Therefore, under these final rules, consistent with the proposed rules, evidentiary standards are not considered to be factors.

The proposed rules provided that the term "evidentiary standards" would mean any evidence, sources, or standards that a plan or issuer considered or relied upon in designing or applying a factor with respect to an NQTL, including specific benchmarks or thresholds. The proposed definition further provides that evidentiary standards may be empirical, statistical, or clinical in nature, and include sources acquired or originating from an objective third party, such as recognized medical literature, professional

standards and protocols (which may include comparative effectiveness studies and clinical trials), published research studies, payment rates for items and services (such as publicly available databases of the "usual, customary, and reasonable" rates paid for items and services), and clinical treatment guidelines. The proposed definition also provides that evidentiary standards would include internal plan or issuer data, such as claims or utilization data or criteria for assuring a sufficient mix and number of network providers, and benchmarks or thresholds, such as measures of excessive utilization, cost levels, time or distance standards, or network participation percentage thresholds.

One commenter recommended not including specific benchmarks or thresholds and professional standards and protocols in the definition of the term "evidentiary standards." The commenter noted that many plans and issuers do not define their evidentiary standards numerically and that finalizing the definition as proposed could require plans and issuers to do so, thereby compelling plans and issuers not to use relevant, critical data in the development of their NQTLs. The commenter also remarked that including professional standards and protocols in the definition would require plans and issuers to incorporate potentially unproven medical guidance as a standard to dictate mental health or substance use disorder benefits, which could override common medical management practices. The commenter added that, if the reference to professional standards and protocols is retained, the Departments should clarify that the definition of "evidentiary standards" does not imply that all professional standards and protocols must be referenced or that benchmarks or thresholds are required to be applied to professional standards and protocols.

The Departments are finalizing the definition of "evidentiary standards" as proposed. The definition is consistent with the use of the term by Congress in the amendments made to MHPAEA by the CAA, 2021. The definition of the term "evidentiary standards" does not require plans and issuers to define their evidentiary standards numerically, nor does it imply that all professional standards and protocols must be referenced or that benchmarks or thresholds are required to be applied to professional standards and protocols (for example, where the standards are qualitative in nature). However, to the extent these types of evidentiary standards are used to design or apply an NQTL, they must be analyzed for

compliance with MHPAEA. The list of examples of evidentiary standards included in the definition is not intended to be exhaustive, nor are any of the evidentiary standards listed required to be considered or relied upon in designing or applying a factor with respect to an NQTL.

In the proposed rules, the Departments proposed that the definition of the term "factors" be read broadly, so that factors are all information, including processes and strategies (but not evidentiary standards), that a plan or issuer considered or relied upon to design an NQTL or to determine whether or how the NQTL applies to benefits under the plan or coverage. The Departments noted that by defining the term "factor" broadly, the Departments' intention was to capture any information used to design or apply an NQTL (other than evidentiary standards), regardless of whether a plan or issuer believes that information could also be characterized as a "process" or a "strategy," as those terms were proposed to be defined. The Departments proposed that the term "factors" includes information (but not evidentiary standards) that the plan or issuer considered but rejected, consistent with previous guidance on MHPAEA in the context of the documents or plan information the Departments consider relevant to a compliance determination.⁶¹ The proposed definition also provided examples of factors, which include, but are not limited to, provider discretion in determining diagnosis or type or length of treatment; clinical efficacy of any proposed treatment or service; licensing and accreditation of providers; claim types with a high percentage of fraud; quality measures; treatment outcomes; severity or chronicity of condition; variability in the cost of an episode of treatment; high cost growth; variability in cost and quality; elasticity of demand; and geographic location.

⁶¹ See FAQs About Affordable Care Act Implementation Part 31, Mental Health Parity Implementation, and Women's Health and Cancer Rights Act Implementation, Q9 (Apr. 20, 2016), <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-31.pdf> and <https://www.hhs.gov/guidance/document/affordable-care-act-implementation-faqs-set-31>, which states that a plan must provide documents and plan information to a participant or beneficiary, or their authorized representative, including the specific underlying processes, strategies, evidentiary standards, and other factors (including, but not limited to, all evidence) considered by the plan (including factors that were relied upon and were rejected) in determining that the NQTL will apply to a particular mental health and substance use disorder benefit or any medical/surgical benefits within the benefit classification at issue.

⁶⁰ The preamble to the proposed rules noted that, for example, Code section 9812(a)(8)(A)(iii), ERISA section 712(a)(8)(A)(iii), and PHS Act section 2726(a)(8)(A)(iii) refer to the evidentiary standards that are used for the factors to determine that an NQTL will apply to benefits, and those provisions go on to distinguish between factors and any other sources or evidence relied upon to design or apply an NQTL. See 88 FR 51552, 51567 (Aug. 3, 2023).

With respect to the “broad” reading of the term “factor,” a commenter stated that the proposed definition subsumes “processes” and “strategies,” and suggested eliminating or clarifying this distinction with additional guidance. The commenter also remarked that the broad definition of “factor” would make the multiple steps in a comparative analysis less distinguishable, and the requirement that plans identify, define, and describe the use of every factor in the design or application of an NQTL unworkably expansive. A few commenters remarked that the breadth of the definition of “factor” makes it unclear how a plan or issuer would demonstrate that a factor is unbiased or not discriminatory for the purposes of the comparative analyses and recommended narrowing the definition of “factor” to distinguish it from evidentiary standards, processes, and strategies, and instead use the term to describe the basis for the plan’s or issuer’s application of an NQTL. Another commenter recommended not including information that the plan or issuer considered but rejected in the definition of factors, because it is not illustrative of the ultimate value of the mental health or substance use disorder benefit or the plan’s or issuer’s compliance with MHPAEA’s NQTL standards. The commenter stated that the actual design of the benefit and how it translates to payments, denials, and reimbursement should substantiate whether the benefit design complies with parity requirements, without examining extraneous information on considerations early in the benefit’s development process. A commenter suggested the Departments include an example of what the Departments would consider a complete definition of a factor and information about how to specify the weight assigned to factors.

The Departments are finalizing the definition of the term “factor” as proposed. The definition and list of examples of factors in the definition contained in these final rules are sufficiently detailed to provide context to plans and issuers in identifying factors, including by distinguishing evidentiary standards from factors and acknowledging that factors other than processes and strategies, which are types of factors, may exist. Under the 2013 final regulations, plans and issuers were permitted to utilize a wide array of factors in designing and applying their NQTLs to mental health and substance use disorder benefits provided they were comparable to, and applied no more stringently than, those utilized to design and apply NQTLs to medical/

surgical benefits. Similarly, the CAA, 2021 did not limit what factors plans and issuers could use to design and apply their NQTLs, but instead required that these factors be identified and analyzed in the comparative analyses.

As noted in the preamble to the proposed rules, taking into account not only the factors that the plan or issuer relied upon, but also those that were considered but ultimately rejected in the definition of factors, is consistent with previous guidance on MHPAEA, namely because it is a factor that a plan or issuer uses in designing and applying an NQTL. The Departments recognize that the language used in the proposed rules, which included factors that were *considered* and rejected, rather than those that are *relied upon* and rejected, could be interpreted as including a broader set of information than prior guidance, which had interpreted “considered” to include “factors that were relied upon and were rejected.” The Departments did not intend to broaden the set of information included as a factor, and agree with the commenter who questioned the utility of providing information that was considered early in the design process but rejected. However, the Departments affirm that taking into account information that the plan or issuer relied upon and rejected in the definition of factors is necessary to analyze compliance with MHPAEA.

In the proposed rules, the Departments proposed to define “processes” and “strategies” as types of factors, and to clarify the differences between the two terms as they relate to the design and application of an NQTL. Specifically, the Departments proposed defining “processes” as relating to the application of an NQTL, while “strategies” would relate to the design of an NQTL. After review of the comments, the Departments continue to be of the view that the best read of the statutory text (as well as the 2013 final regulations) is that processes and strategies are types of factors, rather than components of a factor to be separately evaluated.

The Departments proposed to define “processes” to mean actions, steps, or procedures that a plan or issuer uses to apply an NQTL, including actions, steps or procedures established by the plan or issuer as requirements in order for a participant or beneficiary to access benefits, including through actions by a participant’s or beneficiary’s authorized representative or a provider or facility. Under the proposed rules, processes include, but are not limited to: prior authorization procedures, provider referral requirements, and the

development and approval of a treatment plan. The proposed definition also provided that processes include the specific procedures used by staff or other representatives of a plan or issuer (or the service provider of a plan or issuer) to administer the application of NQTLs, such as how a panel of staff members applies the NQTL (including the qualifications of staff involved, number of staff members allocated, and time allocated), consultations with panels of experts in applying the NQTL, and reviewer discretion in adhering to criteria hierarchy when applying an NQTL.

A commenter expressed appreciation for the proposed rules’ intent and requested the Departments to include more specific examples of “processes.” Another commenter stated that the proposed definition for “processes” is too broad and focuses only on the end result of access to benefits, which the commenter stated is inconsistent with the Departments’ previous guidance and regulations, and recommended narrowing the definition to focus on the operational application of any requirements.

After reviewing comments, the Departments are finalizing the definition of the term “processes,” with minor changes so that the examples of processes more clearly illustrate the way the action, step, or procedure is used to apply an NQTL.⁶² While the Departments decline to add examples to the definition, these modifications will add clarity to the definition in these final rules.⁶³ The Departments note that the final definition of the term does not focus only on the end result of access to benefits, but also includes the operational application of an NQTL, as evidenced by the framing of the definition in terms of actions, steps, or procedures used to apply an NQTL. For example, prior authorization processes include the procedures established by a plan or issuer for a review to determine how a specific request for prior authorization should be granted or denied. Concurrent review processes include the procedures established by a plan or issuer for a review to determine whether a specific request should be

⁶² The Departments are also finalizing a non-substantive modification so that the definition more closely parallels the definition of “strategies.”

⁶³ For example, these final rules clarify that provider referral requirements are processes if they are used to determine when and how a participant or beneficiary may access certain services. Similarly, the development and approval of a treatment plan are processes if they are used in a concurrent review process to determine whether a specific request should be granted or denied.

granted or denied, such as when peer-to-peer review is required.

The proposed rules proposed to define “strategies” as practices, methods, or internal metrics that a plan or issuer considers, reviews, or uses to design an NQTL, and included examples of strategies. The proposed definition of strategies included the following examples: the development of the clinical rationale used in approving or denying benefits; deviation from generally accepted standards of care; the selection of information (such as from medical or clinical guidelines) deemed reasonably necessary to make a medical necessity determination; reliance on treatment guidelines or guidelines provided by third-party organizations; and rationales used in selecting and adopting certain threshold amounts, professional protocols, and fee schedules. The proposed definition of strategies also specifically included: the creation and composition of the staff or other representatives of a plan or issuer (or the service provider of a plan or issuer) that deliberates, or otherwise makes decisions, on the design of NQTLs, including the plan’s or issuer’s decisions related to qualifications of staff involved; number of staff members allocated, and time allocated; breadth of sources and evidence considered; consultations with panels of experts in designing the NQTL; and the composition of the panels used to design an NQTL.

One commenter supported the inclusion in the definition of “strategies” of practices that involve “deviations from generally accepted standards of care.” Several commenters also recommended that the Departments include actions to detect or prevent and prove fraud, waste, and abuse in the definitions of either or both “processes” and “strategies,” rather than including those actions as a stand-alone exception from the NQTL requirements in the final rules. Another commenter appreciated the clear distinction made in the proposed definitions of processes and strategies and stated that they would appreciate if these distinctions tracked with separate steps in the comparative analyses.⁶⁴

The Departments are generally finalizing the definition of the term “strategies” with some minor changes to the examples to add specificity. The definition of the term “strategies” in these final rules includes examples of strategies used to design an NQTL, such as the method of determining whether and how to deviate from generally

accepted standards of care in concurrent reviews; rationales used in selecting and adopting certain threshold amounts to apply an NQTL; professional standards and protocols to determine utilization management standards; and fee schedules used to determine provider reimbursement rates, used as part of an NQTL. The Departments note that, once a plan or issuer uses a strategy to design an NQTL, that design also may result in the establishment or use of processes to apply the NQTL.

While the Departments acknowledge comments suggesting that actions to detect or prevent and prove fraud, waste, and abuse be defined as either “processes” or “strategies,” and acknowledge that such actions certainly could constitute either processes or strategies (depending on whether the action is undertaken to design or apply the NQTL), the Departments decline to add a specific reference to actions to detect or prevent and prove fraud, waste, and abuse to the relevant definitions, as the proposed exception for standards to detect or prevent and prove fraud, waste, and abuse is not being finalized, as discussed later in this preamble.⁶⁵ However, the Departments are providing additional language to explain what constitutes a standard to detect or prevent and prove fraud and abuse (also referred to as “fraud and abuse measures”) later in this preamble and how such standards must comply with MHPAEA under these final rules.

c. Treatment Limitations

The Departments proposed to amend the definition of “treatment limitations” to clarify that the illustrative list of NQTLs to which the definition refers is non-exhaustive and to amend the last sentence to state that a “complete” (rather than “permanent”) exclusion of all benefits for a particular condition or disorder is not a treatment limitation for purposes of the definition. In the preamble to the proposed rules, the Departments noted that, while NQTLs are generally defined as treatment limitations that are not expressed

numerically, the application of an NQTL in a numerical way does not modify its nonquantitative character simply because the NQTL sometimes involves numerical standards, and such NQTLs would still be evaluated in accordance with the rules for NQTLs under the statute and implementing regulations.

Several commenters supported the Departments’ amendment to the definition of “treatment limitation” to specify that “a complete exclusion of all benefits for a particular condition or disorder is not a treatment limitation for purposes of this definition,” rather than retaining the reference in the 2013 final regulations to a “permanent” exclusion. These commenters stated that the proposed definition more clearly specifies that a plan or issuer can exclude a particular condition or service without creating an NQTL, but that in doing so, the exclusion must be total. The commenters suggested the Departments include specific examples of permissible exclusions and impermissible exclusionary language. Other commenters expressed concern that the proposed definition of “treatment limitation” is too broad and argued that the proposed definition would lead to increased uncertainty in determining which common plan practices could constitute an NQTL. One commenter stated that if there is no comparable medical or surgical treatment limitation, there is nothing to compare a treatment limitation on a mental health or substance use disorder benefit to, and that therefore such a limitation on the mental health or substance use disorder benefit is not subject to parity requirements. Several commenters recommended adopting a consistent and exhaustive definition for determining whether a medical management technique is a treatment limitation.

The Departments are finalizing the definition of “treatment limitation” as proposed, with minor modifications to add an example of an NQTL. As reflected in the definition, medical management techniques are NQTLs if they limit the scope or duration of treatment. While the definition as amended is broad, plans and issuers have great latitude in the types of limitations that they may impose, and the Departments understand that plans and issuers do in fact impose a broad range of limitations on the scope or duration of treatment. In enacting MHPAEA and the amendments to MHPAEA contained in the CAA, 2021, Congress did not prohibit the use of these limitations for mental health and substance use disorder benefits, but

⁶⁴ The content elements of comparative analyses are addressed later in this preamble.

⁶⁵ The proposed rules referred to fraud, waste, and abuse. However, as explained later in this preamble, the Departments agree with commenters that the term “waste” can be construed in a manner that is overly broad. Thus, in these final rules, when discussing the exception in the proposed rules for NQTLs that are narrowly and reasonably designed to detect or prevent and prove fraud, waste, and abuse, while minimizing the impact on access to appropriate mental health and substance use disorder benefits, this preamble refers to “fraud, waste, and abuse measures.” When discussing provisions of this final rule related to carefully circumscribed measures reasonably and appropriately designed to detect or prevent and prove fraud and abuse, this preamble refers to “fraud and abuse measures.”

required that plans and issuers ensure that NQTLs satisfy the statutory requirements that (1) any treatment limitations imposed on mental health and substance use disorder benefits are no more restrictive than the predominant treatment limitations imposed on substantially all medical/surgical benefits; (2) that no treatment limitations be imposed only with respect to mental health and substance use disorder benefits; and (3) that plans and issuers perform and document comparative analyses of the design and application of NQTLs. Because of the broad range of treatment limitations that plans and issuers may impose, combined with the freedom that plans and issuers have to design their own unique limitations, the Departments cannot provide a comprehensive and exhaustive list of all limitations, as further explained later in this preamble.

The Departments note that if a plan or issuer applies a treatment limitation to mental health and substance use disorder benefits where medical/surgical benefits are not subject to a comparable treatment limitation in the same classification, the plan or issuer would violate MHPAEA because it must not apply separate treatment limitations only to mental health and substance use disorder benefits. Further, the Departments have stated that, if a plan or issuer provides any benefits for a mental health condition or substance use disorder but excludes benefits for items or services for that condition or disorder in a classification in which it provides medical/surgical benefits, such an exclusion of a benefit for a condition or disorder that is otherwise covered is a treatment limitation because it is a limit on the scope or duration of treatment offered.⁶⁶ While the Departments decline to provide additional examples of permissible exclusions and impermissible exclusionary language in these final rules, examples of such exclusions and language have been provided in guidance and in the Departments' reports to Congress.

3. Nonquantitative Treatment Limitations—26 CFR 54.9812–1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4)

In the proposed rules, the Departments proposed changes designed to better ensure that plans and issuers do not design and implement NQTLs that impose greater restrictions on access to mental health and substance use disorder benefits as compared to medical/surgical benefits.

The Departments proposed to add requirements that apply to NQTLs with respect to mental health and substance use disorder benefits, to ensure that plans and issuers do not impose a greater burden on participants and beneficiaries accessing those benefits than the burden imposed on participants and beneficiaries accessing medical/surgical benefits, while preserving the ability of plans and issuers to impose NQTLs to the extent they are consistent with generally recognized independent professional medical or clinical standards or legitimate and narrowly designed standards related to fraud, waste, and abuse. Subject to those two narrow exceptions for those types of NQTLs, the proposed rules provided that plans and issuers would not be permitted to impose an NQTL on mental health or substance use disorder benefits unless they satisfied all of the following three requirements: (1) the NQTL is no more restrictive as applied to mental health and substance use disorder benefits than to medical/surgical benefits (also referred to as the no more restrictive requirement); (2) the plan or issuer satisfies requirements related to the design and application of the NQTL (also referred to as the design and application requirements); and (3) the plan or issuer collects, evaluates, and considers the impact of relevant data on access to mental health and substance use disorder benefits relative to access to medical/surgical benefits; and subsequently takes reasonable action, as necessary, to address any material differences in access shown in the data to ensure compliance with MHPAEA (also referred to as the relevant data evaluation requirements).

Specifically, under the no more restrictive requirement, the proposed rules specified that a plan or issuer may not apply any NQTL to mental health or substance use disorder benefits in any classification that is more restrictive, as written or in operation, than the predominant NQTL that applies to substantially all medical/surgical benefits in the same classification. This requirement was intended to ensure that the implementing regulations more closely mirrored the statutory language in Code section 9812(a)(3)(A), ERISA section 712(a)(3)(A), and PHS Act section 2726(a)(3)(A).

The proposed rules outlined a four-prong test for a plan or issuer to determine compliance with the no more restrictive requirement. Specifically, this provision would have required plans and issuers to determine: (1) the portion of plan payments for medical/surgical benefits subject to an NQTL in

a classification; (2) whether the NQTL applies to substantially all medical/surgical benefits in the classification; (3) if the NQTL applies to substantially all medical/surgical benefits in the classification, the predominant variation of the NQTL that applies to substantially all medical/surgical benefits in the classification; and (4) whether the NQTL, as applied to mental health and substance use disorder benefits in the classification, is more restrictive than the predominant variation of the NQTL as applied to substantially all medical/surgical benefits.

The second proposed requirement for NQTLs, the design and application requirements, retained the requirements for NQTLs from the 2013 final regulations focused on the processes, strategies, evidentiary standards, and other factors used to apply an NQTL, with a proposed modification to better align the rules with the statute's focus on the design of an NQTL in addition to its application. In addition, the Departments proposed to prohibit plans and issuers from relying upon any factor or evidentiary standard if the information, evidence, sources, or standards on which the factor or evidentiary standard was based discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits.

The third requirement for NQTLs under the proposed rules, the relevant data evaluation requirements, proposed to require plans and issuers to collect and evaluate relevant outcomes data and take reasonable action to address material differences in access between mental health and substance use disorder benefits and medical/surgical benefits as necessary to ensure compliance, in operation, with MHPAEA. This requirement also included a proposed special rule for NQTLs related to network composition.

The proposed rules stated that, if a plan or issuer fails to meet any of the three requirements under the proposed rules with respect to an NQTL in a classification, the NQTL would violate MHPAEA and, as a result, could not be imposed on mental health or substance use disorder benefits in the classification without changes to the terms of the plan or coverage, or the way the NQTL is designed or applied, to ensure compliance with MHPAEA.

The Departments proposed two limited exceptions to some of the requirements for NQTLs, consistent with the Departments' intention to avoid interference with a plan's or issuer's attempts to ensure that NQTLs imposed with respect to benefits for

⁶⁶ See 75 FR 5410, 5413 (Feb. 2, 2010).

treatment of mental health conditions or substance use disorders are consistent with generally accepted independent professional medical or clinical standards of care (also referred to as independent professional medical or clinical standards) or are narrowly and reasonably designed to detect or prevent and prove fraud, waste, and abuse, while minimizing the impact on access to appropriate mental health and substance use disorder benefits (also referred to as fraud, waste, and abuse measures). The Departments proposed to exempt NQTLs qualifying for the exception for independent professional medical or clinical standards from compliance with the no more restrictive requirement, the prohibition on discriminatory factors and evidentiary standards, and the relevant data evaluation requirements. The Departments proposed to exempt NQTLs qualifying for the exception for fraud, waste, and abuse measures from compliance with the no more restrictive requirement and the prohibition on discriminatory factors and evidentiary standards, but not the relevant data evaluation requirements.

Finally, the Departments proposed to make clear that a plan or issuer that has received a final determination of noncompliance under the comparative analysis review process established by the CAA, 2021, including a final determination of noncompliance based on failure to provide a sufficient comparative analysis, would also be in violation of the substantive requirements that apply to NQTLs under MHPAEA, as determined by the Departments. Upon such a determination, the proposed rules would permit the Departments to direct the plan or issuer to not impose the NQTL that is the subject of the comparative analysis, unless and until the plan or issuer can demonstrate compliance or take appropriate action to remedy the violation.

The Departments requested comments on all aspects of these proposed amendments, including the exceptions to the proposed rules regarding NQTLs. Many commenters expressed support for these provisions of the proposed rules as a whole, as a means of achieving increased access to mental health and substance use disorder benefits by targeting NQTLs that otherwise impede access. Other commenters expressed support for the proposed rules' enhanced specificity with respect to the requirements for imposing NQTLs, with one commenter also indicating that the proposals would help State insurance regulators better

enforce MHPAEA and clarify plans' and issuers' compliance obligations.

However, other commenters expressed the view that these provisions of the proposed rules were complex, ambiguous, confusing, subject to interpretation, or difficult to operationalize, which they argued could lead to substantial uncertainty for plans and issuers attempting to comply. Commenters also stated that it may be impossible for plans or issuers to meet the proposed mathematical substantially all and predominant tests as applied to NQTLs, leading them to eliminate necessary utilization management tools. Some commenters also indicated that these provisions of the proposed rules could lead to inconsistent application of NQTLs across plans administered by the same TPA or issuer, which could result in administrative complexity and cause confusion for consumers and providers. Other commenters highlighted that the proposed requirements would significantly increase the cost of administering plans and health insurance coverage. One commenter indicated that some plans might consider excluding all treatments or services for a particular mental health condition or substance use disorder as a result of the additional burdens imposed by the substantially all and predominant tests, if finalized as proposed. Some commenters also stated that the additional proposed requirements for NQTLs do not add value beyond distinctions already captured by the design and application requirements included in the 2013 final regulations, with some commenters stating those additional requirements go beyond MHPAEA's statutory requirements. Comments specific to each of the three requirements and two exceptions proposed at 26 CFR 54.9812–1(c)(4)(i), (ii), and (iv); 29 CFR 2590.712(c)(4)(i), (ii), and (iv); and 45 CFR 146.136(c)(4)(i), (ii), and (iv) are discussed in greater detail later in this preamble.

The Departments acknowledge the concerns expressed by commenters and, in response to comments, the Departments are finalizing a modified framework that is still intended to prevent plans and issuers from designing and applying NQTLs that impose greater burdens on access to mental health and substance use disorder benefits as compared to medical/surgical benefits, while limiting uncertainty, increases in cost, operational difficulty, and unintended consequences. These final rules streamline the proposed rules' general requirements to eliminate redundancies and add clarity for plans and issuers in

a manner that remains consistent with the statutory text of MHPAEA, while also ensuring participants and beneficiaries will not face greater restrictions on access to mental health and substance use disorder benefits as compared to medical/surgical benefits.

These final rules do not finalize the language of the proposed “no more restrictive” requirement, as discussed in more detail later in this preamble, and instead incorporate the statutory requirements of Code section 9812(a)(3)(A), ERISA section 712(a)(3)(A), and PHS Act section 2726(a)(3)(A) as the overall general rule for NQTLs in 26 CFR 54.9812–1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4). Specifically, these final rules state that, consistent with the fundamental purpose of MHPAEA, a group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) may not impose any NQTL with respect to mental health or substance use disorder benefits in any classification that is more restrictive, as written or in operation, than the predominant NQTL that applies to substantially all medical/surgical benefits in the same classification. However, as discussed later in this preamble, the Departments are declining to finalize the proposed four-prong test for the no more restrictive requirement, which was proposed to determine compliance with statutory requirements as they apply to NQTLs.⁶⁷ Rather, to demonstrate compliance with the no more restrictive requirement, which is now the general rule for NQTLs, a plan or issuer is required under these final rules to satisfy (1) the design and application requirements and (2) the relevant data evaluation requirements, each of which the Departments are finalizing with modifications, as discussed in more detail later in this preamble. Additionally, the Departments are not finalizing the exceptions set forth in the proposed rules, but have added language to these final rules to explain how plans and issuers should analyze and account for independent professional medical or clinical standards and fraud and abuse measures in designing and applying their NQTLs. Finally, the Departments are finalizing a provision providing that, depending on the relevant facts and circumstances, the Departments or an applicable State authority may direct a plan or issuer that has received a final determination of noncompliance under the comparative analysis review process

⁶⁷ Code section 9812(a)(3)(A), ERISA section 712(a)(3)(A), and PHS Act section 2726(a)(3)(A).

established by the CAA, 2021 to not apply an impermissible NQTL.

a. Requirement That NQTLs Be No More Restrictive for Mental Health Benefits and Substance Use Disorder Benefits—26 CFR 54.9812–1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4)

Through the proposed mathematical substantially all and predominant tests for NQTLs as part of the no more restrictive requirement, the Departments proposed to require plans and issuers to follow similar steps to those that apply when analyzing parity with respect to financial requirements or quantitative treatment limitations under the 2013 final regulations (referred to in this preamble as the proposed mathematical substantially all and predominant tests). As noted in the proposed rules, the steps in the proposed mathematical substantially all and predominant tests would have involved determining the portion of plan payments for medical/surgical benefits subject to an NQTL in a classification; whether the NQTL applies to substantially all medical/surgical benefits in the classification; if the NQTL applies to substantially all medical/surgical benefits in the classification, the predominant variation of the NQTL that applies to substantially all medical/surgical benefits in the classification; and whether the NQTL, as applied to mental health and substance use disorder benefits in the classification, is more restrictive than the predominant variation of the NQTL, as applied to substantially all medical/surgical benefits.

Many commenters generally supported application of the proposed mathematical substantially all and predominant tests to NQTLs, with some indicating that the tests would provide additional clarity, eliminate subjectivity, assist regulators, and result in compliance improvements. Many of these commenters also stated that the statute clearly supports the tests, as it requires treatment limitations to be “no more restrictive” than the predominant treatment limitations that apply to substantially all medical/surgical benefits. Other commenters generally opposed the inclusion of the substantially all and predominant tests for NQTLs as part of the no more restrictive requirement. Some of these commenters stated that the proposed mathematical substantially all and predominant tests are a reversal of policy from the 2013 final regulations and are inconsistent with congressional intent, because Congress codified the design and application requirements

from the 2013 final regulations in the CAA, 2021. These commenters highlighted that the Departments had stated previously that they understood NQTLs could not be easily quantified and that the Departments had not sufficiently explained their change in interpretation under the proposed rules.

Some commenters expressed general concerns that NQTLs are inherently unquantifiable, arguing that the proposal would result in unworkable standards or arbitrary outcomes that could prohibit plans and issuers from using evidence-based medical guidelines or other relevant factors specific to the item or service under consideration. Commenters also raised concerns that imposition of the proposed mathematical substantially all and predominant tests on certain types of NQTLs that are not commonly utilized for medical/surgical benefits may lead to some types of legitimate NQTLs no longer being permitted with respect to mental health and substance use disorder benefits. Specifically, several of these commenters contended that the proposed mathematical substantially all and predominant tests, as proposed, would result in the elimination of plans’ and issuers’ ability to impose certain NQTLs with respect to mental health and substance use disorder benefits, such as step therapy, prior authorization, and concurrent review, which they posited would negatively impact the quality and cost of care. Some commenters also cited potential negative, unintended consequences of the application of the proposed mathematical substantially all and predominant tests, as proposed, including patient safety concerns; impacts on health outcomes, quality, and affordability; and a chilling effect on access improvements and innovation. Further, some commenters expressed concern with the increased costs associated with complying with the proposed mathematical substantially all and predominant tests, with some stating that this increased burden would not be offset by any resulting increase in access to mental health and substance use disorder benefits for participants and beneficiaries.

Several commenters expressed confusion as to how these tests, as proposed, would be applied in practice and highlighted the need for more detail. Specifically, some commenters stated that these proposed provisions lack clarity in how the tests apply to certain types of NQTLs (including those related to network composition), and the potential consequences of enforcement of these requirements. Many commenters provided specific

comments and feedback on aspects of each part of the substantially all and predominant tests included in the proposed rules, as discussed later in this preamble, and highlighted ambiguities and challenges operationalizing the proposed quantitative testing requirements with respect to NQTLs.

Under the first prong of the proposed mathematical substantially all and predominant tests, plans and issuers would have been required to determine the portion of plan payments for medical/surgical benefits in the classification expected to be subject to the NQTL based on the dollar amount of all plan payments for medical/surgical benefits in the classification expected to be paid under the plan or coverage for the plan year (or the portion of the plan year after a change in benefits that affects the applicability of the NQTL). The proposed rules stated that, for purposes of this determination, any reasonable method could be used to determine the dollar amount expected to be paid under a plan for medical/surgical benefits.

The Departments received many comments on the proposed requirement that the plan or issuer determine the portion of plan payments for medical/surgical benefits expected to be subject to an NQTL in the benefit classification. Several commenters indicated that the determination of the dollar amount of all plan payments for medical/surgical benefits expected to be paid may be an inappropriate measure altogether because NQTLs like medical management, assessments related to medical necessity, experimental/investigational treatment exclusions, prior authorization requests, and provider network admission standards are not generally attached to claims. Some commenters highlighted that self-insured plan sponsors may face challenges in obtaining a complete and reliable set of plan-level claims data, and accordingly, would have limited data to use to assess individual NQTLs, or would incur additional costs.

After determining the portion of plan payments for medical/surgical benefits in the classification expected to be subject to the NQTL, the Departments proposed that, under the second prong, plans and issuers would be required to determine whether the NQTL applies to substantially all medical/surgical benefits in the classification, based on the dollar amount of all plan payments for medical/surgical benefits in the classification expected to be paid under the plan for the plan year. Under the proposed rules, an NQTL would be considered to apply to substantially all medical/surgical benefits in a

classification if it applies to at least two-thirds of all medical/surgical benefits in that classification. Under the proposed rules, whether the NQTL applies to at least two-thirds of all medical/surgical benefits would be determined without regard to whether the NQTL was triggered based on a particular factor or evidentiary standard.⁶⁸ The proposed rules further provided that if an NQTL does not apply to at least two-thirds of all medical/surgical benefits in a classification, that NQTL would not be permitted to be applied to mental health or substance use disorder benefits in that classification.

The Departments received many comments regarding this prong of the proposed mathematical substantially all and predominant tests. As mentioned earlier in this preamble, many commenters stated that, in practice, a numerical “substantially all” determination would be difficult to apply and assess for NQTLs for many reasons, including because they are often not quantifiable, and there are more medical/surgical items and services (and associated benefits) than there are mental health and substance use disorder items and services. Additionally, commenters highlighted that plans and issuers already experience difficulty in obtaining data from service providers and would have difficulty in determining which NQTLs apply to at least two-thirds of medical/surgical benefits in a classification. Some commenters predicted that, if the Departments finalize the substantially all and predominant tests as proposed, plans and issuers might increase the application of NQTLs to medical/surgical benefits to meet the two-thirds threshold.

Further, some commenters requested that the Departments specify and provide examples showing how to apply the substantially all test to NQTLs that are not associated with plan payments, such as prescription drug formularies and network composition standards. One commenter highlighted that it is difficult to calculate the amount of plan payments expected to be paid for prescription drugs subject to an NQTL.

⁶⁸ For example, if a plan or issuer applies a general exclusion for all benefits in a classification that are for experimental or investigative treatment, and defines experimental or investigative treatment to be treatments with less than a certain number of peer-reviewed studies demonstrating efficacy, under the proposed rules, the exclusion would be treated as applying to all of the benefits in the classification—not just those that may be subject to the general exclusion for experimental or investigative treatment because they lack the requisite number of peer-reviewed studies (that is, those that actually triggered the NQTL based on the evidentiary standard). 88 FR 51552, 51570 (Aug. 3, 2023).

Another commenter urged the Departments to clarify the determination of whether an NQTL applies regardless of whether the NQTL was triggered. For example, this commenter highlighted that insurers might state that prior authorization “applies” to all benefits in a classification where a benefit is considered or evaluated under the various factors for determining whether to apply prior authorization, even if the benefit ultimately is determined to not be subject to prior authorization based on the application of factors and evidentiary standards.

In addition, in the proposed rules, the Departments solicited comments on whether plans and issuers maintain systems capable of determining, under the proposed mathematical substantially all and predominant tests, whether an NQTL applies to substantially all medical/surgical benefits in a classification, and the administrative burden that would be associated with such determinations. Several commenters highlighted that it would be difficult to comply with the substantially all and predominant tests as proposed, including because the requisite data may be housed in different parts of a plan’s or issuer’s organization. One commenter emphasized that current administrative systems would need to be adapted, and plans and issuers would need to hire additional staff or service providers to be able to perform the analysis that would be required under the proposed mathematical substantially all and predominant tests.

Under the proposed rules, if a plan or issuer determined that an NQTL applies to substantially all medical/surgical benefits in a classification, the third prong of the test would require a plan or issuer to determine the predominant variation of the NQTL that is applied to substantially all medical/surgical benefits subject to the NQTL in the classification. The Departments proposed that the term “predominant” would, for this purpose, mean the most common or most frequent variation of an NQTL within a benefit classification.

The Departments received many comments regarding this part of the proposed tests. Numerous commenters stated that this aspect of the substantially all and predominant tests is unworkable. Some commenters noted that, with a lack of guidance on how to identify all the variations of a particular NQTL (especially those that are complex and nuanced), the proposed rules may not be feasible for plans, issuers, and regulators to apply in real-life situations. Several commenters

stated that, while financial requirements and quantitative treatment limitations will have only a few different variations, NQTLs are multifactorial and each difference could be considered a different variation, or even a separate NQTL. For example, some of these commenters highlighted that prior authorization or concurrent review may take varied forms: an admission that requires advance prior authorization; an admission that requires notification but no clinical review; a nonclinical review based on predetermined standards; a first-level or nurse clinical review; a second-level or physician clinical review; and a peer-to-peer clinical review. These commenters noted that some processes may be automated or manual, some may be handled by vendors or directly by the plan or issuer, and some may have multiple utilization management systems within all of the aforementioned categories. Another commenter highlighted that a plan or regulator could conceivably determine that “variations” include a wide range of aspects, such as the credentials of the reviewer, the type or source of clinical criteria applied, the timing of the review (for example, urgent vs. nonurgent), the modality of authorization submission (for example, via electronic health record vs. fax or pdf form), among others. As a result, these commenters stated that determining how to identify the predominant variation of an NQTL may not be feasible without additional clarifications. Many commenters requested that the Departments provide a definition of the term “variation” and an explanation of how to determine whether a variation exists, as well as additional guidance and examples illustrating when an NQTL has no variation and when an NQTL has multiple variations (beyond variations based on numerical distinctions). These commenters also noted that, under the proposed rules, the predominant variation may only apply to a small percentage of medical/surgical services or items in the applicable benefit classification.

Lastly, under the fourth prong, the proposed rules provided that an NQTL applied to mental health or substance use disorder benefits cannot be *more restrictive* than the predominant variation of the NQTL applied to substantially all medical/surgical benefits in the same classification. Under the proposed rules, for this purpose, an NQTL would be considered restrictive if it imposes conditions, terms, or requirements that limit access to benefits under the terms of the plan or coverage. For this purpose,

conditions, terms, or requirements would include, but not be limited to, those that compel an action by or on behalf of a participant or beneficiary to access benefits or limit access to the full range of treatment options available for a condition or disorder under the plan. As discussed later in this preamble, the Departments also proposed that an NQTL applied to mental health or substance use disorder benefits in any classification would not be considered to violate the no more restrictive requirement if the NQTL impartially applies independent professional medical or clinical standards or fraud, waste, and abuse measures, that meet specific requirements.

Some commenters supported this approach to the “more restrictive” part of the test in the proposed rules because, according to these commenters, it provided a more concrete and less subjective standard. Other commenters emphasized, as discussed earlier in this preamble, that the proposed mathematical substantially all and predominant tests, which provide a quantitative basis for comparison, are unworkable for NQTLs and administratively burdensome. Many of these commenters requested that, if the proposed mathematical substantially all and predominant tests are finalized, the Departments provide extensive and detailed implementation guidance to assist plans and issuers in complying with what the commenters characterized as this challenging framework. Another commenter suggested that the Departments establish a safe harbor for plans and issuers from the substantially all and predominant tests for any variation in NQTL outcomes data driven by State law or regulation.

The Departments appreciate the detailed comments received on all aspects of the proposed mathematical substantially all and predominant tests, including comments particular to each aspect of the proposed four-prong test. The Departments acknowledge that many commenters expressed concerns that applying to NQTLs the same proposed mathematical substantially all and predominant tests that are applicable to financial requirements or quantitative treatment limitations may be difficult to operationalize and could be unworkable. The Departments acknowledge that this framework was first developed for financial requirements and quantitative treatment limitations, where there are relatively clear and limited numbers of variations, and that the framework might be impractical or impossible for NQTLs,

which differ in how they are designed and applied to various benefits.

At the same time, the Departments agree with commenters who stated that applying the statutory no more restrictive requirement to NQTLs under the proposed rules would assist regulators tasked with enforcing MHPAEA’s requirements and result in overall compliance improvements by formalizing and providing greater clarity on what plans and issuers must do to comply with MHPAEA. The Departments also agree with commenters who emphasized the importance of the statutory requirement that plans and issuers shall ensure that the treatment limitations they impose on mental health and substance use disorder benefits generally are no more restrictive than those they impose on medical/surgical benefits. The proposed rules made clear that the incorporation of this statutory language into regulations is key to ensuring that people seeking mental health and substance use disorder treatment do not face a greater burden on access to benefits for such treatment than on access to benefits for medical treatment and surgical procedures, a premise that is central to MHPAEA.

After reviewing all the comments on the proposed four prongs of the no more restrictive requirement, the Departments have sought to address many of the workability concerns expressed by commenters, while honoring statutory requirements. Specifically, due to concerns raised by the commenters, the Departments are declining to finalize the proposed mathematical substantially all and predominant tests for NQTLs, which would have based these determinations on the dollar amount of all plan payments for medical/surgical benefits expected to be paid, similar to the steps that apply when analyzing parity with respect to financial requirements or quantitative treatment limitations under the 2013 final regulations. These final rules address commenters’ operability and feasibility concerns with respect to the proposed mathematical substantially all and predominant tests, while continuing to set forth a standard for parity compliance that is grounded in MHPAEA’s statutory text and is also sufficiently flexible to account for the unique and nonquantifiable nature of NQTLs. As noted later in this preamble, these final rules retain the focus on the design and application of NQTLs, including with respect to relevant outcomes measures, to ensure that NQTLs are no more restrictive in the context of mental health and substance

use disorder benefits than in the context of medical/surgical benefits.

Therefore, these final rules do not finalize the provisions proposed under 26 CFR 54.9812–1(c)(4)(i)(A) through (E), 29 CFR 2590.712(c)(4)(i)(A) through (E), and 45 CFR 146.136(c)(4)(i)(A) through (E). Instead, consistent with MHPAEA’s express statutory requirement,⁶⁹ the Departments are finalizing under 26 CFR 54.9812–1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4) the general rule that, consistent with the fundamental purpose of MHPAEA, a group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) may not impose any NQTL with respect to mental health or substance use disorder benefits in any classification that is more restrictive, as written or in operation, than the predominant NQTL that applies to substantially all medical/surgical benefits in the same classification. Through this requirement, the Departments reiterate the importance of promoting the goals of the statute and ensuring that individuals have access to the mental health and substance use disorder benefits under their plan or coverage in a way that is not more restrictive than their access to the medical/surgical benefits under their health coverage. For this purpose, consistent with the fundamental purpose of MHPAEA, an NQTL is more restrictive than the predominant NQTL that applies to substantially all medical/surgical benefits in the same classification if the plan or issuer fails to satisfy the design and application requirements at 26 CFR 54.9812–1(c)(4)(i), 29 CFR 2590.712(c)(4)(i), and 45 CFR 146.136(c)(4)(i) or the relevant data evaluation requirements at 26 CFR 54.9812–1(c)(4)(iii), 29 CFR 2590.712(c)(4)(iii), and 45 CFR 146.136(c)(4)(iii). Accordingly, plans and issuers must ensure that the processes, strategies, evidentiary standards, and other factors used to design and apply an NQTL to mental health or substance use disorder benefits are comparable to, and applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to design and apply the NQTL for medical/surgical benefits, including by ensuring that the information, evidence, sources, or standards on which factors and evidentiary standards are based are not biased and are objective. Additionally, plans and issuers must comply with the relevant data evaluation requirements,

⁶⁹ Code section 9812(a)(3)(A), ERISA section 712(a)(3)(A), and PHS Act section 2726(a)(3)(A).

including by collecting and evaluating relevant data, determining whether the data suggest an NQTL contributes to material differences in relevant outcomes related to access to mental health and substance use disorder benefits as compared to medical/surgical benefits, and if material differences in relevant outcomes related to access exist, taking reasonable action, as necessary, to address the material differences to ensure compliance, in operation, with 26 CFR 54.9812–1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4). Absent compliance with both the design and application requirements and the relevant data evaluation requirements with respect to an NQTL, which are addressed in more detail later in this preamble, a plan or issuer fails to comply with Code section 9812(a)(3)(A)(ii), ERISA section 712(a)(3)(A)(ii), and PHS Act section 2726(a)(3)(A)(ii), as applicable, and may not impose the NQTL with respect to mental health or substance use disorder benefits. These requirements, taken together, require a plan to consider and evaluate an NQTL's design, application, and resulting outcomes to ensure that an NQTL is not more restrictive, as written or in operation, than the predominant NQTL that applies to substantially all medical/surgical benefits in the same classification.

These final rules also include a few technical changes to this language, including relocation of the reference to 26 CFR 54.9812–1(a)(1), 29 CFR 2590.712(a)(1), and 45 CFR 146.136(a)(1) from the beginning of the general rule of the design and application requirements to the beginning of the regulatory requirements for NQTLs at 26 CFR 54.9812–1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4), to make clear that plans and issuers should consider the fundamental purpose of MHPAEA in complying with all parts of the requirements for NQTLs. Additionally, the Departments are incorporating the phrase “may not impose” from the beginning of the proposed regulatory requirements for NQTLs, to make clear that this standard applies both to the design and application of NQTLs. The Departments are also replacing the word “applied” with “applies” in the clause describing “the predominant NQTL that applies to substantially all medical/surgical benefits in the same classification.” This adjustment from past to present tense is intended to clarify that plans and issuers should evaluate compliance with MHPAEA with respect to NQTLs that are currently imposed under the plan or coverage,

rather than just those that might have been imposed at some point in the past.

b. Requirements Related to Design and Application of the NQTL—26 CFR 54.9812–1(c)(4)(i), 29 CFR 2590.712(c)(4)(i), and 45 CFR 146.136(c)(4)(i)

The Departments proposed to redesignate the requirement at 26 CFR 54.9812–1(c)(4)(i), 29 CFR 2590.712(c)(4)(i), and 45 CFR 146.136(c)(4)(i) in the 2013 final regulations as paragraph (c)(4)(ii)(A) and amend it to align with the Departments' interpretation that a plan or issuer may not impose an NQTL with respect to mental health or substance use disorder benefits in any classification unless, under the terms of the plan (or health insurance coverage) as written and in operation, any processes, strategies, evidentiary standards, or other factors used in *designing and applying* (as compared to only *applying*, as under the 2013 final regulations) the NQTL to mental health and substance use disorder benefits are comparable to, and are applied no more stringently than those used in designing and applying the limitation with respect to medical/surgical benefits in the classification. To codify this interpretation, and for consistency with the statutory language added by the CAA, 2021, the Departments proposed to revise the regulatory text to make this requirement with respect to designing the NQTL explicit.

Some commenters generally supported the proposed design and application requirements as part of an overall framework for evaluating compliance with MHPAEA's requirements with respect to NQTLs. Some commenters indicated that they have encountered barriers in identifying whether plans and issuers comply with MHPAEA's requirements, and this proposal would help them identify whether the plan or issuer is compliant with respect to the design and application of NQTLs. Other commenters generally opposed the proposed changes to the design and application requirements. One commenter also stated that the design and application requirements would not improve benefit quality and would also constitute an impermissible retroactive application of the regulation in the case of regulated entities that were not required to comply with MHPAEA when they designed their benefit plans.

With respect to commenters' concern that the design and application requirements would not improve benefit quality, the Departments anticipate that greater clarity with respect to these

requirements, including the definitions of the terms “processes,” “strategies,” “evidentiary standards,” and “factors” under these final rules, as discussed earlier in this preamble, will help plans and issuers assess their compliance and remedy any parity violations, which will result in improved benefit quality overall. The Departments also disagree with the concern expressed by commenters that the design and application requirements impermissibly apply to plans and issuers that were not required to comply with MHPAEA when they designed their benefit plans. As stated earlier in this preamble, this provision codifies the Departments' longstanding interpretation of the design and application requirements and the CAA, 2021 amendments to the MHPAEA statute. The CAA, 2021 amendments apply generally to plans and issuers that offer both medical/surgical benefits and mental health or substance use disorder benefits and impose NQTLs on mental health or substance use disorder benefits. Congress did not exempt plans or issuers whose plans or benefit designs predated these requirements, and the Departments similarly did not take such an approach in implementing the 2010 interim final regulations or the 2013 final regulations. In fact, as described in more detail later in this preamble, Congress included a provision in the CAA, 2023 that sunsets the option for self-funded non-Federal governmental plans to elect to opt out of compliance with respect to MHPAEA, so that plans that previously were exempt from the requirements as a result of an opt-out election will no longer be able to make such an election.

The Departments are finalizing as proposed the general rule with respect to the design and application requirements for NQTLs, with a few minor amendments. Accordingly, this provision clarifies that to satisfy these requirements, a plan or issuer must consider, as part of its assessment of an NQTL's compliance with the no more restrictive requirement, whether any processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than those used in designing and applying the limitation with respect to medical/surgical benefits in the classification. By requiring processes, strategies, evidentiary standards, or other factors used to be comparable to and applied no more stringently than, the design and application requirements

of these final rules give meaning to the statutory terms “substantially all” and “predominant.” By making explicit in these final rules the Departments’ interpretation of the design and application requirements, and codifying the requirements of the CAA, 2021, this provision will help plans and issuers better understand their MHPAEA compliance obligations with respect to NQTLs, by emphasizing that, as written and in operation, the design of an NQTL is equally relevant as how it is applied. The design and application requirements of these final rules will also ensure that plans and issuers do not place greater burdens on access to mental health and substance use disorder benefits as compared to medical/surgical benefits.

The Departments note that a plan or issuer must comply with the relevant requirements under these final rules with respect to NQTLs applicable to mental health or substance use disorder benefits once the final rules become applicable to the plan or coverage, including with respect to any NQTLs that were developed and imposed when a plan or issuer was not subject to MHPAEA and that continue to be imposed after the applicability date. However, these final rules are not applicable to an NQTL imposed with respect to mental health or substance use disorder benefits for any such prior period of time (including a period when MHPAEA was not applicable).

In these final rules, the Departments are codifying the design and application requirements at 26 CFR 54.9812–1(c)(4)(i)(A), 29 CFR 2590.712(c)(4)(i)(A), and 45 CFR 146.136(c)(4)(i)(A), rather than as proposed at 26 CFR 54.9812–1(c)(4)(ii)(A), 29 CFR 2590.712(c)(4)(ii)(A), and 45 CFR 146.136(c)(4)(ii)(A) because, as discussed earlier in this preamble, these final rules structure the design and application requirements as part of the statutory no more restrictive requirement, rather than as a unique prong of the three requirements for NQTLs included in the proposed rules. In addition, the Departments are making a technical correction by amending the regulatory text to refer to health insurance coverage, rather than an issuer, to generally use consistent terminology throughout the regulations. Finally, as noted earlier in this preamble, these final rules move the reference to 26 CFR 54.9812–1(a)(1), 29 CFR 2590.712(a)(1), and 45 CFR 146.136(a)(1) from the beginning of the general rule of the design and application requirements to the beginning of the regulatory

requirements for NQTLs at 26 CFR 54.9812–1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4).

Prohibition on Discriminatory Factors and Evidentiary Standards

The proposed rules would add a new provision that, for purposes of determining comparability and stringency under the design and application requirements of proposed 26 CFR 54.9812–1(c)(4)(ii)(A), 29 CFR 2590.712(c)(4)(ii)(A), and 45 CFR 146.136(c)(4)(ii)(A), plans and issuers would be prohibited from relying upon any factor or evidentiary standard if the information, evidence, sources, or standards on which the factor or evidentiary standard is based discriminate against mental health or substance use disorder benefits as compared to medical/surgical benefits. The proposed rules stated that information would be considered to discriminate against mental health or substance use disorder benefits if it is biased or not objective, in a manner that results in less favorable treatment of mental health or substance use disorder benefits, based on all the relevant facts and circumstances. Such relevant facts and circumstances would include, but not be limited to, the source of the information, the purpose or context of the information, and the content of the information. Therefore, under the proposed rules, plans and issuers would not be permitted to rely on information that reflects bias, as those factors or evidentiary standards would be discriminatory.

For this purpose, the Departments stated in the proposed rules that information resulting in the less favorable treatment of mental health and substance use disorder benefits without legitimate justification or that is otherwise not objective would be considered to be biased and to discriminate against mental health and substance use disorder benefits. When determining which information, evidence, sources, or standards should inform the factors or evidentiary standards used to design or apply an NQTL, plans and issuers would not be permitted under the proposed rules to use information, evidence, sources, or standards if they are biased in favor of imposing greater restrictions on access to covered mental health and substance use disorder benefits or not objective, based on all the relevant facts and circumstances. The Departments also proposed that impartially applied independent professional medical or clinical standards and fraud, waste, and abuse measures that meet specific requirements would qualify for an

exception and would not be considered to discriminate against mental health or substance use disorder benefits.

Additionally, in the preamble to the proposed rules the Departments noted that the proposed prohibition on discriminatory factors and evidentiary standards would prohibit plans and issuers from relying on historical plan data or other historical information from a time when the plan or coverage was not subject to MHPAEA or was in violation of MHPAEA’s requirements, where the use of such data results in less favorable treatment of mental health and substance use disorder benefits. The Departments provided an example illustrating that a plan or issuer would not be permitted to calculate reimbursement rates based on historical data on total plan spending for each specialty that is divided between mental health and substance use disorder providers and medical/surgical providers, when the total spending by the plan was based on a time period when the plan or coverage was not subject to MHPAEA or was in violation of MHPAEA, if the data result in less favorable treatment of mental health and substance use disorder benefits. Consequently, under the framework in the proposed rules, plans and issuers could not use such data to develop a factor or evidentiary standard for the design or application of an NQTL to mental health or substance use disorder benefits. The proposed rules stated, to the extent a plan or issuer relies on any factor or evidentiary standard that discriminates against mental health or substance use disorder benefits, or any information, evidence, sources, or standards that inform such factors or evidentiary standards to design and apply NQTLs, the plan or issuer would violate the prohibition on discriminatory factors and evidentiary standards set forth in proposed 26 CFR 54.9812–1(c)(4)(ii)(B), 29 CFR 2590.712(c)(4)(ii)(B), and 45 CFR 146.136(c)(4)(ii)(B).

Many commenters expressed general support for this provision of the proposed rules. For example, one commenter noted that the prohibition on discriminatory factors and evidentiary standards would more effectively protect against the inappropriate application of NQTLs that, although appearing to be compliant with MHPAEA as written, have a disproportionately negative effect on access to mental health and substance use disorder benefits. Some commenters also indicated that the proposed provision is consistent with the text and purpose of MHPAEA, as well as the ACA, and favored a broad interpretation

of the requirement to address particular examples of discrimination by plans and issuers, to which some of them expressly cited. Other commenters expressed opposition to the proposed prohibition on discriminatory factors and evidentiary standards. Some of these commenters stated that the proposal would be administratively burdensome, and it would be difficult for plans and issuers to operationalize due to ambiguity and inherent subjectivity. Some commenters opposed to the proposed prohibition stated that it is duplicative of the proposed relevant data evaluation requirements. These commenters thought the prohibition on discriminatory factors and evidentiary standards should be eliminated as superfluous, because the required evaluation of outcomes data under the proposed rules is intended to ensure that factors are applied no more stringently to mental health and substance use disorder benefits than medical/surgical benefits and do not result in a material difference in access.

Some commenters expressed concern that the proposed requirement that information must not be biased and must be objective (which is based on facts and circumstances) is too subjective, can only be determined retroactively (yet must be applied prospectively), and is too difficult to apply for plans or issuers to be certain of compliance. One commenter requested clarification on the documentation and evidence required to demonstrate the absence of bias. Another commenter expressed concern that plans may not have the ability to prove that information is unbiased and objective.

One commenter stated that it is unclear whether the Departments intend to focus on the factors and evidentiary standards themselves or on the effects of using those factors and standards. Some commenters assumed that whether a factor or evidentiary standard is discriminatory would be based on an evaluation of outcomes, and that therefore any disparity in outcomes data could be viewed as use of a discriminatory factor or evidentiary standard. These commenters requested examples of outcomes that would demonstrate compliance. In addition, many commenters requested examples of discriminatory factors and evidentiary standards and of nondiscriminatory information and data sources. Several commenters requested the Departments to make clear that plans and issuers may not establish compliance by relying on a fee schedule used by Medicare, although another commenter requested that plans and

issuers be able to access a safe harbor if they paid above-Medicare rates.

After considering commenters' feedback, the Departments are finalizing the prohibition on discriminatory factors and evidentiary standards with modifications. As the Departments stated in the preamble to the proposed rules this provision will help address the concern that various factors and evidentiary standards that plans and issuers have relied on to design NQTLs with respect to mental health or substance use disorder benefits might themselves discriminate against mental health and substance use disorder benefits by treating them in a less favorable manner. At the same time, the Departments acknowledge commenters' concerns about potential ambiguities in the proposed prohibition on discriminatory factors and evidentiary standards, questions about whether this provision is duplicative of other parts of the proposed rules, and confusion about how to operationalize the prohibition.

In response to these concerns, and to assist plans and issuers in complying with the prohibition on discriminatory factors and evidentiary standards in these final rules, the Departments have modified the prohibition by providing additional clarity regarding what it means for information, evidence, sources, or standards to be "biased or not objective." The final rules both clarify the prohibition in a manner to ensure that it can be applied prospectively and revise it to expressly provide that potentially biased or not objective information, evidence, sources, or standards can be corrected, cured, or supplemented, and then relied upon by a plan or issuer to inform a factor or evidentiary standard that is not discriminatory. The Departments also provide additional examples of discriminatory factors and evidentiary standards later in this preamble.

First, with respect to the general prohibition on discriminatory factors and evidentiary standards, these final rules at 26 CFR 54.9812–1(c)(4)(i)(B), 29 CFR 2590.712(c)(4)(i)(B), and 45 CFR 146.136(c)(4)(i)(B) ⁷⁰ provide that, for purposes of determining comparability and stringency under 26 CFR 54.9812–

1(c)(4)(i)(A), 29 CFR 2590.712(c)(4)(i)(A), and 45 CFR 146.136(c)(4)(i)(A), a plan (or health insurance coverage) may not rely upon discriminatory factors and evidentiary standards to design an NQTL to be imposed on mental health or substance use disorder benefits. The Departments intend that the focus of this prohibition be specifically on the design of NQTLs, to further distinguish the prohibition on discriminatory factors and evidentiary standards from the relevant data evaluation requirements. These final rules provide the necessary clarity for plans and issuers to determine whether information, evidence, sources, or standards are biased or not objective, and if so, cannot be used as the basis for a factor or evidentiary standard used to design an NQTL applicable to mental health or substance use disorder benefits.

Specifically, these final rules state that a factor or evidentiary standard is discriminatory if the information, evidence, sources, or standards on which the factor or evidentiary standard are based are biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits. This language is similar to that included under proposed 26 CFR 54.9812–1(c)(4)(ii)(B), 29 CFR 2590.712(c)(4)(ii)(B), and 45 CFR 146.136(c)(4)(ii)(B) but adds the phrase "is biased or not objective in a manner that," preceding the word "discriminates." This phrase, in conjunction with the other changes to the prohibition on discriminatory factors and evidentiary standards discussed later in this preamble, was modified in response to comments and is intended to help clarify that a plan or issuer is expected to assess whether the information, evidence, sources, or standards on which each factor or evidentiary standard are based are biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits. This analysis is distinct from the final rules' requirement to compare the comparability and stringency of factors and evidentiary standards used to design and apply an NQTL.

Second, the Departments are finalizing a modified version of the provision originally proposed under 26 CFR 54.9812–1(c)(4)(ii)(B)(3), 29 CFR 2590.712(c)(4)(ii)(B)(3), and 45 CFR 146.136(c)(4)(ii)(B)(3) as 26 CFR 54.9812–1(c)(4)(i)(B)(1), 29 CFR 2590.712(c)(4)(i)(B)(1), and 45 CFR 146.136(c)(4)(i)(B)(1) of these final rules. This provision of the proposed rules

⁷⁰ As noted earlier in this preamble, the Departments are codifying the design and application requirements (including the prohibition on discriminatory factors and evidentiary standards) at 26 CFR 54.9812–1(c)(4)(i), 29 CFR 2590.712(c)(4)(i), and 45 CFR 146.136(c)(4)(i), rather than as proposed at 26 CFR 54.9812–1(c)(4)(ii), 29 CFR 2590.712(c)(4)(ii), and 45 CFR 146.136(c)(4)(ii), because these final rules structure the design and application requirements as part of the no more restrictive requirement, rather than as a unique prong of the 3-part test proposed in the proposed rules.

provided that information is considered to discriminate against mental health or substance use disorder benefits if it is biased or not objective, in a manner that results in less favorable treatment of mental health or substance use disorder benefits, based on all the relevant facts and circumstances. As mentioned earlier in this preamble, the Departments received many comments opposing this provision as proposed, including comments expressing confusion as to how it is different from the relevant data evaluation requirements, questions regarding the kind of documentation and evidence needed to show compliance, and concern that it is subjective and difficult to operationalize.

The prohibition on discriminatory factors and evidentiary standards is intended to work together with the other provisions of these final rules, including the relevant data evaluation requirements. Like all the provisions of these final rules, the provision further implements the statutory requirement that NQTLs be no more restrictive with respect to mental health or substance use disorder benefits than the predominant limitations applicable to substantially all medical/surgical benefits. The test specifically focuses on the importance of ensuring that the factors and evidentiary standards relied upon by plans and issuers in designing NQTLs do not have built-in biases (at the time NQTLs are designed) against mental health or substance use disorder benefits as compared to medical/surgical benefits. To the extent plans and issuers rely upon factors and evidentiary standards to design NQTLs that systematically disfavor access or are specifically designed to disfavor access to mental health and substance use disorder benefits, the resultant NQTLs are more restrictive with respect to mental health or substance use disorder benefits than for medical/surgical benefits.

The Departments note that a factor or evidentiary standard may be based on or include information that solely relates to medical/surgical benefits (and is silent or without corollary with respect to mental health or substance use disorder benefits). Such a factor or evidentiary standard is not considered discriminatory for this purpose. For example, a plan can reasonably rely on a source of information on the clinical efficacy of a treatment or service to inform a factor used to design a medical management NQTL, even though that source does not address the clinical efficacy of any treatment of any mental health conditions or substance use disorders, without violating the

prohibition on discriminatory factors and evidentiary standards. However, the use of such factor or evidentiary standard must comply with the design and application requirements, as described earlier in this preamble.

In response to comments to provide additional clarity, the final rules elaborate on the meaning of the phrase “biased and not objective in a manner that discriminates against mental health or substance use disorder benefits.” Specifically, these final rules provide that information, evidence, sources, or standards are considered to be biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits if, based on all the relevant facts and circumstances, they systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits.

For purposes of determining whether information, evidence, sources, or standards are considered to be biased or not objective under these final rules, relevant facts and circumstances may include, but are not limited to, the reliability of information, evidence, sources, or standards, including any underlying data and the independence of the information, evidence, sources, and standards relied upon. The Departments note that internal data or information, such as claims data, would generally not be considered independent, but would not necessarily be considered discriminatory on that basis alone. In the Departments’ view, independence is a relevant fact and circumstance for determining whether information, evidence, sources, or standards are considered to be biased or not objective. For example, a standard that is created or funded by the plan or issuer, or its service provider, would likely lack independence compared to a standard created by an impartial third party or governmental entity, and might require strong indicators of reliability in order to demonstrate that it is objective and unbiased. Additionally, relevant facts and circumstances include the analyses and methodologies employed to select the information, evidence, sources, or standards, and the consistency of their application; and any known safeguards deployed to prevent reliance on skewed data or metrics when determining whether they are biased or not objective. The Departments note that these final rules only provide examples, and not a comprehensive list, of relevant facts and circumstances that indicate information,

evidence, sources, or standards are biased or not objective. Because plans and issuers rely on myriad factors and evidentiary standards to design NQTLs for their own unique benefit designs, this evaluation necessarily will be specific to the particular plan or coverage.

Under these final rules, information, evidence, sources, and standards are not considered biased or not objective for purposes of the prohibition on discriminatory factors and evidentiary standards, if a plan or issuer has taken steps necessary to address the bias or lack of objectivity by correcting, curing, or supplementing the information, evidence, sources, or standards that would have been biased or not objective in the absence of such steps. If information, evidence, sources, or standards are corrected, cured, or supplemented, they may be used by plans and issuers as the basis for factors and evidentiary standards used to design an NQTL.

Several commenters asked about the use of a fee schedule used by Medicare and CMS-set standards, such as network time and distance standards, by a plan or issuer to inform plan design. For example, some plans use the Medicare Physician Fee Schedule⁷¹ to establish base rates for in-network physician services. The Departments do not consider fee schedules used by Medicare and standards set by CMS to be biased or not objective, as defined under these rules, when used as the basis for a factor or evidentiary standard to design an NQTL such as reimbursement rate methodology.

The Departments note, however, that the mere use of the Medicare Physician Fee Schedule, for example, as one type of information, evidence, source, or standard that informs a factor used to design an NQTL does not automatically

⁷¹ The Medicare Physician Fee Schedule is developed by CMS. To develop the Medicare Physician Fee Schedule, CMS utilizes recommendations from an independent assessment by a multi-specialty body and other market-based information sources, as well as independent assessment by CMS medical officers, to develop proposed relative value units for each physician service. CMS then engages in notice and comment rulemaking, including consideration of public comments, before establishing payment rates for specific services. Furthermore, CMS has made, and continues to make, numerous adjustments to the underlying methodology to increasingly ensure appropriate reimbursement for services paid under the Medicare Physician Fee Schedule, including behavioral health services. *See, e.g.*, Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program, 88 FR 78818 (Nov. 16, 2023).

render the NQTL permissible. For example, in most cases, a plan would be unable to justify a reimbursement rate methodology that paid physicians in medical/surgical specialties 125 percent of the Medicare Physician Fee Schedule rate and that paid physicians in mental health and substance use disorder specialties 75 percent of the Medicare Physician Fee Schedule rate.

The Departments received several comments in support of the example included in the preamble to the proposed rules that illustrated the prohibition on plans' and issuers' reliance on historical plan data or other historical information from a time when the plan or coverage was not subject to MHPAEA, or not compliant with MHPAEA. Some commenters recognized that many plans and issuers have used their own historical data from a time when their plan or coverage was not subject to MHPAEA and have benefited from historic inequities in benefit structures that MHPAEA sought to prohibit. One commenter requested that this example be codified in the regulatory text of the final rules. The Departments agree that the example illustrating how the prohibition on discriminatory factors and evidentiary standards applies to the use of historical data and information to design an NQTL should be clearly set forth in the regulation text at 26 CFR 54.9812–1(c)(4)(ii)(B)(2), 29 CFR 2590.712(c)(4)(ii)(B)(2), and 45 CFR 146.136(c)(4)(ii)(B)(2). To ensure compliance with this standard, plans and issuers that utilize historical data or information from a time when their plan or coverage was not subject to, or not compliant with, MHPAEA should ensure that the use of such data and information (for example, in cost calculations and controls) for mental health and substance use disorder benefits does not include, as a baseline, years when financial requirements and treatment limitations that would have been impermissible under MHPAEA were imposed on such benefits (unless they take steps to correct, cure, or supplement the data or information, as discussed earlier in this preamble).

Some commenters provided other examples that they recommended including as illustrations of discriminatory factors and evidentiary standards in these final rules, including prior authorization for a prescription of buprenorphine to treat opioid use disorder (OUD) requiring additional licensure or certification for mental health and substance use disorder providers that is not required of similar medical/surgical providers; subjecting mental health and substance use

disorder claims to different fraud, waste, and abuse processes, or requiring more documentation, than for medical/surgical claims; not covering nutrition counseling for the treatment of eating disorders while covering it for medical conditions; and requiring that mental health and substance use disorder claims and appeals be filed with a TPA, but not making this clear to enrollees, nor properly coordinating operations between the plan/issuer and TPA.

However, many of these examples focus on the use of a factor to apply an NQTL to mental health and substance use disorder benefits in a manner that is not comparable or is more stringent than the use of the factor to apply an NQTL to medical/surgical benefits, or focus on the NQTL itself (rather than the discriminatory factor or evidentiary standard). The prohibition on discriminatory factors and evidentiary standards in these final rules, however, focuses on the information, evidence, sources, and standards that inform the factors and evidentiary standards used to design an NQTL. Factors and evidentiary standards that incorporate or otherwise rely on underlying data or information that systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits place a greater burden on access to such benefits. Therefore, these final rules prohibit the use of any factor or evidentiary standard to design an NQTL if the underlying information, evidence, sources, and standards are themselves biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits, unless the plan or issuer takes steps to correct, cure, or supplement the information, evidence, sources and standards to address the bias or lack of objectivity.

These final rules set forth a general rule to determine which specific factors and evidentiary standards (and the information, evidence, sources, and standards on which they are based) might or might not be biased and not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits. The Departments have provided new examples in these final rules illustrating the prohibition on discriminatory factors and evidentiary standards, which are discussed later in this preamble. The Departments acknowledge that these examples are not exhaustive and may provide additional examples in future guidance.

Finally, as discussed in greater detail later in this preamble, the Departments are not finalizing the exceptions to the prohibition on discriminatory factors and evidentiary standards for independent professional medical or clinical standards and fraud, waste, and abuse measures. However, these final rules expressly clarify at 26 CFR 54.9812–1(c)(4)(i)(B)(3), 29 CFR 2590.712(c)(4)(i)(B)(3), and 45 CFR 146.136(c)(4)(i)(B)(3) that generally recognized independent professional medical or clinical standards and fraud and abuse measures that minimize the negative impact on access to appropriate mental health and substance use disorder benefits are not information, evidence, sources, or standards that are biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits.

The Departments recognize that commenters requested specificity as to what qualifies as independent professional medical or clinical standards. To ensure that they are not biased and are objective, independent professional medical or clinical standards should reflect the standards of care and clinical practice that are generally recognized in relevant clinical specialties across a range of settings of care and should be transparent. For example, sources that include such standards could be peer-reviewed scientific studies and medical literature, formal published recommendations of Federal Government agencies, drug labeling approved by the United States Food and Drug Administration (FDA), and recommendations of relevant nonprofit health care provider professional associations and specialty societies, including, but not limited to, patient placement criteria and clinical practice guidelines. Additionally, fraud and abuse measures should be reliably established through unbiased and objective data and narrowly tailored in a manner that minimizes the negative impact on access to appropriate mental health and substance use disorder benefits.

These final rules also clarify that plans and issuers that rely on independent professional medical or clinical standards or fraud and abuse measures must comply with the general rule of the design and application requirements at 26 CFR 54.9812–1(c)(4)(i)(A), 29 CFR 2590.712(c)(4)(i)(A), and 45 CFR 146.136(c)(4)(i)(A). If such a standard or measure is used as an NQTL, the plan or issuer also must comply with the relevant data evaluation requirements at 26 CFR 54.9812–1(c)(4)(iii), 29 CFR

2590.712(c)(4)(iii), and 45 CFR 146.136(c)(4)(iii) in these final rules.

c. Illustrative, Non-Exhaustive List of NQTLs—26 CFR 54.9812–1(c)(4)(ii), 29 CFR 2590.712(c)(4)(ii), and 45 CFR 146.136(c)(4)(ii)

The proposed rules proposed to move the illustrative, non-exhaustive list of NQTLs from 26 CFR 54.9812–1(c)(4)(ii), 29 CFR 2590.712(c)(4)(ii), and 45 CFR 146.136(c)(4)(ii) to 26 CFR 54.9812–1(c)(4)(iii), 29 CFR 2590.712(c)(4)(iii), and 45 CFR 146.136(c)(4)(iii) and make several minor changes to this list. First, the Departments proposed amendments to make clear that this illustrative list of NQTLs is non-exhaustive and that there are additional NQTLs not captured in the list. The Departments also proposed to amend the illustrative, non-exhaustive list of NQTLs to replace “[s]tandards for provider admission to participate in a network, including reimbursement rates” with “standards related to network composition, including, but not limited to, standards for provider and facility admission to participate in a network or for continued network participation, including methods for determining reimbursement rates, credentialing standards, and procedures for ensuring the network includes an adequate number of each category of provider and facility to provide covered services under the plan or coverage.” Additionally, the Departments proposed to amend the description of the illustrative NQTL “plan methods for determining usual, customary, and reasonable charges” to encompass a broader range of methods for determining out-of-network rates, such as allowed amounts; usual, customary, and reasonable charges; or application of other external benchmarks for out-of-network rates. Finally, the Departments proposed to add a specific reference to prior authorization requirements as an example of a medical management standard limiting or excluding benefits based on medical necessity or medical appropriateness, consistent with Example 1 in 26 CFR 54.9812–1(c)(4)(iii), 29 CFR 2590.712(c)(4)(iii), and 45 CFR 146.136(c)(4)(iii) of the 2013 final regulations.

Some commenters supported the clarification in the proposed rules that the illustrative list is non-exhaustive and that there are additional NQTLs not included in the list. In general, many commenters found the list to be helpful for plans and issuers to identify NQTLs. Some of these commenters pointed out that the non-exhaustive nature of the list would allow new NQTLs developed by plans and issuers to fall under the scope

of the requirements in these final rules. One commenter also noted that the definition of an NQTL is sufficiently clear such that an exhaustive list would not be needed to put plans or issuers on notice of their compliance obligations.

Other commenters requested that the Departments instead provide an exhaustive list of NQTLs to eliminate uncertainty, promote consistency, and clarify plans’ and issuers’ compliance obligations. Several of these commenters suggested that the Departments update such an exhaustive list as new NQTLs are identified and allow adequate time for plans and issuers to come into compliance with respect to such NQTLs. Other commenters advocated for an approach where an exhaustive list of NQTLs would also represent the scope of NQTLs for which the relevant Secretary could request a comparative analysis. Some of these commenters requested that to the extent the relevant Secretary requested a comparative analysis for an NQTL not on the list, plans and issuers be provided with additional time to respond.

The Departments agree with the commenter generally stating that the definition of an NQTL under 26 CFR 54.9812–1(a), 29 CFR 2590.712(a), and 45 CFR 146.136(a), in addition to the non-exhaustive, illustrative list of NQTLs, is sufficient to put plans and issuers on notice that a given plan provision would fall under the definition of an NQTL. Therefore, the Departments are finalizing as proposed the clarification that this illustrative list of NQTLs is non-exhaustive.

The Departments decline to provide an exhaustive list of NQTLs, as requested by commenters, in these final rules; however, as described further below, the Departments may consider issuing separate guidance to add additional examples if needed. Plans and issuers, rather than the Departments, are best positioned to initially identify NQTLs, including any NQTLs that plans and issuers newly implement as their plan or coverage designs evolve over time. MHPAEA does not limit the scope of NQTLs that plans and issuers may impose on mental health and substance use disorder benefits. However, for any NQTLs applicable to such benefits, a plan or issuer must comply with MHPAEA and its implementing regulations. Any exhaustive list of NQTLs published by the Departments would likely lag behind those actually utilized by plans and issuers due to this information gap, along with the wide variability in NQTLs that exist now and could exist in the future. Furthermore, while some

commonalities exist, plans and issuers generally do not use uniform nomenclature to refer to their medical management techniques or other NQTLs, making the task of identifying an exhaustive list difficult, if not impossible.

An exhaustive list of NQTLs that does not include the full scope of NQTLs utilized by plans and issuers at any given time would undermine the fundamental purpose of MHPAEA and these final rules. While the Departments acknowledge and have considered plans’ and issuers’ requests for a finite list of NQTLs for which the Departments may request comparative analyses, the exhaustive nature of such a list would leave open a compliance loophole by incentivizing plans and issuers to wait to evaluate, document, and address compliance for an NQTL that is newly developed or has not come to the attention of the Departments. The approach some commenters suggested to expressly limit the comparative analysis requirement under 26 CFR 54.9812–2, 29 CFR 2590.712–1, and 45 CFR 146.137 to only those NQTLs identified in an exhaustive list is similarly untenable due to a foreseeable mismatch between the NQTLs included on such an exhaustive list, and those utilized by plans and issuers over time, particularly where the Departments may receive a complaint or have reason to believe there may be a potential violation. The Departments recognize the desire of plans and issuers to have a list of NQTLs on which the Departments will focus their enforcement efforts. The Departments highlight that the most recent reports to Congress on MHPAEA contain lists of the NQTLs on which the Departments have focused their enforcement efforts, and the NQTLs the Departments have mostly commonly found to be noncompliant.⁷² Additionally, the 2020 MHPAEA Self-Compliance Tool includes an illustrative, non-exhaustive list of NQTLs.⁷³ The statute, however, requires the Departments to request

⁷² See, e.g., 2022 MHPAEA Report to Congress (Jan. 2022), pg. 13, 19–20, <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2022-realizing-parity-reducing-stigma-and-raising-awareness.pdf>; 2023 MHPAEA Comparative Analysis Report to Congress (July 2023), pg. 47–48, 55–56, <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2023-mhpaea-comparative-analysis.pdf> and <https://www.cms.gov/ccio/resources/forms-reports-and-other-resources#mental-health-parity>.

⁷³ See Self-Compliance Tool for the Mental Health Parity and Addiction Equity Act (MHPAEA) (2020), <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/self-compliance-tool.pdf>.

comparative analyses from a plan or issuer for any NQTL that involves potential violations of MHPAEA or complaints regarding noncompliance with MHPAEA that concern NQTLs. To limit the Departments to requesting comparative analyses for only certain NQTLs identified in a list would not only be inconsistent with the statute but would also limit the ability of the Departments to dynamically respond to new NQTLs that plans and issuers design and apply that may restrict participant and beneficiary access to mental health and substance use disorder benefits as compared to medical/surgical benefits.

Additionally, allowing plans and issuers to categorically have additional time to assemble a comparative analysis for NQTLs that are not on a finite list of NQTLs, as requested by commenters, would also be inconsistent with the statutory requirement that, without exception, plans and issuers perform and document such comparative analyses of NQTLs applicable to mental health or substance use disorder benefits, beginning 45 days after the enactment of the CAA, 2021, and would result in the post-hoc justifications addressed with the CAA, 2021's enactment.⁷⁴ The Departments nonetheless acknowledge commenters' requests for additional guidance about plan provisions that would be considered to be NQTLs and intend to provide additional examples of NQTLs through future reports to Congress, updates to the 2020 MHPAEA Self-Compliance Tool, and other guidance.

The Departments received a handful of comments on the proposed expansion of the illustrative list's description of standards for provider admission to participate in a network, including reimbursement rates, to also refer to standards for provider and facility admission to participate in a network or for continued network participation, including methods for determining reimbursement rates, credentialing standards, and procedures for ensuring the network includes an adequate number of each category of provider and facility to provide covered services under the plan or coverage. Some commenters supported these proposed amendments to ensure that patients have an adequate provider network. Others suggested that parity requirements for provider networks should address the administrative burden and credentialing requirements on providers when joining networks, which may limit network adequacy. The

Departments are finalizing this amendment as proposed. The Departments agree with commenters who stated that MHPAEA applies to credentialing standards, as well as the procedures to join a network, and note that methods for determining reimbursement rates, credentialing standards, and procedures for ensuring the network includes an adequate number of each category of provider and facility to provide services under the plan or coverage are intended to be interpreted broadly, consistent with the fundamental purpose of MHPAEA. Because these final rules do not retain the proposed mathematical substantially all and predominant tests, the illustrative list appears in these final rules at 26 CFR 54.9812–1(c)(4)(ii), 29 CFR 2590.712(c)(4)(ii), and 45 CFR 146.136(c)(4)(ii) instead of 26 CFR 54.9812–1(c)(4)(iii), 29 CFR 2590.712(c)(4)(iii), and 45 CFR 146.136(c)(4)(iii) as in the proposed rules.

d. Required Use of Outcomes Data and Special Rule for NQTLs Related to Network Composition—26 CFR 54.9812–1(c)(4)(iii), 29 CFR 2590.712(c)(4)(iii), and 45 CFR 146.136(c)(4)(iii)

In the proposed rules, the Departments proposed to amend the 2013 final regulations to add a requirement that, when designing and applying an NQTL, a plan or issuer must collect and evaluate relevant data in a manner reasonably designed to assess the impact of the NQTL on access to mental health and substance use disorder benefits and medical/surgical benefits, and consider the impact as part of the plan's or issuer's analysis of whether the NQTL, in operation, complies with the proposed no more restrictive requirement and the design and application requirements. The proposed rules included the general types of data that plans and issuers would have to collect and evaluate with regard to all NQTLs and additional data sets that would have to be collected and evaluated for NQTLs related to network composition standards. To the extent the relevant data collected and evaluated by the plan or issuer show material differences in access to mental health benefits and substance use disorder benefits as compared to medical/surgical benefits, under the proposed rules, the differences would be considered a strong indicator that the plan or issuer violated the proposed rules. In these instances, a plan or issuer would be required to take reasonable action to address any material differences in access as necessary to

ensure compliance, in operation, with proposed 26 CFR 54.9812–1(c)(4)(i) and (ii), 29 CFR 2590.712(c)(4)(i) and (ii), and 45 CFR 146.136(c)(4)(i) and (ii), and would also be required to document the action that has been or is being taken by the plan or issuer to mitigate any material differences in access in the plan's or issuer's comparative analysis for the NQTL in that classification.

Additionally, the Departments noted in the preamble to the proposed rules their concerns about standards related to network composition and other related NQTLs. Specifically, the Departments noted that network composition is the result of the design and application of myriad NQTLs and is informed by various processes, strategies, evidentiary standards, and other factors, many of which interact in complex ways. The Departments also expressed concern that NQTLs related to network composition inherently impact a participant's or beneficiary's access to mental health and substance use disorder benefits. Accordingly, the proposed rules included a special rule applicable to NQTLs related to network composition. Specifically, under the proposed rules, when designing and applying one or more NQTLs related to network composition standards, a plan or issuer would fail to meet the requirements of proposed 26 CFR 54.9812–1(c)(4)(i) and (ii), 29 CFR 2590.712(c)(4)(i) and (ii), and 45 CFR 146.136(c)(4)(i) and (ii), in operation, if the relevant data show material differences in access to in-network mental health benefits and substance use disorder benefits as compared to in-network medical/surgical benefits in a classification.

The Departments also proposed that plans and issuers would not be required to comply with the relevant data evaluation requirements for NQTLs that impartially apply independent professional medical or clinical standards. However, proposed 26 CFR 54.9812–1(c)(4)(iv)(D), 29 CFR 2590.712(c)(4)(iv)(D), and 45 CFR 146.136(c)(4)(iv)(D) did not provide a comparable exception for fraud, waste, and abuse measures, as the Departments stated these tools, while important, are more likely to result in NQTLs that improperly restrict access to mental health or substance use disorder benefits and therefore the impact of those NQTLs should be assessed.

In General

The Departments received many comments expressing general support for the proposal to require plans and issuers to collect and evaluate relevant data to assess an NQTL's impact on

⁷⁴ Code section 9812(a)(8)(A), ERISA section 712(a)(8)(A), and PHS Act section 2726(a)(8)(A).

access to mental health and substance use disorder benefits and medical/surgical benefits, including the proposed requirement related to data for network composition NQTLs. These commenters noted that the data collection and evaluation requirements would promote transparency and compliance with MHPAEA, stating that collecting and evaluating outcomes data is essential to assessing in-operation compliance and that plans and issuers had failed to conduct and share such analyses. Other commenters noted that collection and evaluation of data is critical to assessing an NQTL's impact on access to mental health and substance use disorder benefits as compared to medical/surgical benefits, and by requiring plans and issuers to collect and assess outcomes data and to address material differences in access, the Departments are better aligning the focus of NQTL compliance with the fundamental purpose of MHPAEA. These commenters stated that, under the 2013 final regulations, plans and issuers rarely appropriately measure and analyze an NQTL's impact on access in the manner outlined in the proposed rules, and instead rely on process-related rationales to justify disparate access to treatment for mental health conditions and substance use disorders as compared to access to treatment for medical conditions and surgical procedures.

Other commenters stated that requiring plan sponsors to evaluate outcomes data to determine whether access to mental health and substance use disorder benefits is in parity with access to medical/surgical benefit is not supported by the statute and stated this provision of the proposed rules would be a significant departure from previous guidance under MHPAEA, under which the Departments stated that outcomes are not determinative of compliance. These commenters also stated that, because not all NQTLs are quantifiable, data metrics should not be required to determine parity, and disagreed with the Departments' interpretation of the term "in operation" as the basis for the requirement that plans and issuers measure outcomes. The Departments also received many comments on the various components and specific comment solicitations related to the relevant data evaluation requirements in the proposed rules.

The determination of whether an NQTL is "more restrictive," within the meaning of the statute, as applied to mental health and substance use disorder benefits, cannot be divorced from the impact the NQTL has on access to these benefits. Accordingly, the

Departments are finalizing the relevant data evaluation requirements, with some modifications based on the comments. These final rules require that plans and issuers be attentive to the impact of their NQTLs, in operation, by collecting and evaluating relevant data in a manner reasonably designed to assess the impact of the NQTL on relevant outcomes related to access, and carefully considering the impact as part of the plan's or issuer's evaluation.

For this purpose, the term "relevant data" under these final rules is meant to be interpreted broadly but does not require a plan or issuer to collect and evaluate duplicative or overlapping data that reflect the same analysis. The obligation is to collect and evaluate relevant data in a manner reasonably designed to assess the impact of NQTLs. It is not a requirement to exhaustively survey all available data, nor a requirement that plans and issuers evaluate additional data that is duplicative or unlikely to change the determination of whether there is a material difference in access to mental health and substance use disorder benefits as compared to medical/surgical benefits. However, as discussed later in this preamble, a plan or issuer may be required to collect and evaluate more than one form of data to assess the aggregate impact of the NQTL (or NQTLs as related to network composition). For example, under these final rules, to assess the aggregate impact of NQTLs related to network composition, a plan or issuer could evaluate, as appropriate, in-network and out-of-network utilization rates (including data related to provider claim submissions), network adequacy metrics (including time and distance data, and data on providers accepting new patients), and provider reimbursement rates (for comparable services and as benchmarked to a reference standard).

Further, a plan's or issuer's data collection and evaluation approach will not be considered to be conducted in a manner reasonably designed to assess the impact of an NQTL on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits if the plan or issuer does not consider data that it knows or reasonably should know suggest that the NQTL is associated with a material difference in access. The Departments expect that, in designing their data collection and evaluation approach, plans and issuers will consider outcomes data as necessary to assess the impact of the NQTL on access to mental health and substance use disorder benefits and medical/surgical benefits in the same

classification. As explained later in this preamble, the plan's or issuer's evaluation of this data must be included as part of the comparative analysis of the NQTL. The Departments may require a plan or issuer to submit additional information to ensure that plans and issuers do not only collect and evaluate the impact of some relevant data, while disregarding other relevant data that is reasonably available and suggests the NQTL contributes to material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits.

The statutory language requires that a plan or issuer ensure that the treatment limitations (quantitative or nonquantitative) themselves that are applicable to mental health or substance use disorder benefits "are no more restrictive than the predominant treatment limitations applied to substantially all medical and surgical benefits covered" by the plan (or coverage).⁷⁵ The relevant data evaluation requirements at 26 CFR 54.9812-1(c)(4)(iii), 29 CFR 2590.712(c)(4)(iii), and 45 CFR 146.136(c)(4)(iii) are intended to give particular meaning to the statutory language with respect to an NQTL itself, which, in these final rules, also requires compliance, in operation, with the design and application requirements under 26 CFR 54.9812-1(c)(4)(i), 29 CFR 2590.712(c)(4)(i), and 45 CFR 146.136(c)(4)(i). The Departments agree with commenters who noted that these requirements will promote transparency and compliance with MHPAEA, that such information is critical to assessing an NQTL's compliance with the statute, and that requiring plans and issuers to collect and assess outcomes data and address material differences in access appropriately aligns the focus of NQTL compliance more closely with the fundamental purpose of MHPAEA.

As stated in the preamble to the proposed rules, it is necessary to review and consider quantitative outcomes data to ascertain how the NQTL functions in the context of the plan's or issuer's administration and provision of benefits.⁷⁶ Because the relevant data evaluation requirements in these final rules are meant to ensure and determine compliance, in operation, with the statutory language in Code section 9812(a)(3)(A)(ii), ERISA section 712(a)(3)(A)(ii), and PHS Act section 2726(a)(3)(A)(ii), as noted earlier in this

⁷⁵ Code section 9812(a)(3)(A)(ii), ERISA section 712(a)(3)(A)(ii), and PHS Act section 2726(a)(3)(A)(ii).

⁷⁶ 88 FR 51552, 51575. (Aug. 3, 2023).

preamble, plans and issuers must comply with both the design and application requirements and the relevant data evaluation requirements in these final rules to demonstrate compliance with MHPAEA. That is, if, with respect to an NQTL, a plan or issuer fails to comply with either set of requirements in 26 CFR 54.9812–1(c)(4)(i) or (iii), 29 CFR 2590.712(c)(4)(i) or (iii), and 45 CFR 146.136(c)(4)(i) or (iii), as applicable, the plan or issuer will be considered to violate MHPAEA and the relevant NQTL may not be imposed with respect to mental health or substance use disorder benefits in the classification unless and until the plan or issuer takes appropriate action to remedy the violation.

Relevant Data

The proposed rules identified types of relevant data that plans and issuers would be required to collect and evaluate for all NQTLs in each individual comparative analysis. Under the proposed rules, relevant data for all NQTLs would include, but would not be limited to, the number and percentage of claims denials and any other data relevant to the NQTL as required by State law or private accreditation standards. Additionally, relevant data for network composition NQTLs would include, but would not be limited to, in-network and out-of-network utilization rates (including data related to provider claim submissions), network adequacy metrics (including time and distance data, and data on providers accepting new patients), and provider reimbursement rates (including as compared to billed charges). The proposed rules further provided that the Departments may specify the type, form, and manner for the relevant data evaluation requirements in future guidance.⁷⁷

Many commenters supported the required use of data outcomes as proposed. Several commenters noted that many plans and issuers do not have

access to the data they would need to comply with the relevant data evaluation requirements. Specifically, the Departments received several comments regarding limited access to data held by service providers, highlighting inconsistencies in service providers' willingness or ability to provide data and the extensive systems changes and expenses necessary to allow data to be provided. Some commenters suggested that, because plan sponsors do not have access to complete and reliable sets of claims data, the final rules should specify that a plan or issuer can meet its obligations related to the relevant data evaluation requirements by requesting access to data, documenting such requests, and advising service providers that their refusal to provide data will be relayed to the Departments.

Some commenters suggested the Departments issue the "type, form, and manner of collection and evaluation" for the relevant data evaluation requirements in guidance that can be periodically updated. Other commenters suggested that the final rules provide an exception from the relevant data evaluation requirements for NQTLs for which no such data are reasonably available, and that data evaluation be required only for outcomes that can be reasonably measured. One of these commenters highlighted that many NQTLs, including certain types of medical management techniques, assessments related to medical necessity, and exclusions for experimental/investigational treatments, are not generally associated with claims. Some commenters requested that the Departments provide an exhaustive list of a uniform set of outcomes data that plans and issuers are required to collect and assess as part of their comparative analysis with respect to an NQTL.

Commenters suggested additional or different types of data that should be considered relevant data and that could be provided by plans and issuers, as well as their service providers, including the percentage of in-network claims covered vs. those submitted; time and distance data that includes virtual or telehealth visits; median in-network payments as compared to Medicare rates for inpatient benefits, office visits, and outpatient benefits; member satisfaction, as reported by standardized surveys such as the Consumer Assessment of Healthcare Providers and Systems program; and allowed amounts for certain specific Current Procedural Terminology (CPT) codes for various types of mental health and substance use disorder and medical/surgical providers. Many commenters suggested

that relevant data include the number of authorizations issued for participants and beneficiaries for each of the levels (and sub-levels) of care described in the American Society for Addiction Medicine (ASAM) criteria and the age-specific Level of Care Utilization Services family of criteria. Some of these commenters also suggested outcomes data be reported separately for both mental health and substance use disorder services. Another commenter also suggested that relevant data include the number and percentage of drugs subject to prior authorization and step therapy (as an alternative to claims denials for the prescription drug classification), turnaround time for prior authorization, and inter-rater reliability. One commenter suggested using, as a parity indicator, a ratio of mental health utilization to primary care (for both initial and follow-up services) using data from the Medical Expenditure Panel Survey. Some commenters requested that, for fully insured coverage, the relevant data evaluation requirements apply at the issuer or "product" level instead of the "plan" level (as those terms are defined in 45 CFR 144.103),⁷⁸ while others sought clarification regarding whether the data to be analyzed should be group-specific or aggregate-level, as well as any differences in the level of data needed for fully insured and self-funded plans.

Some commenters objected to the proposal to require the collection and evaluation of out-of-network utilization data for NQTLs related to network composition, stating that high out-of-network utilization of mental health and substance use disorder services alone does not necessarily indicate a network access deficiency and could instead be the product of other factors, such as a patient's preference to use a particular provider. One commenter suggested requiring the collection and evaluation of provider-to-enrollee ratio data, and another commenter expressed support for requiring the collection and evaluation of data on whether in-network providers are accepting new patients. Some commenters expressed support for the collection and evaluation of data on appointment wait times, time and distance data, types and numbers of mental health and substance

⁷⁷ Contemporaneously with the proposed rules, DOL, in collaboration with HHS and the Treasury, issued Technical Release 2023–01P, which set out principles and asked for public comment to inform future guidance with respect to data submissions for NQTLs related to network composition and a potential enforcement safe harbor. The comment period for the Technical Release closed on October 2, 2023. Comments on the Technical Release are available on DOL's website at <https://www.dol.gov/agencies/ebsa/laws-and-regulations/rules-and-regulations/public-comments/tr-23-01>. Those comments were solicited separately and are not addressed in these final rules. Plans and issuers would be allowed adequate time to conform to any future guidance on the type, form, and manner of collection and evaluation for the relevant data required under the final rules.

⁷⁸ 45 CFR 144.103 states "[p]roduct" means "a discrete package of health insurance coverage benefits that are offered using a particular product network type (such as health maintenance organization, preferred provider organization, exclusive provider organization, point of service, or indemnity) within a service area" and "[p]lan" means, "with respect to a product, the pairing of the health insurance coverage benefits under the product with a particular cost-sharing structure, provider network, and service area."

use disorder providers that are available in a network, and telehealth. Some commenters suggested collection and evaluation of provider reimbursement rates, stating that those rates have an impact on whether providers are able to join a network, how many patients they treat, and whether they can provide wages to attract and retain staff. Other commenters objected to the requirement to collect and evaluate provider reimbursement data, arguing that reimbursement rates are not equivalent data when comparing between medical/surgical and mental health and substance use disorder benefits because of the nature of mental health and substance use disorder treatment and the associated time and cost. Other commenters objected to the inclusion of billed charges, arguing that these are arbitrary amounts not necessarily tied to any independent standard or benchmark of what is a reasonable charge and that Medicare rates should be used instead.

After review of the comments, the Departments decline to provide a list of all relevant outcomes data required to be collected and evaluated by plans and issuers at this time; however, the Departments intend to issue in future guidance the type, form, and manner of collection and evaluation for the data required and the lists of examples of data that are relevant across the majority of NQTLs,⁷⁹ as well as additional relevant data for NQTLs related to network composition. As part of this guidance, the Departments intend to update the MHPAEA Self-Compliance Tool to provide a robust framework and roadmap for plans and issuers to determine which data to collect and evaluate.

While, as discussed earlier in this preamble, commenters provided various suggestions for relevant outcomes data to be collected and evaluated, many comments also suggested that what data are considered relevant depends on the nature of an NQTL. The Departments agree and intend to issue future guidance to help ensure that the data required to be collected and evaluated under the relevant data evaluation requirements of these final rules provide a meaningful representation of whether a plan or issuer is improperly applying an NQTL under MHPAEA. In developing this guidance, the

Departments intend to take into consideration the feedback received regarding relevant data elements.

Until additional guidance is provided, the Departments expect a plan or issuer with a typical plan or coverage design will collect and evaluate certain data that are likely to be relevant for the majority of NQTLs under the relevant data evaluation requirements. As the relevant data for any given NQTL will depend on the facts and circumstances of the NQTL at issue and the circumstances under which the NQTL was designed and applied, these final rules provide some flexibility for plans and issuers to determine what relevant data should be collected and evaluated, as appropriate.

Under these final rules, relevant data for the majority of NQTLs could include, as appropriate, but are not limited to, the number and percentage of claims denials in a classification of benefits and any other data relevant to the NQTL required by State law or private accreditation standards. However, the Departments note that these final rules do not mandate that plans or issuers use private accreditation standards or evaluate data under State laws to which they are not subject. In addition, relevant data for a typical plan or coverage might include utilization data for mental health and substance use disorder services and medical/surgical services. For NQTLs such as prior authorization, relevant data could include rates of approvals and denials of prior authorization requests, rates of denials of post-service claims, application of penalties for a failure to obtain prior authorization, and turnaround times for prior authorization requests. Such information could be provided for benefits subject to prior authorization in each benefit classification in which the NQTL is imposed on mental health and substance use disorder benefits and medical/surgical benefits. All such examples of relevant data are non-exhaustive and whether any particular type of data is relevant for a plan or coverage is based on each plan's or coverage's unique design.

Relevant data for NQTLs related to network composition standards could include, as appropriate, but are not limited to, in-network and out-of-network utilization rates (including data related to provider claim submissions); network adequacy metrics (including time and distance data, and data on providers accepting new patients); and provider reimbursement rates (for comparable services and as benchmarked to a reference standard). The Departments modified this

illustrative list of relevant data for NQTLs related to network composition by specifying that provider reimbursement rates should be analyzed for comparable services and as benchmarked to a reference standard, to better ensure that comparisons between access to mental health and substance use disorder benefits and medical/surgical benefits will be informative. Thus, for example, the Departments expect a plan or issuer with a typical plan or coverage design could look at the ratio of inpatient, in-network and outpatient, in-network mental health and substance use disorder and medical/surgical claims, as compared to inpatient, out-of-network and outpatient, out-of-network mental health and substance use disorder and medical/surgical claims. Plans and issuers could also look at the number of providers (or facilities) within specified mental health and substance use disorder and medical/surgical provider categories (or categories of facilities) per 1,000 participants and beneficiaries who have actively submitted claims within the past 6 months, which would reflect the experience of a plan's or issuer's participants and beneficiaries within a recent period of time, controlled for plan or issuer size. Additionally, a plan or issuer could look at the turnaround time for applications to be approved for a provider to join the plan's or issuer's network and the approval and denial rates for applications submitted by mental health and substance use disorder providers as compared to medical/surgical providers. The Departments recognize that providers may differ in education, training, and specialization, and the categories of mental health and substance use disorder and medical/surgical providers for which data is compared should take this into account. Additionally, relevant data could include the percentage of participants and beneficiaries who can access, within a specified time and distance by county-type designation, one (or more) in-network providers who are available to accept new patients for mental health and substance use disorder and medical/surgical provider categories. Relevant data for NQTLs related to network composition could also include median in-network reimbursement rates for services with the same CPT codes, as well as median in-network reimbursement rates for inpatient mental health and substance use disorder benefits and medical/surgical benefits, as compared to Medicare rates; and median in-network reimbursement rates for outpatient mental health and substance use

⁷⁹ As explained later in this preamble, these final rules provide additional provisions on how to comply with the relevant data evaluation requirements for an NQTL newly imposed by a plan or issuer or an NQTL where no data exist that can reasonably assess any relevant impact of the NQTL on access. The provisions of these final rules with respect to these types of NQTLs shall only apply in very limited circumstances.

disorder benefits, and medical/surgical benefits, as compared to Medicare rates.

The Departments have the authority to request data—in addition to what a plan or issuer determines to be relevant data for any particular NQTL and includes in its comparative analyses—to sufficiently analyze the plan's or issuer's assertions, pursuant to the applicable enforcement statutes and as permitted by the amendments made by the CAA, 2021 to the Code, ERISA, and the PHS Act.⁸⁰ Similarly, nothing in these final rules would prohibit an applicable State authority from requesting additional data with regard to an issuer's comparative analysis. Accordingly, plans and issuers may be required to take reasonable action if the additional data requested by the Departments or an applicable State authority reveal material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits.

The Departments understand that many plans and issuers rely on TPAs and other service providers to administer a group health plan or health insurance coverage and acknowledge that several commenters highlighted the difficulty plans and issuers sometimes face obtaining the necessary information from their service providers to perform and document their comparative analyses. However, other commenters highlighted categories of data that TPAs and other service providers are able to provide for purposes of the relevant data evaluation requirements. Plans and issuers remain responsible for compliance with MHPAEA, and for ERISA-covered group health plans, fiduciaries, including TPAs or other service providers who are acting as fiduciaries, must work with plan sponsors and issuers to ensure that the plans and coverage they help establish and administer comply with the law. In the preamble to the proposed rules, the Departments highlighted that, under ERISA, TPAs may be fiduciaries with respect to private sector, employment-based group health plans. To the extent these TPAs are fiduciaries for those plans, they are subject to the provisions governing fiduciary conduct and liability, including the provisions for co-fiduciary liability under ERISA section 405. The Departments also noted their commitment to using all available authority to ensure compliance by plans and issuers with MHPAEA and requested specific comments on how best to ensure all the entities involved

in the design and administration of a group health plan's benefits provide the necessary information to plans and issuers to support their efforts to comply with MHPAEA.

Some commenters requested that the Departments require that plan sponsors include MHPAEA compliance provisions in their contracts with TPAs, likening such a requirement to actions taken by HHS to require that covered entities include provisions in their contracts with outside entities related to obligations under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. Others suggested focusing on compliance at the service provider level and working with Congress to obtain the ability to issue civil monetary penalties for violations of MHPAEA.

The Departments decline to make any changes in these final rules to specifically address these issues after consideration of the suggestions contained in the comments. These proposals, including requiring the inclusion of contracting provisions similar to HIPAA "business associate agreements," would go beyond the scope of this rulemaking. However, these types of contract provisions are a best practice that could be helpful to many plans and issuers in complying with their obligations to perform and document comparative analyses of NQTLs applied to mental health or substance use disorder benefits and medical/surgical benefits.

Additionally, DOL also underscores its commitment to holding fiduciaries of ERISA-covered group health plans liable through existing means and working with all relevant entities, including service providers, to effectuate MHPAEA compliance. DOL remains committed to its current enforcement approach, which prioritizes potential violations that affect not just one plan or coverage, but hundreds or thousands of plans that provide coverage for thousands or millions of individuals. Where NQTL violations are identified in a plan or coverage, DOL generally examines the role that each of the plan's or issuer's service providers have in the design and administration of each NQTL to ascertain whether any of the service providers play a similar role serving other plans or issuers that might have the same violations, and seeks to bring them into compliance. Where necessary, DOL determines who is a fiduciary under ERISA and what additional enforcement actions are necessary. DOL notes that determinations of fiduciary liability are often based on the facts and circumstances specific to individual

cases, but to the extent a TPA exercises discretionary authority or discretionary responsibility in the administration of an ERISA-covered health plan, DOL generally considers them to be fiduciaries.⁸¹

The Departments acknowledge both the challenges, cost, and complexity of collecting and evaluating data and the importance of data to measure the impact of an NQTL on access. The Departments also understand the importance of performing and documenting comparative analyses consistent with the statute. Therefore, these final rules provide additional provisions on how to comply with the relevant data evaluation requirements for an NQTL newly imposed by a plan or issuer or an NQTL where no data exist that can reasonably assess any relevant impact of the NQTL on access. A rule of construction at 26 CFR 54.9812-1(c)(4)(iii)(A)(3)(iii), 29 CFR 2590.712(c)(4)(iii)(A)(3)(iii), and 45 CFR 146.136(c)(4)(iii)(A)(3)(iii) in these final rules explains that the provisions of these final rules with respect to these types of NQTLs shall only apply in very limited circumstances and, where applicable, shall be construed narrowly, consistent with the fundamental purpose of MHPAEA. The Departments are of the view that relevant data can be collected and evaluated for nearly all NQTLs, and note that, when designing a new NQTL, or making changes to an existing NQTL, plans and issuers must consider what data is relevant and how it will be collected and evaluated.

The Departments recognize that there may be a lag between when an NQTL is newly designed and applied and when relevant data are available if there are no data available initially to assess the NQTL's impact on access to mental health and substance use disorder benefits and medical/surgical benefits. Under these final rules, if a plan or issuer newly imposes an NQTL (including because the plan or coverage itself is newly offered) for which data are initially and temporarily unavailable, and the plan or issuer therefore cannot comply with the relevant data evaluation requirements for the NQTL, a plan or issuer must include in its comparative analysis a detailed explanation of the lack of relevant data, the basis for the plan's or

⁸¹ ERISA section 3(21)(A). See, e.g., *Mertens v. Hewitt Assocs.*, 508 U.S. 248, 262 (1993) (stating that a fiduciary is defined "not in terms of formal trusteeship, but in functional terms of control and authority over the plan"); *Hamilton v. Allen-Bradley Co., Inc.* 244 F.3d 819, 824 (11th Cir. 2001) (stating a person is a fiduciary "to the extent" that "he has any discretionary authority or discretionary responsibility in the administration of such plan").

⁸⁰ See Code section 9812(a)(8)(B)(ii), ERISA sections 504 and 712(a)(8)(B)(ii), and PHS Act sections 2723 and 2726(a)(8)(B)(ii).

issuer's conclusion that there is a lack of relevant data, and when and how the data will become available and be collected and analyzed. Additionally, the plan or issuer must comply with the relevant data evaluation requirements as soon as practicable once relevant data becomes available. These additional provisions are intended to be applicable only in very limited circumstances where a plan or issuer newly imposes an NQTL for which no relevant data is available for a limited time after it is first imposed, and will not be available for a new NQTL where data is available but not evaluated due to lack of collection. The Departments note that a change in an NQTL's design or application is generally not considered a new NQTL for which there is no data initially available. In the very limited situations where a data lag exists for a new NQTL, the Departments expect a plan or issuer to comply with the relevant data evaluation requirements and include data in its comparative analyses within a limited amount of time (as soon as practicable, but no later than the end of the second plan year that follows the imposition of a new NQTL).

These final rules also acknowledge that some limited circumstances may exist in which no data exists that can reasonably assess any relevant impact of an NQTL on access to mental health and substance use disorder benefits as compared to medical/surgical benefits. Such NQTLs might include, in certain circumstances, for example, some exclusions based on whether a treatment is experimental or investigative. As commenters have highlighted, these NQTLs are not generally attached to claims, so plans and issuers may not have reliable data on the impact of these excluded services with respect to participants and beneficiaries. In the limited circumstances where no relevant data exist relating to an NQTL, these final rules require the plan or issuer to include in its comparative analysis a reasoned justification as to the basis for its conclusion that there are no data that can reasonably assess the NQTL's impact, why the nature of the NQTL prevents the plan or issuer from reasonably measuring its impact, an explanation of what data was considered and rejected, and documentation of any additional safeguards or protocols used to ensure that the NQTL complies with MHPAEA. A plan or issuer also must comply with the relevant data evaluation requirements as soon as practicable if the plan or issuer becomes aware (or

reasonably should become aware) of data that can reasonably assess any relevant impact of the NQTL.

The Departments also note that the unavailability of data for purposes of the relevant data evaluation requirements of these final rules does not affect the plan's or issuer's obligation to comply with the design and application requirements.

Material Differences in Access

Under the proposed rules, to the extent the relevant data evaluated show material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, the differences would be considered a strong indicator that the plan or issuer has violated the proposed no more restrictive requirements or the design and application requirements. In such instances, the proposed rules would require plans and issuers to take reasonable action to address the material differences in access as necessary to ensure compliance, in operation, with the proposed no more restrictive requirement and design and application requirements, and document the action that has been or is being taken by the plan or issuer to address any material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits. The Departments stated in the preamble to the proposed rules that material differences alone would not automatically result in a finding of noncompliance, except where related to network composition, as discussed in more detail later in this preamble.

Some commenters supported the proposal that material differences in access would constitute a strong indicator of noncompliance, stating that such approach is a reasonable method to identify potential instances of noncompliance while allowing for instances where disparities in access are due to factors beyond the plan's or issuer's control. Several commenters opposed the proposal that material differences would constitute a strong indicator of noncompliance, stating that this would be inconsistent with the Departments' previous statements in the 2020 MHPAEA Self-Compliance Tool that negative outcomes data is a red flag, but not determinative of compliance. One commenter stressed that it was important to provide clarity on how the Departments would impose this standard.

Several commenters requested that the Departments define the term "material differences," and many commenters provided suggested

meanings for the term. A number of commenters requested that the term be defined as a serious or significant variation, or one that would have a major effect on access to care. One commenter suggested that the definition of material differences should set a high standard to identify clear outliers and major differences in access rather than moderate variations. Some commenters stated that any definition of material differences in access should be based only on statistical significance. One commenter suggested a 10-percent difference as the definition of a material difference. Other commenters requested that the Departments adopt a "de minimis" standard, rather than a material differences in access standard. Additionally, some commenters suggested that material differences in access should mean that a substantial number of members could not access mental health and substance use disorder benefits. Several other commenters suggested that material differences be defined to allow an acceptable level of difference in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, accounting for participant behavior as a driver of accessibility, with consideration of data credibility and the amount of available data. Another commenter highlighted that relevant factors should include the size of the data pool, variability over time, availability of complementary measures, and the degree of control.

Some commenters suggested that differences in data outcomes might result from a wide variety of reasons that do not indicate noncompliance, including random variability, provider or member behavior, changes to unrelated Federal or State laws, or other factors that are outside of the plan's or issuer's control. One commenter requested that plans and issuers be permitted to take into account relevant context (for example, there are many more drugs that are considered medical/surgical benefits than mental health and substance use disorder benefits, so the percentage of mental health and substance use disorder drugs to which NQTLs apply may be higher).

The Departments are finalizing language specifying that, to the extent the relevant data evaluated suggest that the NQTL contributes to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits in a classification, such differences will be considered a strong indicator that the plan or issuer is in violation of MHPAEA. The material differences standard reflects an interpretation of the

statutory terms “substantially all” and “predominant” in a manner that takes into account the multifaceted nature of NQTLs, as well as the complexity of analyzing such NQTLs. The material differences standard is intended to set forth a principle-based approach to determining whether relevant data suggest that an NQTL applied to mental health or substance use disorder benefits is more restrictive than the predominant NQTL applied to substantially all medical/surgical benefits in a classification. The standard also allows plans and issuers, when applying an outcomes-based analysis, the flexibility to assess comparability in a way that can be tailored to a variety of different types of NQTLs, and to account for outliers or claims experience that may not be reflective of a difference in access resulting from the NQTL itself.

The Departments emphasize that the material differences standard works together with the other requirements contained in these final rules. A plan or issuer cannot determine whether an NQTL applied to mental health or substance use disorder benefits is more restrictive than the predominant NQTL applied to substantially all medical/surgical benefits without evaluating the effect of imposing the NQTL on access to mental health and substance use disorder benefits as compared to medical/surgical benefits. Additionally, when the plan or issuer knows or should know that one or more of its NQTLs is contributing to material differences in access, it cannot simply disregard or avoid ascertaining that information, and continue its current practices, but instead must act consistent with its obligation to ensure that NQTLs applied to mental health and substance use disorder benefits generally are no more restrictive than those applied to medical/surgical benefits.

While the preamble to the 2013 final regulations stated that “[d]isparate results alone do not mean that the NQTLs in use do not comply with these requirements,”⁸² the Departments have consistently stressed in subregulatory guidance that disparate results are a red flag or a warning sign of noncompliance, including in the 2020 MHPAEA Self-Compliance Tool, which states that “. . . while outcomes are not determinative of a MHPAEA violation, they can often serve as red flags or warning signs to alert the plan or issuer that a particular provision may warrant

further review.”⁸³ The experience of the Departments in enforcing MHPAEA, moreover, has shown that plans and issuers are commonly unprepared to explain material differences in outcomes data, and in some cases, have mistakenly considered the 2013 final regulations as granting freedom to ignore potentially problematic or significant differences, even where such differences appear to have a direct causal link to the plan’s practices and limitations.

These final rules, as discussed later in this preamble, make clear that plans and issuers must consider whether such material differences exist, and whether the differences are attributable to the NQTL. In instances where the relevant data suggest that the NQTL contributes to material differences, these final rules require plans and issuers to take reasonable action, as necessary, to address the material differences and to document that such action has or will be taken to ensure compliance, in operation, with the requirements for NQTLs under these final rules.

This increased emphasis on outcomes data and the material differences standard will help ensure that more restrictive NQTLs are not imposed on mental health and substance use disorder benefits as compared to the predominant NQTLs applied to substantially all medical/surgical benefits in the same classification by identifying when an NQTL results in differences in access that are likely to have a negative impact on access to mental health or substance use disorder benefits as compared to medical/surgical benefits. This standard generally would not include a de minimis difference in access or a difference driven by an outlier, such as a single plan participant’s claims experience or a single claim. The Departments also note that the existence of material differences in access do not automatically result in a finding of noncompliance, and that plans and issuers will continue to have the opportunity provide additional information as part of the NQTL comparative analysis process, as well as to respond to the Departments in any

enforcement actions, by submitting additional data, the sources of the data, explanatory material, related documents, evidence of reasonable actions that have been or are being taken by the plan or issuer to address such differences, and other material and information to demonstrate compliance with MHPAEA.

The Departments acknowledge comments from plans and issuers asking for guidance on how to determine whether a difference is material for purposes of the relevant data evaluation requirements, as well as those asking for a principle-based approach rather than specific thresholds for each outcome measure, because what is material will likely vary by NQTL, market, plan, and benefit classification for each item or service, as well as the number of participants and beneficiaries affected. In these final rules, the Departments set forth a standard that takes into account the range of commenters’ suggestions and incorporates them into a single standard, while helping to ensure that participants’ and beneficiaries’ access to mental health and substance use disorder benefits is in parity with their access to medical/surgical benefits.

Specifically, under these final rules, relevant data are considered to suggest that the NQTL contributes to material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits if, based on all relevant facts and circumstances, and taking into account specific considerations,⁸⁴ the difference in the data suggests that the NQTL is likely to have a negative impact on access to mental health or substance use disorder benefits as compared to medical/surgical benefits. For this purpose, these final rules specify that relevant facts and circumstances may include, but are not limited to, the terms of the NQTL at issue, the quality or limitations of the data, causal explanations and analyses, evidence as to the recurring or non-recurring nature of the results, and the magnitude of any disparities. The Departments note that plans and issuers may consider other

⁸³ Final FAQs About Mental Health and Substance Use Disorder Parity Implementation and the 21st Century Cures Act Part 39, Q 7 (Sept. 5, 2019), <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-39-final.pdf> and <https://www.hhs.gov/guidance/document/affordable-care-act-implementation-faqs-final-set-39> (FAQs Part 39); EBSA, Self-Compliance Tool for the Mental Health Parity and Addiction Equity Act (MHPAEA) (2020), pg. 27, <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/self-compliance-tool.pdf>.

⁸⁴ The considerations outlined in these final rules refer to differences in access to mental health or substance use disorder benefits attributable to generally recognized independent professional medical or clinical standards or carefully circumscribed measures reasonably and appropriately designed to detect or prevent and prove fraud and abuse that minimize the negative impact on access to appropriate mental health and substance use disorder benefits. See 26 CFR 54.9812–1(c)(4)(iii)(B)(2)(ii), 29 CFR 2590.712(c)(4)(iii)(B)(2)(ii), and 45 CFR 146.136(c)(4)(iii)(B)(2)(ii). Differences solely attributable to such standards or measures are not treated as material differences for purposes of these final rules.

⁸² 78 FR 68240, 68245 (Nov. 13, 2013).

relevant facts and circumstances that are not specifically listed in these final rules, as appropriate, and that differences in access to mental health or substance use disorder benefits attributable to independent professional medical or clinical standards or fraud and abuse measures are not considered to be material, as discussed later in this preamble.

The Departments are of the view that the quality or limitations of the relevant data are a key consideration in determining whether a difference in the data suggests that an NQTL contributes to a material difference in access to mental health and substance use disorder benefits as compared to medical/surgical benefits. As discussed earlier in this preamble, the Departments acknowledge the difficulty some plans and issuers may face in obtaining the necessary information, including data, from their service providers to perform and document their comparative analyses. The Departments are also aware that plans and issuers might not have direct control over the quality of the data they receive from a service provider. Despite this, the Departments do not intend for this consideration to create a loophole that allows plans and issuers to avoid determining materiality when evaluating differences in relevant data. Rather, the Departments expect plans and issuers to consider the quality and limitations of any available relevant data as just one of multiple potential facts and circumstances when assessing the impact of an NQTL on access to mental health and substance use disorder benefits and medical/surgical benefits.

When considering causal explanations and analyses in determining whether a difference in the data suggests that an NQTL contributes to a material difference in access, plans and issuers should consider whether they are attributable to the NQTL, instead of being attributable to other factors or considerations. As discussed in more detail later in this preamble, a plan's or issuer's comparative analysis for an NQTL applicable to mental health and substance use disorder benefits and medical/surgical benefits must include a discussion of the actions that have been or are being taken by the plan or issuer to address any material differences in access. This discussion must include, as applicable, a reasoned explanation of any considerations beyond a plan's or issuer's control that contribute to the existence of material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits, including

those that result in the persistence of such material differences despite reasonable actions that have been or are being taken to address such differences by the plan or issuer.

For example, if a plan or issuer identifies, based on reliably established indicia of fraud and abuse, that a particular provider or facility has submitted fraudulent claims for mental health or substance use disorder benefits, resulting in a higher percentage of denials of claims for mental health or substance use disorder benefits than for medical/surgical benefits in the same classification, the evidence of fraud and abuse could be considered part of the relevant facts and circumstances for purposes of determining whether a material difference in access exists. Further, if a material difference in access exists, the evidence of fraud and abuse could also be considered part of the relevant facts and circumstances for purposes of determining whether the difference is attributable to the NQTL. In such a case, the plan or issuer might reasonably conclude that the difference in outcomes is attributable to higher underlying levels of fraud for mental health and substance use disorder benefits than for medical/surgical benefits in the same classification (with the commission of the fraud being a circumstance that is beyond the plan's or issuer's control), rather than the application of a more restrictive NQTL to mental health or substance use disorder benefits. As explained later in this preamble, under these final rules, the plan or issuer must include in its comparative analysis a reasoned explanation of the reliably established indicia of fraud and abuse beyond the plan's or issuer's control that contribute to the existence of material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits.

The Departments note that a difference in access to mental health or substance use disorder benefits as compared to medical/surgical benefits that is driven by an outlier, such as a single plan participant's claims experience or a single claim, will generally not be considered material for this purpose because the nature of the results of the evaluation of relevant data would not be considered recurring. Therefore, such a difference would not trigger the requirement to take reasonable action, as necessary, under these final rules.

In the preamble to the proposed rules, the Departments solicited comments on whether materiality should be defined in terms of the results of statistical testing and requested feedback from

interested parties on the optimal method for assembling data and statistical analysis. As highlighted earlier in this preamble, commenters requested that the definition of material differences account for statistically significant differences, and take into account the amount of available data, while also excluding differences related to random variability. The Departments are of the view that plans and issuers can explain in their comparative analyses whether differences are or are not statistically significant and why, based on the relevant facts and circumstances, such differences are determined to be or not to be material. However, the Departments also recognize that statistical significance might not always be appropriate to consider, and that there would be challenges with requiring plans and issuers to use a statistical analysis in determining whether material differences in access exist for all NQTLs, as well as whether and how those differences are attributable to the NQTL or NQTLs in question.⁸⁵

Plans and issuers should carefully consider the magnitude of any negative impact on access to mental health or substance use disorder benefits as compared to medical/surgical benefits and whether the relevant data therefore suggest an NQTL contributes to a material difference in access that might require the plan or issuer to take reasonable action, as necessary, to ensure compliance, in operation, with the requirements for NQTLs under these final rules. As noted earlier in this preamble, a difference in access to mental health or substance use disorder benefits as compared to medical/surgical benefits that is de minimis will not be considered material for purposes of the relevant data evaluation requirements. The size of any negative impact on access, even if small, is part of the relevant facts and circumstances that could determine whether a disparity in access is material. These final rules do not require a plan or issuer to obtain a statistical, actuarial, or other equivalent opinion to support a conclusion as to whether a difference in access demonstrated by relevant data is material, based on the relevant facts and

⁸⁵ The Departments also recognize that smaller plans may have limited relevant data to evaluate, which could result in the plan not having sufficient data to identify statistically significant differences in the data. The Departments note that, because these final rules do not require that a difference be statistically significant to constitute a material difference, small sample size does not amount to circumstances under which the provisions in 26 CFR 54.9812-1(c)(4)(iii)(A)(3), 29 CFR 2590.712(c)(4)(iii)(A)(3), and 45 CFR 146.136(c)(4)(iii)(A)(3) would apply.

circumstances. However, a plan or issuer may obtain such an opinion, and if relying on it as part of performing its comparative analysis, the plan or issuer should document the relevance of that opinion to the conclusion that a difference in data suggests or does not suggest material difference in access, as part of the comparative analysis. For plans and issuers that do use such an opinion to support a conclusion as to the materiality of differences in access, the Departments would expect these opinions or determinations to be made by a qualified and, if applicable, licensed or otherwise accredited individual or organization. Additionally, the individual's or organization's qualifications must be documented as part of the comparative analysis, along with a description of the extent to which the plan or issuer ultimately relied upon the individual's or organization's evaluation in performing and documenting the comparative analysis of the design and application of the NQTL, as discussed in more detail later in this preamble. The Departments note that a statistical, actuarial, or other equivalent opinion obtained by a plan or issuer to support a conclusion as to whether a difference in access based on relevant data is or is not material is not dispositive simply because it is made by a qualified, licensed or otherwise accredited individual or organization. In the course of enforcement, the Departments and applicable State authorities may review and assess the validity of the assertions, and the factors upon which such assertions are based, contained in such an opinion, as well as a plan's or issuer's determination as to whether any particular difference in access to mental health or substance use disorder benefits as compared to medical/surgical benefits is or is not material.

In these final rules, the Departments decline to finalize the proposed exception to the relevant data evaluation requirements for independent professional medical or clinical standards, as discussed later in this preamble. The Departments are of the view that plans and issuers that impose NQTLs that utilize such standards as the basis for, or as, factors or evidentiary standards, should collect and evaluate relevant data, to determine the impact of NQTLs developed or applied using these standards on access to mental health and substance use disorder benefits as compared to medical/surgical benefits. However, reliance on such standards can improve care and health outcomes for participants and beneficiaries. The

Departments also recognize that clinical differences between mental health conditions, substance use disorders, medical conditions, and surgical procedures may sometimes drive apparent differences in data outcomes, even where plans and issuers rely on independent professional medical or clinical standards. Therefore, under these final rules, differences in access to mental health or substance use disorder benefits attributable to generally recognized independent professional medical or clinical standards that are used as the basis for a factor or evidentiary standard used to design or apply an NQTL are not considered to be material. To the extent a plan or issuer attributes any differences in access to the application of such standards, the plan or issuer must explain its bases for that conclusion in the plan's or issuer's comparative analysis, as discussed later in this preamble.

The Departments did not propose that NQTLs related to fraud, waste, and abuse measures would be excepted from the relevant data evaluation requirements. However, as discussed earlier in this preamble, reliably established indicia of fraud and abuse could, if appropriate, be considered relevant facts and circumstances taken into account by a plan or issuer when determining whether a difference in access is material. Indicia of fraud and abuse could also be relevant in determining whether a material difference in access is attributable to an NQTL or, instead, is attributable to the use of fraud and abuse measures. Therefore, under these final rules, a difference in access to mental health or substance use disorder benefits attributable to carefully circumscribed measures reasonably and appropriately designed to detect or prevent and prove fraud and abuse that minimize the negative impact on access to appropriate mental health and substance use disorder benefits are not considered to be material. As discussed later in this preamble, in such a case, a plan's or issuer's comparative analysis must provide a thorough and reasoned explanation that indicia for fraud and abuse have been reliably established through objective and unbiased data, and that such measures are narrowly designed to minimize the negative impact on access to appropriate mental health and substance use disorder benefits as compared to medical/surgical benefits in the same classification.

Reasonable Action, as Necessary, To Address Material Differences in Access

The proposed rules provided that a plan or issuer would be required to take reasonable action to address any material differences in access as necessary to ensure compliance, in operation, with the proposed no more restrictive requirement and design and application requirements. The preamble to the proposed rules noted that whether any particular action would be considered reasonable in response to any material differences in access resulting from an evaluation of outcomes data would be determined based on the relevant facts and circumstances, including the NQTL itself, the relevant data, the extent of the material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, and the impact of the material differences in access on participants and beneficiaries. The Departments proposed that, in addition to taking reasonable action to address material differences, a plan or issuer would also be required to document in its comparative analyses any such action that has been or is being taken by the plan or issuer to mitigate any material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits. The Departments noted in the preamble to the proposed rules that plans and issuers could use this documentation to explain why material differences demonstrated by the relevant outcomes data should not be considered a violation of the rules for NQTLs (other than NQTLs related to network composition) and solicited comments on what additional information is necessary to clarify what would constitute reasonable action in response to relevant data that reveal material differences in access.

Several commenters supported the requirement to take reasonable action in response to relevant data that reveals material differences in access. Some commenters suggested that "reasonable action" should be defined and should mean actions, including, but not limited to, internal reforms and modifications or elimination of the NQTL to resolve the material differences. One commenter stated that requiring reasonable action where there is no violation of the law and without an opportunity to explain why material differences in access may not in fact be a violation of MHPAEA is arbitrary and capricious and goes beyond the authority of the Departments. Therefore, the commenter noted reasonable action should be

required only after an opportunity to rebut a presumption of noncompliance.

Under these final rules, when a plan or issuer knows or reasonably should know that NQTLs may be contributing to material differences in access, it must take reasonable action, as necessary, to ensure compliance, in operation, with the requirements for NQTLs under these final rules. The standard is not focused on inconsequential differences, but rather only on those that are material, meaning those that are likely to have a negative impact on access to mental health or substance use disorder benefits as compared to medical/surgical benefits. If a plan or issuer is aware of information that suggests a potential violation of MHPAEA, the statute requires the plan or issuer to address such potential violations as necessary to satisfy its obligation to ensure that the NQTLs comply with the substantive requirements of the statute,⁸⁶ and to be able to continue to impose the NQTL. The requirement to take reasonable action, as necessary, where material differences in access exist is consistent with the statutory requirement that plans and issuers ensure that treatment limitations (including NQTLs) applicable to mental health or substance use disorder benefits are no more restrictive than the predominant treatment limitations applied to substantially all medical/surgical benefits. If the relevant data suggest that an NQTL contributes to material differences in access, a plan or issuer generally is not able to ensure compliance with MHPAEA, in operation, unless the plan or issuer takes action that is reasonably designed to try to close the gap and address those differences.

The proposed rules would have required plans and issuers to take reasonable action to address material differences in access as necessary to ensure compliance, in operation, with the proposed no more restrictive requirement and design and application requirements. However, as discussed earlier in this preamble, these final rules do not retain the proposed mathematical substantially all and predominant tests and instead retain language that incorporates the statutory requirements of Code section 9812(a)(3)(A), ERISA section 712(a)(3)(A), and PHS Act section 2726(a)(3)(A), as the general rule for NQTLs. Therefore, these final rules make technical changes to replace the cross-references in the material differences standard to the proposed no more restrictive requirement and design

and application requirements, and replace them with a cross-reference to the general rule for NQTLs.

The Departments acknowledge commenters' requests for guidance on what constitutes reasonable action for this purpose. The Departments anticipate that, in many cases, the reasonable actions that plans and issuers might take, as necessary, to address material differences in access will be similar to actions they might have taken independent of the requirements contained in these final rules. For example, some plans and issuers may already take certain action in response to changes in demand for services, needs of patients, or requests from plan sponsors, which could be considered reasonable action for this purpose, depending on the relevant facts and circumstances. Commenters highlighted that, since the enactment of MHPAEA, plans and issuers have increased spending and raised reimbursement rates for mental health and substance use disorder services, and invested in programs to help members identify mental health and substance use disorder care needs and to connect them to the appropriate services as early as possible. Commenters also highlighted that plans and issuers have also developed mental health assessment screening tools for youth populations to detect those at risk. Depending on the facts and circumstances, all of these actions could be examples of reasonable actions that plans and issuers can take, as necessary, where the relevant data suggest that an NQTL contributes to material differences, as required under these final rules. However, plans and issuers will ultimately be responsible for assessing the nature of a material difference in access to determine what reasonable action should be taken, as necessary, to address those differences.

In addition, a plan or issuer must document the actions that have been or are being taken in the plan's or issuer's comparative analysis and include a reasoned explanation of any material differences in access that persist despite reasonable actions that have been or are being taken. For a plan or issuer designing and applying one or more NQTLs related to network composition standards, the comparative analysis must include a discussion of the actions that have been or are being taken to address material differences in access to in-network mental health and substance use disorder benefits as compared to in-network medical/surgical benefits.

Special Rule for NQTLs Related to Network Composition

In the preamble to the proposed rules, the Departments noted a growing disparity between in-network reimbursement rates for mental health and substance use disorder providers and medical/surgical providers, as well as a significant disparity between how often participants and beneficiaries have little or no choice under their plan or coverage but to utilize out-of-network mental health and substance use disorder providers and facilities, as compared to medical/surgical providers and facilities. The Departments also expressed their specific concerns about standards related to network composition and other related NQTLs, because these standards are critical to ensuring parity in access to mental health and substance use disorder benefits for participants and beneficiaries. Therefore, the Departments included in the proposed rules a requirement that, in addition to the relevant data required for all NQTLs, plans and issuers would also be required to collect and evaluate relevant data for NQTLs related to network composition. For this purpose, the proposed rules stated that network composition NQTLs include, but are not limited to, standards for provider and facility admission to participate in a network or for continued network participation, including methods for determining reimbursement rates; credentialing standards; and procedures for ensuring the network includes an adequate number of each category of provider and facility to provide services under the plan or coverage. Under the proposed special rule, when designing and applying one or more NQTLs related to network composition standards, a plan or issuer would fail to meet the requirements of the proposed no more restrictive requirement and design and application requirements, in operation, if the relevant data show material differences in access to in-network mental health or substance use disorder benefits as compared to in-network medical/surgical benefits in a classification. This standard proposed to set a higher bar for NQTLs related to network composition than for other NQTLs by treating material differences in access to in-network mental health or substance use disorder benefits as compared to in-network medical/surgical benefits as a failure to meet the requirements of MHPAEA, instead of as a strong indicator of a violation of MHPAEA.

The Departments proposed that plans and issuers be required to take action to

⁸⁶ Code section 9812(a)(3)(A), ERISA section 712(a)(3)(A), and PHS Act section 2726(a)(3)(A).

address material differences in access for NQTLs related to network composition or no longer impose the relevant NQTLs to avoid a violation of MHPAEA. Examples of such actions listed by the Departments in the preamble to the proposed rules for NQTLs related to network composition include ensuring that plans and issuers or their service providers (as applicable) make special efforts to contract with a broad range of mental health and substance use disorder providers who are available, including authorizing greater compensation or other inducements to the extent necessary; expanding telehealth arrangements as appropriate to manage regional shortages; notifying participants and beneficiaries in clear and prominent language on the plan's or issuer's website, employee brochures, and the summary plan description of a toll-free number for help finding in-network providers; ensuring that the plan's or issuer's service providers (as applicable) reach out to the treating professionals and facilities to see if they will enroll in the network; and ensuring the network directories are accurate and reliable. The Departments also recognized that shortages of mental health and substance use disorder providers could pose challenges to issuers, plans, and their service providers. The preamble to the proposed rules noted that, if, despite taking appropriate action, relevant data collected and evaluated for NQTLs related to network composition continue to reveal material differences due to, for example, provider shortages that the plan or issuer cannot effectively address through no fault of its own, the Departments would not cite such a plan or issuer for failure to comply with the proposed relevant data evaluation requirements with respect to NQTLs related to network composition if the plan or issuer otherwise complied with other applicable MHPAEA requirements. However, the Departments noted that plans and issuers should be prepared to document the actions they have taken and to demonstrate why any disparities are attributable to provider shortages in the geographic area, rather than their NQTLs related to network composition.

Several commenters supported the special rule for NQTLs related to network composition, stating that it would address significant barriers to accessing mental health and substance use disorder services, and requested that the heightened requirement for such NQTLs be maintained in the final rules. Some commenters questioned the justification for treating standards for

network composition differently than all other NQTLs. Several commenters stated that the Departments misrepresented several of the key studies they relied on to support the proposed special rule. Some commenters highlighted that analyzing outcomes data related to network composition is a long-recognized and widely accepted tool in population health management but stated that the proposed rules would turn this tool into a compliance standard that would be virtually impossible to satisfy. One commenter highlighted that MHPAEA requires equity in treatment, not equity in outcomes, and that the special rule would go beyond what is required by statute, as well as the Departments' own admission that parity across mental health and substance use disorder and medical/surgical networks does not necessarily mean an equal number of providers in a classification. Another commenter stressed that the special rule was inappropriate without clarity about what the definition of a material difference would be. This commenter stated that the Departments should finalize, following additional public comment, an NQTL definition, a specific set of measures with technical specifications, and a benchmark for what they will consider to be "material difference" for each NQTL type. Other commenters suggested that the Departments not finalize this proposed provision.

Some commenters noted that there can be many reasons why outcomes might be different for mental health and substance use disorder benefits than medical/surgical benefits when evaluating relevant data, particularly with respect to network composition. Some of these commenters highlighted reasons that are outside the control of plans and issuers, such as shortages of mental health and substance use disorder providers or specialists. Some commenters requested that the final rules address situations where material differences in access are due to a lack of mental health and substance use disorder providers, while other commenters stated that general citations to provider shortages as the only cause of material differences in access should be rejected as inadequate, especially without evidence that those shortages drove disparities, rather than plan or issuer choices. One commenter argued that plans and issuers should have the opportunity to address any apparent gaps in network access and explain long-term initiatives to address those gaps.

Several commenters expressed concern that the special rule as

proposed would have adverse consequences for patient outcomes and safety because it would encourage plans and issuers to accept lower quality providers into their networks. One commenter noted that behavioral health care is commonly provided by primary care providers, and without including those providers in relevant data, a significant percentage of mental health treatment would not be captured when determining whether material differences in access exist. Other commenters expressed the importance of taking into account telehealth providers when analyzing relevant data for purposes of NQTLs related to network composition.

The Departments acknowledge the concerns raised by commenters on this aspect of the proposed rules; namely, the fact that a variety of metrics could be consulted as a plan or issuer evaluates its parity compliance regarding NQTLs related to network composition, and that parity for mental health and substance use disorder benefits as compared to medical/surgical benefits does not necessarily mean an equal number of mental health or substance use disorder and medical/surgical network providers. The Departments also understand the value of a consistent approach with regard to all NQTLs, while recognizing the impact of NQTLs related to network composition on access to care. Additionally, the Departments acknowledge the questions some commenters raised requesting more specific details on how to account for material differences in access for network composition NQTLs, including those due to provider shortages, which plans and issuers may not be able to effectively address through no fault of their own despite taking reasonable action. The Departments also note that certain outcomes measures, such as high out-of-network utilization for mental health or substance use disorder benefits as compared to medical/surgical benefits, may not necessarily represent a per se violation of MHPAEA.

The Departments agree with commenters that it is important to allow plans and issuers to address apparent gaps in relevant data, and that it is also important that the regulatory standard for NQTLs related to network composition is one that plans and issuers are able to satisfy. However, as stated in the preamble to the proposed rules, the Departments also recognize that network composition and access to mental health and substance use disorder benefits are the product of myriad NQTLs; processes, strategies, evidentiary standards, and other factors

used to design and apply NQTLs; and information, evidence, sources, and standards on which factors and evidentiary standards are based. As a result, the Departments remain concerned that plans and issuers could too readily evade their obligations under MHPAEA, if they were not obligated to diligently collect and evaluate relevant data, perform a careful analysis to determine whether material differences in access to mental health and substance use disorder benefits exist as a result of the cumulative impact of NQTLs related to network composition, and take reasonable actions that meaningfully address such differences in access.

After consideration of the comments, the Departments are not finalizing the proposed special rule for NQTLs related to network composition, and are instead including language in these final rules to explain how plans and issuers are expected to comply with the relevant data evaluation requirements with respect to those NQTLs. Specifically, these final rules require that a plan or issuer must collect and evaluate data in a manner reasonably designed to assess the aggregate impact of all such NQTLs on access to mental health and substance use disorder benefits and medical/surgical benefits, instead of evaluating relevant data for each NQTL separately (which is generally required under these final rules for NQTLs other than those related to network composition), to determine if there is a material difference in access. Furthermore, the final rules provide examples of possible actions that a plan or issuer could take to comply with the requirement to take reasonable action, as necessary, to address any material differences in access with respect to network composition NQTLs. While under these final rules, material differences in access related to network composition NQTLs are not automatically treated as a violation of MHPAEA (and instead are treated as a strong indicator of a violation, the same as all other NQTLs), the Departments emphasize that plans and issuers must engage in, and document in their comparative analyses, all reasonable actions, as necessary, to address any material differences in access.

While the approach to material differences for NQTLs related to network composition is different than that set forth in the proposed rules, these final rules will achieve the same goal of ensuring access to mental health and substance use disorder benefits in parity with access to medical/surgical benefits, by requiring plans and issuers to take reasonable action, as necessary, to address material differences in access

for in-network mental health and substance use disorder benefits as compared to in-network medical/surgical benefits. Furthermore, the approach for NQTLs related to network composition in these final rules will ensure that participants and beneficiaries are not subject to NQTLs with respect to mental health and substance use disorder benefits that are more restrictive than the predominant NQTLs applied to substantially all medical/surgical benefits under the plan or coverage.

The Departments stress the importance of the requirement under these final rules that plans and issuers take reasonable action, as necessary, where relevant data suggest that NQTLs related to network composition contribute to a material difference in access to in-network mental health and substance use disorder benefits as compared to in-network medical/surgical benefits in a classification, to ensure compliance with MHPAEA. These final rules provide an illustrative list of possible actions the Departments expect plans and issuers, working with their service providers, to take, as necessary, to address any material differences in access with respect to NQTLs related to network composition under the relevant data evaluation requirements. This includes plans and issuers working with their service providers, as applicable, to strengthen efforts to recruit and encourage a broad range of available mental health and substance use disorder providers and facilities to join the plan's or issuer's network of providers, including taking actions to increase compensation or other inducements, streamline credentialing processes, or contact providers reimbursed for items and services provided on an out-of-network basis to offer participation in the network, and expand the availability of telehealth arrangements to mitigate overall mental health and substance use disorder provider shortages in a geographic area. Additionally, plans and issuers should provide additional outreach and assistance to participants and beneficiaries enrolled in the plan or coverage to assist them in finding available in-network mental health and substance use disorder providers and facilities, and ensure that provider directories are accurate and reliable (including in accordance with Code section 9820(a), ERISA section 720(a), PHS Act section 2799A–5(a), and future implementing regulations and guidance). The Departments also expect plans and issuers to take other reasonable actions, as necessary, that are

intended to mitigate any material differences (even if not enumerated in these final rules).

As with other types of NQTLs, these final rules require plans and issuers to explain in their comparative analyses for NQTLs related to network composition the circumstances of any material differences in access and the actions that have been or are being taken to address these differences. If such actions do not fully resolve the material differences, a plan or issuer must provide a reasoned explanation in its comparative analysis of any material differences that persist despite reasonable actions that have been or are being taken. The Departments stress that a comparative analysis making only a cursory reference to provider shortages with little or no explanation of reasonable actions taken to address material differences in access will likely result in a finding by the relevant Secretary that the comparative analysis is insufficient and, without additional comparative analyses in response to an insufficiency notice or initial determination of noncompliance from the Secretary, may result in a final determination of noncompliance. As noted elsewhere in this preamble, the Departments expect that, if a plan or issuer intends to rely on an explanation of existing circumstances that cannot effectively be addressed through reasonable action, the explanation should include significant detail as to the circumstances resulting in material differences in access that are outside the plan's or issuer's control, and a robust discussion of the reasonable actions the plan or issuer has taken or is taking in an attempt to address such material differences.

Exception for Independent Professional Medical or Clinical Standards

The proposed rules specified a narrow exception under which plans and issuers would not be required to comply with the relevant data evaluation requirements for NQTLs that impartially apply independent professional medical or clinical standards.⁸⁷ As discussed in the following section of the preamble to these final rules, the Departments are not finalizing this proposed exception.

e. Independent Professional Medical or Clinical Standards and Fraud and Abuse Measures

In the preamble to the proposed rules, the Departments acknowledged that the application of independent professional

⁸⁷ The proposed rules did not include a similar exception from the relevant data evaluation requirements for standards related to fraud, waste, and abuse.

medical or clinical standards and fraud, waste, and abuse measures generally improve and help to ensure appropriate care for participants and beneficiaries, rather than restrict access to needed benefits. The Departments stated that NQTLs that reflect independent professional medical or clinical standards or guard against fraud, waste, and abuse (while minimizing the negative impact on access to appropriate benefits) are premised on standards that generally provide an independent and less suspect basis for determining access to mental health and substance use disorder treatment. Accordingly, the Departments proposed two narrow exceptions; one for NQTLs that impartially apply independent professional medical or clinical standards, and one for NQTLs reasonably designed to detect or prevent and prove fraud, waste, and abuse. Under those proposed exceptions, an NQTL that, with respect to mental health or substance use disorder benefits in any classification, impartially applies independent professional medical or clinical standards (consistent with generally accepted standards of care) would not be considered under the proposed rules to violate the proposed no more restrictive requirements, the prohibition on discriminatory factors and evidentiary standards, and the relevant data evaluation requirements. An NQTL that applies fraud, waste, and abuse measures would not be considered under the proposed rules to violate the proposed no more restrictive requirements or the prohibition on discriminatory factors and evidentiary standards.

The Departments noted in the preamble to the proposed rules that they do not intend to interfere with a plan's or issuer's ability to ensure that coverage for benefits for the treatment of mental health conditions and substance use disorders is consistent with independent professional medical or clinical standards or fraud, waste, and abuse measures. The Departments also recognized that there are instances in which the application of independent professional medical or clinical standards or fraud, waste, and abuse measures might result in differences in the design or application of NQTLs to mental health or substance use disorder benefits as compared to medical/surgical benefits due to clinical differences between mental health conditions and substance use disorders and medical/surgical conditions, as well as differences in the model of care, in a manner that could otherwise violate

certain aspects of the requirements for NQTLs in the proposed rules.

Several commenters opposed the proposed exceptions because they stated that plans and issuers would exploit them to improperly limit access to mental health and substance use disorder services. Some of these commenters stated that the Departments lack authority or a legal basis to implement the proposed exceptions because, in their view, the statute does not provide authority to establish exceptions to MHPAEA's requirements. Commenters also stated that the proposed exceptions could significantly undermine the other provisions of the proposed rules that would otherwise strengthen MHPAEA protections by creating opportunities for misuse or exploitation. Conversely, some commenters generally supported the proposed exceptions, but highlighted ambiguities related to how the exceptions would operate under the proposed rules to allow NQTLs to be applied with respect to mental health and substance use disorder benefits. These commenters also stated that the exceptions may be too narrow as proposed and that it is unclear how and what a plan or issuer must demonstrate to confidently rely on the proposed exceptions.

The Departments acknowledge these comments, as well as the comments received on each of the two proposed exceptions, which are addressed in more detail in this section of the preamble. After considering the comments, and for the reasons discussed later in this preamble, the Departments are not finalizing the proposed exceptions for independent professional medical or clinical standards or fraud, waste, and abuse measures, but explain how plans and issuers can account for such standards and fraud and abuse measures in implementing the provisions of these final rules.

Exception for Independent Professional Medical or Clinical Standards

To qualify for the exception for independent professional medical or clinical standards under the proposed rules, an NQTL would have to impartially apply those standards (consistent with generally accepted standards of care) to medical/surgical benefits and mental health or substance use disorder benefits. The NQTL could not deviate from those standards in any way, such as by modifying or otherwise imposing additional or different requirements. Under the proposed rules, an NQTL qualifying for this exception would not be required to satisfy the

proposed no more restrictive requirement or the proposed relevant data evaluation requirements. In addition, the independent professional medical or clinical standards would not be considered a discriminatory factor or evidentiary standard. The Departments noted that, under the proposed rules, the plan or issuer would still be required to ensure that such an NQTL complies with the rest of the design and application requirements. Additionally, the plan or issuer would be required to perform and document comparative analyses for NQTLs that impartially apply independent professional medical or clinical standards.

Some commenters stated that the exception for NQTLs that impartially apply independent professional medical or clinical standards should not be finalized, because the Departments rejected a similar exception in previous rulemaking. Specifically, these commenters highlighted that the Departments included an exception to the NQTL requirements for "recognized clinically appropriate standards of care" in the 2010 MHPAEA interim final regulations, which was later deleted in the 2013 final regulations. The preamble to the 2013 final regulations supported the decision to eliminate the exception by pointing to commenters' concern about abuse and the use of this exception by plans and issuers to try to justify stricter application of NQTLs.⁸⁸ These commenters highlighted that MHPAEA's statutory standard, as amended by the CAA, 2021 does not contain such exceptions to the NQTL requirements.

Some commenters urged the Departments to not finalize the proposed exception for NQTLs that impartially apply independent professional medical or clinical standards and instead require those standards to be considered as a factor in the NQTL comparative analysis, subject to all applicable requirements for NQTLs under the proposed rules. Alternatively, commenters requested that plans and issuers be required to document in their comparative analyses the ways in which the clinical standards and practices used to design and apply NQTLs deviate from independent professional medical or clinical standards, which should be tied to criteria or guidelines from relevant nonprofit clinical specialty associations. These commenters also stated that they support analogous State definitions of "generally accepted standards of care" instead of the proposed "generally recognized independent professional

⁸⁸ 78 FR 68240, 68245 (Nov. 13, 2013).

medical or clinical standards.”⁸⁹ Additionally, they suggested support for tying the definition to the criteria or guidelines from the relevant nonprofit clinical specialty associations.

Some commenters highlighted that the proposed exception appears to presume that there is a single set or “gold standard” of independent professional medical or clinical standards, when in practice, these standards can vary greatly, and consensus may not always exist for a particular condition. The commenters noted that medical and clinical standards are generally designed to guide health care providers and facilities in determining appropriate care for a given diagnosis or stage of treatment, not to determine how the standards should best be utilized for other purposes, so plans and issuers may need to adapt clinical standards to apply them in the context of health coverage. Therefore, they stated, it is unclear that the exception for independent professional medical or clinical standards as proposed could be relied on by plans and issuers as they design and apply NQTLs as it is unclear if this necessary adaptation would cause a plan or issuer to fail to impartially apply such standards.

Other commenters, who generally supported this proposed exception, stated that they found it to be generally vague and undefined. These commenters urged the Departments to define more clearly what constitutes independent professional medical or clinical standards for purposes of the proposed exception, and many commenters suggested language for the Departments to consider providing as additional clarifications. Some commenters noted that to “apply” such standards should be understood to mean to primarily rely on these resources when developing NQTLs and claimed that these standards lack the precision and detail necessary for the exception to be useful. Additionally, commenters requested that the Departments provide examples of standards that would qualify for the proposed exception and descriptions of their application.

After considering the comments, the Departments are not finalizing the exception for independent professional medical or clinical standards as

proposed. In light of the modifications to the requirements made in the final rules, the Departments agree with commenters that it is more appropriate for plans and issuers to include independent professional medical or clinical standards under the framework of the existing NQTL parity analysis than to provide an exception from the requirements of the final rules. Therefore, instead of finalizing the exception, the Departments are instead providing clarifications for how independent professional medical and clinical standards will be treated under these final rules. Specifically, NQTLs that are designed or applied, are based on, or are related to independent professional medical or clinical standards are subject to the design and application requirements and the relevant data evaluation requirements. As noted earlier in this preamble, such medical or clinical standards are not information, evidence, sources, or standards that are biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits. Additionally, for purposes of the relevant data evaluation requirements, differences in access to mental health or substance use disorder benefits that are attributable to the use of independent professional medical or clinical standards as the basis for a factor or evidentiary standard used to design or apply an NQTL are not considered to be material. To the extent the plan or issuer attributes any differences in access to the application of such standards, the plan or issuer must explain the bases for that conclusion in their comparative analysis.

Exception for Measures To Detect or Prevent and Prove Fraud and Abuse

The Departments also proposed an exception for NQTLs reasonably designed to detect or prevent and prove fraud, waste, and abuse. To qualify for the exception under the proposed rules, fraud, waste, and abuse measures would have to be reasonably designed to detect or prevent and prove fraud, waste, and abuse, based on indicia that have been reliably established through objective and unbiased data. The proposed rules also required that such standards be narrowly designed to minimize the negative impact on access to appropriate mental health and substance use disorder benefits. Under the proposed rules, an NQTL qualifying for this exception would not be required to satisfy the proposed no more restrictive requirement. In addition, fraud, waste, and abuse measures would not be

considered a discriminatory factor or evidentiary standard. The Departments noted that, under the proposed rules, the plan or issuer would still be required to ensure that such an NQTL complies with the rest of the design and application requirements. The proposed rules would also apply the relevant data evaluation requirements to these NQTLs, as the Departments stated that these tools, while important, are more likely than independent professional medical or clinical standards to result in NQTLs that may improperly restrict access to mental health and substance use disorder benefits because these NQTLs are largely both designed by, and applied within the control of, the plan or issuer. Additionally, the plan or issuer would be required to perform and document comparative analyses for NQTLs that are fraud, waste, and abuse measures.

Many commenters opposed the exception for NQTLs that are fraud, waste, and abuse measures. Similar to the objections to the exception for independent professional medical or clinical standards, these commenters highlighted that MHPAEA’s statutory language, as amended by the CAA, 2021 does not contain exceptions for any NQTLs. These commenters voiced concern that the two proposed exceptions, together, could allow plans and issuers to avoid compliance with the strengthened requirements of MHPAEA set forth in the proposed rules. Commenters opposing the fraud, waste, and abuse exception generally recommended that the Departments remove it altogether; however, some commenters recommended that, if retained, the exception should include stronger language limiting plans’ and issuers’ ability to invoke the exception. These commenters also recommended that the Departments eliminate references to “waste,” as this is arguably targeted by all forms of utilization management. Commenters requested that, alternatively, plans and issuers be required to document in their comparative analyses how their efforts to combat fraud, waste, and abuse comply with MHPAEA (including as a factor used to design or apply an NQTL).

Other commenters were generally supportive of the exception but expressed concerns that the Departments would interpret it too narrowly. They generally recommended that the Departments add definitional clarity to allow for flexibility and account for the use of a range of NQTLs that are fraud, waste, and abuse measures and provide examples. Some commenters also sought clarification

⁸⁹ 215 Ill. Comp. Stat. 5/370c, <https://www.ilga.gov/legislation/ilcs/fulltext.asp?DocName=021500050K370c>; Cal. Health & Saf. Code section 1374.72, https://leginfo.ca.gov/faces/billTextClient.xhtml?bill_id=201902000SB855; Ga. Code section 33–1–27 <https://www.legis.ga.gov/api/legislation/document/20212022/211212>; and N.M. Stat. section 59A–23–22, <https://www.nmlegis.gov/Sessions/23%20Regular/final/SB0273.pdf>.

about the documentation or evidence required for a plan or issuer to prove its qualification for the exception.

The Departments acknowledge that many NQTLs consider the potential for fraud, waste, and abuse as a factor in their design and application and have concluded that it is appropriate for plans and issuers to be required to treat these types of factors and NQTLs following the same framework as other NQTLs, subject to all applicable requirements. The Departments also agree that the term “waste” is too broad and could arguably include all forms of utilization management. Therefore, instead of finalizing the exception as proposed, the Departments are providing clarifications on how fraud and abuse measures will be treated under these final rules. Specifically, NQTLs that are designed or applied, are based on, or are related to fraud and abuse measures are subject to the design and application requirements and the relevant data evaluation requirements. However, for purposes of the prohibition on discriminatory factors and evidentiary standards, the final rules provide that fraud and abuse measures are not information, evidence, sources, or standards that are biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits. Additionally, for purposes of the relevant data evaluation requirements, a difference in access to mental health and substance use disorder benefits attributable to the use of fraud and abuse measures as the basis for a factor or evidentiary standard used to design or apply an NQTL is not considered to be material. To the extent that a plan or issuer attributes any differences in access to the application of such measures, the plan or issuer must explain the bases for that conclusion in their comparative analyses.

Requests for Additional Exceptions

Some commenters suggested additional exceptions to the requirements for NQTLs that the Departments should consider adding to the final rules. Specifically, some commenters requested an exception for NQTLs related to the quality and safety of mental health and substance use disorder services. Similarly, another commenter recommended the Departments include an exception for practices to ensure high-quality care, based on the view that the two exceptions (for independent professional medical or clinical standards and fraud, waste, and abuse measures) in the proposed rules are not

sufficient to curb substandard and ineffective treatment that does not reach the level of fraud, waste, and abuse.

Other commenters suggested exceptions for compliance with Federal and State law, an exception to ensure the quality and safety of mental health and substance use disorder benefits, an exception to the quantitative testing and discriminatory factor analysis for Network NQTLs, and an exception for when no outcomes data are reasonably available.

The Departments have considered whether additional exceptions beyond those included in the proposed rules should be included in these final rules. As discussed earlier in this preamble, there are a very limited number of NQTLs where no data exist that can reasonably assess the NQTL’s impact on access. Such NQTLs might include, for example, exclusions based on whether the treatment is experimental or investigative. Therefore, the Departments have provided guidance in these final rules on how plans and issuers must comply with the relevant data evaluation requirements for such NQTLs. However, as noted earlier in this preamble, such plans and issuers must still consider whether data can be used to reasonably assess the impact of the NQTL on relevant outcomes related to mental health and substance use disorder benefits and medical/surgical benefits. Consistent with the reasons described earlier in this preamble as to why the Departments declined to finalize the exceptions contained in the proposed rules, these final rules do not contain any additional exceptions.

f. Effect of Final Determination of Noncompliance—26 CFR 54.9812–1(c)(4)(v), 29 CFR 2590.712(c)(4)(v), and 45 CFR 146.136(c)(4)(v)

The proposed rules provided that if a plan or issuer receives a final determination from the relevant Secretary that it is not in compliance with the comparative analysis requirements with respect to an NQTL, the NQTL would violate the substantive requirements for NQTLs,⁹⁰ and the relevant Secretary may direct the plan or issuer not to impose the NQTL unless and until the plan or issuer demonstrates to the relevant Secretary compliance with the requirements of MHPAEA or takes appropriate action to remedy the violation. Whereas the requirement in the introductory paragraph of proposed 26 CFR 54.9812–1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4) states that a plan or issuer may not impose an NQTL in the

first instance unless it meets all of the applicable substantive requirements for NQTLs under the proposed rules, this proposed provision addresses the effect of a final determination of noncompliance with the NQTL comparative analysis documentation requirements under proposed 26 CFR 54.9812–2, 29 CFR 2590.712–1, and 45 CFR 146.137.

The Departments noted in the proposed rules that MHPAEA requires that “such plan or coverage shall ensure that” the treatment limitations comply with the substantive requirements of the statute.⁹¹ The Departments also noted that the statute further requires that the plan or issuer perform and document adequate comparative analyses for NQTLs to ensure compliance.⁹² Therefore, to comply with MHPAEA, plans and issuers must comply with both the substantive MHPAEA requirements and the documentation requirements. Under the proposed rules, plans and issuers would be required to ensure both that they are complying with MHPAEA’s substantive requirements at all times an NQTL is imposed with respect to mental health or substance use disorder benefits, and that they have properly performed and documented comparative analyses for the NQTLs imposed on mental health or substance use disorder benefits (regardless of the timing of any request for such documentation).

Under the proposed rules, when a plan or issuer receives a final determination from the Departments with respect to an NQTL that it has failed to demonstrate compliance with the NQTL comparative analysis documentation requirements under proposed 26 CFR 54.9812–2, 29 CFR 2590.712–1, or 45 CFR 146.137, including because the plan or issuer has not submitted a sufficient comparative analysis to demonstrate compliance, the failure would be treated not only as a violation of the NQTL comparative analysis documentation requirements but also as a violation of the substantive NQTL rules under proposed 26 CFR 54.9812–1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4). The Departments acknowledged that immediate cessation of the application of an NQTL may not be feasible for all NQTLs. Therefore, under the proposed rules, a determination by the Departments of whether to require immediate cessation would be based on the evaluation of facts and

⁹¹ Code section 9812(a)(3)(A), ERISA section 712(a)(3)(A), and PHS Act section 2726(a)(3)(A).

⁹² Code section 9812(a)(8), ERISA section 712(a)(8), and PHS Act section 2726(a)(8).

⁹⁰ See 88 FR 51552, 51579 (Aug. 3, 2023).

circumstances involved in the specific violation and nature of the underlying NQTL. The Departments provided examples of such facts and circumstances, including the level of disruption in the provision of benefits under the plan or coverage if the NQTL immediately ceased to apply, the practicality and complexities involved in the cessation of the NQTL, the effect on participants and beneficiaries, and the likely time needed to cease or modify the NQTL. Additionally, the Departments noted that this kind of determination would take into account feedback from the plan or issuer. The Departments provided that these facts and circumstances would also be relevant to the Departments' assessment of the plan's or issuer's overall efforts to come into compliance with MHPAEA. The Departments solicited comments on this proposed provision, including whether there are specific challenges or considerations the Departments should be aware of regarding ceasing application of particular NQTLs.

Several commenters supported a provision that would give the Secretaries the ability to direct a plan or issuer to not impose an NQTL after a final determination of noncompliance and stated that meaningful consequences are important to incentivize plans and issuers to comply with MHPAEA. Some commenters urged the Departments to change the proposed language stating that "the relevant Secretary *may* direct the plan or issuer not to impose the NQTL" to "the relevant Secretary *shall* direct the plan or issuer not to impose the NQTL" to indicate that a plan or issuer will not be permitted to apply a noncompliant NQTL. Several commenters recommended extending this provision to States with primary enforcement authority for MHPAEA with respect to issuers. Some commenters opposed the proposed provision, stating that in their view there is no legal authority under MHPAEA or the CAA, 2021 to demand immediate cessation of an NQTL without intervention of a court of law. Some commenters raised concerns about the ability of plans and issuers to immediately stop imposing an NQTL, particularly mid-year, and with regard to NQTLs related to network composition. Several commenters suggested that, in light of the significant potential consequences of a final determination of noncompliance, the Departments should provide some type of appeals process modeled on the process for appeals of civil money penalties for Medicare Advantage Organizations or require review by

EBSA's national office or the director of the Center for Consumer Information and Insurance Oversight (CCIO) within CMS before taking such action when there is a final determination of noncompliance.

The Departments are finalizing the provision governing the effect of a final determination of noncompliance, with modifications. The language contained in proposed 26 CFR 54.9812–1(c)(4)(vii), 29 CFR 2590.712(c)(4)(vii), and 45 CFR 146.136(c)(4)(vii) is being finalized at 26 CFR 54.9812–1(c)(4)(v)(A), 29 CFR 2590.712(c)(4)(v)(A), and 45 CFR 146.136(c)(4)(v)(A). These final rules add references to the relevant statutory citation,⁹³ to make clear that the effect of the final determination of noncompliance provision of these final rules, including the evaluation of the relevant facts and circumstances used to determine whether cessation of an NQTL is appropriate, is only applicable with respect to a plan's or issuer's violation of the comparative analysis requirements, as set forth in Code section 9812(a)(8), ERISA section 712(a)(8), and PHS Act section 2726(a)(8). If, however, the plan or issuer violates MHPAEA's substantive requirements, as set forth in Code section 9812(a)(3), ERISA section 712(a)(3), and PHS Act section 2726(a)(3), and 26 CFR 54.9812–1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4), by imposing an NQTL that violates the "no more restrictive" standard, the statute clearly contemplates that the plan or issuer not apply the NQTL, and the Departments have full authority to prohibit the plan or issuer from continuing to impose the unlawful NQTL.⁹⁴

The HHS final rules at 45 CFR 146.136(c)(4)(v)(A) also add references to an applicable State authority, as requested by commenters, so that the regulations are clear that, like the Departments, States with enforcement

authority with respect to MHPAEA⁹⁵ are also permitted to direct issuers not to impose an NQTL when there is a final determination of noncompliance, unless and until the issuer demonstrates compliance or takes appropriate action to remedy the violation. These final rules also provide additional specificity by clarifying that this provision allows the Departments (and an applicable State authority) to direct a plan or issuer not to impose an NQTL with respect to mental health or substance use disorder benefits in the relevant classification.

Additionally, these final rules add new paragraph (c)(4)(v)(B) to make clear that a determination of whether the Departments will require cessation of the application of an NQTL will be based on an evaluation of the relevant facts and circumstances involved in the specific final determination and the nature of the underlying NQTL. For this purpose, the Departments expect that such facts and circumstances may include, but are not limited to, the level of disruption in the provision of benefits under the plan or coverage if the NQTL immediately ceased to apply, the practicality and complexities involved in the cessation of the NQTL, the effect on participants and beneficiaries of continuing or ceasing to apply the NQTL, and the likely time needed to cease or modify the NQTL. Under these final rules, such a determination will also take into account the interest of plan participants and beneficiaries and feedback from the plan or issuer. States that are the primary enforcers of MHPAEA may take into account these or other facts and circumstances when determining whether the State will require cessation of application of an NQTL.

The Departments decline to modify the proposed language to provide that the Secretary "shall" direct the plan or issuer not to impose the NQTL after a final determination of noncompliance with the comparative analysis requirements. In the preamble to the proposed rules and in these final rules, the Departments acknowledged that immediate cessation of the application of an NQTL may not be feasible for all NQTLs and that feedback from the plan or issuer would be taken into account. The Departments understand that not requiring immediate cessation of a noncompliant NQTL in every situation that involves a final determination of noncompliance with the comparative analysis requirements may allow participants and beneficiaries to be subject to noncompliant NQTLs. As these commenters noted, meaningful

⁹³ Code section 9812(a)(8), ERISA section 712(a)(8), and PHS Act section 2726(a)(8).

⁹⁴ Specifically, Code section 9812(a)(3)(A), ERISA section 712(a)(3)(A), and PHS Act section 2726(a)(3)(A) state that a plan or coverage "shall ensure that . . . the treatment limitations applicable to such mental health or substance use disorder benefits are no more restrictive than the predominant treatment limitations applied to substantially all medical and surgical benefits covered" by the plan (or coverage). If a plan or coverage does not ensure compliance with these statutory requirements, the Departments may require the plan or issuer to no longer impose the NQTL or to otherwise come into compliance. Similarly, 26 CFR 54.9812–1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4) of these final rules state that a plan (or coverage) may not impose any NQTL unless it complies with the statutory requirement in Code section 9812(a)(3)(A), ERISA section 712(a)(3)(A), and PHS Act section 2726(a)(3)(A).

⁹⁵ PHS Act section 2723(a)(1).

consequences are important to incentivize plans and issuers to comply with MHPAEA. However, the Departments are of the view that the potential negative impacts for participants and beneficiaries of continuing to apply the NQTL should be balanced with the operational feasibility of immediately modifying business practices, particularly for NQTLs that are inherent to the plan design and may require time to reform. Such potential negative impacts for participants and beneficiaries may be better evaluated after the Departments review the specific facts and circumstances of the relevant determination of noncompliance with the comparative analysis requirements. Therefore, these final rules specify that, when determining the effect of a final determination of noncompliance with the comparative analysis requirements, each specific violation will have its own analysis of the applicable facts and circumstances that will be taken into account.

The Departments stress that MHPAEA requires plans and issuers to ensure that the treatment limitations, including NQTLs imposed on mental health or substance use disorder benefits in a classification, are not more restrictive than those applied to medical/surgical benefits in the same classification. In many cases, a failure to submit a sufficient or compliant comparative analysis is evidence that a plan or issuer cannot substantiate an NQTL's compliance with these applicable requirements, and therefore is violating MHPAEA's substantive parity requirements. Therefore, where the Departments have come to a final conclusion that a comparative analysis is not compliant and are issuing a final determination of noncompliance, including because the plan or issuer has not submitted a sufficient comparative analysis to demonstrate compliance, the required corrective action may include the removal of such NQTL. The CAA, 2021 also requires the Departments to specify the actions a plan or issuer must take to address the violation, and include the required actions in the annual report to Congress.⁹⁶ This provision makes clear the Departments have broad authority to determine the appropriate remedy where a plan's or issuer's comparative analysis is not compliant, and this authority allows the Departments, depending on the relevant facts and circumstances, to specify removal of the NQTL as the appropriate

remedy to address a determination of noncompliance. Nothing, however, prevents the Departments or applicable State authorities from specifying other or additional corrective actions or from taking enforcement action within their respective authorities.

As stressed in the Departments' reports to Congress, the Departments generally engage plans and issuers in repeated exchanges—asking follow-up questions, seeking additional documentation, performing further assessments, and affording opportunities for explanation—before making a final determination of noncompliance.⁹⁷ The Departments note that plans and issuers are given multiple opportunities to engage with the Departments after an initial request for comparative analysis and before a final determination of noncompliance. As described later in this preamble, after an initial request for a comparative analysis, if the Department concludes that a plan or issuer has not submitted sufficient information to review the requested comparative analyses, the plan or issuer will be provided with another opportunity to respond to the Department's initial request. If the Department reviews the comparative analyses (and any additional information submitted upon request) and makes an initial determination that the plan or issuer is not in compliance, the plan or issuer is provided another opportunity to respond to the Department. Because of the multiple opportunities to engage with the Departments prior to a final determination of noncompliance, the Departments decline to add any additional formal appeal or review requirements beyond that required under the statute. Any direction not to impose an NQTL provided to a plan or issuer by the relevant Department will take into account all correspondence and discussions with the plan or issuer.

g. NQTL Examples—26 CFR 54.9812–1(c)(4)(vi), 29 CFR 2590.712(c)(4)(vi), and 45 CFR 146.136(c)(4)(vi)

The proposed rules contained thirteen examples illustrating the NQTL requirements, including revised versions of some examples included in the 2013 final regulations and several new examples. Additionally, the proposed rules proposed to eliminate some examples that were included in

the 2013 final regulations, in light of the additional proposed requirements.

The Departments received comments on each of the proposed examples and comments recommending additional examples be added. Some commenters suggested the Departments use different data elements in the examples related to the relevant data evaluation requirements that in their view would better evaluate compliance with MHPAEA. Other commenters expressed concerns regarding how the proposed exceptions to the NQTL requirements discussed earlier in this preamble would apply and requested that the examples address what a plan or issuer would be required to document to rely on these exceptions. One of these commenters also requested an example showing analysis of an NQTL that is developed based on multiple standards, some of which qualify for the proposed exception for independent professional medical or clinical standards and some of which do not. Some commenters expressed concern regarding whether the proposed mathematical substantially all and predominant tests could be performed on all NQTLs and requested more detailed examples of how to apply such tests.

As noted earlier in this preamble, the Departments are declining to finalize the proposed mathematical substantially all and predominant tests, as well as the proposed exceptions for NQTLs that impartially apply independent professional medical or clinical standards or fraud, waste, and abuse measures. Therefore, rather than providing examples to address these provisions, the examples address the substantive provisions the Departments are finalizing in these final rules, including the general requirement that NQTLs for mental health and substance use disorder benefits not be more restrictive, as written or in operation, than the predominant NQTL that applies to substantially all medical/surgical benefits in the same classification, the design and application requirements, and the relevant data evaluation requirements (including potential data elements that plans and issuers may consider to be relevant data with respect to an NQTL).

The Departments are adapting some of the fact patterns used in the examples in the proposed rules related to provisions that are not being finalized to instead illustrate concepts applicable in these final rules, but these final rules do not include all of the examples included in the proposed rules (or all of the examples included in the 2013 final regulations). The Departments note that the exclusion in these final rules of any

⁹⁶ Code section 9812(a)(8)(B)(iv)(V), ERISA section 712(a)(8)(B)(iv)(V), and PHS Act section 2726(a)(8)(B)(iv)(V).

⁹⁷ See, e.g., 2023 MHPAEA Comparative Analysis Report to Congress (July 2023), pg. 52, <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2023-mhpaea-comparative-analysis.pdf> and <https://www.cms.gov/ccio/resources/forms-reports-and-other-resources#mental-health-parity>.

particular fact pattern that was previously addressed in examples in the proposed rules or the 2013 final regulations is not intended to indicate that any particular set of facts is permissible or prohibited under these final rules. Rather, the examples in these final rules are included to illustrate the application of the various provisions included in these final rules. Thus, plans and issuers are expected to apply the requirements in paragraph (c)(4) of these final rules to the specific facts and circumstances of the benefit design of their respective plans and coverage options with respect to all NQTLs applicable to mental health and substance use disorder benefits, as well as the processes, strategies, evidentiary standards, and other factors used to design or apply them, and any information, evidence, sources, or standards on which a factor or evidentiary standard is based. Additionally, as in the proposed rules, any example that concludes that the plan violates or complies with a requirement of these final rules for NQTLs should not be read to imply compliance with any other requirements of these final rules for NQTLs.

Example 1—Not comparable and more stringent factors for reimbursement rate methodology, in operation. In the proposed rules, Example 4 illustrated how plans and issuers would be required to ensure compliance in operation with the proposed design and application requirements for a plan's reimbursement rate methodology NQTL.⁹⁸ These final rules redesignate proposed Example 4 as Example 1 and illustrate the application of the general rule of the design and application requirements of these final rules with respect to a plan's reimbursement rate methodology NQTL. The language in the facts and conclusion of proposed Example 4 referencing an assumption that the plan's methods for determining reimbursement rates for mental health and substance use disorder benefits satisfy the no more restrictive requirement has been eliminated to reflect, as discussed earlier in this preamble, that the Departments decline to finalize the proposed mathematical substantially all and predominant tests in these final rules.

Accordingly, the facts of Example 1 in these final rules assume a plan's

reimbursement rate methodology for outpatient, in-network providers is based on a variety of factors. As written, for mental health, substance use disorder, and medical/surgical benefits, all reimbursement rates for physicians and non-physician practitioners for the same CPT code are based on a combination of factors, such as the nature of the service, duration of the service, intensity and specialization of training, provider licensure and type, number of providers qualified to provide the service in a given geographic area, and market need (demand). In operation, the plan utilizes an additional strategy to further reduce reimbursement rates for mental health and substance use disorder non-physician providers from those paid to mental health and substance use disorder physicians by the same percentage for every CPT code but does not apply the same reductions for non-physician medical/surgical providers.

Example 1 concludes that the plan violates the rules of paragraph (c)(4). The plan reimburses non-physician providers of mental health and substance use disorder services by reducing their reimbursement rates from the rates for physician providers of such services by the same percentage for every CPT code but does not apply the same reduction to non-physician providers of medical/surgical services from the rate for physician providers of medical/surgical services. Therefore, in operation, the factors used in designing and applying the NQTL to mental health and substance use disorder benefits in the outpatient, in-network classification are not comparable to, and are applied more stringently than, the factors used in designing and applying the NQTL with respect to medical/surgical benefits in the same classification. As a result, the NQTL with respect to mental health or substance use disorder benefits in the outpatient, in-network classification is more restrictive than the predominant NQTL that applies to substantially all medical/surgical benefits in the same classification, in violation of 26 CFR 54.9812-1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4) of these final rules. This example illustrates that the plan violates the design and application requirements and does not address whether the plan complies with the relevant data evaluation requirements.

Example 2—Strategy for exclusion for experimental or investigative treatment more stringently applied to Applied Behavior Analysis (ABA) therapy in operation. These final rules redesignate proposed Example 10 as Example 2 with modifications to the conclusion. Proposed Example 10 concluded that

the plan violates the proposed no more restrictive requirements because, in operation, the plan's exclusion for experimental or investigative treatment imposed on ABA therapy limits access to the full range of treatment options available for a condition or disorder under the plan as compared to medical/surgical benefits in the same classification. As discussed earlier in this preamble, the Departments declined to finalize the proposed mathematical substantially all and predominant tests. However, multiple commenters in response to the proposed rules expressed support for including an example that specifically addresses the exclusion of benefits to treat ASD. Therefore, in Example 2 of these final rules, the Departments are adapting proposed Example 10 to demonstrate how a strategy for a plan's exclusion of benefits for experimental or investigative treatment that applies more stringently to ABA therapy, in operation, violates the design and application requirements, and therefore violates the requirements for NQTLs under these final rules.

In Example 2, the facts of proposed Example 10 are generally unchanged. A plan, as written, generally excludes coverage for all treatments that are experimental or investigative for medical/surgical benefits and mental health and substance use disorder benefits in the outpatient, in-network classification. As a result, the plan generally excludes, as experimental, a treatment or procedure when no professionally recognized treatment guidelines include the treatment or procedure as a clinically appropriate standard of care for the condition or disorder and fewer than two randomized controlled trials are available to support the treatment's use with respect to the given condition or disorder. As written, the plan provides benefits for the treatment of ASD, which is a mental health condition, but, in operation, excludes coverage for ABA therapy to treat children with ASD, deeming it experimental. More than one professionally recognized treatment guideline defines clinically appropriate standards of care for ASD as including ABA therapy and more than two randomized controlled trials are available to support the use of ABA therapy as one intervention to treat certain children with ASD.

Example 2 concludes that the plan violates the design and application requirements with respect to the exclusion of ABA therapy because, in operation, the plan deviates from its strategy to exclude coverage of experimental treatment of medical

⁹⁸ As stated in the preamble to the proposed rules, Example 4 was based in part on guidance in FAQs Part 39, Q6, <https://www.dol.gov/sites/dolgov/files/EBSA/about-ehsa/our-activities/resource-center/faqs/aca-part-39-final.pdf> and <https://www.hhs.gov/guidance/document/affordable-care-act-implementation-faqs-final-set-39>.

conditions and surgical procedures, mental health conditions, and substance use disorders because more than one professionally recognized treatment guideline defines clinically appropriate standards of care for ASD as including ABA therapy to treat certain children with ASD and more than two randomized controlled trials are available to support the use of ABA therapy as one intervention to treat certain children with ASD. Therefore, in operation, the strategy used to design the NQTL for benefits for the treatment of ASD, which is a mental health condition for purposes of MHPAEA, in the outpatient, in-network classification is not comparable to, and is applied more stringently than, the strategy used to design and apply the NQTL for medical/surgical benefits in the same classification. As a result, the example concludes that the NQTL is more restrictive and therefore violates MHPAEA. This example illustrates that the plan violates the design and application requirements and does not address whether the plan complies with the relevant data evaluation requirements.

Example 3—Step therapy protocol with exception for severe or irreversible consequences, discriminatory factor. The Departments received several comments asking the Departments to provide additional clarification on what would be considered discriminatory factors and evidentiary standards for purposes of determining compliance with the design and application requirements. Accordingly, the Departments are including in these final rules a new Example 3 to provide an example of circumstances under which a plan or issuer would violate the prohibition against discriminatory factors and evidentiary standards in the context of step therapy with exceptions for severe or irreversible consequences.

The facts of Example 3 assume a plan has a step therapy protocol that requires participants and beneficiaries who are prescribed certain drugs to try and fail a generic or preferred brand name drug before the plan will cover the treatment or medication originally prescribed by a provider. The plan has an exception to this protocol that was developed solely by relying on a methodology developed by an external third-party organization. The third-party organization's methodology, which is not based on an independent professional medical or clinical standard, identifies instances in which a delay in treatment with a drug prescribed for a medical condition or surgical procedure could result in either severe or irreversible consequences. However, with respect to a drug

prescribed for a mental health condition or a substance use disorder, the third-party organization's methodology only identifies instances in which a delay in treatment could result in both severe and irreversible consequences. The plan does not take any steps to correct, cure, or supplement the methodology.

The conclusion to Example 3 explains that the plan violates the prohibition on discriminatory factors and evidentiary standards under 26 CFR 54.9812–1(c)(4)(i)(B), 29 CFR 2590.712(c)(4)(i)(B), and 45 CFR 146.136 (c)(4)(i)(B). The source upon which the factor used to apply the step therapy protocol is based is biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits because it addresses instances in which a delay in treatment with a drug prescribed for a medical condition or surgical procedure could result in either severe or irreversible consequences, but only addresses instances in which a delay in treatment with a drug prescribed for a mental health condition or substance use disorder could result in both severe and irreversible consequences, and the plan fails to take the steps necessary to correct, cure, or supplement the methodology so that it is not biased and is objective. Based on the relevant facts and circumstances, this source systematically disfavors access or is specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits. Therefore, the factor used to design exceptions to the step therapy protocol is discriminatory, for purposes of determining comparability and stringency under the design and application requirements, and it may not be relied upon by the plan unless the plan takes the steps necessary to correct, cure, or supplement it (by, for example, taking into account instances in which a delay in treatment with a drug prescribed for a mental health condition or a substance use disorder could result in severe or irreversible consequences).

Example 4—Use of historical plan data and steps the plan or issuer can take to correct, cure, or supplement. The Departments are including as Example 4 of these final rules a revised example illustrating how plans and issuers can correct, cure or supplement the use of historical data or other historical information from a time when the plan or coverage was not subject to MHPAEA or was in violation of MHPAEA's requirements so that the information is not considered to be biased or not objective and can be used as the basis

for a factor or evidentiary standard that is not discriminatory. The Departments stated in the preamble to the proposed rules that the proposed rules would prohibit reliance on historical plan data or other historical information from a time when the plan or coverage was not subject to MHPAEA (or was in violation of MHPAEA's requirements) and provided an example addressing calculation of reimbursement rates based on historical data on total plan spending. Example 4 of these final rules references the fact pattern from Example 4 in the proposed rules but provides additional detail and analysis to illustrate the application of the prohibition on discriminatory factors and evidentiary standards under these final rules, including how a plan or issuer could correct, cure, or supplement the use of such data so that the information is not considered to be biased or not objective.

Specifically, the facts of Example 4 assume a plan's methodology for calculating provider reimbursement rates relies only on historical plan data on total plan spending for each specialty, divided between mental health and substance use disorder providers and medical/surgical providers from a time where the plan was not subject to MHPAEA. The plan used these historical plan data for many years to establish base reimbursement rates in all provider specialties for which it provides medical/surgical, mental health, and substance use disorder benefits in the inpatient, in-network classification. In evaluating the use of these historical plan data in the design of the methodology for calculating provider reimbursement rates, the plan determined, based on all the relevant facts and circumstances, that the historical plan data systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits. To ensure this information about historical reimbursement rates is not biased and is objective, the plan supplements its methodology to develop the base reimbursement rates for mental health and substance use disorder providers in accordance with additional information, evidence, sources, and standards that reflect the increased demand for mental health and substance use disorder benefits in the inpatient, in-network classification and to attract sufficient mental health and substance use disorder providers to the network. The relevant facts and circumstances indicate that the supplemented

information, evidence, sources, or standards do not systematically disfavor access and are not specifically designed to disfavor access to mental health and substance use disorder benefits as compared to medical/surgical benefits.

Example 4 of these final rules concludes that the plan does not violate the prohibition on discriminatory factors and evidentiary standards with respect to the plan's methodology for calculating provider reimbursement rates in the inpatient, in-network classification. The relevant facts and circumstances indicate that the plan's use of only historical plan data to design its methodology for calculating its provider reimbursement rates in the inpatient, in-network classification would otherwise be considered to be biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits since the historical data systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits. However, the plan took the steps necessary to supplement the information, evidence, sources, and standards to reasonably reflect the increased demand for mental health and substance use disorder benefits in the inpatient, in-network classification, and adjusted the methodology to increase reimbursement rates for those benefits, thereby ensuring that the information, evidence, sources, and standards relied upon by the plan for this purpose are not biased and are objective. Therefore, the factors and evidentiary standards used to design the plan's methodology for calculating provider reimbursement rates in the inpatient, in-network classification are not considered discriminatory factors and evidentiary standards.

Example 5—Generally recognized independent professional medical or clinical standards and more stringent prior authorization requirement in operation. In the proposed rules, the Departments proposed Example 6 to illustrate the exception for impartially applied independent professional medical or clinical standards and when a plan fails to satisfy the exception. The Departments received comments requesting examples to provide further clarity on how a plan or issuer may properly rely on independent professional medical or clinical standards in the design and application of NQTLs. As described earlier in this preamble, the Departments are not finalizing this exception as proposed. Instead, these final rules specify that the

use of independent professional medical or clinical standards generally will not be considered to be biased and not objective under these final rules. The Departments note that, under these final rules, the use of such standards must also comply with the other provisions of these final rules, including the general rule in the design and application requirements and the relevant data evaluation requirements. Therefore, the Departments are modifying proposed Example 6 and redesignating it as Example 5 in these final rules, to illustrate a violation of the design and application requirements of these final rules when a plan relies on independent professional medical or clinical standards to inform a factor used to design an NQTL with respect to mental health and substance use disorder benefits that, in operation, is not comparable to, and is applied more stringently than, the same factor used to design the NQTL for medical/surgical benefits in the same classification.

In Example 5 of these final rules, the provisions of a plan state that it relies on, and does not deviate from, independent professional medical or clinical standards to inform the factor used to design prior authorization requirements for both medical/surgical and mental health and substance use disorder benefits in the prescription drug classification. In this example, the plan uses the ASAM national practice guidelines as the independent professional medical or clinical standard to inform the factors used to design and apply the prior authorization requirement for treatment of OUD. The ASAM practice guidelines do not support prior authorization every 30 days for buprenorphine/naloxone combination for treatment of OUD. However, in operation, the plan requires prior authorization for buprenorphine/naloxone combination for treatment of OUD every 30 days, which is inconsistent with independent professional medical standards on which the factor used to design the limitation is based. The plan's factor used to design and apply prior authorization requirements for medical/surgical benefits in the prescription drug classification relies on, and does not deviate from, independent professional medical or clinical standards.

The conclusion to Example 5 in these final rules states that the plan violates the requirements for NQTLs. The ASAM national practice guidelines on which the factor used to design prior authorization requirements for substance use disorder benefits is based are independent professional medical or

clinical standards that are not considered to be biased or not objective in a manner that discriminates against mental health and substance use disorder benefits under these final rules. However, the plan must comply with other requirements in these final rules for NQTLs, as applicable, with respect to such standards or measures that are used as the basis for a factor or evidentiary standard used to design or apply an NQTL. In operation, the plan's factor used to design and apply prior authorization requirements with respect to substance use disorder benefits is not comparable to, and is applied more stringently than, the same factor used to design and apply prior authorization requirements for medical/surgical benefits, because the factor relies on, and does not deviate from, independent professional medical or clinical standards for medical/surgical benefits, but deviates from the relevant guidelines for substance use disorder benefits. As a result, the NQTL with respect to substance use disorder benefits in the prescription drug classification is more restrictive than the predominant NQTL that applies to substantially all medical/surgical benefits in the same classification.

Example 6—Plan claims no data exist to reasonably measure impact of NQTL on access; medical necessity criteria. As described earlier in this preamble, these final rules require plans and issuers to collect and evaluate relevant data in a manner reasonably designed to assess the impact of an NQTL on relevant outcomes related to access to mental health and substance use disorder benefits as compared to medical/surgical benefits. Additionally, these final rules provide guidance for plans and issuers to comply with the relevant data evaluation requirements when data are initially temporarily unavailable for a newly imposed NQTL or no data exist that can reasonably measure any relevant impact of an NQTL on access.⁹⁹

Under the facts of new Example 6, a plan approves or denies claims for mental health and substance use disorder benefits and for medical/surgical benefits in the inpatient, in-network and outpatient, in-network classifications based on medical necessity criteria. The plan states in its comparative analysis that no data exist that can reasonably measure any

⁹⁹ As explained earlier in this preamble, these final rules state that the provisions with respect to these types of NQTLs shall only apply in very limited circumstances and, where applicable, shall be construed narrowly, consistent with the fundamental purpose of MHPAEA. The Departments are of the view that data can be collected and evaluated for nearly all NQTLs.

relevant impact of the medical necessity criteria NQTL on access to mental health or substance use disorder benefits as compared to the NQTL's impact on access to medical/surgical benefits in the relevant classifications, without further explanation.

The example concludes that the plan violates the requirements of these final rules. The plan does not comply with the requirements under these final rules for NQTLs where no data exist that can reasonably measure any relevant impact of the NQTL on access because the plan did not include in its comparative analysis a reasoned justification as to the basis for its conclusion that there are no data that can reasonably measure the NQTL's impact, an explanation of why the nature of the NQTL prevents the plan from reasonably measuring its impact, an explanation of what data was considered and rejected, and documentation of any additional safeguards or protocols used to ensure the NQTL complies with the requirements of MHPAEA. For example, data the plan could have considered that could reasonably assess the NQTL's impact might include the number and percentage of claims denials, or the number and percentage of claims that were approved for a lower level of care than the level requested on the initial claim. The plan has violated the relevant data evaluation requirements, as it has not collected and evaluated relevant data in a manner reasonably designed to assess the impact of the NQTL on relevant outcomes related to access nor did it include sufficient information in its comparative analysis with respect to the lack of relevant data.

Example 7—Concurrent review data collection; no material difference in access. Example 7 in these final rules illustrates the application of the relevant data evaluation requirements to a concurrent review NQTL. This example is based on similar facts from Example 2 in the proposed rules, but language in the facts and conclusion of proposed Example 2 referencing the no more restrictive requirement have been eliminated to reflect, as discussed earlier in this preamble, that the Departments decline to finalize the proposed mathematical substantially all and predominant tests in these final rules (that would prohibit any NQTL that is more restrictive than the most common or most frequent variation of the NQTL applied to at least two-third of medical/surgical benefits in a classification).

In this example as modified in these final rules, a plan follows a written process to apply a concurrent review NQTL to all medical/surgical benefits

and mental health and substance use disorder benefits within the inpatient, in-network classification. Under this process, a first-level review is conducted in every instance in which concurrent review applies and an authorization request is approved by the first-level reviewer only if the clinical information submitted by the facility meets the plan's criteria for a continued stay. If the first-level reviewer is unable to approve the authorization request because the clinical information submitted by the facility does not meet the plan's criteria for a continued stay, it is sent to a second-level reviewer who will either approve or deny the request. The plan collects relevant data, including the number of referrals to second-level review, and the number of denials of concurrent review claims as compared to the total number of concurrent review claims in the inpatient, in-network classification. The plan also collects the number of denied claims that are overturned on appeal, separately for mental health and substance use disorder benefits and medical/surgical benefits in the inpatient, in-network classification. The plan evaluates the relevant data and determines that, based on the facts and circumstances, the data do not suggest that the concurrent review NQTL contributes to material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits in the inpatient, in-network classification. Upon requesting the plan's comparative analysis for the concurrent review NQTL and reviewing the relevant data, the Secretary does not request additional data and agrees that the data do not suggest material differences in access.

In Example 7 of these final rules, the conclusion explains that the plan does not violate the relevant data evaluation requirements as it collected and evaluated relevant data in a manner reasonably designed to assess the impact of the NQTL on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits and considered the impact as part of its evaluation. Because the relevant data do not suggest that the NQTL contributes to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits in the inpatient, in-network classification, there is no strong indicator that the plan violates the requirements for NQTLs under these final rules. However, the plan is still required to comply with the design and

application requirements under these final rules, including the prohibition on discriminatory factors and evidentiary standards.

Example 8—Material difference in access for prior authorization requirement with reasonable action. In the proposed rules, Example 1 illustrates the effect of a disparity in the routine approval of benefits for mental health conditions and substance use disorders compared to benefits for medical/surgical conditions in a classification under the no more restrictive requirement in the proposed rules. However, as discussed earlier in this preamble, the Departments have declined to finalize the proposed mathematical substantially all and predominant tests. Therefore, the Departments are adapting proposed Example 1 for use as Example 8 of these final rules to illustrate how a plan or issuer can satisfy the requirement to take reasonable action to address any material differences in access as necessary to ensure compliance with the relevant data evaluation requirements, in the context of material differences in access in the routine approval of benefits for mental health conditions and substance use disorders compared to medical/surgical benefits in a classification.

In Example 8 of these final rules, a plan requires prior authorization that a treatment is medically necessary for all inpatient, in-network medical/surgical benefits and for all inpatient, in-network mental health and substance use disorder benefits. The plan collects and evaluates relevant data in a manner reasonably designed to assess the impact of the prior authorization requirement on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits in the inpatient, in-network classification. The plan's written process for prior authorization states that the plan approves inpatient, in-network benefits for medical conditions and surgical procedures and mental health and substance use disorder benefits for periods of 1, 3, and 7 days, after which a treatment plan must be submitted by the patient's attending provider and approved by the plan. Approvals for mental health and substance use disorder benefits are most commonly given only for 1 day, after which a treatment plan must be submitted by the patient's attending provider and approved by the plan. The relevant data show that approvals for 7 days are most common for medical conditions and surgical procedures under this plan. Based on all the relevant facts and

circumstances, the difference in the data suggests that the NQTL is likely to have a negative impact on access to mental health and substance use disorder benefits as compared to medical/surgical benefits. Therefore, the differences in the data suggest that the NQTL contributes to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits. To address these material differences, the plan consults more recent medical guidelines to update the factors that inform its medical necessity NQTLs and modifies the prior authorization NQTL so that inpatient, in-network prior authorization requests for mental health or substance use disorder benefits are approved for similar periods to what is approved for medical/surgical benefits. The plan includes documentation of this action as part of its comparative analysis.

The conclusion to Example 8 provides that, while relevant data for the plan's prior authorization requirements suggested that the NQTL contributes to material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits in the classification, the plan has taken reasonable action, as necessary, to ensure compliance, in operation, with the requirements for NQTLs under these final rules by updating the factors that inform its prior authorization NQTL for inpatient, in-network mental health and substance use disorder benefits, so that such benefits are approved for similar periods to what is approved for medical/surgical benefits, and documenting its action taken to address material differences in access to inpatient, in-network benefits, as required under these final rules.

Example 9—Differences attributable to the use of independent professional medical or clinical standards. In the proposed rules, the Departments proposed to add new Example 5 to illustrate how a plan may satisfy the proposed exception for independent professional medical or clinical standards. As noted earlier in this preamble, the Departments are not finalizing that exception, and instead, under these final rules, the use of independent professional medical or clinical standards are not considered to be information, evidence, sources, or standards that are biased and not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits, as long as the use of these standards to design or apply an NQTL complies with other applicable requirements. Furthermore,

under these final rules, differences in access attributable to the use of independent professional medical or clinical standards for both medical/surgical benefits and mental health and substance use disorder benefits are not considered to be material. However, to the extent a plan or issuer attributes any differences in access to the application of such standards, the plan or issuer must explain its bases for reaching that conclusion in its comparative analysis. Therefore, the Departments are adapting Example 5 of the proposed rules for use as Example 9 of these final rules to illustrate the treatment of the use of independent professional medical or clinical standards.

In Example 9 of these final rules, a plan develops a medical management requirement for all inpatient, out-of-network benefits for both medical/surgical benefits and mental health and substance use disorder benefits to ensure treatment is medically necessary. The factors and evidentiary standards used to design and apply the medical management requirement rely on independent professional medical or clinical standards that are generally recognized by health care providers and facilities in relevant clinical specialties. The processes, strategies, evidentiary standards, and other factors used in designing and applying the medical management requirement to mental health and substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the requirement with respect to medical/surgical benefits. The plan collects and evaluates relevant data in a manner reasonably designed to assess the impact of the medical management NQTL on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits, and considers the impact as part of the plan's evaluation. Within the inpatient, out-of-network classification, the application of the medical management requirement results in a higher percentage of denials for mental health and substance use disorder claims than medical/surgical claims because the benefits were found to be medically necessary for a lower percentage of mental health and substance use disorder claims. The plan correctly determines that these differences in access are attributable to the independent professional medical or clinical standards that are used as the basis for the factors and evidentiary standards used to design or apply the

NQTL and adequately explains the bases for that conclusion as part of its comparative analysis.

Example 9 concludes that the plan does not violate the requirements under these final rules for its medical management NQTL. Independent professional medical or clinical standards are not considered to be information, evidence, sources, or standards that are biased and not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits and the plan otherwise complies with the design and application requirements. Additionally, the plan does not violate the relevant data evaluation requirements because it has collected and evaluated relevant data, the differences in access are attributable to the independent professional medical or clinical standards that are used as the basis for the factors and evidentiary standards used to design or apply the medical management NQTL, and the plan explains the bases for this conclusion in its comparative analysis. As a result, the NQTL with respect to mental health or substance use disorder benefits in the inpatient, out-of-network classification is no more restrictive than the predominant NQTL that applies to substantially all medical/surgical benefits in the same classification.

Example 10—Material difference in access for standards for provider admission to a network with reasonable action. In the proposed rules, the Departments proposed new Example 13 to illustrate how plans and issuers may comply with the proposed relevant data evaluation requirements with respect to NQTLs related to network composition, including NQTLs for provider and facility admission to participate in a network or for continued network participation, methods for determining reimbursement rates, credentialing standards, and procedures for ensuring the network includes an adequate number of each category of providers and facilities to provide covered services under the plan or coverage. These final rules largely adopt Example 13 as proposed, with some modifications to reflect the standards included in these final rules, and redesignate it as Example 10.

In Example 10 of these final rules, a plan applies NQTLs related to network composition in the inpatient, in-network and outpatient, in-network classifications. The plan's networks are constructed by separate service providers for medical/surgical benefits and mental health and substance use disorder benefits. The facts also assume

that the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTLs related to network composition for mental health or substance use disorder benefits in the inpatient, in-network and outpatient, in-network classifications are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTLs with respect to medical/surgical benefits in the same classifications. In order to ensure, in operation, that the NQTLs are no more restrictive than the predominant NQTLs applied to substantially all medical/surgical benefits in the classification, the plan collects and evaluates relevant data in a manner reasonably designed to assess the aggregate impact of all the NQTLs related to network composition on relevant outcomes related to access to mental health and substance use disorder benefits as compared with medical/surgical benefits and considers the impact as part of the plan's evaluation. The plan considers relevant data that is known, or reasonably should be known, including metrics relating to the time and distance from plan participants and beneficiaries to network providers in rural and urban regions; the number of network providers accepting new patients; the proportions of mental health and substance use disorder and medical/surgical providers and facilities that provide services in rural and urban regions who are in the plan's network; provider reimbursement rates (for comparable services and benchmarked to a reference standard, as appropriate); and in-network and out-of-network utilization rates (including data related to the dollar value and number of provider claims submissions). The plan determines that the relevant data suggest that the NQTLs in the aggregate contribute to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits in the classifications because, based on all the relevant facts and circumstances, the differences in the data suggest that the plan's NQTLs related to network composition are likely to have a negative impact on access to mental health or substance use disorder benefits as compared to medical/surgical benefits in the same classifications. The plan takes reasonable actions, as necessary, to address the material differences in access, to ensure compliance, in operation, with the requirements for

NQTLs under these final rules, by strengthening its efforts to recruit and encourage a broad range of available providers and facilities to join the plan's network of providers, including by taking actions to increase compensation and other inducements, streamline credentialing processes, contact providers reimbursed for items and services provided on an out-of-network basis to offer participation in the network, and develop a process to monitor the effects of such efforts; expanding the availability of telehealth arrangements to mitigate overall provider shortages in certain geographic areas; providing additional outreach and assistance to participants and beneficiaries enrolled in the plan to assist them in finding available in-network providers and facilities; and ensuring that the plan's provider directories are accurate and reliable. The plan documents the efforts that it has taken to address the material differences in access that the data revealed, and also documents the reasons beyond the plan's control that the plan believes may contribute to the material differences in access, and the plan includes the documentation as part of its comparative analysis submission.

Example 10 concludes that the plan does not violate the requirements for NQTLs under these final rules. The plan complies with the design and application requirements, and also collects and evaluates relevant data, as required under these final rules, in a manner reasonably designed to assess the aggregate impact of all such NQTLs on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits. While the data suggest that the NQTLs contribute to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, the plan takes reasonable action, as necessary, to ensure compliance with these final rules. The plan also documents the actions that have been and are being taken by the plan to address material differences in access and documents the reasons beyond the plan's control that the plan believes may contribute to the material differences in access. As a result, the network composition NQTLs with respect to mental health or substance use disorder benefits in the inpatient, in-network and outpatient, in-network classifications are no more restrictive than the predominant NQTLs that apply to substantially all medical/surgical benefits in the same classifications.

Example 11—Separate employee assistance program (EAP) exhaustion

treatment limitation applicable only to mental health or substance use disorder benefits. Example 11 in the proposed rules amended Example 6 of the 2013 final regulations. These final rules retain this example as proposed with minor, non-substantive changes.

Specifically, in Example 11, an employer maintains both a major medical plan and an EAP. The EAP provides, among other benefits, a limited number of mental health or substance use disorder counseling sessions. These sessions, together with other benefits provided by the EAP, are not significant benefits in the nature of medical care. Participants are eligible for mental health or substance use disorder benefits under the major medical plan only after exhausting the counseling sessions provided by the EAP, and no similar exhaustion requirement applies with respect to medical/surgical benefits provided under the major medical plan.

Example 11 concludes that the requirement that limits eligibility for mental health and substance use disorder benefits under the major medical plan until benefits under an EAP are exhausted is an NQTL subject to MHPAEA. Because the limitation does not apply to medical/surgical benefits, it violates the prohibition on a separate NQTL applicable only to mental health or substance use disorder benefits. The Departments have also included language to note that under other Departmental regulations,¹⁰⁰ the EAP does not qualify as excepted benefits because participants in the major medical plan are required to use and exhaust benefits under the EAP (making the EAP a gatekeeper) before they are eligible for benefits under the plan.

Example 12—Separate exclusion for treatment in a residential facility applicable only to mental health and substance use disorder benefits. Under Example 12 of these final rules, which is substantively identical to Example 12 in the proposed rules and only includes minor, non-substantive changes, a plan generally covers inpatient, in-network and inpatient, out-of-network treatment without any limitations on setting, including skilled nursing facilities and rehabilitation hospitals, provided other medical necessity standards are satisfied. The plan has an exclusion for treatment at residential facilities, which the plan defines as an inpatient benefit for mental health and substance use disorder benefits. This exclusion was

¹⁰⁰ 26 CFR 54.9831-1(c)(3)(vi)(B)(1), 29 CFR 2590.732(c)(3)(vi)(B)(1), and 45 CFR 146.145(b)(3)(vi)(B)(1).

not generated through any broader NQTL (such as medical necessity or other clinical guideline).

Example 12 concludes that the plan violates these final rules. The exclusion of residential treatment is a separate NQTL applicable only to mental health and substance use disorder benefits in the inpatient, in-network and inpatient, out-of-network classifications because the plan does not apply a comparable exclusion with respect to any medical/surgical benefits in the same benefit classification.

Example 13—Impermissible NQTL imposed following a final determination of noncompliance and direction by the Secretary. In the proposed rules, Example 7 provides that a plan that continues to impose an NQTL after the Secretary issues a final determination of noncompliance with the NQTL comparative analysis documentation requirements and directs the plan not to impose the NQTL by a certain date, would not comply with the requirements applicable to NQTLs. These final rules retain this example with modifications to add specificity and reflect the substantive provisions of the final rule and redesignate it as Example 13.

In this example, following an initial request by the Secretary for a plan's comparative analysis of the plan's exclusion of mental health and substance use disorder benefits for failure to complete a course of treatment in the inpatient, in-network classification, the plan submits a comparative analysis for the NQTL. The comparative analysis included insufficient information to conduct an appropriate comparison of the NQTL. After review of the comparative analysis, as well as additional information submitted by the plan after the Secretary determines that the plan has not submitted sufficient information to be responsive to the request, the Secretary makes an initial determination that the comparative analysis fails to demonstrate that the processes, strategies, evidentiary standards, and other factors used in designing and applying the exclusion to mental health or substance use disorder benefits in the inpatient, in-network classification are comparable to, and applied no more stringently than, those used in designing and applying the NQTL to medical/surgical benefits in the classification. Although the plan submits a corrective action plan and additional comparative analyses within 45 calendar days after the initial determination, it does not eliminate or alter the exclusion or alter the processes, strategies, evidentiary standards, and other factors used in

designing and applying the exclusion. Moreover, the additional comparative analysis still does not include sufficient information. The Secretary determines that the additional comparative analyses do not demonstrate compliance with the requirements for NQTLs under MHPAEA. Accordingly, the plan receives a final determination of noncompliance with the statutory comparative analysis documentation requirements from the Secretary, which concludes that the plan did not demonstrate compliance through the comparative analysis process. After considering the relevant facts and circumstances, and considering the interests of plan participants and beneficiaries, as well as feedback from the plan, the Secretary directs the plan not to impose the NQTL by a certain date, unless and until the plan demonstrates compliance to the Secretary or takes appropriate action to remedy the violation. The plan makes no changes to its plan terms by that date and continues to impose the exclusion of benefits for failure to complete a course of treatment in the inpatient, in-network classification.

This Example 13 concludes that, by continuing to impose the exclusion of mental health and substance use disorder benefits for failure to complete a course of treatment in the inpatient, in-network classification after the Secretary directs the plan not to impose this NQTL, the plan violates the requirements of these final rules related to the effect of a final determination of noncompliance.

4. Prohibition on Financial Requirements and Treatment Limitations Applicable Only to Mental Health or Substance Use Disorder Benefits—26 CFR 54.9812–1(c)(2)(i) and (c)(4)(iv), 29 CFR 2590.712(c)(2)(i) and (c)(4)(iv), and 45 CFR 146.136(c)(2)(i) and (c)(4)(iv)

The Departments proposed to amend the general parity requirement set forth in 26 CFR 54.9812–1(c)(2)(i), 29 CFR 2590.712(c)(2)(i), and 45 CFR 146.136(c)(2)(i) by adding a sentence to reiterate that a plan or issuer may not impose any financial requirement or treatment limitation that is applicable only with respect to mental health or substance use disorder benefits and not to any medical/surgical benefits in the same benefit classification. The preamble to the proposed rules noted that the 2013 final regulations do not explicitly incorporate the statutory prohibitions on separate financial requirements and treatment limitations that are imposed only with respect to mental health or substance use

disorders in Code sections 9812(a)(3)(A)(i) and (ii), ERISA sections 712(a)(3)(A)(i) and (ii), and PHS Act sections 2726(a)(3)(A)(i) and (ii), respectively, but noted that financial requirements and quantitative treatment limitations imposed only with respect to mental health or substance use disorder benefits generally could not comply with the parity requirements contained in paragraph (c)(3) of 26 CFR 54.9812–1, 29 CFR 2590.712, and 45 CFR 146.136. Additionally, the Departments referred to an example in the 2013 final regulations that demonstrates and affirms that an NQTL applied only to mental health or substance use disorder benefits would not be permissible.¹⁰¹ The Departments noted in the proposed rules that these amendments would directly incorporate the statutory prohibitions by expressly stating that plans and issuers are not permitted to impose any type of financial requirement or treatment limitation that applies only to mental health or substance use disorder benefits and not to medical/surgical benefits in the same classification.

Additionally, since the 2013 final regulations state that the application of paragraph (c)(2) to NQTLs is addressed in paragraph (c)(4) of the regulations, the Departments also proposed to add similar language to the proposed rules for NQTLs at 26 CFR 54.9812–1(c)(4)(vi), 29 CFR 2590.712(c)(4)(vi), and 45 CFR 146.136(c)(4)(vi), which cross-reference the language proposed to be added to 26 CFR 54.9812–1(c)(2)(i), 29 CFR 2590.712(c)(2)(i), and 45 CFR 146.136(c)(2)(i). The Departments proposed that a plan or issuer may not apply any NQTL that is applicable only with respect to mental health or substance use disorder benefits and not with respect to any medical/surgical benefits in the same benefit classification. The Departments noted that an exclusion of benefits for a mental health condition or substance use disorder in a classification that is merely an expression of another NQTL, such as medical necessity requirements or experimental or investigational exclusions, that is applied with respect to medical/surgical benefits in the same classification would not be considered a separately applicable treatment limitation. As a result, such an NQTL would be evaluated to determine whether such NQTL complies with all applicable requirements of these final rules.

¹⁰¹ See 26 CFR 54.9812–1(c)(4)(iii), Example 6, 29 CFR 2590.712(c)(4)(iii), Example 6, and 45 CFR 146.136(c)(4)(iii), Example 6.

Many commenters supported reiterating the statutory requirement that a plan or issuer must not impose a financial requirement or treatment limitation that is applicable only to mental health or substance use disorder benefits and specifying that if an exclusion of a mental health or substance use disorder treatment or service is not due to the application of another NQTL to both mental health or substance use disorder benefits and medical/surgical benefits in a classification, such exclusion would be subject to this prohibition. Commenters also agreed with the Departments that, if an exclusion of benefits for a mental health condition or substance use disorder is not generated through a process, strategy, or factor, or informed by an evidentiary standard of a broader NQTL like medical necessity, such an exclusion would need to be evaluated for parity compliance (and would therefore be prohibited, provided it does not apply to medical/surgical benefits). One commenter requested the Departments clarify that a specific NQTL need not be applicable to medical/surgical benefits in the same classification to overcome the notion that the limitation is separately applicable.

The Departments agree with commenters that the proposed prohibition on NQTLs applicable only to mental health or substance use disorder benefits is consistent with the statute, and that an exclusion of benefits for a mental health condition or substance use disorder otherwise covered under the plan or coverage not generated through a process, strategy, or factor, or informed by an evidentiary standard of a broader NQTL like medical necessity should be evaluated for MHPAEA compliance. This exclusion is prohibited as an impermissible separate treatment limitation if a comparable exclusion does not apply to medical/surgical benefits in the classification. Additionally, as evaluation of a plan's or issuer's compliance with MHPAEA is generally assessed within a classification of benefits, the prohibition on separately applicable financial requirements or treatment limitations applies with respect to benefits in the same benefit classification. Therefore, the Departments are finalizing these amendments as proposed at 26 CFR 54.9812–1(c)(2)(i) and (c)(4)(iv), 29 CFR 2590.712(c)(2)(i) and (c)(4)(iv), and 45 CFR 146.136(c)(2)(i) and (c)(4)(iv) to reiterate that a plan or issuer may not impose any financial requirement or treatment limitation that is applicable

only with respect to mental health or substance use disorder benefits and not with respect to any medical/surgical benefits in the same benefit classification.

5. Other Amendments

a. Meaningful Benefits

The Departments proposed to amend 26 CFR 54.9812–1(c)(2)(ii)(A), 29 CFR 2590.712(c)(2)(ii)(A), and 45 CFR 146.136(c)(2)(ii)(A) to specify that, if a plan (or health insurance coverage) provides any benefits for a mental health condition or substance use disorder in any classification of benefits, benefits for that mental health condition or substance use disorder must be provided in every classification in which medical/surgical benefits are provided. The proposed rules proposed that for purposes of this provision, if a plan (or health insurance coverage) provides any benefits for a mental health condition or substance use disorder in any classification of benefits, the plan or issuer would not be considered to provide benefits for the mental health condition or substance use disorder in every classification in which medical/surgical benefits are provided unless the plan or issuer provides meaningful benefits for treatment for that condition or disorder in each classification, as determined in comparison to the benefits provided for medical conditions and surgical procedures in such classification. The Departments noted in the preamble to the proposed rules that this requirement would ensure that, when plans and issuers cover benefits for a range of services or treatments for medical/surgical conditions in a classification, plans and issuers cannot provide, for example, only one limited benefit for a mental health condition or substance use disorder in that classification. The Departments requested comments on this provision of the proposed rules, including whether and how to define “meaningful benefits” and other potential alternatives.

Many commenters expressed support for this provision of the proposed rules. Several of these commenters noted that this requirement is essential to ensure that plans and issuers are no longer able to deny reimbursement of fundamental evidence-based services for the treatment of mental health conditions and substance use disorders in a way that similar services would never be excluded for medical/surgical care.

Conversely, some commenters opposed adopting any “meaningful benefit” or similar standard in these final rules. Several commenters argued

that this proposed requirement exceeds the Departments’ statutory authority, and that by requiring “meaningful benefits,” the Departments would convert MHPAEA into a mandate to cover mental health and substance use disorder benefits. Other commenters stated that the approach would require plans and issuers to compare specific treatments, which is inconsistent with congressional intent to preserve the ability of a plan or issuer to determine whether a specific treatment is medically necessary or appropriate, instead of comparing coverage for medical/surgical benefits and mental health or substance use disorder benefits more generally. Additionally, one commenter stated this provision would significantly broaden the scope and complexity of a plan’s or issuer’s compliance analysis and limit flexibility in benefit design. Some commenters noted that the meaningful benefits standard, as proposed, might adversely affect the operation of closed panel plans, as the provision of any services outside the network could require such plans to evaluate and expand the scope of covered mental health and substance use disorder benefits, or alternatively, restrict out-of-network benefits.

Commenters also expressed concern that the term “meaningful benefits” may not include services such as coordinated specialty care for first episode psychosis, and without a clear definition of the term, such services would not be covered for privately insured individuals. Another commenter stated that the proposed meaningful benefit standard may overlook and devalue the mental health and substance use disorder services provided by primary care physicians and pediatricians, who are generally considered to be medical/surgical providers.

The Departments received many comments on how to define the term “meaningful benefits,” as well as potential alternatives, including whether it would be more practical to require plans and issuers to provide “substantial coverage” of mental health and substance use disorder benefits or benefits for the “primary or most common or frequent types of treatment for a covered condition or disorder” in each classification in which medical/surgical benefits are provided. Many commenters generally recommended defining “meaningful benefits” based on independent medical and clinical guidelines or primary evidence-based treatment based on independent standards of current medical practice. Some commenters recommended that “meaningful benefits” be defined as the

full continuum of services that are consistent with independent professional medical or clinical standards (or, equivalently, the term “generally accepted standards of care”). Other commenters recommended that these final rules require coverage of at least one primary treatment for a mental health condition or substance use disorder in a classification or coverage that aligns with coverage under the State’s designated EHB-benchmark plan. A few commenters recommended that the definition of “meaningful benefits” or primary treatment be further developed through additional notice and comment rulemaking or a request for information.

The Departments recognize, as commenters stated, that additional clarifications are warranted regarding the definition of the term “meaningful benefits.” With regard to comments stating that this provision of the proposed rules is a benefit mandate that would require plans and issuers to cover specific treatments, as well as comments that raised concerns about specific mental health and substance use disorder services not being considered meaningful benefits (and therefore not being covered by plans and issuers), the Departments reiterate that this requirement does not require plans and issuers to cover mental health and substance use disorder benefits independently or irrespective of what is provided with respect to medical/surgical benefits.

After considering comments received, the Departments are finalizing the proposed meaningful benefits standard, with modifications and clarifications. These final rules require that, if a plan (or health insurance coverage) provides any benefits for a mental health condition or substance use disorder in any classification of benefits, it must provide meaningful benefits for that mental health condition or substance use disorder in every classification in which medical/surgical benefits are provided. For this purpose, whether the benefits provided are meaningful benefits is determined in comparison to the benefits provided for medical conditions and surgical procedures in the classification, and requires, at a minimum, coverage of benefits for that condition or disorder in each classification in which the plan (or coverage) provides benefits for one or more medical conditions or surgical procedures. Additionally, a plan (or coverage) does not provide meaningful benefits under these final rules unless it also provides benefits for a core treatment for that condition or disorder in each classification in which the plan

(or coverage) provides benefits for a core treatment for one or more medical conditions or surgical procedures.

The Departments note that, while these final rules only require plans and issuers to cover a minimum of one core treatment for a covered mental health condition or substance use disorder in every classification of benefits in which the plan (or coverage) provides benefits for a core treatment for one or more medical conditions or surgical procedures, plans and issuers are strongly encouraged to provide more robust coverage to ensure that participants and beneficiaries have access to the mental health and substance disorder care they need. The Departments incorporate this requirement in 26 CFR 54.9812–1(c)(2)(ii), 29 CFR 2590.712(c)(2)(ii), and 45 CFR 146.136(c)(2)(ii) of these final rules, as suggested by commenters, to ensure that plans and issuers offering mental health or substance use disorder benefits do not provide coverage for the full range of medical/surgical benefits in a classification, yet cover only one or a few isolated ancillary benefits for a covered mental health condition or substance use disorder in the same classification. As noted earlier in this preamble, a commenter expressed the concern that this requirement would broaden the scope and complexity of analyzing MHPAEA NQTL compliance and limit benefit design. However, as noted above, this provision amends the general requirement and limits the ability of a plan or issuer to implement a benefit design that provides robust benefits for medical conditions and surgical procedures while offering minimal benefits for mental health conditions and substance use disorders. This requirement, in combination with the other amendments to these final rules, will help to better ensure equitable access to mental health and substance use disorder benefits as compared to medical/surgical benefits.

For purposes of these final rules, a core treatment for a condition or disorder is a standard treatment or course of treatment, therapy, service, or intervention indicated by generally recognized independent standards of current medical practice. This definition of “meaningful benefits” takes an approach that is similar to the suggestion made by multiple commenters, as noted earlier in this preamble, that meaningful benefits be defined as the primary treatment for a condition or disorder based on generally recognized independent standards of current medical practice. However, instead of defining “meaningful benefits” as coverage for the primary

treatment for a condition or disorder in a classification, these final rules require the coverage of a core treatment because, from a medical or clinical perspective, there may not be a single primary treatment in many cases for a given condition or disorder (even where there are evidence-based treatments, services, therapies, and standards of care).

These final rules do not set forth specific requirements for plans and issuers to determine what constitutes a core treatment for any particular condition or disorder, but plans and issuers, in determining a core treatment for a condition or disorder in this context, should rely on current evidence-based medical and clinical information. The Departments note that a core treatment for a particular condition or disorder may not necessarily refer to a single item or service but may instead encompass a suite of items and services that together constitute a core treatment, depending on the relevant generally recognized independent standards of current medical practice. In such a case, the Departments expect that under this provision, plans and issuers will cover all components of at least one core treatment if the items and services provided as part of the treatment span a number of classifications, provided the plan or coverage provides benefits for one or more core treatments for any medical conditions or surgical procedures in those classifications. For example, one core treatment for major depressive disorder generally includes prescription drugs and psychotherapy. However, a core treatment may also include only prescription drugs or only psychotherapy (and in cases of severe depression, may also include inpatient hospitalization or other types of residential or outpatient treatment). The Departments note that a core treatment, with respect to a classification, may include the same item or service in other benefit classifications. For example, for major depressive disorder, psychotherapy could be a core treatment with respect to both the outpatient, in-network and outpatient, out-of-network classifications. In response to commenter requests for examples of meaningful benefits, the Departments have modified proposed Examples 5 and 6, and added examples that further illustrate the application of the meaningful benefit standard, as discussed in more detail later in this preamble.

The Departments also recognize the workability concerns raised by commenters with respect to the proposed meaningful benefits standard

in the proposed rules. In response to these comments, the Departments include language in these final rules to provide that, if there is no core treatment for a mental health condition or substance use disorder with respect to a classification, the plan (or coverage) is not required to provide benefits for a core treatment for such condition or disorder in that classification. Instead, the plan (or coverage) must provide benefits for such condition or disorder in every classification in which medical/surgical benefits are provided. Additionally, under these final rules, if the plan (or coverage) does not provide meaningful benefits for any medical condition or surgical procedure in a classification, the plan (or coverage) is not required to provide meaningful benefits for any mental health conditions or substance use disorders in the classification. This language further makes clear that the requirement to provide coverage of meaningful benefits for a condition or disorder is not a coverage mandate, but rather another approach to ensuring parity between mental health or substance use disorder benefits and medical/surgical benefits in a classification.

The Departments also stated in the preamble to the proposed rules that they recognize that the meaningful benefits proposal is related to an issue characterized as “scope of services” or “continuum of care,” as addressed in the preamble to the 2013 final regulations.¹⁰² “Scope of services,” when used in this context, generally refers to the types of treatment and treatment settings that are covered by a plan or coverage. The Departments requested comments on whether additional guidance is needed regarding how the proposed meaningful benefits standard would interact with the approach related to scope of services adopted under the 2013 final regulations.

Commenters suggested the Departments add “scope of services” or “scope of covered services” to the illustrative, non-exhaustive list of NQTLs. These commenters noted the importance of psychiatric care being fully integrated with the rest of medicine in primary care settings and in hospitals. Despite the language in the 2013 final regulations on intermediate services,¹⁰³ these commenters

highlighted that plans and issuers sometimes exclude fundamental services and do not assess those exclusions as NQTLs. These commenters noted that identifying “scope of services” or “scope of covered services” as a covered NQTL would remove ambiguity and require plans and issuers to determine whether an exclusion of mental health or substance use disorder benefits met the NQTL comparability and stringency test.

The Departments acknowledge these comments and the importance of psychiatric care being fully integrated in primary care settings and in hospitals but decline to add scope of services as an NQTL in the illustrative list in these final rules. Like the 2013 final regulations, these final rules are not intended to mandate coverage of any particular benefits. These final rules continue to require mental health and substance use disorder benefits and medical/surgical benefits to be assigned to the six classifications set forth in the regulations. For intermediate services like residential treatment, partial hospitalization, and intensive outpatient treatment, the Departments continue to require plans and issuers to assign covered intermediate mental health and substance use disorder benefits to the existing six benefit classifications in the same way that they assign comparable intermediate medical/surgical benefits to these classifications.¹⁰⁴ The Departments point to the examples in these final rules that address coverage restrictions based on geographic location, facility types, provider specialty, and other criteria that limit the scope or duration of benefits. Plans and issuers are required to comply with the NQTL requirements with respect to these types of restrictions. Further, the Departments note that exclusions of services to treat a condition or disorder otherwise covered by the plan or coverage are NQTLs that must comply

surgical benefits to these classifications. The 2013 final regulations also included additional examples illustrating the application of the NQTL rules to plan exclusions affecting the scope of services and clarified that plan or coverage restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of treatment must comply with the NQTL parity standard under the final rules.

¹⁰⁴ *Id.* at 68247. For example, as described in the preamble to the 2013 final regulations, if a plan or issuer classifies care in skilled nursing facilities or rehabilitation hospitals as inpatient benefits, then the plan or issuer must likewise treat any covered care in residential treatment facilities for mental health or substance use disorders as an inpatient benefit. In addition, if a plan or issuer treats home health care as an outpatient benefit, then any covered intensive outpatient mental health or substance use disorder services and partial hospitalization must be considered outpatient benefits as well.

with the provisions applicable to NQTLs under the final rules (including that there are no separate NQTLs that apply only to mental health or substance use disorder benefits in a classification).

In response to questions about whether the No Surprises Act’s requirements that certain out-of-network items and services be covered by plans and issuers might adversely affect the operation of closed panel plans by effectively requiring the coverage of out-of-network mental health or substance use disorder benefits (including in the context of the meaningful benefits standard in these final rules), the Departments note that nothing in these final rules requires a plan or coverage that provides coverage for medical/surgical benefits in the inpatient, out-of-network and outpatient, out-of-network classifications only to the extent required under Code sections 9816 and 9817, ERISA sections 716 and 717, and PHS Act sections 2799A–1 and 2799A–2 to provide additional mental health or substance use disorder benefits in the inpatient, out-of-network and outpatient, out-of-network classifications in accordance with this section. This approach is consistent with language in the 2013 final regulations which stated that compliance with PHS Act section 2713 (requiring coverage for recommended preventive services without any cost-sharing requirements) should not require that the full range of benefits for a mental health condition or substance use disorder be provided under MHPAEA. The proposed amendments to 26 CFR 54.9812–1(c)(2)(ii), 29 CFR 2590.712(c)(2)(ii), and 45 CFR 146.136(c)(2)(ii) would also make explicit the Departments’ interpretation that the requirement to provide coverage for mental health and substance use disorder benefits in each classification in which medical/surgical benefits are provided applies on a condition or disorder basis, an interpretation that the Departments have held since the 2010 interim final rules implementing MHPAEA.¹⁰⁵

The Departments solicited comments on the provisions of the proposed rules on classifications of benefits, including whether additional flexibility is needed to account for benefits that are difficult to place into classifications under the current structure, and whether additional guardrails or protections should be required. The Departments received very few comments on this issue. Most of the comments received related to the classification of certain

¹⁰² See 78 FR 68240, 68246–68247 (Nov. 13, 2013).

¹⁰³ *Ibid.* In the preamble to the 2013 final regulations, the Departments stated that plans and issuers must assign covered intermediate mental health and substance use disorder benefits to the existing six benefit classifications in the same way that they assign comparable intermediate medical/

¹⁰⁵ 75 FR 5410, 5413 (Feb. 2, 2010).

benefits as medical/surgical instead of mental health or substance use disorder. One comment suggested that a new classification of “urgent/crisis care” should be added to encompass both medical/surgical urgent care and mental health or substance use disorder crisis services. Because additional classifications are not required or necessary, the Departments are finalizing these amendments as proposed. Plans and issuers are reminded that the list of the current classifications in these final rules is exhaustive. Classification of benefits as medical/surgical benefits instead of mental health or substance use disorder benefits is discussed in more detail earlier in this preamble. The Departments will consider whether and to what extent additional guidance may be needed to address the application of MHPAEA to urgent/crisis care.

In the proposed rules, the Departments proposed to add two examples to 26 CFR 54.9812–1(c)(2)(ii)(C), 29 CFR 2590.712(c)(2)(ii)(C), and 45 CFR 146.136(c)(2)(ii)(C) to illustrate the application of these proposed amendments. The Departments are finalizing these examples with modifications to align with these final rules and are providing additional clarity on the application of the meaningful benefits standard to plans and issuers by redesignating proposed Example 6 as Example 7 and adding new Examples 6 and 8.

In proposed Example 5, a plan generally covers treatment for ASD, a mental health condition,¹⁰⁶ and covers outpatient, out-of-network developmental evaluations for ASD but excludes all other benefits for outpatient treatment for ASD, including ABA therapy, when provided on an out-of-network basis. The preamble of the proposed rules stated that, based on generally recognized independent standards of current medical practice consulted, ABA therapy is the primary treatment for ASD in children. In this proposed example, the plan generally covers the full range of outpatient treatments and treatment settings, including primary treatments, for medical conditions and surgical procedures when provided on an out-of-network basis. The proposed example

concluded that the plan violates the proposed meaningful benefits standard because, by not providing benefits for ABA therapy, it fails to provide meaningful benefits for ASD in the outpatient, out-of-network classification, but generally covers the full range of medical/surgical benefits in the classification.

In proposed Example 6, a plan generally covers diagnosis and treatment for eating disorders, a mental health condition, but specifically excludes coverage for nutrition counseling to treat eating disorders, including in the outpatient, in-network classification. The example in the proposed rules noted that nutrition counseling is the primary treatment for eating disorders in the outpatient, in-network classification and stated that the plan generally provides benefits for the primary treatments for medical conditions and surgical procedures in the outpatient, in-network classification. The proposed example concluded that the plan violates the proposed meaningful benefits standard because, by not providing benefits for nutrition counseling, it fails to provide meaningful benefits for the treatment of eating disorders in the outpatient, in-network classification, as determined in comparison to the benefits provided for medical/surgical conditions in the classification. The Departments noted that, if the plan covers medical/surgical benefits for nutrition counseling, the plan would also violate the prohibition on separate NQTLs applicable only to mental health or substance use disorder benefits.

Several commenters generally expressed support for the proposed Examples 5 and 6, which illustrated clear instances where exclusions of key services for ASD and eating disorders violate MHPAEA, noting that these examples remove any ambiguity whether such exclusions are inconsistent with MHPAEA’s requirements. One commenter expressed concerns about references to ABA therapy specifically because referring to a specific treatment may be limiting as evidence evolves regarding ASD. This commenter also cited a relatively weak evidence base for ABA therapy as a reason why the example should not specifically reference ABA therapy. Another commenter requested that Example 6 define “primary treatments” and “meaningful benefits” based on independent medical and clinical guidelines. A few commenters suggested that the Departments use the term “medical nutrition therapy” instead of nutrition counseling, to better reflect the clinical term used in

treatment codes. Another commenter suggested providing an additional example related to the treatment of OUD, to reinforce the clear requirement to cover opioid treatment program services as part of the “meaningful” coverage of substance use disorder benefits in all classifications in which meaningful medical/surgical services are covered.

After considering comments, the Departments are finalizing Examples 5 and 6 in the proposed rules with modifications, to make the examples consistent with the clarifications described earlier in this preamble stating that a plan or issuer will be required to provide meaningful benefits for a mental health condition or substance use disorder in a classification if it provides meaningful benefits for one or more medical conditions or surgical procedures in the same classification. These final rules also make minor clarifying changes to reflect more appropriate clinical terminology and introduce two new, additional examples. In each example in these final rules that illustrates the meaningful benefits standard, the group health plan is subject to the requirements of MHPAEA and provides both medical/surgical benefits and mental health and substance use disorder benefits. Additionally, these final rules note that references in these examples to any particular core treatment are included for illustrative purposes only and are not intended to limit coverage in any way. The Departments remind plans and issuers that they must consult generally recognized independent standards of current medical practice to determine the applicable core treatment, therapy, service, or intervention for any covered condition or disorder, and note that, as medical evidence evolves, the core treatment options for any condition or disorder may change.

In Example 5 of these final rules, a plan covers treatment for ASD. As explained earlier in this preamble and in the proposed rules, for purposes of MHPAEA, ASD is a mental health condition under generally recognized independent standards of current medical practice.¹⁰⁷ Specifically, the plan covers outpatient, out-of-network developmental screenings for ASD, but excludes all other benefits for outpatient treatment for ASD, including ABA therapy, when provided on an out-of-network basis. The plan generally covers the full range of outpatient treatments (including core treatments)

¹⁰⁶ As stated earlier in this preamble, the proposed rules stated, and these final rules continue to state, that for purposes of MHPAEA, ASD is a mental health condition under generally recognized independent standards of current medical practice. Therefore, benefits for this condition are considered mental health benefits, and are subject to the protections of MHPAEA and its implementing regulations.

¹⁰⁷ DSM (5th ed.), Section II: Diagnostic Criteria and Codes, Autism Spectrum Disorder.

and treatment settings for medical conditions and surgical procedures when provided on an out-of-network basis. Under the generally recognized independent standards of current medical practice consulted by the plan, developmental screenings alone that are covered for diagnostic purposes, without any coverage for a therapeutic intervention, do not constitute a core treatment for ASD. Example 5 concludes that the plan violates these final rules. Although the plan covers benefits for ASD, in the outpatient, out-of-network classification, it only covers developmental screenings, so it does not cover a core treatment for ASD in the classification. Since the plan generally covers the full range of medical/surgical benefits including a core treatment for one or more medical conditions or surgical procedures in the classification, it fails to provide meaningful benefits for treatment of ASD in the classification, as required under these final rules.

New Example 6 of these final rules starts with the same facts as Example 5 and illustrates how these final rules apply where a plan or issuer does not cover a core treatment for any medical conditions or surgical procedures in a classification. The facts of new Example 6 state that the plan is a health maintenance organization (HMO) that does not cover the full range of medical/surgical benefits, including a core treatment for any medical conditions or surgical procedures in the outpatient, out-of-network classification (except as required under Code sections 9816 and 9817, ERISA sections 716 and 717, and PHS Act sections 2799A–1 and 2799A–2), but covers benefits for medical conditions and surgical procedures in the inpatient, in-network; outpatient, in-network; emergency care, and prescription drug classifications. Example 6 concludes that the plan does not violate the rules in 26 CFR 54.9812–1(c)(2)(ii), 29 CFR 2590.712(c)(2)(ii), and 45 CFR 146.136(c)(2)(ii). Because the plan does not provide meaningful benefits including a core treatment for any medical condition or surgical procedure in the outpatient, out-of-network classification (except as required under Code sections 9816 and 9817, ERISA sections 716 and 717, and PHS Act sections 2799A–1 and 2799A–2), the plan is not required to provide meaningful benefits, for any mental health conditions or substance use disorders in that classification.¹⁰⁸ The

Departments note that, nevertheless, the plan must provide meaningful benefits for each mental health condition and substance use disorder for which the plan provides benefits in every classification in which meaningful medical/surgical benefits are provided. Additionally, the Departments note that plans and issuers must comply with other requirements of these final rules, as applicable, including the prohibition on NQTLs applicable only to mental health and substance use disorder benefits.¹⁰⁹

In Example 7 of these final rules, which was redesignated from Example 6 in the proposed rules, a plan provides extensive benefits, including for core treatments for many medical conditions and surgical procedures in the outpatient, in-network classification, including nutrition counseling for diabetes and obesity. The plan also generally covers diagnosis and treatment for eating disorders, which are mental health conditions, including coverage for nutrition counseling¹¹⁰ to treat eating disorders in the outpatient, in-network classification. Under this example, nutrition counseling is a core treatment for eating disorders, in accordance with generally recognized independent standards of current medical practice consulted by the plan. Example 7 concludes that the plan does not violate the meaningful benefits standard in these final rules. The coverage of diagnosis and treatment for eating disorders, including nutrition counseling, in the outpatient, in-network classification results in the plan providing meaningful benefits for the treatment of eating disorders in the classification, as determined in

of-network classification, solely to meet requirements under the provisions of the No Surprises Act.

¹⁰⁹ For example, if the plan excludes coverage for ABA therapy and the exclusion does not comply with the provisions applicable to NQTLs under the final rules—including the design and application requirements and the relevant data evaluation requirements (if the exclusion was generated through a broader NQTL such as medical necessity or other clinical guideline that also applies to medical/surgical benefits in the relevant classification), or the requirement that there are no separate NQTLs that apply only to mental health or substance use disorder benefits in a classification—the plan violates the rules of 26 CFR 54.9812–1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4).

¹¹⁰ The proposed rules and these final rules refer to benefits for “nutrition counseling.” The Departments acknowledge several commenters who noted that other terminology may be more appropriate, such as “medical nutrition therapy” or “medical nutrition therapy provided by a dietitian” using specific CPT codes. The Departments intend that references to nutritional counseling for eating disorders be interpreted broadly to include these and other appropriate types of treatment for eating disorders.

comparison to the benefits provided for medical conditions and surgical procedures in the classification.

In response to commenters who requested an additional example illustrating what plans and issuers must do to provide meaningful benefits for the treatment of OUD, the Departments are also finalizing new Example 8. In this new example, a plan provides extensive benefits for the core treatments for many medical conditions and surgical procedures in the outpatient, in-network and prescription drug classifications. The plan provides coverage for diagnosis and treatment for OUD, a substance use disorder, in the outpatient, in-network classification, by covering counseling and behavioral therapies, also referred to as psychosocial treatments. Additionally, the plan provides coverage for diagnosis and treatment for OUD, in the prescription drug classification, by covering medications to treat opioid use disorder (MOUD). Under this example, counseling and behavioral therapies and MOUD, in combination, are one of the core treatments for OUD, in accordance with generally recognized independent standards of current medical practice consulted by the plan.

Example 8 concludes that the plan does not violate these final rules. The coverage of counseling and behavioral therapies and MOUD, in combination, in the outpatient, in-network classification and prescription drug classification, respectively, results in the plan providing meaningful benefits for the treatment of OUD in the outpatient, in-network and prescription drug classifications.

b. Classification of Benefits

The 2013 final regulations set forth the only classifications of benefits that may be used in applying the parity rules for financial requirements and treatment limitations and listed specific instances when a plan or issuer may divide benefits into sub-classifications beyond the six classifications permitted in paragraph (c)(2)(ii)(A) of the 2013 final regulations. The Departments proposed to reiterate at 26 CFR 54.9812–1(c)(3)(iii), 29 CFR 2590.712(c)(3)(iii), and 45 CFR 146.136(c)(3)(iii) that a plan or issuer may not divide benefits into any sub-classifications other than those specifically permitted under the regulations. The Departments did not propose any substantive changes to the existing sub-classifications or to permit any new sub-classifications. The Departments also proposed non-substantive changes to 26 CFR 54.9812–1(c)(3)(iv), 29 CFR 2590.712(c)(3)(iv), and 45 CFR 146.136(c)(3)(iv) to label the

¹⁰⁸ As discussed earlier in this preamble, the Departments note that this conclusion would hold if the plan provides benefits for a core treatment for a medical/surgical condition in the outpatient, out-

tables in the examples, update references in the examples, and redesignate the examples as paragraphs.

A few commenters expressed concerns about the classification of certain types of benefits and providers into existing classifications and sub-classifications, including intensive outpatient treatment, partial hospitalization programs, and other team-based models of care. Some commenters requested additional clarification, including a standard definition for the outpatient sub-classifications, citing the fact that some plans and issuers use differing variations to define the outpatient, office visit sub-classification. One commenter requested that the Departments indicate that the sub-classifications applicable to financial requirements and quantitative treatment limitations under paragraph (c)(3)(iii) of the 2013 final regulations may also be used for NQTLs.

As discussed earlier in this preamble, plans and issuers must assign covered intermediate mental health and substance use disorder benefits to the existing six benefit classifications in the same way that they assign comparable intermediate medical/surgical benefits to these classifications. Additionally, plans and issuers that opt to use sub-classifications for outpatient benefits must assign covered outpatient benefits to the permissible outpatient sub-classifications for mental health and substance use disorder benefits in the same way they assign comparable medical/surgical benefits. The Departments are finalizing the clarification that a plan or issuer is not permitted to divide benefits into any sub-classifications other than those specifically permitted under the regulations,¹¹¹ as well as the clarification that plans and issuers may use the permissible sub-classifications under the 2013 final regulations when applying all of the rules for financial requirements and treatment limitations, including NQTLs.¹¹² Consistent with the proposed rules, the Departments are not making any substantive changes to the existing sub-classifications or to permit any new sub-classifications of benefits in these final rules. The Departments are also finalizing the non-substantive changes to 26 CFR 54.9812-1(c)(3)(iv), 29 CFR 2590.712(c)(3)(iv), and 45 CFR 146.136(c)(3)(iv), for which no comments were received.

The Departments noted in the preamble to the proposed rules that they have received questions and requests for guidance on how to comply with MHPAEA's requirements with respect to telehealth benefits, including where telehealth fits into the existing classifications and sub-classifications of benefits and whether changes are necessary to account for telehealth benefits. The Departments did not propose any changes in the proposed rules with respect to telehealth benefits and instead stated that they expected plans and issuers to treat telehealth benefits the same way they treat those benefits when provided in person in determining the classification or sub-classifications in which a particular benefit belongs. The Departments requested comments on whether changes to the framework and existing regulations implementing MHPAEA were necessary to account for telehealth benefits.

Several commenters stated that the expansion of telehealth services can supplement a plan's or issuer's network where there are in-person provider shortages and expressed support for treating telehealth benefits the same way those benefits are treated when provided in person. Some commenters discussed the growth and sustained usage of telehealth services since the start of the COVID-19 pandemic, particularly for mental health and substance use disorder services. Commenters stressed that telehealth is particularly valuable in rural and medically underserved areas. However, commenters stressed that telehealth may not be appropriate for all patients and does not fully replace in-person mental health and substance use disorder care. The Departments reiterate that plans and issuers are expected to treat telehealth benefits the same way they treat those benefits when provided in person in determining the classification or sub-classifications in which a particular benefit belongs.

As discussed earlier in the preamble, several commenters requested the Departments take into account telehealth in the relevant data evaluation requirements, as well as the requirements for standards related to network composition; however, the Departments are not addressing any specific data metrics for telehealth in these final rules. After reviewing the comments received on this issue, the Departments are not making changes in these final rules to address how to classify telehealth benefits. The Departments understand that telehealth plays a vital role in the provision of health care, particularly following the

COVID-19 pandemic, and may support access to services for those with transportation barriers. When evaluating MHPAEA compliance, plans and issuers must include any covered telehealth benefits in the six classifications used to apply the parity requirements. The Departments also understand that telehealth can be used by plans and issuers as a tool to address provider shortages. These final rules also acknowledge telehealth can be leveraged to mitigate provider shortages in a geographic area and that leveraging telehealth is a potential reasonable action that can be used to address material differences in in-network access.

c. Availability of Plan Information

Treasury and DOL proposed to amend 26 CFR 54.9812-1(d)(3) and 29 CFR 2590.712(d)(3) by adding cross-references to proposed 26 CFR 54.9812-2 and 29 CFR 2590.712-1 to clarify that the comparative analyses and any other applicable information required under the CAA, 2021 are considered to be instruments under which a plan is established or operated, and therefore ERISA plans generally must furnish those documents to plan participants and beneficiaries upon request within 30 days, as required under section 104 of ERISA and 29 CFR 2520.104b-1. Additionally, the Departments proposed to amend 26 CFR 54.9812-1(d)(3), 29 CFR 2590.712(d)(3), and 45 CFR 146.136(d)(3) to clarify that the comparative analyses and any other applicable information required under the CAA, 2021 and the proposed rules qualify as documents, records, and other information relevant to the claimant's claim for benefits to which plans and issuers must provide reasonable access upon request and free of charge. The Departments noted that this clarification is consistent with proposed 26 CFR 54.9812-2(e)(2), 29 CFR 2590.712-1(e)(2), and 45 CFR 146.137(e)(2), which generally would require plans and issuers to make available the comparative analyses required to be performed and documented under the CAA, 2021 when requested by participants and beneficiaries in ERISA plans, including when requested by a participant or beneficiary (or a provider or other person acting as a participant's or beneficiary's authorized representative) who has received an adverse benefit determination related to mental health or substance use disorder benefits. The Departments noted in the preamble to the proposed rules that participants and beneficiaries in ERISA plans should be able to request copies of comparative analyses to ensure they

¹¹¹ 26 CFR 54.9812-1(c)(3)(iii), 29 CFR 2590.712(c)(3)(iii), and 45 CFR 146.136(c)(3)(iii).

¹¹² 26 CFR 54.9812-1(c)(2)(ii)(A), 29 CFR 2590.712(c)(2)(ii)(A), and 45 CFR 146.136(c)(2)(ii)(A).

are informed about their health plans or group health insurance coverage. Additionally, the Departments noted that these comparative analyses would be relevant to a claimant's claim for benefits and should therefore be available to participants or beneficiaries, and providers or other individuals acting as a participant's or beneficiary's authorized representative.

The Departments received several comments on this aspect of the proposed rules. A few commenters recommended that the Departments add language to the end of paragraph (d)(3) of 26 CFR 54.9812-1, 29 CFR 2590.712, and 45 CFR 146.136 making clear that no part of the comparative analyses or other applicable information required by 26 CFR 54.9812-2, 29 CFR 2590.712-1, or 45 CFR 146.137 may be withheld when requested, including because the information is proprietary, has commercial value, or is commercially protected. One of these commenters also urged the Departments to conform this provision with the standard proposed in 26 CFR 54.9812-2(e), 29 CFR 2590.712-1(e), and 45 CFR 146.137(e), so that individuals can have information at the time of the denial, which is needed to assess whether to raise a parity compliance claim in an internal grievance or appeal.

After considering comments, the Departments are finalizing the amendments to 26 CFR 54.9812-1(d)(3), 29 CFR 2590.712(d)(3), and 45 CFR 146.136(d)(3) as proposed, with a correction. The final rules remove the phrase "upon appeal of an adverse benefit determination" and replace it with "who have received an adverse benefit determination" in the third sentence of 26 CFR 54.9812-1(d)(3), 29 CFR 2590.712(d)(3), and 45 CFR 146.136(d)(3) to conform with the requirements under the DOL claims procedure rule at 29 CFR 2560.503-1 and rules issued by the Departments at 26 CFR 54.9815-2719, 29 CFR 2590.715-2719, and 45 CFR 147.136, which set forth rules regarding claims and appeals. The Departments also decline to exempt plans and issuers from providing certain types of information as part of their comparative analyses, to ensure transparency when an individual (or their authorized representative) requests a comparative analysis. As stated earlier in this preamble, this information is relevant to a claimant's claim for benefits and should therefore be made available.

d. Other Provisions

The proposed rules included proposed amendments to 26 CFR 54.9812-1(e)(4), 29 CFR 2590.712(e)(4),

and 45 CFR 146.136(e)(4) to include a reference to 26 CFR 54.9812-2(g), 29 CFR 2590.712-1(g), and 45 CFR 146.137(g) and to reflect current HHS regulations at 45 CFR 156.115(a)(3). The preamble to the proposed rules noted that existing regulations at 26 CFR 54.9812-1(e)(4), 29 CFR 2590.712(e)(4), and 45 CFR 146.136(e)(4) state that nothing in paragraphs (f) and (g) of the 2013 final regulations related to MHPAEA's small employer exemption and increased cost exemption, respectively, changes the requirement under HHS regulations at 45 CFR 147.150 and 156.115, providing that a health insurance issuer offering non-grandfathered health insurance coverage in the individual or small group market providing mental health and substance use disorder services, including behavioral health treatment services, must comply with the provisions of 45 CFR 146.136 to satisfy the requirement to provide EHB. The preamble further stated that HHS has updated 45 CFR 156.115(a)(3) to state that provision of EHB means that a health plan provides benefits that "[w]ith respect to the mental health and substance use disorder services, including behavioral health treatment services, required under § 156.110(a)(5), comply with the requirements under section 2726 of the Public Health Service Act and its implementing regulations."¹¹³ The Departments did not receive comments on this provision. Therefore, to be consistent with the language contained in 45 CFR 156.115(a)(3), and to ensure that the cross-reference between the Departments' MHPAEA implementing regulations and HHS' EHB implementing regulations includes the requirement to comply with the provisions on comparative analyses, the Departments are finalizing this change as proposed with minor edits for precision, and to reflect that the requirement would only apply to a health insurance issuer offering non-grandfathered health insurance coverage in the individual or small group market that is required to provide mental health and substance use disorder services, including behavioral health treatment services, as part of EHB required under 45 CFR 156.110(a)(5) and 156.115(a).

The proposed rules also included several technical edits to update paragraph (c)(3)(i) of the 2013 final

regulations to add citations, include additional specificity in citations, and strike an outdated reference to limitations on annual deductibles for non-grandfathered health plans in the small group market at PHS Act section 2707(b) and ACA section 1302(c). The Departments did not receive any comments on these provisions and are finalizing as proposed.

The Departments are finalizing proposed technical amendments to 26 CFR 54.9812-1(c)(3)(iii)(A) and (B), 29 CFR 2590.712(c)(3)(iii)(A) and (B), and 45 CFR 146.136(c)(3)(iii)(A) and (B) to update citations. No comments were received on these technical amendments. In finalizing these provisions, the Departments are also restoring parenthetical references to health insurance coverage. Re-insertion of the phrase "health insurance coverage" is not intended to be a substantive change from the proposed rules, but rather corrects this omission and is consistent with the text of the 2013 final regulations.

B. New Regulations at 26 CFR 54.9812-2, 29 CFR 2590.712-1, and 45 CFR 146.137

The CAA, 2021 amended MHPAEA, in part, to expressly require plans and issuers that offer coverage that provides both medical/surgical benefits and mental health or substance use disorder benefits and impose NQTLs on mental health or substance use disorder benefits to perform and document comparative analyses of the design and application of NQTLs, and make their comparative analyses and certain information available to the Departments or applicable State authorities upon request. The Departments proposed to codify this requirement.

Many commenters expressed support for codification of this requirement with several of these commenters noting that such detailed requirements are necessary to clarify what plans' or issuers' analyses must contain, as well as to hold plans and issuers accountable in following such requirements.

Many other commenters criticized the proposed content elements and requested specific changes to the rules as proposed to assist plans and issuers in complying with the requirement to perform and document comparative analyses. Several commenters requested examples of a compliant comparative analysis to assist in understanding what documentation, in the Departments' view, is required to meet the standards. Another commenter stated that critical components of the terms, such as what a test comprises, the standards for

¹¹³ Patient Protection and Affordable Care Act; Updating Payment Parameters, Section 1332 Waiver Implementing Regulations, and Improving Health Insurance Markets for 2022 and Beyond, 86 FR 53412 (Sept. 27, 2021), <https://www.federalregister.gov/documents/2021/09/27/2021-20509/patient-protection-and-affordable-care-act-updating-payment-parameters-section-1332-waiver>.

meeting that test, and compiling the proper information are subject to interpretation, which can lead to regulators and auditors having different perspectives on the requirements, creating substantial uncertainty for plans and issuers that are attempting to comply. Several commenters also expressed a desire for additional clarification regarding the proposed content elements with respect to specific NQTLs. One commenter was concerned that the proposed rules did not provide clarity on how to apply the new comparative analysis requirements to complex NQTLs, such as those related to network administration.

After reviewing comments, the Departments are finalizing the codification of the new statutory requirement that plans and issuers that offer coverage that provides both medical/surgical benefits and mental health or substance use disorder benefits and impose NQTLs on mental health or substance use disorder benefits must perform and document a comparative analysis of the design and application of each such NQTL, with modifications in response to comments as noted. This finalized provision aligns the regulations with the statutory requirements under MHPAEA, as amended by the CAA, 2021. In response to commenter concerns that the proposed rules did not clarify how a plan or issuer should apply the new comparative analysis requirements to factors and evidentiary standards used to design and apply NQTLs that are especially complex (including those related to network composition), the Departments disagree that the proposed rules and these final rules do not rationally relate to factors and evidentiary standards used to design and apply NQTLs like standards related to network composition or methods for determining out-of-network rates. Using the definitions of the terms “processes,” “strategies,” “evidentiary standards,” and “factors” under these final rules to inform the content elements required in a comparative analysis, these final rules provide sufficient guidance for plans and issuers to perform and document their comparative analyses of all NQTLs.

Additionally, these final rules also provide additional guidance on how a plan or issuer with a typical plan or coverage design should collect and evaluate data for NQTLs related to network composition (which must be included in the comparative analysis) under the relevant data evaluation requirements, and provides examples of reasonable actions that plans and issuers may take (and document in the

comparative analysis) if such data suggest that NQTLs related to network composition contribute to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits in a classification. The Departments acknowledge that a plan or issuer imposing a complex NQTL with respect to mental health and substance use disorder benefits by relying on a large number of complicated factors and evidentiary standards will likely require more resources to perform and document their comparative analysis in a manner that is compliant with these final rules. The Departments also appreciate that some of the required content for comparative analyses are described broadly and therefore could lead to the Departments and applicable State authorities taking different approaches in determining what constitutes a sufficient comparative analysis. However, these broad descriptions are necessary to ensure that these final rules set forth a single set of content elements that are flexible enough to apply to the wide variety of different NQTLs imposed by plans and issuers with respect to mental health and substance use disorder benefits.

The Departments are not providing an example of a comparative analysis that complies with these final rules, but continue to consider what additional resources and guidance are necessary to assist the regulated community in complying with MHPAEA and these final rules. A plan or issuer that analyzes the design and application of an NQTL along with the relevant data and considers it in the manner described earlier in this preamble will be well positioned to perform and document a comparative analysis in a manner consistent with these final rules. The Departments also note, as stated earlier in this preamble, that they intend to update the MHPAEA Self-Compliance Tool for plans and issuers to determine which data to collect and evaluate. The Departments note that what constitutes a compliant comparative analysis will depend on all the relevant facts and circumstances, including the provisions of the plan or coverage and the relevant NQTL. The Departments remain committed to providing additional guidance to assist with the implementation of these final rules.

1. Content of Comparative Analyses—26 CFR 54.9812–2(c), 29 CFR 2590.712–1(c), and 45 CFR 146.137(c)

The Departments proposed requirements at 26 CFR 54.9812–2(c), 29 CFR 2590.712–1(c), and 45 CFR

146.137(c) governing the content of the comparative analyses required by Code section 9812(a)(8), ERISA section 712(a)(8), and PHS Act section 2726(a)(8). Specifically, the Departments proposed that each comparative analysis would include, at a minimum, with respect to each NQTL imposed under the plan or coverage on mental health and substance use disorder benefits, six elements:

- (1) a description of the NQTL;
- (2) the identification and definition of the factors used to design or apply the NQTL;
- (3) a description of how factors are used in the design or application of the NQTL;
- (4) a demonstration of comparability and stringency, as written;
- (5) a demonstration of comparability and stringency, in operation; and
- (6) findings and conclusions.

In addition to proposing to require the inclusion of specific elements in each comparative analysis, the proposed rules would require each plan or issuer to prepare and make available to the Departments, upon request, a written list of all NQTLs imposed under the plan or coverage and a general description of any information considered or relied upon by the plan or issuer in preparing the comparative analysis for each NQTL.

Several commenters expressed general support for the proposed elements that plans and issuers would be required to include in their comparative analyses under the proposed rules. Some commenters highlighted that the clarity the proposed rules provided would help to reduce confusion as to how plans and issuers should perform and document their comparative analyses, and others reasoned that, by clarifying the comparative analysis content requirements under the proposed rules, regulators will be able to better determine compliance with MHPAEA.

Some commenters, however, stated that the proposed rules did not provide enough clarity, which they stated may make complying with the requirements more challenging. These commenters stated that providing a list of all NQTLs imposed under a plan or coverage would be challenging without either a definitive list of all NQTLs or requiring that plans and issuers perform and document comparative analyses only for NQTL types that the Departments define through regulations or guidance. As discussed earlier in the preamble, several commenters requested that the Departments provide an exhaustive list of NQTLs for which a comparative analysis would be required.

Commenters also expressed concerns about whether plans and issuers would be able to access the information and data necessary to perform and document a sufficient comparative analysis that includes all of the proposed content requirements. Several of these commenters mentioned difficulty acquiring the necessary information and data from their service providers and business partners, while other commenters stated that the proposed content requirements for comparative analyses are superfluous, unhelpful, or unreasonably burdensome. Some commenters described concerns related to cost and feasibility of preparing comparative analyses that would comply with the proposed content requirements.

After reviewing comments, the Departments are finalizing the requirement that a comparative analysis include, at a minimum, the six content elements listed in the proposed rules, consistent with the statute, with several modifications. This section of the preamble to these final rules discusses the comments received with respect to each content element in the proposed rules and the modifications made to each content element in these final rules.

With respect to the requirement to prepare and make available, upon request, a written list of all NQTLs imposed under the plan or coverage and commenters who noted that this requirement would be challenging to meet without a definitive list of all NQTLs, as stated earlier in this preamble, the Departments decline to provide an exhaustive list of NQTLs in these final rules or separate guidance. The Departments also note that, like the substantive requirements for NQTLs, the comparative analysis requirements of MHPAEA are not limited to a list of specific NQTLs, but apply to all NQTLs that limit the scope or duration of treatment under a plan or coverage. As a result, these final rules require that, in addition to the comparative analysis for each NQTL, each plan or issuer must prepare and make available to the Secretary, upon request, a written list of all NQTLs imposed under the plan or coverage.

Additionally, for ERISA-covered plans, the written list must be provided to the named fiduciaries of the plan who are required to include a certification as part of each comparative analysis, as discussed later in this preamble. However, because the Departments recognize that a sufficient comparative analysis will include descriptions of the information, evidence, sources, and standards, as well as factors and

evidentiary standards, that the plan or issuer considered or relied upon as part of the content elements, these final rules eliminate the separate requirement that proposed to require plans and issuers to provide a general description of any information considered or relied upon by the plan or issuer in preparing a comparative analysis for an NQTL.

The Departments are aware of reports that some self-insured plans have been unsuccessful in receiving comparative analyses (or the information required to perform and document comparative analyses) requested from their TPAs or other service providers. The Departments emphasize that, as of the date of the publication of these final rules, the statutory requirement to perform and document comparative analyses has been applicable to plans and issuers for over 3 years. The Departments have previously stated that TPAs and other service providers are expected to work closely with plans and issuers to support their needs by providing data and other information about the design and application of NQTLs applicable to mental health and substance use disorder benefits and to medical/surgical benefits so that comparative analyses can be performed and documented (regardless of whether the Departments or an applicable State authority have requested them). Because plans and issuers are the entities required by statute to perform and document comparative analyses and there is no exception to the requirement when necessary information cannot be obtained from another entity, plans and issuers must work with their TPAs and service providers to obtain the information they need for their comparative analyses. Any ERISA-governed group health plans that contract with service providers refusing or otherwise failing to provide the requisite information should notify DOL.

Additionally, as noted earlier in this preamble, the Departments acknowledge the challenges, cost, and complexity of collecting and evaluating data, but are of the view that it is important to include specific content requirements in these final rules, including those related to relevant data to measure the impact of an NQTL on access to mental health and substance use disorder benefits. However, in recognition of these challenges and to align with other changes made in these final rules the Departments have modified certain specific provisions within some of the listed content elements as described in the following paragraphs.

a. Description of the NQTL

For each comparative analysis, the proposed rules would require a plan or issuer to identify the NQTL that is the subject of the comparative analysis, including the specific terms of the plan or coverage or other relevant terms regarding the NQTL, the policies or guidelines (internal or external) in which the NQTL appears or is described, and the applicable sections of any other relevant documents, such as provider contracts that describe the NQTL, consistent with the statute. This would include the documents that contain the specific language of the NQTL that the plan or issuer imposes. The plan or issuer would also be required to identify all mental health or substance use disorder benefits and medical/surgical benefits to which the NQTL applies, including a list identifying which of those benefits are considered to be mental health and substance use disorder benefits and which benefits are considered to be medical/surgical benefits (consistent with the proposed definitions of those terms). Additionally, each plan or issuer would be required to include in its comparative analysis a description of which benefits are included in each classification of benefits. Finally, under the proposed rules, the plan or issuer would be required to identify the predominant NQTL applicable to substantially all medical/surgical benefits in each classification, including an explanation of how the plan or issuer determined which variation is the predominant NQTL and how the plan identified the variations of the NQTL.

The Departments received few comments on this proposed first content element. One commenter suggested an alternative approach, arguing that, instead of requiring that plans and issuers provide all policies, guidelines, provider contracts, and any other documents where the NQTL “appears or is described,” plans and issuers should be required under these final rules to provide only the documents, policies, or procedures that govern the NQTL.

After reviewing comments, the Departments are finalizing the requirement that a comparative analysis include a description that identifies the NQTL, identifies all mental health or substance use disorder benefits and medical/surgical benefits to which the NQTL applies, and describes which benefits are included in each classification. The Departments emphasize that these final rules still require a plan or issuer to identify the specific terms of the plan or coverage or other relevant terms regarding the

NQTL, including the policies or guidelines (internal or external) in which the NQTL appears or is described and the applicable sections of any other relevant documents, such as provider contracts, that describe the NQTL. Under these final rules, the entire policy, guideline, or document is not required to be included in a comparative analysis, but could be requested by the Departments in the course of reviewing a comparative analysis. The Departments decline to require the inclusion of only the documents that govern the NQTL, because that might not include all the policies or guidelines that determine how the NQTL is designed or applied with respect to mental health or substance use disorder benefits.

Additionally, as noted earlier in these final rules, the Departments are not finalizing the proposed mathematical substantially all and predominant tests. Therefore, these final rules do not finalize the proposed content requirement that the description of the NQTL in a comparative analysis identify the predominant NQTL applicable to substantially all medical/surgical benefits in each classification, including an explanation of how the plan or issuer determined which variation is the predominant NQTL and how the plan or issuer identified the variations of the NQTL.¹¹⁴

b. Identification and Definition of the Factors and Evidentiary Standards Used To Design or Apply the NQTL

Under the second proposed content element, a plan or issuer would be required to identify and define all of the factors considered or relied upon to design or apply the NQTL. The plan or issuer would be required to identify all of the factors considered, as well as the evidentiary standards considered or relied upon to design or apply each factor and the evidence or sources from which each evidentiary standard was derived, in determining which mental health or substance use disorder benefits and which medical/surgical benefits are subject to the NQTL. The plan or issuer would also be required to define each factor, by including a detailed description of the factor, and providing a description of each evidentiary standard (and the source of each evidentiary standard) identified. The Departments stressed in the preamble to the proposed rules that

when identifying the evidence or sources from which an evidentiary standard is derived, a plan or issuer should be prepared to provide the copies of the actual evidence or source used, as well as the date and relevant citation for the correct version of the document used.

The Departments received few comments on this content element. One commenter noted that the requirement to provide detailed descriptions of each factor, including evidence and sources relied upon with data and relevant citations, may be challenging for plans and issuers to operationalize. One commenter highlighted that it may be difficult to identify evidence and sources for factors that are processes, such as provider referral requirements, requirements to submit information for clinical review, or the development and approval of a treatment plan, and that processes used to apply the NQTL “in operation” should be analyzed under a separate step of the comparative analysis. Another commenter stated that the requirement to do a historical analysis of the factors utilized by plans and issuers, including dating and providing citations for sources (from the time they decided to impose the NQTL), would be burdensome, and recommended such a requirement be eliminated or that the Departments accept references to factors that are generally accepted business standards without the need for specific dates and citations.

After reviewing comments, the Departments are finalizing the requirement that the comparative analysis identify and define all of the factors considered or relied upon to design or apply the NQTL to mental health or substance use disorder benefits and medical/surgical benefits as proposed, with minor non-substantive changes and a modification to align with changes made in these final rules to the prohibition on discriminatory factors and evidentiary standards. Specifically, these final rules clarify that a plan or issuer must identify every factor and the evidentiary standards considered or relied upon to design or apply each factor, instead of all of the factors considered, consistent with other provisions of these final rules. These final rules also add new 26 CFR 54.9812–2(c)(2)(ii)(C), 29 CFR 2590.712–1(c)(2)(ii)(C), and 45 CFR 146.137(c)(2)(ii)(C) to make clear that plans and issuers must describe any steps taken to correct, cure, or supplement any information, evidence, sources, or standards that are the basis for a factor or evidentiary standard and that would otherwise have been

considered biased or not objective in the absence of such steps. Additionally, as discussed earlier in this preamble, these final rules also make minor modifications to better distinguish evidentiary standards from factors within the definitions of those terms, and clarify that, while this content element requires a plan or issuer to include a description of each evidentiary standard used to design or apply each factor, this information is part of the required detailed description of each factor.

While the Departments acknowledge that identifying and defining all factors takes time for a plan or issuer to complete (for newly applied and existing NQTLs), the Departments note that this requirement was not new when it was included in the proposed rules. The CAA, 2021 specifically requires the identification and definition of factors relied upon to design and apply the NQTL,¹¹⁵ and has been applicable to plans and issuers since February 10, 2021. Identification and definition of the factors considered in the design and application of an NQTL was also previously addressed in FAQs Part 45.¹¹⁶ It is important for comparative analyses to include detailed information about factors, evidentiary standards, and their sources when a plan or issuer starts to perform and document its comparative analysis, to support the plan’s or issuer’s analysis of how factors and evidentiary standards are used to design and apply NQTLs. Such analysis should include support for the factors utilized from the time a plan or issuer decided to impose, or continues to impose, an NQTL on the relevant mental health and substance use disorder benefits, as well as medical/surgical benefits. To the extent a plan or issuer cannot support its use of factors and evidentiary standards, including by providing information on the sources of the factors and evidentiary standards considered and relied on by plans and issuers (from the time they decided to impose the NQTL), it is unclear how

¹¹⁵ Code section 9812(a)(8)(A)(iii), ERISA section 712(a)(8)(A)(iii), and PHS Act section 2726(a)(8)(A)(iii).

¹¹⁶ <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-45.pdf> and <https://www.cms.gov/ccio/resources/fact-sheets-and-faqs/downloads/mhpaea-faqs-part-45.pdf>. Additionally, the 2020 MHPAEA Self-Compliance Tool includes robust guidance related to requirements for NQTLs. Step two of the analysis outlined in the 2020 MHPAEA Self-Compliance Tool for NQTLs suggests identifying the factors considered in the design of the NQTL. See EBSA, Self-Compliance Tool for the Mental Health Parity and Addiction Equity Act (MHPAEA) (2020), <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/self-compliance-tool.pdf>.

¹¹⁴ However, as discussed earlier in this preamble, the Departments are of the view that the concept of material differences in access helps to give meaning to the concepts of “substantially all” and “predominant” from the statutory language in the context of NQTLs.

such plan or issuer can ensure that the factors and evidentiary standards are comparable and no more stringently designed and applied for mental health and substance use disorder benefits, than for medical/surgical benefits, as required under the statute (and the fourth and fifth content elements of a comparative analysis under these final rules).

Without such information, a comparative analysis likely would not accurately describe factors and their sources and would not demonstrate that, when factors are used to design or apply an NQTL to mental health or substance use disorder benefits, they are comparable to, and not more stringently applied, than they are when used to design or apply an NQTL to medical/surgical benefits. The absence of this information would also make it difficult for the Departments and applicable State authorities to confirm compliance with MHPAEA. The Departments stress that to the extent a plan or issuer applies factors that are processes, such as provider referral requirements, requirements to submit information for clinical review, or the development and approval of a treatment plan, such processes include both as written and in operation components. In addition, for these processes, a plan or issuer should be prepared to identify any sources utilized in determining the appropriateness of such requirements. To properly evaluate the comparability and stringency of such factors, it is important that any sources utilized be specifically identified in a comparative analysis. As stated earlier in this preamble, if a plan's or issuer's comparative analysis is requested by the Departments, the plan or issuer generally has multiple opportunities to engage with the Departments on these requirements.

c. Description of How Factors Are Used in the Design and Application of the NQTL

Under the third proposed content element, a plan or issuer would be required to provide a description of how each factor identified and defined in the second content element of the comparative analysis is used in the design or application of an NQTL to mental health and substance use disorder benefits and medical/surgical benefits in a classification. This would include a detailed explanation of how each factor identified and defined in the comparative analysis is used to determine which mental health or substance use disorder benefits and which medical/surgical benefits are subject to the NQTL. The description

would also include an explanation of the evidentiary standards or other information or sources (if any) considered or relied upon in designing or applying the factors or relied upon in designing and applying the NQTL, including in the determination of whether and how mental health or substance use disorder benefits or medical/surgical benefits are subject to the NQTL.

In instances in which the application of the factor depends on specific decisions made in the administration of benefits, the comparative analysis would be required to provide information on the nature and timing of the decisions, and the professional designations and qualifications of each decision maker. The proposed rules further provided that, to the extent that more than one factor is identified and defined with respect to an NQTL, the comparative analysis would be required to explain how such factors relate to each other; the order in which all the factors are applied, including when they are applied; whether and how any factors are given more weight than others; and the reasons for the ordering or weighting of the factors. The analysis would also be required to address any deviation(s) or variation(s) from a factor, its applicability, or its definition (including the evidentiary standards used to define the factor and the information or sources from which each evidentiary standard was derived), such as how the factor is used differently to apply the NQTL to mental health and substance use disorder benefits as compared to medical/surgical benefits, and a description of how the plan or issuer establishes such deviations or variations. The Departments noted that the terms “deviations” or “variations” in this context referred to any differences in how a factor is applied with respect to an NQTL.

The Departments received few comments on this content element. One commenter requested that the Departments clarify the requirement to document the qualifications of staff as well as for the professional designations and qualifications of each decision maker involved in the application of a given NQTL factor, requesting that the Departments describe how the requirement to document the professional designations and qualifications of each decision maker should be appropriately applied to health plan operations, and specifically Pharmacy and Therapeutics (P&T) committees.

After reviewing comments, the Departments are finalizing, with minor non-substantive changes, the

requirement that plans and issuers provide a description of how each factor identified and defined in the second content element of the comparative analysis is used in the design or application of an NQTL to mental health and substance use disorder benefits and medical/surgical benefits in a classification. This includes the requirement to include a detailed explanation of how each identified and defined factor is used to determine which benefits are subject to the NQTL, and an explanation of the evidentiary standards or other information or sources (if any) considered or relied upon in designing or applying the factors or relied upon in designing and applying the NQTL, including in the determination of whether and how benefits are subject to the NQTL. If the application of a factor depends on specific decisions made in the administration of benefits, the comparative analysis must also provide information on the nature and timing of the decisions, and the professional designations and qualifications of each decision maker. Additionally, if there is more than one factor, the comparative analysis must explain how all of the factors relate to each other; the order in which all the factors are applied, including when they are applied; whether and how any factors are given more weight than others; and the reasons for the ordering or weighting of the factors. Finally, the comparative analysis must address any deviations or variations from a factor, its applicability, or its definition (including the evidentiary standards used to define the factor and the information or sources from which each evidentiary standard was derived), such as how the factor is used differently to apply the NQTL to mental health or substance use disorder benefits as compared to medical/surgical benefits, and a description of how the plan or issuer establishes such deviations or variations. As used in this context, the terms “deviations” or “variations” in these final rules refer to any differences in how a factor is applied with respect to an NQTL.

In response to the request for how the requirement to document professional designations and qualifications applies to health plan operations, including P&T committees, the Departments emphasize that these committees must have members with similar expertise for mental health conditions and substance use disorders as for medical conditions and surgical procedures. This may not necessarily require the same number of members with expertise relevant to

mental health conditions and substance use disorders as it does for medical conditions and surgical procedures, but plans and issuers should ensure that members of a P&T committee include individuals with similar expertise with respect to these conditions and disorders.

d. Demonstration of Comparability and Stringency, as Written

Under the fourth proposed content element, plans and issuers would be required to evaluate whether, in any classification, under the terms of the plan (or health insurance coverage) as written, any processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL with respect to medical/surgical benefits. The proposed rules would require plans and issuers to include in their comparative analyses, with respect to the NQTL and the factors used in designing and applying the NQTL, documentation of each factor identified and defined in the comparative analysis that was applied to determine whether the NQTL applies to mental health or substance use disorder benefits and medical/surgical benefits in a classification. This would include, as relevant, quantitative data, calculations, or other analyses showing whether, in each classification in which the NQTL applies, mental health or substance use disorder benefits and medical/surgical benefits met or did not meet any applicable threshold identified in the relevant evidentiary standard and the evaluation of relevant data to determine that the NQTL would or would not apply. In addition, such documentation would be required to include records maintained by the plan or issuer documenting the consideration and application of all factors and evidentiary standards, as well as the results of their application. Such records could include meeting minutes, or calculations related to quantitative factors, such as costs.

Plans and issuers would also be required to include in their comparative analyses, in each classification in which the NQTL applies, a comparison of how the NQTL, as written, is applied to mental health or substance use disorder benefits and to medical/surgical benefits, including the specific provisions of any forms, checklists, procedure manuals, or other documentation used in designing and applying the NQTL or that address the

application of the NQTL. Additionally, the plan or issuer would be required to include documentation in its comparative analysis demonstrating how the factors are comparably applied, as written, to mental health or substance use disorder benefits and medical/surgical benefits in each classification, to determine which benefits are subject to the NQTL. If there is any deviation(s) or variation(s) in the application of a factor, the plan or issuer would be required to include in its comparative analysis an explanation of the reason(s) for such deviation(s) or variation(s) in the application of a factor used to apply the NQTL, or the application of the NQTL, to mental health or substance use disorder benefits as compared to medical/surgical benefits in the same classification, and how the plan or issuer establishes such deviation(s) or variation(s), including in the definition of the factors, the evidentiary standards used to define the factors, and the sources from which the evidentiary standards were derived; in the design of the factors or evidentiary standards; or in the application or design of the NQTL. In the preamble to the proposed rules, the Departments noted that the terms “deviations” or “variations” in this context refer to any differences in how a factor is applied with respect to an NQTL.

Multiple commenters expressed support for the requirement to demonstrate comparability and stringency as written through the proposed requirements for the fourth content element. However, other commenters raised concerns about the proposal, with some requesting additional clarification or guidance to assist with achieving compliance. For example, one commenter requested that the Departments clarify the difference between the proposed requirement that plans and issuers provide documentation that demonstrates how factors are comparably applied in step 4 of the comparative analysis content requirements, and the service-by-service documentation requirement for each factor under step 3 of the analysis, which requires a description of how factors are used in the design and application of the NQTL.

Another commenter expressed concerns about how this content element may create operational challenges due to its breadth and how it would require plans to also consider other factors that were considered and not applied. Other commenters suggested ways that the Departments might ease the burden of the proposed fourth content element requirements on plans and issuers. One comment

included a recommendation that the Departments clarify that plans and issuers can document each factor that was applied, including quantitative data, at the issuer level, rather than at the plan or coverage level. Another commenter encouraged the Departments to limit documentation requirements and enforcement to apply only to the comparability of the NQTL, as written and in operation; to acknowledge that subject matter experts may rely on professional knowledge, experience, and judgment to evaluate the evidentiary standard for identified factors; and to not require the use of quantitative data, calculations, or other analyses. Another commenter stated that the requirement to provide records documenting the consideration and application of all factors and evidentiary standards, as well as the results of their application, was inconsistent with the descriptions elsewhere of requiring a “general description” of the factors relied upon, and therefore urged the Departments to eliminate the requirement to include the actual evidence and related records in the comparative analysis itself.

The Departments note that, while the third content element requires a plan or issuer to provide details on how each factor (and evidentiary standards or other information or sources) is used in the design and application of an NQTL, that content element does not require an evaluation of whether the use of those factors complies with MHPAEA. Instead, these final rules require a demonstration of comparability and stringency, both as written and in operation, in the fourth and fifth content requirements for a comparative analysis, respectively. Additionally, the Departments are of the view that a plan or issuer cannot effectively demonstrate comparability and stringency, as written and in operation, without sufficiently identifying and defining each factor (in the second content element), and explaining how each factor is used to design and apply an NQTL (in the third content element).

After reviewing comments, these final rules retain all of the proposed substantive features of the fourth content element requirements, which require that plans and issuers evaluate whether, in any classification, under the terms of the plan (or health insurance coverage) as written, any processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or

other factors used in designing and applying the NQTL with respect to medical/surgical benefits. As finalized, this provision includes a technical modification to a citation that accounts for the reorganization of language in 26 CFR 54.9812–1(c)(4)(iii), 29 CFR 2590.712(c)(4)(iii), and 45 CFR 146.136(c)(4)(iii) and also now specifies that the comparative analysis must include a comparison of how the NQTL, as written, is designed and applied to mental health or substance use disorder benefits and to medical/surgical benefits, instead of only as applied.¹¹⁷ The requirements related to demonstrating comparability and stringency as written under the fourth content element are otherwise being finalized as proposed.

The Departments note that this content requirement does not require the use of quantitative data, calculations, or other analyses, nor does it prohibit plans from relying on professional knowledge, experience, and judgment to evaluate the evidentiary standard for the identified factors. Instead, this content element is meant to show how the factors described in the third content element used in designing and applying an NQTL to mental health and substance use disorder benefits are comparable to, and applied no more stringently than, the factors used in designing and applying the NQTL to medical/surgical benefits in the same classification, as written. Despite the potential operational challenges associated with the breadth of this content element, the Departments are of the view that it is a vital component of comparative analyses and is necessary to demonstrate compliance with MHPAEA as written, consistent with the statute.¹¹⁸ The Departments note that, as discussed earlier in this preamble, these final rules eliminate the duplicative requirement from the proposed rules that plans and issuers include a general description of any information considered or relied upon in preparing

the comparative analysis for each NQTL. The final rules also eliminate a duplicative reference to the evaluation of relevant data in the fourth content element for comparative analyses, which is addressed as part of the fifth content element.

The Departments recognize that a factor may be considered, but not used, to apply an NQTL to a specific benefit; however, to the extent such factor is used to design or apply the NQTL to mental health and substance use disorder benefits, it must be addressed in the plan's or issuer's comparative analysis, including in this fourth content element. The Departments are of the view that, to the extent an issuer or TPA uses factors or evidentiary standards to design and apply an NQTL consistently for multiple plans and coverage they administer, nothing in these final rules specifically prohibits the issuer or TPA from performing and documenting a comparative analysis at the level of the issuer (or TPA). However, to the extent relevant data exists at the level of the plan or coverage that measures access to mental health or substance use disorder benefits in a manner that is different than data at the level of the issuer or TPA, the Departments are of the view that a plan's or issuer's comparative analysis must account for that data, as described later in this preamble.

The Departments note that it is possible that the reasons for any deviations or variations in the application of a factor used to apply the NQTL, or the application of the NQTL, might include steps to correct, cure, or supplement information, evidence, sources, or standards that would otherwise be considered biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits. To the extent a plan or issuer has adequately documented such steps as part of its comparative analysis, as required in the second content element of these final rules requiring the identification and definition of the factors used to design or apply the NQTL, the plan or issuer is not required to address such steps again in the fourth content element if otherwise applicable, and instead may include references to the description of such steps in the second content element, as appropriate.

e. Demonstration of Comparability and Stringency, in Operation

The Departments proposed that plans and issuers be required to evaluate in a comparative analysis whether, in any classification, under the terms of the

plan (or health insurance coverage) in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the limitation with respect to medical/surgical benefits. A comprehensive explanation would be required to include an explanation of any methodology and underlying data used to demonstrate the application of the NQTL in operation, and the sample period, inputs used in any calculations, definitions of terms used, and any criteria used to select the mental health or substance use disorder benefits and medical/surgical benefits to which the NQTL is applicable.

To comply with the proposed fifth content element, plans and issuers would also be required to identify the relevant data collected and evaluated in their comparative analyses and provide an evaluation of the outcomes that resulted from the application of the NQTL to mental health or substance use disorder benefits and medical/surgical benefits to demonstrate compliance with the design and application requirements. Additionally, the comparative analysis would be required to include a detailed explanation of material differences in outcomes that are not attributable to differences in the comparability or relative stringency of the NQTL as applied to mental health or substance use disorder benefits and medical/surgical benefits, as well as the basis for concluding that material differences in outcomes are not attributable to differences in the comparability or relative stringency of the NQTL. Finally, under this content element, the comparative analysis would be required to include a discussion of any measures that have been or are being implemented by the plan or issuer to mitigate any material differences in access with respect to mental health or substance use disorder benefits as compared to medical/surgical benefits.

Many commenters expressed support for the proposed requirement and standards for the demonstration of comparability and stringency in operation captured in the proposed fifth content element, especially with respect to NQTLs related to network composition and the use and application of clinical guidelines. Commenters supported the proposed requirements for detailed comparative analyses because they reasoned that these requirements would help

¹¹⁷ As explained earlier in this preamble, these final rules amend the general rule in the design and application requirements, to align the language of the 2013 final regulations with the Departments' interpretation that a plan or issuer must consider the comparability and relative stringency of any processes, strategies, evidentiary standards, or other factors, used in both designing and applying NQTLs to mental health or substance use disorder benefits as compared to medical/surgical benefits in a classification. These final rules revise the regulatory text to make this requirement with respect to designing the NQTL explicit and for consistency with the statutory language added by the CAA, 2021.

¹¹⁸ Code section 9812(a)(8)(A)(iv), ERISA section 712(a)(8)(A)(iv), and PHS Act section 2726(a)(8)(A)(iv).

regulators understand participant and beneficiary access to mental health and substance use disorder services under real conditions as opposed to only looking to written plan terms and policies. Some commenters also included recommendations for additional data transparency requirements to ensure compliance and ease the burden on the Departments in enforcing MHPAEA's requirements. Several commenters also indicated a desire for additional clarification regarding this proposed content element. For example, one commenter noted that the fifth content element requires the demonstration of comparability and stringency in operation to be comprehensive, without discussion of what that term means.

After reviewing comments, the Departments are finalizing the proposed requirements for the fifth content element with several clarifications and modifications. The Departments are finalizing the requirement that the comparative analysis must evaluate whether, in any classification, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to mental health or substance use disorder benefits are comparable to, and are applied no more stringently than those used with respect to medical/surgical benefits. However, the Departments have removed the references to the terms of the plan (or health insurance coverage) from this requirement, in recognition of the fact that the operations of the plan (or health insurance coverage) may not necessarily be reflected in its terms.

The Departments are also finalizing the requirement that the comparative analysis must include a comprehensive explanation addressing the comparability and stringency of these processes, strategies, evidentiary standards, and other factors. These final rules require that this explanation address how the plan or issuer "evaluates whether" (instead of "ensures that"), in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to mental health or substance use disorder benefits in a classification are comparable to, and are applied no more stringently than, those used in designing and applying the NQTL with respect to medical/surgical benefits.

In these final rules, the Departments finalize with additional clarifications the proposal that, as part of the proposed fifth content element, a comprehensive explanation of how the plan or issuer evaluates in-operation

compliance with the design and application requirements of MHPAEA would include an explanation of the methodology and underlying data used to demonstrate the application of the NQTL, as well as the sample period, inputs used in any calculations, definitions of terms used, and any criteria used to select the mental health or substance use disorder benefits and medical/surgical benefits to which the NQTL is applicable. These final rules also include language to align with changes made to address a lag between when an NQTL is newly designed and applied and when relevant data are available, as well as some limited circumstances in which no data exist that can reasonably assess any relevant impact of an NQTL on access to benefits. Specifically, with respect to an NQTL for which relevant data are temporarily unavailable, the Departments clarify that the comparative analysis must include a detailed explanation of the lack of relevant data, the basis for the plan's or issuer's conclusion that there is a lack of relevant data, and when and how the data will become available and be collected and analyzed.

With respect to an NQTL for which no data exist that can reasonably assess any relevant impact of the NQTL on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits, the fifth content element requires the plan or issuer to include as part of the comparative analysis a reasoned justification as to the basis for the conclusion that there are no data that can reasonably measure the NQTL's impact, an explanation of why the nature of the NQTL prevents the plan or issuer from reasonably measuring its impact, an explanation of what data was considered and rejected, and documentation of any additional safeguards or protocols used to ensure that the NQTL complies with all applicable requirements. As noted earlier in this preamble, the Departments recognize that plans and issuers may encounter difficulties when attempting to collect and evaluate relevant data in certain circumstances, and, accordingly, intend to review the explanation provided in a plan's or issuer's comparative analysis to understand those difficulties in determining whether the plan or issuer is in compliance with these final rules. However, the Departments reiterate their intention that the provisions of these final rules regarding the unavailability of data shall only apply in very limited circumstances and,

where applicable, shall be construed narrowly.

The Departments are finalizing the proposed requirements for the fifth content element that a comparative analysis must include identification of the relevant data collected and evaluated, as well as documentation of the outcomes that resulted from the application of the NQTL to mental health or substance use disorder benefits and medical/surgical benefits, including the evaluation of relevant data as described earlier in this preamble. This also includes a reasoned justification and analysis that explains whether, and if so, why the plan or issuer concluded that differences in relevant data do or do not suggest the NQTL contributes to material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits.

The Departments recognize that, for NQTLs related to network composition, under these final rules, a plan or issuer must collect and evaluate relevant data in a manner reasonably designed to assess the aggregate impact of all such NQTLs on access to mental health and substance use disorder benefits and medical/surgical benefits. Therefore, for NQTLs related to network composition, comparative analyses should analyze their impact as a whole. Plans and issuers may also, however, indicate in these comparative analyses where one particular NQTL may affect differences in access.

Furthermore, in response to comments, these final rules provide more specifics on the requirement for the fifth content element to provide a detailed explanation of any material differences in access demonstrated by the outcomes evaluated, by requiring a reasoned explanation of any material differences in access that are not attributable to differences in the comparability or relative stringency of an NQTL as applied to mental health or substance use disorder benefits and medical/surgical benefits. This explanation should include a detailed discussion of any considerations beyond a plan's or issuer's control that contribute to the existence of material differences, as well as a detailed explanation of the bases for concluding that material differences are not attributable to differences in the comparability or relative stringency of the NQTL. The Departments note that such an explanation should be comprehensive and include evidence to support the conclusion that considerations beyond a plan's or issuer's control contribute to the

existence of material differences in access.

Additionally, these final rules add that, to the extent differences in access to mental health or substance use disorder benefits are attributable to independent professional medical or clinical standards or fraud and abuse measures, and such standards or measures are used as the basis for a factor or evidentiary standard used to design or apply an NQTL, comparative analyses must include documentation explaining how any such differences in access are attributable to those standards or measures. By requiring plans and issuers to analyze and explain material differences in access as demonstrated by outcomes, the Departments aim to encourage plans and issuers to examine closely and critically the extent to which access to benefits is shaped by particular NQTLs so that they can take effective, reasonable actions as necessary to mitigate material differences.

Finally, these final rules specify that, in demonstrating comparability and stringency in operation under the fifth content element in these final rules, plans and issuers must discuss in their comparative analyses the actions that have been or are being taken by the plan or issuer, as necessary, to address any material differences in access. Under these final rules, this discussion must include, as applicable, a reasoned explanation of any material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits that persist despite reasonable actions that have been or are being taken. Additionally, for a plan or issuer designing and applying one or more NQTLs related to network composition, to comply with this aspect of the fifth content element, the comparative analysis must include a discussion of the actions that have been or are being taken, as necessary, to address material differences in access to in-network mental health and substance use disorder benefits as compared to in-network medical/surgical benefits, including those listed in these final rules as examples of possible actions that a plan or issuer could take to comply,¹¹⁹ if any such material differences exist. The Departments recognize that plans and issuers may already be aware of material differences in access to mental health or substance use disorder benefits and, as a result, may have taken actions to comply with MHPAEA's requirements. The

Departments are of the view that comparative analyses should address any such actions taken to address material differences in access and their effectiveness, to improve access to mental health and substance use disorder care for participants and beneficiaries and demonstrate compliance with MHPAEA.

f. Findings and Conclusions

Under the sixth and final proposed content element, a plan or issuer would be required to include in its comparative analysis its findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL to mental health or substance use disorder benefits and medical/surgical benefits within each classification, and the relative stringency of their application, both as written and in operation. For this purpose, the comparative analysis would be required to include any findings or conclusions indicating that the plan or coverage is not (or might not be) in compliance with the provisions of the proposed rules for NQTLs, including any actions the plan or issuer has taken or intends to take to address any potential areas of concern or noncompliance. The comparative analysis would be required to include a reasoned and detailed discussion of those findings and conclusions, as well as citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions.

Additionally, the proposed rules would require that the comparative analysis include the date of the analysis and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis. If the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan or issuer to be an expert, the comparative analysis would be required to include an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of each NQTL applicable to both mental health or substance use disorder benefits and medical/surgical benefits. For plans subject to ERISA, the comparative analysis would be required to include a certification by one or more named fiduciaries who have reviewed the analysis, stating whether they found the comparative analysis to be in compliance with the content requirements of the proposed rules.

With respect to the requirements regarding reliance on an evaluation by an expert, one commenter was supportive of the rule as proposed, and another recommended that the Departments not require that the comparative analyses include the name of the expert so that experts would not be dissuaded from providing their expertise to avoid public identification.

Some commenters were supportive of the fiduciary certification requirement for plans subject to ERISA, with one stating that this would help to ensure that plan fiduciaries meet their obligations to review comparative analyses and monitor their plans for compliance. Many other commenters expressed concern, with some reasoning that requiring a named fiduciary to review and certify that a comparative analysis complies with the content requirements of the proposed rules would put an unrealistic expectation on that fiduciary to understand the required nuance and complexity of the proposed rules. Other commenters opined that the requirement would create an unnecessary burden. These commenters stressed that the requirement would increase compliance costs (as fiduciaries would have to contract with additional service providers to assess compliance) without increasing access to benefits. Other commenters highlighted that Congress knew how to provide for a certification or attestation requirement but refrained from doing so for the MHPAEA comparative analysis. These comments urged against including the fiduciary certification requirement.

The Departments are of the view that requiring plans and issuers to address the findings and conclusions of both comparability and stringency of processes, strategies, evidentiary standards and other factors in their comparative analysis is necessary and appropriate to increase and ensure compliance with MHPAEA. The Departments' experience enforcing the current regulatory framework has shown that, too often, plans and issuers design and apply NQTLs without considering the impact those NQTLs have on access to mental health and substance use disorder benefits as compared to medical/surgical benefits for participants and beneficiaries. In practice, the Departments have encountered many NQTLs that often impose a greater burden on access to mental health and substance use disorder benefits than medical/surgical benefits. Therefore, the Departments are finalizing, with modifications, the requirements for the sixth content element that requires plans and issuers

¹¹⁹ See 26 CFR 54.9812–1(c)(4)(iii)(C), 29 CFR 2590.712(c)(4)(iii)(C), and 45 CFR 146.136(c)(4)(iii)(C).

to address the findings and conclusions as to the comparability and relative stringency of the processes, strategies, evidentiary standards, and other factors used in designing and applying NQTLs in their comparative analyses. The requirement under these final rules that plans and issuers must include any findings and conclusions is consistent with the statutory text, and these final rules also specify that these findings and conclusions must be included whether or not the plan or coverage is or is not (or might or might not be) in compliance. The Departments stress that, while these final rules require an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied on their evaluation (if at all), these final rules do not require the name of the expert in the comparative analysis. These final rules also make additional minor technical edits to the sixth content requirement, for clarity.

In response to comments expressing concern with the named fiduciary certification requirement for plans subject to ERISA in the proposed rules, DOL is modifying this requirement. These final rules continue to require, for plans subject to ERISA, the comparative analysis to include a certification by one or more named fiduciaries. However, instead of requiring noted fiduciaries to state whether they found the comparative analysis to be in compliance with the content requirements, these final rules require certification confirming the fiduciary's engagement in a prudent process to select one or more qualified service providers to perform and document a comparative analysis in connection with the imposition of any NQTLs that apply to mental health and substance use disorder benefits under the plan in accordance with MHPAEA and its implementing regulations, as well as satisfaction of the duty to monitor those service providers. For this purpose, DOL expects that a plan fiduciary making such a certification will, at a minimum, review the comparative analysis prepared by or on behalf of the plan with respect to an NQTL applicable to mental health and substance use disorder benefits and medical/surgical benefits; ask questions about the analysis and discuss it with service providers, as necessary, to understand the findings and conclusions documented in the analysis; and ensure that a service provider responsible (in whole or in part) for performing and documenting a comparative analysis provides assurance that, to the best of its ability, the NQTL and associated

comparative analysis complies with the requirements of MHPAEA and its implementing regulations. While not required, a plan fiduciary may alternatively provide a certification that each comparative analysis is in compliance with the content requirements, consistent with the proposed certification requirement in the proposed rules.¹²⁰ Because the statute expressly places the obligation on the plan (or issuer) to ensure compliance with MHPAEA, these final rules align with the duties ERISA imposes on plan fiduciaries under part 4 of ERISA.

2. Requirement To Provide Comparative Analyses and Notices to the Department and Other Individuals and Entities—26 CFR 54.9812–2(d) and (e), 29 CFR 2590.712–1(d) and (e), and 45 CFR 146.137(d) and (e)

Effective February 10, 2021, plans and issuers have been required, consistent with the statute, to perform and document comparative analyses and make them available to the Departments or applicable State authorities upon request.¹²¹ The proposed rules would require that plans and issuers make a comparative analysis available and submit it upon request to the relevant Secretary (as well as applicable State authorities and participants and beneficiaries in certain circumstances), explain that additional information may be required to be provided after a comparative analysis is deemed insufficient, and outline requirements for plans and issuers after an initial determination of noncompliance and a final determination of noncompliance. Some commenters were supportive of the proposed requirements, though others offered suggestions for improving the various elements, as described later in this preamble.

Once a comparative analysis is requested, plans and issuers would be required to provide a comparative analysis within 10 business days of receipt of a request from the relevant Secretary (or an additional period of time specified by the relevant Secretary). Some commenters remarked

that 10 business days is not sufficient to provide a comparative analysis upon request. While a few commenters requested that the Departments allow plans and issuers at least 30 days to provide the requested information, others requested a 60-day period to provide an updated comparative analysis. Several commenters highlighted that plans and issuers might not anticipate what is regarded as an NQTL by the Departments and requested that the Departments provide additional time to respond to a request for a comparative analysis for an NQTL that was not on an illustrative list of NQTLs provided by the Departments.

After reviewing comments, the Departments are finalizing, as proposed, the requirement that plans and issuers make available a comparative analysis and submit it to the relevant Secretary within 10 business days of receipt of a request from the relevant Secretary (or an additional period of time specified by the relevant Secretary). Plans and issuers are statutorily obligated to perform and document their NQTL comparative analyses, and to be ready to make them available in response to a request, regardless of whether the plan or issuer has actually received a request from the Departments or an applicable State authority, and have been since February 10, 2021. While these final rules specify content elements that comparative analyses must contain, the Departments have expected, and will continue to expect, that plans and issuers perform and document their NQTL comparative analyses without waiting for a request from the Departments or an applicable State authority. Where plans and issuers have performed and documented their NQTL comparative analyses, additional time will not generally be required to respond to an initial request. The language allowing an additional period of time specified by the Secretary for a plan or issuer to submit a comparative analysis to the Secretary provides sufficient flexibility to plans and issuers where the Departments determine it to be appropriate.

Under the proposed rules, in instances in which the Secretary determines that the plan or issuer has not submitted sufficient information for the Secretary to review the requested comparative analysis, the Secretary will specify to the plan or issuer the additional information the plan or issuer must submit to the Secretary to be responsive to the request. The plan or issuer would be required to furnish this additional information to the relevant Secretary within 10 business days after the relevant Secretary specifies the

¹²⁰ See 88 FR 51552, 51651 (Aug. 3, 2023), setting forth the proposed requirement that one or more named fiduciaries who have reviewed a comparative analysis provide a certification stating whether they found the comparative analysis to be in compliance with the content requirements of the regulations.

¹²¹ Code section 9812(a)(8), ERISA section 712(a)(8), and PHS Act section 2726(a)(8). This requirement was reiterated in FAQs Part 45, <https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-45.pdf> and <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/MHPAEA-FAQs-Part-45.pdf>.

additional information to be submitted (or an additional period of time specified by the relevant Secretary). The Departments noted in the preamble to the proposed rules that a request for additional information by the relevant Department or an applicable State authority may include a request for data to analyze the assertions made in the comparative analyses, consistent with existing authority. This additional information or data may relate to the data required by the Departments to be collected and evaluated under the relevant data evaluation requirements. A few commenters stated that 10 business days was not enough time to respond with supplemental information, calling the timeframe overly restrictive and unrealistically short. One requested 60 days to respond to such a request instead of 10 business days as proposed.

After reviewing comments, the Departments are finalizing with minor technical edits the requirement that plans and issuers furnish the additional requested information to the relevant Secretary within 10 business days after the relevant Secretary specifies the additional information to be submitted (or an additional period of time specified by the relevant Secretary). The Departments acknowledge that in some, but not all, cases, 10 business days may not be enough time to respond with supplemental information and recognize that not all requests for supplemental information are equal in terms of the volume and complexity of the information requested, which is why these final rules allow for additional time to be specified by the relevant Secretary (for example, where the volume or complexity of the additional information requested would take more time to collect and provide). The Departments emphasize that additional information must be provided within 10 business days, rather than calendar days, and are of the view that, in the majority of cases, 10 business days should be sufficient. However, unless otherwise specified, the other timelines associated with the comparative analysis requirements generally refer to calendar days.

In instances where the relevant Secretary has reviewed a plan's or issuer's comparative analyses (and any additional information submitted upon request), and made an initial determination that the plan or issuer is not in compliance with the requirements related to NQTLs, the Departments proposed to require the plan or issuer to respond to the relevant Secretary, specifying the actions it will take to come into compliance. The plan or issuer would also be required to

provide to the relevant Secretary additional comparative analyses meeting the requirements of the proposed rules that demonstrate compliance with MHPAEA. The plan or issuer would be required to submit these responses to the relevant Secretary not later than 45 calendar days after the relevant Secretary's initial determination that the plan or issuer is not in compliance.

One commenter stated that the proposed penalties for noncompliance are not strict enough to discourage noncompliant issuer behavior and stated that, without strict enforcement penalties, issuers will continue to attempt to skirt the law. Additionally, as discussed earlier in the preamble, other commenters urged the Departments to provide procedural guardrails and due process protections for plans and issuers prior to the final determination of noncompliance, suggesting that the plan or issuer should have an opportunity to meet with the DOL or HHS national office, review the determination, and work together to achieve compliance.

After reviewing comments, the Departments are finalizing this requirement with minor edits. These final rules clarify, however, that the plan or issuer must respond to the initial determination by the Secretary, instead of more generally requiring the plan or issuer to respond to the Secretary, as proposed, to better match the statutory text. In response to the commenter who criticized the penalties for noncompliance, the Departments note that they do not have the statutory authority to increase penalties for violations of MHPAEA, but, as discussed earlier in this preamble, have stepped up enforcement efforts and anticipate continuing to prioritize enforcement of these requirements.

As discussed earlier in the preamble, the statute establishes the comparative analysis request process, as well as the penalties for failing to comply, and, working within this process, the Departments have worked with many plans and issuers to achieve compliance, often without issuing a final determination of noncompliance, as described at length in our MHPAEA Reports to Congress.¹²² The Departments expect that this approach will continue to work after the issuance of these final rules. To the extent

possible, the Departments expect to continue to work with plans and issuers to ensure compliance, without need of issuance of a final determination of noncompliance.

If the relevant Department makes a final determination that the plan or issuer is not in compliance with MHPAEA (after issuance of an initial determination of noncompliance, a failure by the plan or issuer to sufficiently respond to the initial determination and specify the actions the plan or issuer will take to bring the plan or coverage into compliance, and a failure to provide additional sufficient comparative analyses within the 45-calendar-day corrective action period), the plan or issuer must, within 7 calendar days of the receipt of the final determination of noncompliance, provide a standalone notice that is not combined with any other notices or disclosures, as required under applicable Federal or State law, to all participants and beneficiaries enrolled in the plan or coverage that the plan or issuer has been determined to not be in compliance with the requirements of the proposed rules. The plan or issuer would also be required to provide a copy of the notice to the relevant Secretary, any service provider involved in the claims process, and any fiduciary responsible for deciding benefit claims within the same timeframe. The Departments noted in the preamble to the proposed rules that this notice gives participants and beneficiaries (or their authorized representatives) critically important information for the pursuit and protection of their own benefit claims and rights and provides a powerful incentive for the plan or issuer to take necessary corrective actions to come into compliance following an initial determination of noncompliance. The proposed rules set forth requirements for the content of this notice and the manner in which it would be required to be provided, including that the notice be written in plain language and in a manner calculated to be understood by the average plan participant. The notice would also be required to include the following statement prominently displayed on the first page, in no less than 14-point font:

Attention! The [Department of Labor/ Department of Health and Human Services/ Department of the Treasury] has determined that [insert the name of group health plan or health insurance issuer] is not in compliance with the Mental Health Parity and Addiction Equity Act.

The proposed rules would also require the notice contain a summary of

¹²² See, e.g., 2023 MHPAEA Comparative Analysis Report to Congress (July 2023), <https://www.dol.gov/sites/dolgov/files/ebsa/laws-and-regulations/laws/mental-health-parity/report-to-congress-2023-mhpaea-comparative-analysis.pdf>. Other reports are available at <https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/reports>.

any changes the plan or issuer has made as part of its corrective action plan specified to the Secretary following the initial determination of noncompliance, including an explanation of any opportunity for a participant or beneficiary to have a claim for benefits reprocessed. Additionally, the notice would be required to include a summary of the Secretary's final determination that the plan or issuer is not in compliance, including any provisions or practices identified to be in violation of MHPAEA, any additional corrective actions identified by the Secretary in the final determination notice, and information on how participants and beneficiaries can obtain a copy of the final determination of noncompliance from the plan or issuer. This notice would also be required to include any other actions the plan or issuer is taking to come into compliance with MHPAEA, information on when the plan or issuer will take (or has taken) such actions, and a clear and accurate statement explaining whether the Secretary has concurred with those actions. Finally, the proposed rules would require that the notice include contact information for questions and complaints, with a statement explaining how participants and beneficiaries can obtain more information about the notice, including a phone number and an email or web portal address for the plan or issuer, and contact information for the relevant Department.

Under the proposed rules, a plan or issuer would be required to make the notice available in paper form. The plan or issuer may alternatively make the notice available electronically (such as by email or an internet posting) if the format is readily accessible, the notice is provided in paper form free of charge upon request, and, in a case in which the electronic form is an internet posting, the plan or issuer timely notifies participants and beneficiaries in paper form (such as a postcard) or email that the documents are available on the internet, provides the internet address, and notifies participants and beneficiaries that the documents are available in paper form upon request. The Departments noted that this approach is similar to standards for when a plan or issuer is permitted to provide a copy of its plan's or coverage's summary of benefits and coverage with respect to participants and beneficiaries who are eligible but not enrolled for coverage.¹²³ For ERISA plans, the plan or issuer would also be required to

ensure that the notice is provided to any service provider involved in the claims process and any fiduciary responsible for deciding benefit claims within 7 calendar days of receipt of the final determination of noncompliance, so that the service provider or fiduciary can appropriately take the violation into account in deciding claims in compliance with the requirements of 29 CFR 2590.712(c)(4) and in accordance with section 404(a)(1)(D) of ERISA.

Multiple commenters recommended that the requirement for plans and issuers to include information in the notice about any opportunity for a participant or beneficiary to have claims reprocessed be revised to instead place affirmative obligations on plans and issuers who receive a final determination of noncompliance to identify affected participants or beneficiaries, reprocess claims, and take other necessary steps to rectify harms. One commenter further suggested that plans or issuers be required to describe the process they will follow and the time frames for reprocessing claims in the notice of noncompliance. Another commenter opposed the requirement that a plan deemed noncompliant send a notice to all beneficiaries, arguing that it amounted to public shaming and that it was beyond the scope of the authorizing statute.

Several commenters suggested that the notice should be provided to participating providers, as such providers may have experienced issues submitting claims to plans and issuers for reimbursement, including improper denials, and stopped submitting further claims. One commenter requested that these final rules be accompanied by guidance and online compliance resources developed by the Departments to help the affected plans and issuers draft their notices of noncompliance.

Several commenters expressed concern that providing notice within 7 calendar days would not be feasible, particularly with the level of information that a plan or issuer is required to compile and provide. Some commenters requested a 30-day period to provide this notice and others requested a 45-day period.

After reviewing comments, the Departments are finalizing with minor clarifications the provision that a plan or issuer must notify all participants and beneficiaries enrolled in the plan or coverage that the plan or issuer has been determined to not be in compliance with the requirements of MHPAEA if the Secretary makes a final determination of noncompliance, as required by the statute. The Departments highlight that the statute

specifies the notice be provided within 7 days, and the Departments lack the statutory authority to extend this timeframe, such as to 30 or 45 days, as suggested by commenters. However, in response to comments, these final rules provide that plans and issuers have 7 business days instead of 7 calendar days to notify participants and beneficiaries of a final determination of noncompliance, to provide plans and issuers additional time to prepare the notice of final determination as required under these final rules.

The Departments also note that the relevant statutory language requires notice to be sent to "all individuals enrolled in the plan or applicable health insurance coverage offered by the issuer," which includes participants and beneficiaries, rather than attending providers. However, if a single notice is provided to a participant and any beneficiaries at the participant's last known address, the requirement to provide notice to participants and beneficiaries is considered satisfied, unless the plan or issuer knows (or reasonably should have known) that the beneficiary's last known address is different, in which case a notice is required to be provided to the beneficiary at the beneficiary's last known address.

The Departments are also finalizing the requirement for ERISA-covered plans that the plan or issuer must provide a copy of the notice to any service provider involved in the claims process, and any fiduciary responsible for deciding benefit claims within 7 business days of receipt of the final determination of noncompliance. DOL recognizes that, depending on the nature of the NQTL and the final determination of noncompliance, not all such determinations will impact adjudicated claims, but is of the view that it is important for such information to be disclosed to relevant service providers and fiduciaries, so they can properly consider whether such changes are required.

The Departments are finalizing the proposed notice content requirements and stress that the notice must describe any other actions the plan or issuer is taking to come into compliance with MHPAEA. Generally, when noncompliance has been identified, the Departments will require plans and issuers to take steps to identify affected participants, reprocess claims, and take other necessary steps to rectify harms; however, the specific steps a plan or issuer will be required to take in response to a final determination of noncompliance will depend on the facts and circumstances of the violations.

¹²³ See 26 CFR 54.9815–2715(a)(4)(ii)(B), 29 CFR 2590.715–2715(a)(4)(ii)(B), and 45 CFR 147.200(a)(4)(ii)(B).

While these final rules generally require a plan or issuer to include an explanation of any opportunity for a participant or beneficiary to have a claim for benefits reprocessed (or, as explained below, submitted) in a notice describing a final determination of noncompliance, the Departments do not intend that provision to imply that plans and issuers will not be obligated to take any other particular actions intended to provide appropriate corrections to affected individuals or otherwise remediate potential harms.

As noted throughout this preamble to these final rules, the Departments are committed to ensuring that participants and beneficiaries have access to the mental health and substance use disorder benefits covered under their plan or coverage and are not adversely affected by violations of MHPAEA. The Departments are, however, modifying the requirement that plans and issuers must include a clear and accurate statement as to whether the Secretary has indicated that those actions, if completed, will result in compliance, to reflect that the Secretary may not be able to know whether the actions taken or being taken will bring the plan into compliance. Instead, under these final rules, plans and issuers must indicate whether the relevant Secretary has concurred with those actions. The Departments are also modifying the requirement that the notice include a description of any opportunity for a participant or beneficiary to have a claim for benefits reprocessed to include any opportunity to submit a new claim, to account for participants and beneficiaries who did not initially file a claim for a mental health or substance use disorder benefit that could have been covered.

In the proposed rules, the Departments solicited comment on other measures to increase transparency and better inform the general public regarding final agency determinations of noncompliance of plans or issuers with MHPAEA. One commenter suggested that to improve transparency, all informational materials published to the public following final agency determinations of noncompliance should clearly state the name of the insurer who holds contracts with the TPA or MBHO if a TPA or MBHO is found to be in violation of MHPAEA. The commenter also recommended that the Departments require all States to make notices of MHPAEA violations publicly available via State agency websites and other avenues easily accessible by beneficiaries within a reasonable timeframe after determinations of noncompliance with

MHPAEA are made. The Departments acknowledge these comments and will continue to consider them.

In addition to making the comparative analyses available upon request to the relevant Secretary, the Departments proposed to codify a requirement that plans and issuers make available the comparative analyses when requested by any applicable State authority, as well as participants and beneficiaries (including a provider or other person acting as a participant's or beneficiary's authorized representative) who has received an adverse benefit determination related to mental health or substance use disorder benefits and, for ERISA-covered plans, participants and beneficiaries at any time, under authority under ERISA section 104. The Departments noted that, while the proposed rules would codify the statutory requirement to make comparative analyses available to the applicable State authority upon request, the proposed rules would not otherwise apply the timeframes and processes regarding the Secretarial request process to requests for comparative analyses made by applicable State authorities. The Departments requested comments on these proposals, including whether the proposed requirements should apply to plans and issuers with respect to a request made by the applicable State authority for an NQTL comparative analysis, including the proposed notice requirement following a final determination of noncompliance.

Some commenters recommended that the Departments emphasize that health insurance issuers have an unambiguous duty to share their MHPAEA comparative analyses with applicable State authorities upon request even if the relevant Secretary has not also made the same request. Commenters also recommended that the Departments work closely with State insurance authorities to incentivize and facilitate the implementation of comparable review and notice standards. Several other commenters requested the Departments include applicable State authorities in proposed 26 CFR 54.9812-2(b), 29 CFR 2590.712-1(b), and 45 CFR 146.137(b), to make clear that States have the authority to request comparative analyses. Some commenters noted that some issuers refuse to provide comparative analyses to the applicable State authority upon request. Commenters requested guidance concerning requests from participants, beneficiaries, and authorized representatives who have received an adverse benefit determination related to mental health and substance use disorder benefits,

including one commenter requesting guidance on how participants, beneficiaries, and their authorized representatives may report potential violations of MHPAEA, and another commenter that requested clear guidelines regarding when the issuance of an adverse benefit determination triggers a requirement by the plan to disclose its comparative analyses, upon request.

After reviewing comments, the Departments are finalizing as proposed the requirement that plans and issuers must make available a copy of the comparative analysis when requested by any applicable State authority, a participant or beneficiary (or a provider or other person acting as a participant's or beneficiary's authorized representative) who has received an adverse benefit determination related to mental health or substance use disorder benefits, and, for ERISA-covered plans, participants and beneficiaries generally, who may request the comparative analysis at any time under ERISA section 104. The Departments are of the view that it is important that participants and beneficiaries are able to access comparative analyses of NQTLs imposed on mental health and substance use disorder benefits under their plan or coverage. In implementing MHPAEA, the Departments have heard repeated complaints that plans and issuers fail to disclose information on the processes, strategies, evidentiary standards, and other factors used to design and apply an NQTL, including the relevant comparative analyses to participants and beneficiaries, despite clear statements by the Departments regarding this requirement.¹²⁴ The Departments are concerned that limiting the ability of participants and beneficiaries (or their authorized representatives) to request the

¹²⁴ See, e.g., 26 CFR 54.9812-1(d)(3), 29 CFR 2590.712(d)(3), and 45 CFR 146.136(d)(3); FAQs About Affordable Care Act Implementation Part V and Mental Health Parity Implementation (Dec. 22, 2010), <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-v.pdf> and <https://www.hhs.gov/guidance/document/affordable-care-act-implementation-faqs-set-5>; FAQs About Affordable Care Act Implementation Part 31, Mental Health Parity Implementation and Women's Health and Cancer Rights Action Implementation (Apr. 20, 2016), <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-31.pdf> and <https://www.hhs.gov/guidance/document/affordable-care-act-implementation-faqs-set-31>; FAQs About Mental Health Parity Implementation and the Consolidated Appropriations Act, 2021 Part 45 (Apr. 2, 2021), <https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-45.pdf> and <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/MHPAEA-FAQs-Part-45.pdf>.

comparative analyses to only those situations where there is an adverse benefit determination related to mental health or substance use disorder benefits, would frustrate participants' and beneficiaries' ability to get the information they need about their mental health and substance use disorder benefits to effectuate their rights, including in situations where they forgo submitting a claim for benefits. The Departments remain committed to responding to inquiries and complaints about compliance with MHPAEA, and participants, beneficiaries, and enrollees, as well as their authorized representatives, may contact EBSA at 1-866-444-3272 or <https://www.dol.gov/agencies/ebsa/about-ebsa/ask-a-question/ask-ebsa> or HHS at 1-800-985-3059 or <https://www.cms.gov/medical-bill-rights/help/submit-a-complaint>.

As specified earlier in the preamble, the statute requires that plans and issuers must provide a copy of the comparative analysis to any applicable State authority upon request. The statute does not require applicable State authorities to follow the same procedure to review and request comparative analyses as that applicable to the Departments, and, therefore, these final rules do not include "applicable State authorities" in the regulatory text that describes this procedure. However, these final rules at 26 CFR 54.9812-2(e), 29 CFR 2590.712-1(e), and 45 CFR 146.137(e) provide that a health insurance issuer in a State must provide the comparative analysis to the applicable State authority (that is, the State insurance commissioner or official or officials designated by the State to enforce the requirements of title XXVII of the PHS Act for the State involved with respect to such issuer) upon request. Additionally, compliance with MHPAEA is not determinative of compliance with other State or Federal laws. Applicable State authorities retain independent authority over issuers of group and individual health insurance coverage and may request or require additional information under their own authorities. Issuers of group and individual health insurance coverage must also comply with State insurance laws, to the extent they do not prevent the application of the requirements of MHPAEA.

C. Applicability—26 CFR 54.9812-1(i), 29 CFR 2590.712(i), and 45 CFR 146.136(i) and 26 CFR 54.9812-2(g), 29 CFR 2590.712-1(g), and 45 CFR 146.137(g)

The Departments proposed to amend 26 CFR 54.9812-1(i)(1), 29 CFR

2590.712(i)(1), and 45 CFR 146.136(i)(1) to specify that, except as provided in paragraph (i)(2), the proposed rules applicable to group health plans (and health insurance coverage offered by an issuer in connection with such plans)¹²⁵ would apply on the first day of the first plan year beginning on or after January 1, 2025. The Departments acknowledged in the preamble of the proposed rules that the proposed requirements would take time for plans and issuers to implement. Therefore, the Departments sought to strike an appropriate balance for the date by which plans and issuers must comply with final rules. The Departments noted that until the proposed applicability date, plans and issuers would be required to continue to comply with the most recent MHPAEA regulations codified in the CFR,¹²⁶ as applicable. The Departments similarly proposed that the requirements in 26 CFR 54.9812-2, 29 CFR 2590.712-1, and 45 CFR 146.137 of the proposed rules, governing the requirements for comparative analyses under MHPAEA, would apply for plan years beginning on or after January 1, 2025. However, the Departments reminded plans and issuers that the statutory provisions added to MHPAEA by the CAA, 2021 are self-implementing and took effect on February 10, 2021. As such, the proposed delayed applicability date for the comparative analysis requirements in the proposed rules would not alter a plan's or issuer's obligations under the statute. The Departments solicited comments on the proposed applicability dates.

Several commenters stated that the proposals put forward sweeping changes to the existing rules. To allow time for implementation, commenters requested that the applicability date of the final rules for plans and issuers be for plan years beginning on or after January 1, 2026, or 2 years following publication of the final rules. Several commenters requested an

¹²⁵ Coverage offered by Medicaid managed care organizations, CHIP, and Medicaid Alternative Benefit Programs are subject to separate mental health parity regulations at codified at 42 CFR parts 438, 440, 456, and 457. See Medicaid and Children's Health Insurance Programs; Mental Health Parity and Addiction Equity Act of 2008; Application of Mental Health Parity Requirements to Coverage Offered by Medicaid Managed Care Organizations, the Children's Health Insurance Program (CHIP), and Alternative Benefit Plans; Final Rule. 81 FR 18390 (Mar. 30, 2016), <https://www.federalregister.gov/documents/2016/03/30/2016-06876/mcicaid-and-childrens-health-insurance-programs-mental-health-parity-and-addiction-equity-act-of>.

¹²⁶ 26 CFR 54.9812-1, revised as of April 1, 2023, 29 CFR 2590.712, revised as of July 1, 2022, and 45 CFR 146.136, revised as of October 1, 2021.

implementation period ranging from 1 to 2 years. Some of these commenters additionally requested a 1-year good faith enforcement safe harbor to allow plans and issuers additional time to comply with the new requirements. Another commenter requested that the proposed rules be effective in 2024, in order to not delay access to vital mental health and substance use disorder benefits.

In order to effectuate these final rules in a timely manner and to ensure that participants and beneficiaries seeking benefits to treat mental health conditions or substance use disorders do not face a greater burden on access to mental health and substance use disorder benefits than medical/surgical benefits, while acknowledging the challenges to plans and issuers of implementing some of the requirements in these final rules, the Departments are finalizing the applicability provision, with some modifications. Accordingly, these final rules apply to group health plans (and health insurance coverage offered by an issuer in connection with a group health plan) on the first day of the first plan year beginning on or after January 1, 2025, except for the meaningful benefits standard, the prohibition on discriminatory factors and evidentiary standards, the relevant data evaluation requirements, and the related requirements in the provisions for comparative analyses, which apply on the first day of the first plan year beginning on or after January 1, 2026. Until these rules are applicable, plans and issuers must continue to comply with the regulations implementing MHPAEA as in effect prior to the effective date of these final rules, and must comply with the statutory provisions of MHPAEA, as amended by the CAA, 2021, both before and after these final rules become applicable. The Departments remind plans and issuers that guidance provided in FAQs Part 45 addresses what information plans and issuers should make available under MHPAEA, as amended by the CAA, 2021, in response to the Departments' request for comparative analyses and can be relied on pending the applicability dates of these final rules.

In response to the comments raising concerns about the magnitude of the changes of the proposed requirements in the proposed rules, particularly in relation to the amount of data collection and analysis that would be required and the time needed by plans and issuers to implement these changes, the Departments are delaying the applicability date with respect to certain provisions in these final rules, as

discussed in this section of the preamble.

As part of the request to the Departments to extend the applicability date of these final rules, several commenters raised concerns regarding the amount of new documentation and the time necessary to implement the relevant data evaluation requirements, which, as noted earlier in this preamble, require plans and issuers to collect and evaluate data in a manner that is not currently required. The Departments acknowledge that the relevant data evaluation requirements and the related requirements in the provisions requiring the comparative analyses to demonstrate comparability and stringency, in operation, impose specific new obligations that plans and issuers must comply with in order to demonstrate that an NQTL with respect to mental health or substance use disorder benefits in any classification is no more restrictive in operation than the predominant NQTL that applies to substantially all medical/surgical benefits in the same classification. These final rules identify examples of relevant data that a plan or issuer may be required to collect, but ultimately the plan or issuer will need to determine which data must be collected and analyzed to comply with these final rules, whether any differences reflected in the data are material, and what reasonable actions to take, as necessary, when there are material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits in the same classification. Similarly, the Departments recognize that the meaningful benefits standard under these final rules could impose new obligations for plans and issuers, which may require changes to benefit design that may be difficult to implement within a short period of time after the issuance of these final rules. Additionally, the Departments acknowledge that the prohibition on discriminatory factors may require plans and issuers to evaluate their NQTLs to determine whether such limitations are based on prohibited factors or evidentiary standards and whether changes need to be made to such factors or evidentiary standards in order to comply with these final rules.

The Departments agree with commenters that this process will take time and that plans and issuers will face difficulty complying with these requirements by the start of a plan year beginning on or after January 1, 2025. Therefore, the Departments are delaying the applicability date for the meaningful benefits standard under 26 CFR

54.9812–1(c)(2)(ii)(A), 29 CFR 2590.712(c)(2)(ii)(A), and 45 CFR 146.136(c)(2)(ii)(A); the prohibition on discriminatory factors and evidentiary standards under 26 CFR 54.9812–1(c)(4)(i)(B), 29 CFR 2590.712(c)(4)(i)(B), and 45 CFR 146.136(c)(4)(i)(B); the relevant data evaluation requirements under 26 CFR 54.9812–1(c)(4)(iii), 29 CFR 2590.712(c)(4)(iii), and 45 CFR 146.136(c)(4)(iii); and the related requirements in the provisions for comparative analyses;¹²⁷ to apply on the first day of the first plan year beginning on or after January 1, 2026. The Departments emphasize that plans and issuers must continue to comply with the 2013 final regulations until the respective applicability dates in these final rules. For example, even though the prohibition on discriminatory factors does not apply to plans and issuers until plan years beginning on or after January 1, 2026, plans and issuers should still be prepared to demonstrate that the factors used to design or apply an NQTL to mental health and substance use disorder benefits are comparable to and applied no more stringently than the factors used to design and apply an NQTL to medical/surgical benefits in the same classification in accordance with the 2013 final regulations. The Departments expect that plans and issuers will utilize the delayed applicability period to work in good faith to update systems and processes to comply with the new requirements of these final rules. Accordingly, the Departments encourage plans and issuers to start working to ensure that they are in a position to comply with all aspects of these final rules in a timely manner, including by working to comply with the meaningful benefits standard, the prohibition on discriminatory factors and evidentiary standards, and the relevant data evaluation requirements, as well as the associated comparative analysis requirements, no later than for plan years beginning on or after January 1, 2026.

D. Severability—26 CFR 54.9812–1(j), 29 CFR 2590.712(j), and 45 CFR 146.136(j) and 26 CFR 54.9812–2(h), 29 CFR 2590.712–1(h), and 45 CFR 146.137(h)

The Departments proposed severability clauses in the proposed rules to capture the Departments' intent that, to the extent a reviewing court holds that any provision of the final rules is unlawful by its terms or as

¹²⁷ 26 CFR 54.9812–2(c)(2)(ii)(C), (c)(5)(i)(C) and (D), and (c)(5)(ii) through (v); 29 CFR 2590.712–1(c)(2)(ii)(C), (c)(5)(i)(C) and (D), and (c)(5)(ii) through (v); and 45 CFR 137(c)(2)(ii)(C), (c)(5)(i)(C) and (D), and (c)(5)(ii) through (v).

applied to any person or circumstance, or stayed pending further agency action, the provision would be construed so as to continue to be given the maximum effect permitted by law. The Departments expressed their view that if the proposed rules were finalized as proposed or as a substantially similar version, such rules would provide comprehensive protections that implement MHPAEA's requirements. The Departments noted that the aim of the proposed rules is to ensure that individuals with mental health conditions and substance use disorders benefit from the full protections afforded to them under MHPAEA, and that separate elements of the proposed rules would individually contribute to furthering that aim. Therefore, the Departments proposed that if a court were to hold that any provisions were invalid or unenforceable, any affected provisions would be severable from the rest of the proposed rules, if finalized, and would not affect any other provisions or their application to persons not similarly situated or to dissimilar circumstances.

The Departments did not receive any comments relating to the proposed severability provisions and are finalizing these provisions without change. The Departments note that, while the requirements under 26 CFR 54.9812–1(c)(4)(i) and (iii), 29 CFR 2590.712(c)(4)(i) and (iii), and 45 CFR 146.136(c)(4)(i) and (iii) are part of a comprehensive regulatory scheme, the provisions are separate aspects of the parity analysis and can continue to apply independently if other provisions of these final rules are invalidated. While the Departments have made some changes from the proposed rules in these final rules, as discussed earlier in this preamble, the Departments are not of the view that these changes affect the severability of the provisions of these final rules.

E. Request for Information

In the preamble to the proposed rules, the Departments requested information on ways to improve the coverage of mental health and substance use disorder benefits through other consumer protection laws, including the ACA. The Departments requested comments on ways to incentivize TPAs to facilitate compliance with MHPAEA on behalf of the plans that they design and administer and methods to enhance access to mental health and substance use disorder benefits through the Departments' implementation of PHS Act section 2706(a), the provider nondiscrimination requirements. The Departments also requested comments

on ways that they could improve the coverage of and enhance access to mental health and substance use disorder benefits through their implementation of the provider directory requirements under Code section 9820(a) and (b), ERISA section 720(a) and (b), and PHS Act section 2799A–5(a) and (b), the requirements for telehealth, and the ways in which the Departments could leverage ERISA's and the ACA's existing claims procedure requirements to help facilitate access to mental health and substance use disorder benefits. Finally, the Departments requested information on whether HHS and the Treasury should consider potential amendments to the minimum value rule and on how behavioral health crisis services fit within the existing MHPAEA classifications or the EHB categories.

The Departments appreciate the many comments received in response to the request for information and will use the comments to inform potential future rulemaking and guidance.

III. Overview of the Final Rules— Department of HHS

A. Sunset of MHPAEA Opt-Out for Self-Funded Non-Federal Governmental Plans

Prior to the enactment of the CAA, 2023 on December 29, 2022, sponsors of self-funded non-Federal governmental plans were permitted to elect to exempt those plans from (opt out of) compliance with the MHPAEA requirements, among other specified requirement categories, in title XXVII of the PHS Act.¹²⁸

The CAA, 2023 included a provision that sunsets the election option with respect to MHPAEA.¹²⁹ Specifically, that provision amended PHS Act section 2722(a)(2) to specify that no MHPAEA opt-out election may be made on or after the date of the enactment of the CAA, 2023, and that, subject to certain exceptions, no MHPAEA opt-out election expiring on or after the date that is 180 days after the date of such enactment may be renewed.¹³⁰

The CAA, 2023 included an exception for certain collectively bargained plans with an opt-out election in effect for MHPAEA that allows for a longer transition to come into compliance with MHPAEA. Specifically, the CAA, 2023 added language to PHS Act section 2722(a)(2) indicating that a self-funded non-Federal governmental plan that is subject to multiple collective bargaining

agreements of varying lengths that has a MHPAEA opt-out election in effect as of the date of enactment of the CAA, 2023, that expires on or after the date that is 180 days after the enactment of the CAA, 2023, may extend such election until the date on which the term of the last such agreement expires.¹³¹

As a result of the CAA, 2023 amendments to PHS Act section 2722(a)(2), self-funded non-Federal governmental plan sponsors may elect to opt out of only the following three PHS Act requirement categories: standards relating to benefits for newborns and mothers (PHS Act section 2725), required coverage for reconstructive surgery following mastectomies (PHS Act section 2727), and coverage for dependent students on a medically necessary leave of absence (PHS Act section 2728).

In the proposed rules, HHS proposed to amend 45 CFR 146.180 to align with the CAA, 2023 amendments to PHS Act section 2722(a)(2). Specifically, HHS proposed to redesignate paragraphs (a)(3) through (7) as paragraphs (a)(4) through (8) and add a new paragraph (a)(3) specifying that a sponsor of a self-funded non-Federal governmental plan may not elect to exempt its plans from any of the MHPAEA requirements on or after December 29, 2022 (the date of enactment of the CAA, 2023), through the process specified in 45 CFR 146.180. HHS also proposed to add new paragraph (f)(4)(iii) specifying that in the case of a self-funded non-Federal governmental plan that is subject to multiple collective bargaining agreements of varying lengths and that has an election with respect to any of the MHPAEA requirements in effect as of December 29, 2022, through the process specified in 45 CFR 146.180, that expires on or after June 27, 2023 (the date that is 180 days after the date of enactment of the CAA, 2023), the plan may extend such election until the date on which the term of the last such agreement expires. HHS also proposed to make conforming edits to paragraph (a)(2), paragraphs (a)(5)(i) and (ii) and (a)(6)(ii), as proposed to be redesignated, and paragraph (f)(1). HHS proposed that the amendments to 45 CFR 146.180 would apply on the effective date of the final rule.¹³² HHS sought comments on these proposed amendments, including whether additional guidance or clarifications were necessary to

implement the sunset of the MHPAEA opt-out election provision.

Several commenters expressed support for the proposal to codify the sunset for sponsors of self-funded non-Federal governmental plans to opt out of compliance with the MHPAEA requirements. Many of these commenters recommended prioritizing MHPAEA compliance reviews of these plans as soon as their respective opt-outs are no longer valid. Furthermore, some commenters suggested these plans should immediately be requested to submit the NQTL comparative analyses required under PHS Act section 2726(a)(8)(A) to ensure compliance with MHPAEA. One commenter encouraged HHS to oversee self-funded non-Federal governmental plans to ensure full MHPAEA compliance by such plans that previously opted out of compliance with the MHPAEA requirements.

HHS appreciates the support for the proposed amendments to codify the sunset of the option for self-funded non-Federal governmental plans to elect to opt out of compliance with the MHPAEA requirements. HHS did not receive any comments objecting to the proposed amendments to 45 CFR 146.180 and is finalizing those amendments as proposed in these final rules. HHS is committed to ensuring that self-funded non-Federal governmental plans that previously opted out of compliance with MHPAEA come into compliance with MHPAEA requirements. In determining the degree to which HHS will prioritize compliance reviews, NQTL comparative analysis reviews, and enforcement of MHPAEA with respect to self-funded non-Federal governmental plans once the plans' respective opt-outs sunset, HHS will weigh all relevant considerations, such as the number of complaints of MHPAEA noncompliance with respect to such plans.

One commenter suggested HHS implement a tiered approach to penalty assessment for compliance with MHPAEA that employs varying levels of penalties which consider the severity of and frequency of violations. This approach, according to the commenter, would encourage greater compliance as non-Federal governmental entities diligently work to modify their health plans, and would mitigate detrimental fiscal impacts that would reduce the ability of non-Federal governmental entities to both recruit and retain a strong workforce and continue to provide necessary services to residents.

With respect to penalties for violations of MHPAEA and other PHS Act requirements, HHS has determined that the enforcement processes and

¹²⁸ PHS Act section 2722(a)(2); 45 CFR 146.180.

¹²⁹ Division FF, Title I, Subtitle C, Chapter 3, section 1321, Public Law 117–328, 136 Stat. 4459 (Dec. 29, 2022).

¹³⁰ PHS Act section 2722(a)(2)(F)(i).

¹³¹ PHS Act section 2722(a)(2)(F)(ii).

¹³² The statutory provisions implemented by 45 CFR 146.180 became effective December 29, 2022 (the date of enactment of the CAA, 2023).

procedures set forth in existing regulations are sufficient to address the tiered approach to penalty assessment recommended by the commenter. The HHS enforcement processes and procedures applicable to self-funded non-Federal governmental plans are set forth at 45 CFR 150.301 through 150.347. Rather than specifying a specific set penalty amount for any and all violations, the regulations at 45 CFR 150.317, 150.319, 150.321, and 150.323 specify the factors HHS uses in determining the amount of any penalty, including the entity's previous record of compliance and the gravity of the violation; mitigating circumstances; aggravating circumstances; and other matters as justice may require.¹³³ These factors allow HHS to structure penalties in a manner that encourages compliance while taking into account the relevant facts and circumstances.

One commenter requested that HHS provide guidance on how self-funded non-Federal governmental plans can leverage the expertise of TPAs to comply with MHPAEA.

HHS acknowledges that most self-funded group health plans contract with one or more TPAs to administer, and in some cases, to design plan benefits. To the extent a self-funded non-Federal governmental plan that contracts with a TPA has previously elected to opt out of MHPAEA compliance, HHS urges the sponsors of such plans to work with their TPAs to ensure that, under the plan's contract with the administrator, if the TPA is required to administer benefits, it collects and analyzes data, and provides data to the sponsor in such a way that will enable the sponsor to comply with all the requirements of MHPAEA. HHS also notes that Federal regulations at 45 CFR 150.305 identify the entity liable for civil money penalties for noncompliance with applicable PHS Act requirements, including MHPAEA. Under the regulations, if a non-Federal governmental plan is sponsored by two or more employers and fails to comply with an applicable PHS Act requirement, the plan is subject to a civil money penalty, irrespective of whether the plan is administered by a health insurance issuer, an employer sponsoring the plan, or a TPA.¹³⁴ If a non-Federal governmental plan is sponsored by a single employer and fails to comply with an applicable PHS Act requirement, the employer is subject

to a civil money penalty, irrespective of whether the plan is administered by a health insurance issuer, the employer, or a TPA.¹³⁵

B. Applicability of MHPAEA to Individual Health Insurance Coverage

The HHS regulation implementing MHPAEA for individual health insurance coverage is codified at 45 CFR 147.160. The regulation currently provides that the group market regulation implementing MHPAEA at 45 CFR 146.136 applies to health insurance coverage offered by a health insurance issuer in the individual market in the same manner and to the same extent as such provisions apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the large group market, for policy years beginning on or after the applicability date set forth in 45 CFR 146.136(i). Therefore, through cross-reference, the proposed amendments to 45 CFR 146.136 would apply in the same manner to health insurance issuers offering individual health insurance coverage. Further, HHS proposed to include a cross reference in 45 CFR 147.160 to the comparative analysis requirements that were proposed in 45 CFR 146.137. The cross reference would similarly make clear that the comparative analysis requirements apply to health insurance issuers offering individual health insurance coverage in the same manner that those provisions apply to group health plans and health insurance issuers offering coverage in connection with such plans. HHS proposed that these provisions would apply to health insurance issuers offering individual health insurance coverage for policy years beginning on or after January 1, 2026. Finally, for greater clarity and precision and to align with the statutory terminology, HHS proposed to modify the regulation text to refer to "individual health insurance coverage offered by a health insurance issuer" as opposed to "health insurance coverage offered in the individual market."

Commenters expressed support for HHS' proposal to apply the proposed amendments to 45 CFR 146.136 in the same manner to individual health insurance coverage. HHS is finalizing this proposal as proposed.

HHS received one comment supporting its proposal to include a cross reference in 45 CFR 147.160 to the comparative analysis requirements that were proposed in 45 CFR 146.137 to make clear that the comparative analysis requirements apply to health insurance

issuers offering individual health insurance coverage in the same manner that those provisions apply to group health plans and health insurance issuers offering coverage in connection with such plans, and did not receive any comments opposing that proposal. HHS did not receive any comments on its proposal to modify the regulation text to refer to "individual health insurance coverage offered by a health insurance issuer" as opposed to "health insurance coverage offered in the individual market." HHS is finalizing these proposals as proposed.

With respect to HHS' proposal that these provisions would apply to individual health insurance coverage for policy years beginning on or after January 1, 2026, one commenter stated that this applicability date should align with the applicability date for self-funded non-Federal governmental plans to come into compliance with MHPAEA's requirements under PHS Act section 2726 and its implementing regulations, while other commenters requested that the applicability date for individual health insurance coverage be delayed until January 1, 2027. As stated in the proposed rules, non-grandfathered individual health insurance coverage must be offered on a calendar year basis. Premium rates must be submitted to the applicable regulator and finalized prior to January 1 of each calendar year and rates cannot be modified during the year. The proposed applicability date is intended to provide time for issuers offering individual health insurance coverage to account for the effects of these rules following publication of the final rules, which precludes alignment with the applicability date for self-funded non-Federal governmental plans, and prior to when rates and benefits must be finalized and approved for the following calendar year. In addition, HHS declines to delay the applicability date until January 1, 2027, in order to ensure the protections of these final rules apply in a timely manner. Therefore, with respect to its proposal that these provisions would apply to individual health insurance coverage, HHS is finalizing the applicability date of January 1, 2026, as proposed.

Until the applicability date, issuers are required to continue to comply with the most recent MHPAEA regulations codified in the CFR¹³⁶ and must comply with the statutory provisions of MHPAEA, as amended by the CAA, 2021, both before and after these final

¹³³ HHS proposed amendments to the provisions in 45 CFR part 150 related to enforcement processes and procedures and penalties for noncompliance. 86 FR 51730 (Sept. 16, 2021).

¹³⁴ 45 CFR 150.305(b).

¹³⁵ 45 CFR 150.305(c).

¹³⁶ Specifically, issuers must continue to comply with 45 CFR 147.160, incorporating 45 CFR 146.136, each revised as of October 1, 2023.

rules become applicable. HHS reminds issuers that the guidance in FAQs Part 45 addresses what information plans and issuers should make available under MHPAEA, as amended by the CAA, 2021, in response to the Departments' request for comparative analyses and can be relied on pending the applicability date of these final rules.

IV. Regulatory Impact Analysis

Summary—Departments of Health and Human Services and Labor

The Departments¹³⁷ have examined the impacts of these final rules as required by Executive Order 12866,¹³⁸ Executive Order 13563,¹³⁹ Executive Order 14094,¹⁴⁰ the Paperwork Reduction Act of 1995,¹⁴¹ the Regulatory Flexibility Act,¹⁴² section 202 of the Unfunded Mandates Reform Act of 1995,¹⁴³ Executive Order 13132,¹⁴⁴ and the Congressional Review Act.¹⁴⁵

1. Executive Orders 12866 and 13563—Departments of Health and Human Services and Labor

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). As amended by Executive Order 14094,¹⁴⁶ entitled “Modernizing Regulatory Review,” 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 \$200 million or more

(adjusted every 3 years by the Administrator of the Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product); 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, Territorial, 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 entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

Based on the Departments' estimates, OMB's OIRA has determined this rulemaking is significant per section 3(f)(1) as measured by the \$200 million or more in any one year. Therefore, the Departments have provided an assessment of the potential costs, benefits, transfers, and alternatives associated with these final rules, and OMB has reviewed these final rules.

2. Introduction and Need for Regulations

Mental health is crucial to a person's overall well-being, and access to quality mental health and substance use disorder treatment is as essential for health as access to medical/surgical treatment.¹⁴⁷ According to the NSDUH, in 2022, 50.6 percent of adults in the United States with any mental illness had received treatment within the past year; 66.7 percent of adults with a serious mental illness had received treatment.¹⁴⁸

Failure to treat mental health conditions or substance use disorders can be costly. For example, depression is associated with increased risk of cardiovascular disease, diabetes, stroke, Alzheimer's disease, suicidality, and osteoporosis, and an untreated substance use disorder may result in

hospital emergency room care for a drug overdose.¹⁴⁹ One study examined the costs and benefits of 58 grants provided through the Garrett Lee Smith Memorial Suicide Prevention Program (GPP) between 2005 and 2009, which provides Federal funding to States, Tribes, and colleges for community-based suicide prevention programs. The study estimated that the programs resulting from GPP funding prevented 79,379 suicide attempts and resulted in \$4.50 in medical cost savings for each dollar invested.¹⁵⁰

Individuals with mental health conditions or substance use disorders have faced stigma, discrimination, and other barriers inside and outside of the health care system, which can operate as impediments to seeking and obtaining treatment. In 2022, approximately 27 percent of adults 18 and older with any mental illness in the past year who did not receive mental health treatment reported a perceived unmet need for treatment.¹⁵¹ Individuals reported a variety of reasons for not receiving treatment: 59 percent thought it would cost too much; 26 percent were concerned their information would not be kept private; 20 percent were unable to get an opening in the treatment program or with the health care professional they wanted to see; 16 percent thought it may cause their community to have a negative opinion about them; and 15 percent thought it might impact their job, parental rights or housing.¹⁵²

The Departments are particularly concerned with access barriers for individuals seeking mental health or substance use disorder treatments. A 2022 Harris Poll sponsored by the National Council for Mental Wellbeing found that 21 percent of adults with unmet mental health care needs in the

¹⁴⁹ Government Accountability Office (GAO), *Behavioral Health: Research on Health Care Costs of Untreated Conditions is Limited*, GAO-19-274 (Feb. 2019), <https://www.gao.gov/assets/gao-19-274.pdf>.

¹⁵⁰ Lucas Godoy Garraza, Christine Walrath, Simone Peart Boyce, & David Goldston, *An Economic Evaluation of the Garrett Lee Smith Memorial Suicide Prevention Programs*, 48(1) *Suicide and Life-Threatening Behavior* (2018), <https://onlinelibrary.wiley.com/doi/10.1111/sltb.12321>.

¹⁵¹ SAMHSA, *Center for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health*, Figure 64 (2022), <https://www.samhsa.gov/data/sites/default/files/reports/rpt42731/2022-nsduh-nnr.pdf>.

¹⁵² SAMHSA, *Center for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health*, Table A.47B (2022), <https://www.samhsa.gov/data/sites/default/files/reports/rpt42731/2022-nsduh-nnr.pdf>. Respondents could indicate multiple reasons for not receiving treatment and so response categories are not mutually exclusive.

¹³⁷ The Department of the Treasury is not included as part of the Departments in the regulatory impact analysis.

¹³⁸ Regulatory Planning and Review, 58 FR 51735 (Oct. 4, 1993).

¹³⁹ Improving Regulation and Regulatory Review, 76 FR 3821 (Jan. 18, 2011).

¹⁴⁰ Modernizing Regulatory Review, 88 FR 21879 (Apr. 6, 2023).

¹⁴¹ 44 U.S.C. 3506(c)(2)(A) (1995).

¹⁴² 5 U.S.C. 601 *et seq.* (1980).

¹⁴³ 2 U.S.C. 1501 *et seq.* (1995).

¹⁴⁴ Federalism, 64 FR 153 (Aug. 4, 1999).

¹⁴⁵ 5 U.S.C. 801 *et seq.* (1996).

¹⁴⁶ Modernizing Regulatory Review, 88 FR 21879 (Apr. 6, 2023).

¹⁴⁷ Commonwealth Fund, *Behavioral Health Care in the United States: How It Works and Where It Falls Short* (Sept. 7, 2022), <https://www.commonwealthfund.org/publications/explainer/2022/sep/behavioral-health-care-us-how-it-works-where-it-falls-short>.

¹⁴⁸ SAMHSA, *Center for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health*, Table 6.21B (2022), <https://www.samhsa.gov/data/sites/default/files/reports/rpt42728/NSDUHDetailedTabs2022/NSDUHDetailedTabs2022/NSDUHDetTabsSect6pe2022.htm>.

past year and 28 percent of those with unmet substance use disorder care needs in the past year reported that their inability to get an immediate appointment had prevented them from getting needed care.¹⁵³

Obtaining appointments with primary care physicians instead of behavioral health specialists can be significantly easier. According to the 2023 KFF Employer Health Benefits Survey, 91 percent of firms that offer physical health benefits believe there is a sufficient number of primary care providers in the plans' network, whereas only 67 percent and 59 percent, respectively, believe there is a sufficient number of mental health providers and substance use disorder providers.¹⁵⁴ However, while up to 70 percent of all primary care visits include a behavioral health component,¹⁵⁵ research suggests that primary care providers face significant barriers to delivering these services, including insufficient resources, inadequate related knowledge, and limited time with patients.¹⁵⁶

In seeking out specialists, individuals tend to face less adequate mental health provider networks than medical/surgical provider networks through their plan or coverage. A 2024 study of 2019–2021 claims and enrollment data for employer-sponsored health plans reported that office visits with psychiatrists and psychologists occurred out-of-network 8.9 and 10.6 times more, respectively, than those with medical/surgical specialist physicians.¹⁵⁷

According to a 2021 study, which compared the experiences of patients receiving both specialty mental health and medical/surgical care, patients who were receiving mental health treatment from only a mental health practitioner were more likely to rate their plan's mental health network as inadequate compared with their plan's medical/surgical provider network.¹⁵⁸ The study referenced research that found specialty mental health networks tend to be narrower due to a growing workforce shortage of mental health providers, a high demand for mental health services, and specialty mental health practitioners opting out of participating in provider networks due to low reimbursements for mental health services compared with other specialties. These factors have consequently resulted in higher out-of-network utilization rates for mental health care services.^{159 160 161}

Use of out-of-network providers can place additional burdens on families seeking mental health and substance use disorder treatments. A 2022 study of families experiencing out-of-network behavioral health expenditures in their employer-sponsored insurance claims found that roughly half of the families were subject to "balance billing," with the yearly mean total for those families being \$861. This study, however, focused on out-of-network claims submitted by providers to insurers, which suggests that, for individuals seeking treatment from behavioral health care from providers not accepting insurance, the out-of-pocket costs could be even greater.¹⁶²

Despite access barriers to seeking mental health and substance use disorder treatment, the need for these services has only increased. An

estimated 37 percent of U.S. adults reported being diagnosed with a mental health condition in 2023, a 5-percentage-point increase from pre-pandemic levels in 2019.¹⁶³ Research suggests that the need for mental health services has also increased among children and adolescents. For instance, a 2022 study using 2009 to 2019 data from the NSDUH found that the prevalence of a major depressive episode among adolescents aged 12 to 17 increased by 7.7 percentage points, from approximately 8.1 percent in 2009 to 15.8 percent in 2019. The study found that the increase in prevalence of major depressive episodes was even higher among female adolescents, finding a 12.0-percentage-point increase.¹⁶⁴

The enactment of MHPAEA, as well as the CAA, 2021¹⁶⁵ and associated regulations and guidance issued by the Departments, were intended to assist plans and issuers in improving their policies and procedures to ensure parity between mental health and substance use disorder benefits and medical/surgical benefits, particularly with regards to applying NQTLs.¹⁶⁶ However, as documented in the past two Reports to Congress^{167 168} and discussed later in this regulatory impact analysis, the Departments have found from their initial reviews that plans and issuers failed to comply with these requirements.

In order to address these issues and improve the health and well-being of both individuals and their communities, the Departments are committed to promoting equal access to treatment for

¹⁵³ National Council for Mental Wellbeing, *2022 Access to Care Survey Results* (May 11, 2022), <https://www.thenationalcouncil.org/wp-content/uploads/2022/05/2022-Access-To-Care-Survey-Results.pdf>.

¹⁵⁴ KFF, *2023 Employer Health Benefits Survey* (Oct. 18, 2023), <https://www.kff.org/report-section/ehbs-2023-section-13-employer-practices-telehealth-provider-networks-coverage-limits-and-coverage-for-abortion/>.

¹⁵⁵ Health Affairs, *Combating a Crisis by Integrating Mental Health Services and Primary Care*, *Health Affairs Forefront* (July 8, 2022), <https://www.healthaffairs.org/doi/10.1377/forefront.20220706.603540>.

¹⁵⁶ Danielle F. Loeb, Elizabeth A. Bayliss, Ingrid A. Binswanger, Carey Candrian, & Frank V. Degruy, *Primary Care Physician Perceptions on Caring for Complex Patients with Medical and Mental Illness*, 27(8) *Journal of General Internal Medicine* pp. 945–952 (2012), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3403152/>; Lusine Poghosyan, Allison A. Norful, Affan Ghaffari, Maureen George, Shruti Chhabra, Mark Olsson, *Mental Health Delivery in Primary Care: The Perspectives of Primary Care Providers*, 33(5) *Archives of Psychiatric Nursing* pp. 63–67 (Oct. 2019), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7077950>.

¹⁵⁷ Tami L. Mark & William Parish, *Behavioral Health Parity—Pervasive Disparities in Access to In-Network Care Continue*, RTI International (2024), <https://dpjh8a9zd3a4.cloudfront.net/publication/behavioral-health-parity-pervasive-disparities-access-network-care-continue/fulltext.pdf>.

¹⁵⁸ Susan H. Busch & Kelly Kyanko, *Assessment of Perceptions of Mental Health vs Medical Health Plan Networks Among US Adults with Private Insurance*, 4(10) *JAMA Network Open* (2021).

¹⁵⁹ Davenport, Stoddard, Travis Gray, & Stephen P. Melek, *Addiction and Mental Health vs. Physical Health: Widening Disparities in Network Use and Provider Reimbursement*, Milliman (Nov. 20, 2019), <https://www.milliman.com/en/insight/addiction-and-mental-health-vs-physical-health-widening-disparities-in-network-use-and-p/>.

¹⁶⁰ Tara F. Bishop, Joanna K. Seirup, Harold Alan Pincus, & Joseph S. Ross, *Population of US Practicing Psychiatrists Declined, 2003–13, Which May Help Explain Poor Access to Mental Health Care*, 35(7) *Health Affairs (Millwood)* (2016) pp. 1271–1277.

¹⁶¹ Daria Pelech & Tamara Hayford, *Medicare Advantage and Commercial Prices for Mental Health Services*, 38(2) *Health Affairs (Millwood)* (2019) pp. 262–267.

¹⁶² Sarah A. Friedman, Haiyong Xu, Francisca Azocar, & Susan L. Ettner, *Quantifying Balance Billing for Out-of-Network Behavioral Health Care in Employer-Sponsored Insurance*, 73(9) *Psychiatric Services* pp. 1019–1026 (2022).

¹⁶³ American Psychological Association, *Stress in America 2023: A Nation Recovering from Collective Trauma* (Nov. 2023), <https://www.apa.org/news/press/releases/stress/2023/collective-trauma-recovery>.

¹⁶⁴ Michael Daly, *Prevalence of Depression Among Adolescents in the US from 2009 to 2019: Analysis of Trends by Sex, Race/Ethnicity, and Income*, 70 *Journal of Adolescent Health* 3 pp. 496–499 (2022). Additional information regarding these trends in mental health services among children and adolescents is addressed earlier in this preamble.

¹⁶⁵ Public Law 116–260 (Dec. 27, 2020).

¹⁶⁶ NQTLs consist of any limitations on the scope and duration of benefits that are not expressed numerically. Because they are non-quantitative, it can be difficult to measure their impact on restricting access and whether they are applied in parity across mental health and substance use disorder benefits and medical/surgical benefits.

¹⁶⁷ 2022 MHPAEA Report to Congress, <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2022-realizing-parity-reducing-stigma-and-raising-awareness.pdf>.

¹⁶⁸ 2023 MHPAEA Comparative Analysis Report to Congress, www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2023-mhpaea-comparative-analysis.pdf.

mental health conditions and substance use disorders. These final rules, by clarifying requirements for comparative analyses and setting forth additional requirements for how NQTLs must be designed and applied for group health plans and health insurance coverage, will serve to improve compliance with MHPAEA by plans and issuers. This will in turn promote more equitable access to affordable and comprehensive care for individuals with mental health conditions and substance use disorders and reduce barriers to mental health and substance use disorder treatments, resulting in greater access and utilization of these services as well as better patient outcomes.

2.1. History of MHPAEA Related Government Actions

To implement the requirements of MHPAEA, the Departments published a request for information soliciting comments on issues under MHPAEA in 2009¹⁶⁹ and interim final regulations in 2010.¹⁷⁰ After considering the comments and other feedback received from interested parties, the Departments published the 2013 final regulations.¹⁷¹ In subsequent years, the Departments provided extensive guidance and compliance assistance materials to the regulated community, State regulators, and other interested parties to facilitate the implementation and enforcement of MHPAEA, including the 2020 MHPAEA Self-Compliance Tool, which provided a basic framework for plans and issuers to assess whether their NQTLs satisfy MHPAEA's parity requirements. The Departments also have provided materials to educate consumers, their family members, and policymakers about parity for mental health and substance use disorder benefits,¹⁷² and may develop new materials and undertake additional educational efforts as necessary after the publication of these final rules.

The CAA, 2021 amended MHPAEA, in part, by expressly requiring group health plans and health insurance issuers that provide both medical and

surgical benefits and mental health or substance use disorder benefits and impose NQTLs on mental health or substance use disorder benefits to perform and document their comparative analyses of the design and application of NQTLs. Plans and issuers must provide those analyses to the Departments or applicable State authorities, upon request. Moreover, the CAA, 2021 compels the Departments to request and evaluate no fewer than 20 NQTL comparative analyses per year and submit to Congress and make available to the public an annual report summarizing the Departments' review process and findings. Shortly after the enactment of the amendments to MHPAEA made by the CAA, 2021, the Departments issued FAQs Part 45 to help plans and issuers comply with the comparative analysis requirements.¹⁷³

As documented in the 2022 MHPAEA Report to Congress,¹⁷⁴ the Departments found that under the first year of the CAA, 2021, none of the NQTL comparative analyses they reviewed contained sufficient information and documentation from plans and issuers upon initial receipt. Similarly, the 2023 MHPAEA Comparative Analysis Report to Congress¹⁷⁵ notes that nearly all the comparative analyses reviewed by the Departments contained insufficient information upon initial receipt and identified common deficiencies in the comparative analyses prepared by plans and issuers. Moreover, despite plans' and issuers' longstanding obligations under MHPAEA to ensure that the processes, strategies, evidentiary standards, and other factors used to apply NQTLs are equitable, it was apparent upon review of the analyses, that plans and issuers had not carefully designed and implemented their NQTLs to be compliant with MHPAEA prior to the enactment of the CAA, 2021. Many plans and issuers appeared to generate their analyses for the first time in response to the Departments' requests, rather than in advance, as required by law and as a critical part of the design

and application of a MHPAEA-compliant NQTL. Consequently, the comparative analyses appeared to focus on finding after-the-fact rationales for decisions and designs involving NQTLs, rather than reflecting proper attention to MHPAEA compliance in the first place.

The Departments are committed to ensuring parity in access to mental health and substance use disorder benefits as compared to medical/surgical benefits. By issuing these final rules, the Departments will provide additional guidance to affected parties to facilitate compliance with MHPAEA and to help ensure that individuals with mental health conditions and substance use disorders benefit from the full protections required by law consistent with the fundamental purpose of MHPAEA.

2.2. Current Regulatory Actions

These final rules amend existing regulatory definitions and add new definitions of key terms, including "factors," "processes," "strategies," and "evidentiary standards." They also add more specificity as to what conditions or disorders plans and issuers must treat as mental health conditions and substance use disorders for purposes of MHPAEA to be consistent with generally recognized independent standards of current medical practice. These final rules also clarify the way the parity requirements apply to NQTLs, including by prohibiting discriminatory factors and evidentiary standards, and provide additional examples of the application of MHPAEA to NQTLs to improve the understanding and ability of the regulated community to comply with the law. Additionally, these final rules require that plans and issuers provide meaningful benefits for covered mental health conditions and substance use disorders in each classification in which meaningful medical/surgical benefits are provided.

Under these final rules, plans and issuers are required to collect and evaluate relevant data in a manner reasonably designed to assess the impact of the NQTL on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits. These final rules provide guidance for how to comply with the relevant data evaluation requirements in limited circumstances where data is initially and temporarily unavailable for new and newly imposed NQTLs and where no data exists that can reasonably measure any relevant impact of the NQTL on relevant outcomes related to access to mental health and substance use disorder benefits and medical/

¹⁶⁹ 74 FR 19155 (Apr. 28, 2009).

¹⁷⁰ 75 FR 5410 (Feb. 2, 2010).

¹⁷¹ 78 FR 68240 (Nov. 13, 2013).

¹⁷² SAMHSA, *Know Your Rights: Parity for Mental Health and Substance Use Disorder Benefits* (2022), <https://store.samhsa.gov/product/know-your-rights-parity-mental-health-and-substance-use-disorder-benefits/pep21-05-00-003>; SAMHSA, *The Essential Aspects of Parity: A Training Tool for Policymakers* (2022), <https://store.samhsa.gov/product/essential-aspects-parity-training-tool-policymakers/pep21-05-00-001>; DOL, *Understanding Your Mental Health and Substance Use Disorder Benefits*, <https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/publications/understanding-your-mental-health-and-substance-use-disorder-benefits>.

¹⁷³ FAQs about Mental Health and Substance Use Disorder Parity Implementation and the Consolidated Appropriations Act, 2021 Part 45 (Apr. 2, 2021), <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-45.pdf> and <https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/downloads/mhpaea-faqs-part-45.pdf>.

¹⁷⁴ 2022 MHPAEA Report to Congress, <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2022-realizing-parity-reducing-stigma-and-raising-awareness.pdf>.

¹⁷⁵ 2023 MHPAEA Comparative Analysis Report to Congress, www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2023-mhpaea-comparative-analysis.pdf.

surgical benefits. In those instances, the plan or issuer must include specific information in their comparative analyses, as explained earlier in this preamble.

These final rules also set forth specific content requirements for comparative analyses required by the CAA, 2021, and outline the process for plans and issuers to provide their comparative analyses to the Departments or an applicable State authority upon request. Additionally, in these final rules, HHS finalizes regulatory amendments to implement a provision in the CAA, 2023 that sunsets the election option for sponsors of self-funded non-Federal governmental plans to opt out of requirements under MHPAEA.

In their reviews of plans' and issuers' comparative analyses under the requirements of the CAA, 2021, the Departments identified exclusions related to treatment for ASD with ABA therapy and OUD with medication assisted treatment, as well as gatekeeping provisions for treatment applied with respect to mental health or substance use disorder benefits but not to medical/surgical benefits, such as requiring referrals for appointments and prior authorization for mental health and substance use disorder outpatient services, resulting in corrections by the plans and issuers.¹⁷⁶ However, the comparative analyses alone are often less effective in identifying substantive parity violations for more complex NQTLs, such as those related to network composition. The Departments expect that these additional requirements will provide plans and issuers with a better understanding of the requirements of MHPAEA with respect to NQTLs and improve how they measure, compare, and demonstrate parity, while clarifying appropriate ways for plans and issuers to modify their policies and procedures to meet parity requirements. As such, these final rules will help plans and issuers comply with these requirements, increase the ability of plans and issuers to provide compliant comparative analyses during future reviews or investigations, and result in improved access to treatment and coverage of mental health conditions and substance use disorders, as intended by MHPAEA.

3. Baseline

The baseline for this analysis includes the MHPAEA statute, as amended, implementing regulations, and subsequent guidance. Benefits, costs,

and transfers are measured as changes from the baseline under these final rules. For example, the CAA, 2021 requires that plans and issuers perform and document NQTL comparative analyses. Starting 45 days after the enactment of the CAA, 2021, plans and issuers were required to make their comparative analyses available to the Departments or an applicable State authority upon request. Plans and issuers are further required to make these comparative analyses and other applicable information required by the CAA, 2021 available upon request to participants, beneficiaries, and enrollees in all non-grandfathered group health plans and non-grandfathered group or individual health insurance coverage (including a provider or other person acting as a participant's, beneficiary's, or enrollee's authorized representative) in connection with an adverse benefit determination, as well as to participants and beneficiaries in plans subject to ERISA.¹⁷⁷

The 2022 and 2023 MHPAEA Reports to Congress documented that many comparative analyses prepared by plans and issuers prior to these final rules were deficient even after multiple requests for correction by the Departments.^{178 179} In addition, at least some plans and issuers failed to conduct the required comparative analyses until after the Departments requested them, rather than performing and documenting them prospectively within 45 days following the enactment of the CAA, 2021.

The Departments' view is that plans and issuers that were already timely fulfilling the comparative analysis requirements outlined in CAA, 2021 will incur only incremental costs to comply with these final rules. Plans and issuers not already meeting those requirements may, on the other hand, face significant costs to come into compliance with the CAA, 2021 comparative analysis requirements and these final rules. However, because those actions to comply with the CAA, 2021 comparative analysis requirements would need to occur absent these final rules, those costs are included in the baseline.

Therefore, this regulatory impact analysis does not include benefits or

costs for performing and documenting comparative analyses for NQTLs applicable to mental health and substance use disorder benefits and medical/surgical benefits, or making them available upon request, as these are already required by the provisions of the CAA, 2021 and are in the baseline. However, this regulatory impact analysis does take into account the expected impacts of these final rules on the preparation of plans' and issuers' comparative analyses, how these final rules will impact plans' and issuers' compliance and, in turn, access for participants, beneficiaries, and enrollees needing mental health and substance use disorder treatments, and whether plans and issuers need to change their policies and procedures to provide benefits in parity.

Some commenters stated that the proposal would require plans and issuers to substantially revise their comparative analyses, arguing the significance of those revisions makes the Departments' approach of conducting an incremental analysis of the additional requirements of this rulemaking inappropriate. In particular, one commenter stated that the imposition of the new "substantially all" test would require all comparative analyses to be redone, thereby imposing the full cost of performing these analyses under the proposed rules. In response, the Departments note that, as discussed earlier in this preamble, they are not finalizing the proposed mathematical tests for applying the substantially all and predominant tests, which would have based these determinations on the dollar amount of all plan payments for medical/surgical benefits expected to be paid. Instead, these final rules provide that an NQTL with respect to mental health or substance use disorder benefits is more restrictive, as written or in operation, than the predominant NQTL that applies to substantially all medical/surgical benefits in the same classification if the plan or issuer fails to satisfy the design and application requirements or the relevant data evaluation requirements. Additionally, the material differences standard in the relevant data evaluation requirements reflects an interpretation of the statutory terms "substantially all" and "predominant" in a manner that takes into account the multi-faceted nature of NQTLs, as well as the complexity of analyzing such NQTLs.

Because the CAA, 2021 requires that comparative analyses be performed and documented, the fact that plans and issuers were not adequately conducting the required analyses and documenting

¹⁷⁷ FAQs Part 45, Q6.

¹⁷⁸ 2022 MHPAEA Report to Congress, <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2022-realizing-parity-reducing-stigma-and-raising-awareness.pdf>.

¹⁷⁹ 2023 MHPAEA Comparative Analysis Report to Congress, www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2023-mhpaea-comparative-analysis.pdf.

¹⁷⁶ 2023 MHPAEA Comparative Analysis Report to Congress, <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2022-realizing-parity-reducing-stigma-and-raising-awareness.pdf>.

how they determined NQTLs were being applied in parity, is not a justification for why these final rules should account for the full cost of those actions. Rather, these final rules consider as the baseline what plans and issuers should have done given the relevant statute and guidance irrespective of these final rules. Therefore, for this category of cost, the effect of these final rules is limited to those additional requirements included by the Departments in the final rules. Estimates are made based on the impact from the baseline on plans and issuers affected by these final rules, and assuming full compliance with the new requirements.

4. Summary of Impacts

These final rules define certain terms associated with MHPAEA's requirements for NQTLs and require that plans and issuers provide meaningful benefits for covered mental health conditions and substance use disorders in each classification in which meaningful medical/surgical benefits are provided. These final rules also provide that a group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) may not impose any NQTL with respect to mental health or substance use disorder benefits in any classification that is more restrictive, as written and in operation, than the predominant NQTL that applies to substantially all medical/surgical benefits in the same classification. For this purpose, the plan and issuer must ensure that the NQTL satisfies both the design and application requirements and the relevant data evaluation requirements. Specifically, under these final rules, plans and issuers must continue to satisfy the design and application requirements from the 2013 final regulations, which require an analysis of the processes, strategies, evidentiary standards, and other factors used to design and apply NQTLs to mental health and substance use disorder benefits as compared to medical/surgical benefits. Plans and issuers have struggled with these requirements, as detailed in the Departments' 2022 MHPAEA Report to Congress¹⁸⁰ and the 2023 MHPAEA Comparative Analysis Report to Congress.¹⁸¹ Additionally, plans and

issuers are not permitted to use any discriminatory factors or evidentiary standards to design or apply an NQTL, and they must satisfy new relevant data evaluation requirements as well as new requirements related to the elements and documentation of their comparative analyses.

In particular, to comply with the required content elements for a comparative analysis, plans and issuers must describe each NQTL and identify and define all the factors and evidentiary standards used to design or apply the NQTL. The plan or issuer must also describe how the factors identified are used in the design and application of the NQTL, and evaluate whether any processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, those with respect to medical/surgical benefits, both as written and in operation. Finally, plans and issuers must address the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTLs within each classification, and the relative stringency of their application, both as written and in operation.

Accordingly, these final rules will increase plan and issuer compliance with the requirements for imposing NQTLs under MHPAEA and help ensure that NQTLs applicable to mental health and substance use disorder benefits are no more restrictive than the predominant NQTLs applicable to substantially all medical/surgical benefits in the same classification. The Departments acknowledge that past parity implementation has lacked consistency and thus had varied results, particularly for laws limiting management of behavioral health benefits or NQTLs. A 2012 study on the implementation of Oregon's 2007 comprehensive parity law, which mandated benefits for substance use disorders and restricted the use of behavioral health management for fully insured commercial group plans, compared their expenditures for treatments to those of self-funded plans not covered by Oregon's law. The study found that while plan expenditures for alcohol treatment services increased, other substance use treatments were not associated with a statistically significant increase in expenditures and that overall, the impact of parity on

spending was not significantly different from zero.¹⁸² However, a broader study conducted in 2013 looked at treatment counts at specialty substance use disorder facilities between 2000 and 2008 across the United States to assess the impact of State-level substance use disorder parity laws on State aggregate treatment rates. While the study was not able to control for the source of insurance and employment status of those receiving treatment, the study did find that the implementation of any State substance use disorder parity laws was associated with increased access to specialty substance use disorder treatments—by 9 percent in all specialty substance use disorder treatment facilities and 15 percent in facilities accepting private insurance.¹⁸³

The Departments are of the view that, by finalizing these rules and requiring better documentation related to how plans and issuers design and apply NQTLs, the Departments and applicable State authorities will be better able to enforce existing parity requirements. In doing so, access to in-network, medically necessary treatments will increase for a significant segment of individuals whose health coverage will be affected by these final rules, resulting in better health outcomes and lower out-of-pocket costs related to mental health and substance use disorder benefits for participants, beneficiaries, and enrollees.

Plans and issuers will incur costs to comply with the requirements in these final rules. However, the Departments have determined that the benefits of these final rules justify the costs. In accordance with OMB Circular A-4, Table 1 depicts an accounting statement summarizing the Departments' assessment of the benefits, costs, and transfers associated with these regulatory actions. The Departments are unable to quantify all benefits, costs, and transfers of these final rules, 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 these final rules.

¹⁸² K. John McConnell, M. Susan Ridgely, & Dennis McCarty, *What Oregon's Parity Law Can Tell Us About the Federal Mental Health Parity and Addiction Equity Act and Spending on Substance Abuse Treatment Services*, 124(3) *Drug and Alcohol Dependence* pp. 340–346 (2012).

¹⁸³ Hefei Wen, Janet R. Cummings, Jason M. Hockenberry, Laura M. Gaydos, & Benjamin G. Druss, *State Parity Laws and Access to Treatment for Substance Use Disorder in the United States: Implications for Federal Parity Legislation*, 70 (12) *JAMA Psychiatry* pp. 1355–1362 (2013).

¹⁸⁰ 2022 MHPAEA Report to Congress, <https://www.doi.gov/sites/doi.gov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2022-realizing-parity-reducing-stigma-and-raising-awareness.pdf>.

¹⁸¹ 2023 MHPAEA Comparative Analysis Report to Congress, www.doi.gov/sites/doi.gov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2023-mhpaea-comparative-analysis.pdf.

TABLE 1—ACCOUNTING STATEMENT

Benefits:

- Improved understanding of and compliance with MHPAEA by plans and issuers, resulting in better frameworks for determining whether plans and issuers are complying with MHPAEA with respect to NQTLs applicable to mental health and substance use disorder benefits and medical/surgical benefits.
- Greater access and utilization of mental health and substance use disorder services by reducing barriers to coverage of mental health and substance use disorder treatment, which will result in better health outcomes for those with mental health conditions or substance use disorders.
- Reduction in the negative impacts on families, friends, caregivers, and coworkers of those with untreated or poorly managed mental health conditions or substance use disorders based on their improved access to treatment.

Costs:

- Increased costs to plans and issuers to implement changes associated with the revision of plan provisions, which would result in increased costs from expanded coverage of mental health and substance use disorder services.
- Costs to plans and issuers from collecting and evaluating outcomes data and documenting NQTL comparative analyses consistent with the requirements of these final rules of approximately \$656.2 million in the first year and approximately \$131.2 million in subsequent years or between 0.07 percent and 0.01 percent of total health insurance premiums in the group and individual markets.
- Costs to plans and issuers for preparing and mailing the comparative analyses upon request to participants, beneficiaries, and enrollees of approximately \$14.8 million annually.
- Cost to plan and issuers for providing comparative analyses for audits is approximately \$23,800.
- First-year regulatory review costs to plans and issuers for familiarizing themselves with these final rules of approximately \$10.8 million.
- Cost to plan and issuers to maintain recordkeeping is approximately \$12.2 million.
- Potential increase in cost-sharing requirements and/or treatment limitations for medical/surgical benefits for participants, beneficiaries, and enrollees, if plans and issuers try to achieve parity by imposing new restrictions on medical/surgical benefits, rather than by reducing restrictions on access to mental health or substance use disorder benefits.
- Potential costs to self-funded non-Federal governmental plans that opted out of MHPAEA to come into compliance with requirements under MHPAEA.
- Cost savings to self-funded non-Federal governmental plans of approximately \$11,783 annually in total from no longer sending opt-out notices regarding a plan's MHPAEA opt-out election.
- Cost savings for the Federal Government of approximately \$5,200 annually from fewer opt-out notices being submitted by self-funded non-Federal governmental plans.

Costs	Estimate	Year dollar	Discount rate (percent)	Period covered
Annualized Monetized (\$million/Year)	\$217.35	2024	7	2024–2033
	207.04	2024	3	2024–2033

Transfers:

- Potential transfers from plans and issuers to participants, beneficiaries, and enrollees resulting in lower out-of-pocket spending on mental health and substance use disorder services.
- Potential transfers from participants, beneficiaries, and enrollees to plans and issuers caused by higher premiums or contributions associated with increased utilization of mental health and substance use disorder services, provider network improvements, and increased provider reimbursement rates.
- Potential transfers from primary care providers to mental health providers for the treatment of mental health conditions and substance use disorders as a result of an increased number of in-network mental health and substance use disorder providers and decisions by participants, beneficiaries, and enrollees to obtain treatment from those providers instead of a primary care provider.

5. Affected Entities

The following table summarizes the number of plans, issuers,¹⁸⁴ TPAs, and

multiple employer welfare arrangement (MEWAs) that would be affected by the final rules.¹⁸⁵ These estimates are

discussed in greater detail later in this regulatory impact analysis.

TABLE 2—AFFECTED ENTITIES

	Self-funded plan count	Mixed insured plan count	Total
Issuers (health insurance company/State combinations)			1,467
TPAs			205
Plan MEWAs that are not fully insured			132
Non-plan MEWAs that are not fully insured			21
Plans (total) ^{186 187}	46,080	4,501	50,581
Under 100 participants	25,150	176	25,326
100 to 199 participants	5,209	402	5,611
200 to 499 participants	6,861	755	7,616

¹⁸⁴ For purposes of this regulatory impact analysis, *health insurance company* refers to a single entity that offers health insurance coverage in one or multiple States, which might own or be affiliated with one or multiple entities that are separately required to be licensed to engage in the

business of insurance in each such State. *Health insurance issuer or issuer* means an insurance company, insurance service, or insurance organization (including an HMO) that is required to be licensed to engage in the business of insurance in a State and that is subject to State law that

regulates insurance. PHS Act section 2791(b)(2) and 45 CFR 144.103.

¹⁸⁵ The Departments note that the number of issuers may be underestimated, since some managed behavioral health organizations may not be included in the issuer count.

TABLE 2—AFFECTED ENTITIES—Continued

	Self-funded plan count	Mixed insured plan count	Total
500 to 999 participants	3,812	671	4,483
1,000 to 2,499 participants	2,880	948	3,828
2,500 to 4,999 participants	1,119	561	1,680
5,000 and above participants	1,049	988	2,037
Plans with less than 500 participants that will seek assistance with the comparative analyses from TPAs, MEWAs, or service providers	37,220	1,333	38,553
Plans with more than 500 participants that will conduct the comparative analysis themselves	709	253	962
Plans with more than 500 participants that will receive generic comparative analyses from TPAs or service providers and will then customize it	4,076	1,458	5,534
Non-Federal governmental plans with less than 500 participants that will seek assistance with the comparative analyses from TPAs or service providers	26,584		26,584
Non-Federal governmental plans with more than 500 participants that will conduct the comparative analysis themselves	505		505
Non-Federal governmental plans with more than 500 participants that will initially receive generic comparative analyses from TPAs or service providers and will then customize it	2,906		2,906

5.1. Issuers, TPAs, and MEWAs

Under the Departments' final rules, issuers are responsible for providing data and comparative analyses for individual market plans. For small and large group market fully insured, employer-sponsored plans, including non-Federal governmental plans, both employer-sponsored health plans and health insurance issuers are responsible for providing data and comparative analyses, though for those plans, underlying data and analyses will likely

be provided by issuers that design and market the plans. Self-funded group health plans, while responsible for complying with these rules, will likely seek assistance from their TPAs, MEWA administrators, and other service providers for collecting and analyzing the data, and generating the comparative analyses.

The Departments estimate that the final rules will affect 479 health insurance companies nationwide that provide coverage, including mental health and substance use disorder benefits, in the group and individual health insurance markets, with 1,467 issuers (health insurance company/State combinations).¹⁸⁸ In addition, there are an estimated 205 TPAs that provide services to group health plans, particularly for self-funded plans where TPAs often establish provider networks and adjudicate claims, which would be impacted by these final rules.¹⁸⁹ The Departments estimate that the final rules will affect at least 40 managed behavioral health organizations providing mental health and substance use disorder benefits to group health plans.¹⁹⁰ Additionally, based on the Form M-1 filings, the Departments estimate that there are 687 plan MEWAs, of which 132 are not fully insured, and 50 non-plan MEWAs, of

which 21 are not fully insured.¹⁹¹ These MEWAs, similar to issuers, are likely to provide support to employers or plans.

Issuers, TPAs, and MEWAs provide key support for plan compliance with laws and regulations for group health plans, including MHPAEA. The Departments' understanding, based on discussions with the regulated community and numerous direct investigations of plans, including the review of comparative analyses, is that issuers of fully insured coverage provide a menu of benefit combinations from which interested parties select their coverage designs. These coverage designs may include different features, such as varying deductibles, copayments, and coverage for specific items and services, allowing interested parties to choose the plan that best suits their health care needs. While issuers of fully insured health plans are responsible for overseeing the compliance framework and ensuring that plans comply with legal and regulatory requirements, TPAs play a crucial role in facilitating compliance for self-funded plans by providing administrative support, including claims adjudication, member enrollment, and customer service.

TPAs and insurance companies providing administrative services only (ASO) to self-funded plans overwhelmingly design the plans, administer the networks, manage claims, provide plan services, maintain and hold the data relevant for the comparative analyses, and help ensure MHPAEA compliance.¹⁹² Self-funded plans rarely build independent provider networks and instead rely on those built

¹⁸⁶ The Departments note that the final rules will affect approximately 106,000 fully insured plans with 50 to 100 participants. (Note: The Departments estimate that there are 140,998 ERISA-covered group health plans with 50 to 100 participants based on the Medical Expenditure Panel Survey Insurance Component (MEPS-IC) and the 2020 County Business Patterns from the Census Bureau. The Departments also estimate that 75 percent of ERISA-covered group health plans with 50 to 100 participants are fully insured based on assumptions referencing these same data. Thus, the Departments have calculated the number of fully insured plans with 50 to 100 participants in the following manner: 140,998 ERISA-covered group health plans with 50 to 100 participants × 75 percent = 105,749.)

¹⁸⁷ The Departments also note that the final rules will affect approximately 1,719,000 fully insured, non-grandfathered plans with less than 50 participants. (Note: The Departments estimate that there are 2,465,483 ERISA-covered group health plans with less than 50 participants based on data from the 2022 MEPS-IC and the 2020 County Business Patterns from the Census Bureau. The Departments also estimate that 83 percent of group health plans with less than 50 participants are fully insured based on data from the 2022 MEPS-IC. The 2020 KFF Employer Health Benefits Survey reported that in 2020, 16 percent of firms offering health benefits offered at least one grandfathered health plan; therefore, the Departments assume the percent of firms offering at least one non-grandfathered health plan is 84 percent (100 percent – 16 percent). KFF, *2020 Employer Health Benefits Survey* (Oct. 8, 2020), <https://files.kff.org/attachment/Report-Employer-Health-Benefits-2020-Annual-Survey.pdf>. Thus, the Departments have calculated the number of fully insured, non-grandfathered plans with less than 50 participants in the following manner: 2,465,483 small ERISA-covered group health plans × 83 percent × 84 percent = 1,718,935.)

¹⁸⁸ The Departments' estimate of the number of health insurance issuers is based on medical loss ratio (MLR) reports submitted by issuers for the 2022 reporting year. CMS, *Medical Loss Ratio Data and System Resources* (2022), <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr>.

¹⁸⁹ Non-issuer TPAs based on data derived from the 2016 benefit year reinsurance program contributions.

¹⁹⁰ The Departments' estimate of the number of managed behavioral health organizations is based on industry trade association membership, including the National Behavioral Consortium (<https://www.nbcgroup.org/member-directory/>) and ABHW (<https://abhw.org/about/>).

¹⁹¹ EBSA, *2020 Form M-1 Bulletin*, Table 1, <https://www.dol.gov/sites/dolgov/files/ebsa/researchers/statistics/health-and-welfare-bulletins/m-1/2020.pdf>.

¹⁹² 85 FR 72158 (Jan 11, 2021).

by TPAs (including those that are also health insurance companies). According to the 2019 KFF Employer Health Benefits Survey, only 8 percent of large, self-funded plans with 200 or more employees reported that they directly contracted with hospitals and health systems, independent of the plan's TPA, to provide health care services separate from the provider networks included in the plan network.¹⁹³

While the requirement to comply with MHPAEA is directly applicable to group health plans and health insurance issuers, the Departments anticipate that issuers and TPAs are best situated to conduct comparative analyses as required under the CAA, 2021 and these final rules, and to provide the analyses in an efficient and cost-effective manner, helping to reduce the compliance burden. Self-funded plans may, however, incur some additional costs to complete the comparative analysis initially prepared by the issuer or TPA to address unique plan issues and include all the information necessary to perform comparative analyses.

One commenter stated they are not aware of any TPA that has assumed compliance obligations wholesale, though they acknowledged that TPAs had cooperated and provided data in response to a government audit. Another commenter reported that TPAs working on behalf of group health plan sponsors struggle to obtain needed information to perform and document comparative analyses, such as when claims expenditure data collected by TPAs is not compatible for testing purposes and, moreover, is not reported at the plan sponsor level. It should be noted that these reported challenges are not unique to TPAs, but are the same issues facing issuers and self-funded plans. However, TPAs are more likely than plan sponsors to have expertise to navigate the challenges.

Other commenters supported the Departments' assumptions that employer-sponsored plans rely on their services providers and TPAs to conduct their comparative analyses. One commenter noted that only the insurance carriers, TPAs, and service providers that play a role in designing plans, administering networks, managing claims, providing plan services, and maintaining and holding the data relevant for the comparative analyses have the expertise to comply with and fulfill all the requirements

outlined in the proposed rules. Another commenter noted that self-funded plan sponsors rely on TPAs and/or the owners of provider networks to develop plan designs and develop and impose NQTLs, arguing that if the TPA or owner of the provider networks do not share claims data, then the TPA or owner of the provider networks should be required to conduct analyses for the plans.

While the Departments acknowledge these concerns, based on their own observations when reviewing comparative analyses, the Departments expect that issuers, TPAs, and service providers will continue to provide assistance to evaluate NQTLs and perform and document comparative analyses, including data required under these final rules, for their plan clients. The Departments emphasize that the requirement to perform and document comparative analyses of the design and application of NQTLs has been effective under the CAA, 2021 for more than 3 years (since February 10, 2021) and is an independent statutory obligation that is not dependent upon a request by the Secretaries or an applicable State authority. Issuers and plans, in conjunction with their TPAs for self-funded group health plans, have had ample time to develop the internal structures required for analyzing NQTLs to ensure that their plans and coverage comply with MHPAEA. Finally, while plans could be charged for the services of issuers, TPAs, and other service providers, this arrangement provides for economies of scale in compliance, as issuers evaluate NQTLs, produce or assist in producing the comparative analyses for their products and plan designs, and, in combination with TPAs and other service providers, provide support for other requirements.

5.2. Group Health Plans

Group health plans sponsored by employers with 50 or more employees that offer mental health and substance use disorder benefits are generally required to comply with MHPAEA. Although MHPAEA includes a small employer exemption, group health plans sponsored by employers with less than 50 employees who purchase non-grandfathered small group coverage are required to comply with MHPAEA under the EHB requirements of the ACA. In this analysis, plan size is used as a proxy for employer size to determine if a plan is affected. Evidence suggests that most large group plans offer mental health and substance use

disorder benefits and nearly all participants are covered.¹⁹⁴

The Departments estimate that approximately 1,719,000 fully insured, non-grandfathered ERISA-covered group health plans with less than 50 participants and approximately 411,000 ERISA-covered group health plans with 50 or more participants, of which approximately 246,000 are self-funded group health plans, will be affected by these final rules.¹⁹⁵ In addition, the Departments estimate that these final rules will affect approximately 90,900 non-Federal governmental plans,¹⁹⁶ of which approximately 12,700 are plans with 50 or more participants.¹⁹⁷ The Departments requested comments on these estimates in the proposal, but did not receive any.

The estimated compliance costs associated with these final rules are

¹⁹⁴ DOL, *Selected Medical Benefits: A Report from the Department of Labor to the Department of Health and Human Services* (Apr. 15, 2011), <https://www.bls.gov/ebs/additional-resources/selected-medical-benefits-a-report-from-dol-to-hhs.pdf>.

¹⁹⁵ The Departments estimate that there are 2,465,483 ERISA-covered group health plans with less than 50 participants and that 83 percent of group health plans with less than 50 participants are fully insured based on data from the 2022 MEPS-IC and the 2020 County Business Patterns from the Census Bureau. The 2020 KFF Employer Health Benefits Survey reported that in 2020, 16 percent of firms offering health benefits offered at least one grandfathered health plan. KFF, *2020 Employer Health Benefits Survey* (Oct. 8, 2020), <https://files.kff.org/attachment/Report-Employer-Health-Benefits-2020-Annual-Survey.pdf>. Thus, the Departments have calculated the number of fully insured, non-grandfathered plans with less than 50 participants in the following manner: 2,465,483 small ERISA-covered group health plans $\times$ 83 percent $\times$ (100 percent $-$ 16 percent) = 1,718,935. Based on the 2022 MEPS-IC and the 2020 County Business Patterns from the Census Bureau, the Departments estimate 60 percent of ERISA-covered group health plans with 50 or more participants are self-funded. Thus, the Departments calculate the number of self-funded group health plans in the following manner: 410,581 ERISA-covered group health plans with 50 or more participants $\times$ 60 percent = 246,349.

¹⁹⁶ Based on data from the 2022 Census of Governments (<https://www.census.gov/data/tables/2022/econ/gus/2022-governments.html>), there are 90,887 State and local entities. The Departments assume there is one plan per entity on average. Therefore, the Departments estimate that there are 90,887 non-Federal governmental plans.

¹⁹⁷ MHPAEA applies to non-Federal governmental plans. Using data from the 2022 MEPS-IC and the 2020 County Business Patterns from the Census Bureau, the Departments estimate that 14 percent of ERISA-covered group health plans have 50 or more participants. The Departments use the percent of ERISA-covered group plans with 50 or more participants as a proxy for the percent of non-Federal governmental plans with 50 or more participants. Therefore, the Departments estimate that there are 12,724 public, non-Federal governmental plans with 50 or more participants that offer mental health or substance use disorder benefits (90,887 non-Federal governmental plans $\times$ 14 percent of plans with 50 or more employees = 12,724).

¹⁹³ KFF, *2019 Employer Health Benefits Survey*, Table 14.15 (Sept. 25, 2019), <https://www.kff.org/report-section/ehbs-2019-section-14-employer-practices-and-health-plan-networks/>.

impacted by whether a plan is fully insured or self-funded. The Departments anticipate that fully insured plans will receive compliance support in the form of comparative analyses and data analyses prepared by the issuer. For these plans, the burden is estimated as a cost for the issuer to prepare the analyses and analyze the data. Self-funded plans may rely on issuers or TPAs acting as service providers, receive some support from their service providers that they supplement themselves, or produce the required information themselves.

Most employer-sponsored health plans are exempt from filing a Form 5500 due to size and the absence of plan assets, the majority of which are fully insured. Large health plans are required to file a Form 5500, regardless of funding arrangement. For statistical year 2021, 81,800 health plans filed a Form 5500. Of these plans, 50,600 were self-funded or mixed-insured,¹⁹⁸ of which 38,600 had less than 500 participants.¹⁹⁹ Additionally, the Departments estimate that there are 26,600 self-funded non-Federal governmental plans with less than 500 participants.²⁰⁰ The Departments assume that self-funded plans with less than 500 participants will receive assistance with the comparative analyses and data requirements from TPAs or service providers involved with the plans.

The Departments assume that some of the largest plans will incur the full cost of preparing the comparative analysis and conducting the required data analyses. Commenters suggested that some large, self-funded plans would conduct the comparative analyses themselves. To account for these plans, the Departments estimate that 8 percent of self-funded plans with 500 or more

participants, or 962 ERISA covered plans²⁰¹ and 505 non-Federal governmental plans,²⁰² will prepare the comparative analysis and conduct the required data analyses themselves. The Departments estimate that 50 percent of the remaining self-funded plans with 500 or more participants, or 5,535 self-funded plans,²⁰³ and 2,900 self-funded non-Federal governmental plans with 500 or more participants will receive a generic comparative analysis from the TPA,²⁰⁴ which they will subsequently customize to suit their specific needs. These plans will incur costs, but not at

²⁰¹ Based on the 2021 Form 5500 data, there are 12,028 self-funded plans with 500 or more participants. According to the 2019 KFF Employer Health Benefits Survey, only 8 percent of large, self-funded plans with 200 or more employees reported that they directly contracted with hospitals and health systems, independent of the plan's TPA, in order to provide health care and services separate from the provider networks included in the plan network. KFF, *2019 Employer Health Benefits Survey* (Sept. 25, 2019), Table 14.15, <https://www.kff.org/report-section/ehbs-2019-section-14-employer-practices-and-health-plan-networks/>. Thus, 12,028 self-funded plans with 500 or more participants $\times$ 8 percent = 962 self-funded plans with more than 500 participants.

²⁰² Based on the 2022 Census of Governments, there are 90,887 non-Federal governmental plans. Based on the 2022 MEPS-IC, the Departments estimate that 36.2 percent of non-Federal governmental plans are self-funded. Thus, 90,888 plans $\times$ 36.2 percent = 32,901 self-funded non-Federal governmental plans. Based on the 2021 Form 5500 data, the Departments estimate that 19.2 percent of health plans with more than 500 participants have filed the Form 5500. The Departments use the percent of health plans with more than 500 participants that have filed a Form 5500 as a proxy for the percent of non-Federal governmental plans with more than 500 participants. According to the 2019 KFF Employer Health Benefits Survey, only 8 percent of large, self-funded plans with 200 or more employees reported that they directly contracted with hospitals and health systems, independent of the plan's TPA, in order to provide health care and services separate from the provider networks included in the plan network. KFF, *2019 Employer Health Benefits Survey* (Sept. 25, 2019), Table 14.15, <https://www.kff.org/report-section/ehbs-2019-section-14-employer-practices-and-health-plan-networks/>. Thus, 32,901 non-Federal governmental plans $\times$ 19.2 percent $\times$ 8 percent = 505 non-Federal governmental plans with more than 500 participants.

²⁰³ Based on the 2021 Form 5500 data, there are a total of 50,581 self-funded plans. Thus, (50,581 self-funded plans – 38,533 self-funded plans with less than 500 participants – 962 self-funded plans with more than 500 participants) $\times$ 50 percent = 5,535 self-funded plans with more than 500 participants.

²⁰⁴ Based on the 2022 Census of Governments, there are 90,887 non-Federal governmental plans. Based on the 2022 MEPS-IC, the Departments estimate that 36.7 percent of non-Federal governmental plans are self-funded. Thus, 90,888 plans $\times$ 36.2 percent = 32,901 self-funded non-Federal governmental plans. Thus, (32,901 non-Federal governmental plans – 26,584 non-Federal governmental plans with less than 500 participants – 505 self-funded plans with more than 500 participants) $\times$ 50 percent = 2,906 non-Federal governmental plans with more than 500 participants.

the same level other entities preparing the comparative analysis and data for themselves.

Finally, HHS estimates that 230 self-funded non-Federal governmental plans will be affected by the implementation of the CAA, 2023 provision that sunsets the MHPAEA opt-out election.²⁰⁵ HHS is aware of at least 14 plans with collective bargaining agreements whose sponsors' MHPAEA opt-out elections could be in effect beyond 2024. The MHPAEA opt-out election of these plans with collective bargaining agreements will remain in effect until the last of these plans' respective collective bargaining agreements expires, all of which are anticipated to expire by 2028. HHS does not have precise information about the number of participants and beneficiaries of the plans that have elected to opt out of requirements under MHPAEA, as those plans are not required to report this information to HHS. However, HHS estimates that there are approximately 261 participants, on average, in each self-funded non-Federal governmental plan.²⁰⁶ HHS also estimates that there is one beneficiary for each plan participant on average. Therefore, approximately 120,000 participants and beneficiaries will be affected by this final provision.²⁰⁷

HHS solicited comments on the estimated number of self-funded non-Federal governmental plans and the estimated number of plan participants and beneficiaries that would be affected by the implementation of the CAA, 2023 provision that sunsets the MHPAEA opt-out election. Although HHS did not receive comments on the estimated

²⁰⁵ CMS, HIPAA Opt-Out Elections for Self-Funded Non-Federal Governmental Plans, as of January 6, 2023.

²⁰⁶ According to data from the 2022 MEPS-IC (<https://meps.ahrq.gov/mepsweb/>), there are 19,231,948 State and local government employees, and 67.1 percent of these employees (12,904,637) are enrolled in health coverage through their jobs. Of these employees, 66.5 percent (8,581,584 employees) are participants in self-funded plans. Based on data from the 2022 Census of Governments (<https://www.census.gov/data/tables/2022/econ/gus/2022-governments.html>), there are 90,887 State and local government entities, and according to the 2022 MEPS-IC, 36.2 percent, or 32,901, of State and local government entities self-fund at least one plan. Therefore, the average number of participants per self-funded non-Federal governmental plan is (8,581,584 $\div$ 32,901) = 260.8. Since HHS also estimates that there is one beneficiary for each plan participant on average, the average number of participants and beneficiaries per self-funded non-Federal governmental plan is (260.8 $\times$ 2) = 521.7.

²⁰⁷ This estimate is calculated as follows: 230 self-funded non-Federal governmental plans that have elected to opt out of the requirements under MHPAEA $\times$ approximately 521.7 participants and beneficiaries for each self-funded non-Federal governmental plan on average = 119,991.

¹⁹⁸ A mixed-insured plan is funded through a mixture of insurance and self-insurance. EBBA, *Self-Insured Health Benefit Plans 2024: Based on Filings through 2021* (Sept. 30, 2023), Table 2, <https://www.dol.gov/sites/dolgov/files/EBBA/researchers/statistics/retirement-bulletins/annual-report-on-self-insured-group-health-plans-2024-appendix-b.pdf>.

¹⁹⁹ Estimates based on the 2021 Form 5500 data.

²⁰⁰ Based on the 2022 Census of Governments, there are 90,887 non-Federal governmental plans. Based on the 2022 MEPS-IC, the Departments estimate that 36.2 percent of non-Federal governmental plans are self-funded. Thus, 90,888 plans $\times$ 36.2 percent = 32,901 self-funded non-Federal governmental plans. Based on the 2021 Form 5500 data, the Departments estimate that 80.8 percent of self-funded health plans with less than 500 participants have filed the Form 5500. The Departments use the percent of self-funded health plans with less than 500 participants that have filed a Form 5500 as a proxy for the percent of self-funded non-Federal governmental plans with less than 500 participants. Thus, 32,901 self-funded non-Federal governmental plans $\times$ 80.8 percent = 26,584 self-funded non-Federal governmental plans with less than 500 participants.

number of self-funded non-Federal governmental plans or the estimated number of plan participants and beneficiaries that would be affected by the implementation of this provision, many commenters indicated that hundreds of thousands of public employees and their family members have been denied the critical MHPAEA protections due to the election option for self-funded non-Federal governmental plans to opt out of requirements under MHPAEA. Another commenter indicated that the ability to opt out of requirements under MHPAEA has compromised the health and well-being of State and local government employees, such as teachers, firefighters, and civil servants across the country. HHS agrees that a significant number of individuals will be impacted by the CAA, 2023 provision that sunsets the MHPAEA opt-out election and that these regulatory amendments will ultimately increase access to mental health and substance use disorder services by requiring self-funded non-Federal governmental plans that had previously opted out to come into compliance with the requirements under MHPAEA.

5.3. Participants, Beneficiaries, and Enrollees Receiving Mental Health and Substance Use Disorder Treatment

There are approximately 56,984,000 participants and 50,407,000 beneficiaries in ERISA-covered group health plans with 50 or more participants,²⁰⁸ approximately 17,483,000 participants and approximately 14,854,000 beneficiaries in non-Federal governmental plans with 50 or more participants,²⁰⁹ approximately 10,258,000 participants and 8,629,000 beneficiaries in ERISA covered, non-grandfathered, fully insured health plans with less than 50

participants,²¹⁰ and approximately 12,000,000 individual health insurance coverage policyholders (with approximately 16,000,000 total enrollees).²¹¹

Since the enactment of MHPAEA, participants have increasingly utilized behavioral health services through their health coverage. Between 2007 and 2017, private insurance claim lines for behavioral health diagnoses increased by 320 percent.²¹² Claims data show that between 2013 and 2019, the percentage of the employment-based coverage population under the age of 65 diagnosed with major depressive disorder increased from 4.1 percent to 5.3 percent, and the percentage of the population diagnosed with anxiety increased from 4.8 percent to 8.1 percent.²¹³ In 2020, 41 million Americans who were enrolled in employment-based coverage, including 6 million children, received mental health support, which constituted nearly 25 percent of employment-based health plan participants and beneficiaries.²¹⁴ A 2022 survey by SAMHSA indicated that among adults aged 18 or older, 23.1 percent (or 59.3 million people) had any mental illness and 6.0 percent (or 15.4 million people) had serious mental illness in the past year. The same survey also indicated that among individuals aged 12 or older,

17.3 percent (or 48.7 million people) had a substance use disorder in the past year, and of those only 14.9 percent (7.3 million people) received treatment for substance use disorder in the past year.²¹⁵

The COVID-19 public health emergency (PHE) exacerbated the need for mental health and substance use disorder treatments. During the pandemic, many adults consistently reported anxiety and depressive disorders symptoms, with 4 in 10 adults reporting symptoms in February 2021. Two years later in 2023, even as the pandemic receded from its peak, approximately 3 in 10 adults were still reporting symptoms of anxiety and depression.²¹⁶ The pandemic likewise negatively impacted the mental health of children and adolescents, worsening reported rates of anxiety or depression which, in the 5 years preceding the pandemic, had already increased by 29 percent and 27 percent, respectively.²¹⁷

The pandemic may have long-term effects on mental health and substance use disorders, suggesting that the number of individuals affected by expanding access through their health plans will only continue to grow. A 2022 study examined the chronic effects of the pandemic on the mental health of Veterans and found that COVID-19 survivors were associated with a higher risk of developing mental health disorders, including anxiety, stress, depression, substance use, and neurocognitive decline, compared to individuals who did not have COVID-19.²¹⁸ Another 2022 study examined the mental health outcomes of COVID-19 survivors during the 12 months following their infection and found that COVID-19 survivors reported a high prevalence of depression, anxiety, and post-traumatic stress disorder at both the 6- and 12-months follow-up, indicating that the pandemic has long-term adverse mental health impacts on

²¹⁰ The Departments estimate that there are 12,212,484 participants and 10,272,985 beneficiaries in fully insured, private-sector health plans with less than 50 participants based on the Departments' tabulations of the March 2022 CPS Auxiliary Data (<https://www.dol.gov/agencies/ebsa/researchers/data/auxiliary-data>). Assuming, based on KFF assumptions that 84 percent of participant and beneficiaries are in non-grandfathered plans (KFF, 2020 Employer Health Benefits Survey (Oct. 8, 2020), <https://files.kff.org/attachment/Report-Employer-Health-Benefits-2020-Annual-Survey.pdf>), this will translate into an estimated 10,258,487 participants and 8,629,307 beneficiaries in fully insured, private-sector, non-grandfathered plans with less than 50 participants.

²¹¹ Based on MLR reports submitted by issuers for the 2022 reporting year, the number of policyholders in individual health insurance coverage offered in the individual market is approximately 12 million and the number of enrollees was approximately 16,000,000. CMS, *Medical Loss Ratio Data and System Resources* (2022), <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr>.

²¹² Robin Gelburd, *The Mental Health Parity Act: 10 Years Later*, *American Journal of Managed Care* (Nov. 22, 2018), <https://www.ajmc.com/view/the-mental-health-parity-act-10-years-later>.

²¹³ Paul Fronstin & Christopher Roebuck, *How Do High-Deductible Health Plans Affect Use of Health Care Services and Spending Among Enrollees with Mental Health Disorders?*, EBRI Issue No. 555 Figure 3 (Mar. 10, 2022), https://www.ebri.org/docs/default-source/ebri-issue-brief/ebri_ib_555_mentalhealth-10mar22.pdf?sfvrsn=aec3b2f_2.

²¹⁴ AHIP, *How Employer-Provided Coverage Improves Access to Mental Health Support* (May 2022), https://www.ahip.org/documents/202205-CaW_MentalHealth-v03.pdf.

²¹⁵ SAMHSA, *Key Substance Use and Mental Health Indicators in the United States: Results from the 2022 National Survey on Drug Use and Health*, pp. 33, 51–52 (Nov. 2023), <https://www.samhsa.gov/data/sites/default/files/reports/rpt42731/2022-nsduh-nnr.pdf>.

²¹⁶ Nirmita Panchal, Heather Saunders, Robin Rudowitz, & Cynthia Cox, *The Implications of COVID-19 for Mental Health and Substance Use*, KFF Issue Brief (Mar. 20, 2023), <https://www.kff.org/coronavirus-covid-19/issue-brief/the-implications-of-covid-19-for-mental-health-and-substance-use/>.

²¹⁷ Kristen Figas, Theodoros V. Giannouchos, & Elizabeth Crouch, *Child and Adolescent Anxiety and Depression Prior to and During the COVID-19 Pandemic in the United States*, 24 *Child Psychiatry & Human Development* pp. 1–11 (2023).

²¹⁸ Yan Xie, Evan Xu, & Ziyad Al-Aly, *Risks of Mental Health Outcomes in People with Covid-19: Cohort Study*, 376 *The BMJ* (2022), <https://www.bmj.com/content/376/bmj-2021-068993>.

²⁰⁸ The Departments have not identified what share of plans with 50 or more participants offer mental health or substance use disorder benefits and so has assumed that all of these plans offer them. The Departments estimate that there are 56,983,874 participants and 50,407,439 beneficiaries in ERISA-covered group health plans with 50 or more participants. Estimates are based on the Departments' tabulations of the March 2022 Current Population Survey (CPS) Auxiliary Data (<https://www.dol.gov/agencies/ebsa/researchers/data/auxiliary-data>).

²⁰⁹ The Departments have not identified what share of plans with 50 or more participants offer mental health or substance use disorder benefits and so has assumed that all of these plans offer them. The Departments estimate that there are 17,482,879 participants in non-Federal governmental plans with 50 or more participants. Estimates are based on the Departments' tabulations of the March 2022 CPS Auxiliary Data (<https://www.dol.gov/agencies/ebsa/researchers/data/auxiliary-data>).

COVID-19 survivors.²¹⁹ Finally, a 2023 study found that the pandemic resulted in a long-term increase in the number of psychiatric inpatient admissions, suggesting that there is a post-pandemic need to prioritize psychiatric care.²²⁰

6. Studies Examining the Impact of MHPAEA and State Parity Laws

6.1. Research Examining the Impact of State Parity Laws

6.1.1. Research Finding State Parity Laws Increase the Utilization of Mental Health and Substance Use Disorder Care

Research has found mixed evidence on the impact of State parity laws prior to the implementation of MHPAEA. While the specifics of the State-level programs might be different from MHPAEA, this research can nonetheless provide important context and suggestive evidence for how modifications to parity policies such as the MHPAEA program²²¹ might impact healthcare demand and quality. While some studies did not identify a significant change in costs or usage of behavioral health treatments following the passage of State parity laws, others found that State parity laws increased the utilization of mental health care and substance use disorder care among populations at risk.

For example, a 2006 study evaluated changes in mental health care utilization before and after States implemented parity laws, comparing them with States that did not enact such laws in the same year controlling for State and year fixed effects. Using data from the 2001, 2002, and 2003 NSDUH, the study categorized individuals with individual or employer-sponsored health insurance by their level of mental and emotional distress during their most challenging month in the past year and found that State parity laws increased the likelihood of using any mental health care in the past year by up to 1.2 percentage points for individuals with lower distress levels and up to 1.8

percentage points for those with moderate distress levels. However, it is important to note that the study did not find a statistically significant effect on the mental health care utilization for individuals with severe distress levels. The authors noted that this group had already been more likely to use mental health care even before the State parity laws were implemented, suggesting they may have sought such care regardless of these laws.²²²

Similarly, a 2008 study examined whether State parity laws affect mental health care utilization differently among low-income individuals and those with poor mental health conditions. To examine these effects, the study used pooled cross-sectional data from the National Survey of America's Families conducted in 1997, 1999, and 2001 and found that employees of small firms were more likely to use mental health and substance use disorder care after the implementation of State parity laws. While the study found no effect of parity for low-income adults for all employers, when limiting the sample to small employers, the study found that parity was associated with a 5-percentage-point increase in the probability of low-income individuals using mental health services. The study also found a large increase among those with poor mental health conditions employed by small employers, although this finding is only significant at a 10-percent significance level. The study did not find an effect for individuals with poor mental health for medium or large employers. The authors attributed these inconclusive results to the small sample size; therefore, the findings in this study should be interpreted with caution.²²³

Additionally, a 2013 study examined the effect of State parity laws on substance use disorder treatment using national survey data from 2000 to 2008 using State and year fixed effects to compare non-parity States to parity States prior to the implementation of MHPAEA. The authors reported that the baseline substance use disorder treatment rate before State parity laws were enacted was 1.40 percentage points in all specialty substance use disorder treatment facilities and 1.10 percentage points in facilities accepting private insurance. Relative to these

baseline rates, this study found that the implementation of any parity law increased the treatment rate by 9 percent in all specialty substance use disorder treatment facilities and by 15 percent in all treatment facilities accepting private insurance. When controlling for the comprehensiveness of the State parity law, the study found that full parity²²⁴ and parity-if-offered²²⁵ increased the substance use disorder treatment rate in all facilities by 13 percent and 8 percent, and by 21 percent and 10 percent in those accepting private insurance, respectively; States with partial parity²²⁶ did not have a significant effect on the substance use disorder treatment rates. The study conducted sensitivity analyses for facilities not accepting private insurance and found no difference in the treatment rates attributable to parity, suggesting that the effect of parity on the treatment rate is primarily driven by the increased treatment rate among the target population.²²⁷

6.1.2. Research Finding State Parity Laws Have Other Positive Effects

Other studies have found that State parity laws have positive effects that extend beyond the use of mental health care. For example, a 2013 study comparing suicide rates in States with and without parity laws during two distinct periods: 1990 to 1997 and 1998 to 2004, the period when the majority of States (22 out of 29) had implemented parity laws. The study found that State parity laws were associated with a 5-percent decrease in suicide rates, even after subjecting the analysis to several robustness checks.²²⁸

Similarly, a 2022 study examined how State parity laws affected suicide rates and educational outcomes among college-level students. Utilizing survey

²²⁴ The study defined "full parity" as "requiring SUD [substance use disorder] coverage to be offered and offered on par with the comparable medical/surgical coverage in all aspects of cost sharing and treatment limitations."

²²⁵ The study defined "parity-if-offered" as "not requiring SUD coverage to be offered, but if offered, it should be on par with the comparable medical/surgical coverage in all aspects of cost sharing and treatment limitations."

²²⁶ The study defined "partial parity" as "requiring SUD coverage to be offered, allows for discrepancies between SUD coverage and comparable medical/surgical coverage in some aspects of cost sharing and treatment limitations."

²²⁷ Hefei Wen, Janet R. Cummings, Jason M. Hockenberry, Laura M. Gaydos, & Benjamin G. Druss, *State Parity Laws and Access to Treatment for Substance Use Disorder in the United States: Implications for Federal Parity Legislation*, 70(12) *JAMA Psychiatry* pp. 1355–1362 (2013).

²²⁸ Matthew Lang, *The Impact of Mental Health Insurance Laws on State Suicide Rates*, 22(1) *Health Economics* pp. 73–88 (2013).

²¹⁹ Mario G. Mazza, Mariagrazia Palladini, Rebecca De Lorenzo, Beatrice Bravi, Sara Poletti, Roberto Furlan, Fabio Ciceri, Patrizia Rovere-Querini, & Francesco Benedetti, *One-Year Mental Health Outcomes in a Cohort of COVID-19 Survivors*, 145 *Journal of Psychiatric Research* pp. 118–124 (2022).

²²⁰ Sean Warwicker, Denise Sant, Adrian Richard, Jake Cutajar, Annalise Bellizzi, Gertrude Micallef, Daniel Refalo, Liberato Camilleri, & Anton Grech, *A Retrospective Longitudinal Analysis of Mental Health Admissions: Measuring the Fallout of the Pandemic*, 20(2) *International Journal of Environmental Research and Public Health* p. 1194 (2023).

²²¹ The "MHPAEA program" refers to the MHPAEA statute, as amended, implementing regulations, and subsequent guidance, as discussed in section IV.3.

²²² Katherine M. Harris, Christopher Carpenter, & Yuhua Bao, *The Effects of State Parity Laws on the Use of Mental Health Care*, 44(6) *Medical Care* pp. 499–505 (2006).

²²³ Susan H. Busch & Colleen L. Barry, *New Evidence on the Effects of State Mental Health Mandates*, *INQUIRY: The Journal of Health Care Organization*, 45(3) *Provision, and Financing* pp. 308–322 (2008).

and administrative data spanning from 1998 to 2008, the study employed a difference-in-differences model and found that State parity laws reduced the suicide rates, increased college grade point averages, and reduced the likelihood of college-level students reporting any poor mental health days. However, the study did not find evidence that State parity laws affect the likelihood of disenrolling from college. These findings remain consistent even after subjecting the analysis to several robustness checks. The authors acknowledged some limitations in the study. Specifically, the reported number of poor mental health days reported is based on self-assessment, rather than on clinical measures. There is also a possibility of underreporting due to the stigma associated with mental health.²²⁹

Finally, a 2015 study examined the effect of State parity laws on individuals aged 25 to 64 with moderate levels of distress.²³⁰ Using individual-level data from the National Health Interview Survey (1997 to 2001) and the Medical Expenditure Panel Survey (1998 to 2003), the study employed a triple-difference model and found a statistically significant increase in employment, weekly wages, and the number of hours worked following the passage of parity. The authors noted that the results do not indicate a shift in the labor demand curve, but rather an increase in the productivity of workers with moderate levels of distress.²³¹

Although the previous three studies suggest mental health outcomes may improve following the initiation of State parity policies, it is not clear from this research the mechanism driving any outcome improvements. Given a lack of data in both studies, the authors cannot directly show that State parity laws increase mental healthcare utilization. The causal impact of these policies, including whether parity would increase mental healthcare utilization, which would in turn improve health outcomes such as the suicide rate, can therefore not be directly ascertained. Absent any utilization increases, it is possible that parity policies could improve the quality of care itself

without additional demand, but further research is needed to answer how specifically parity laws affect downstream health outcomes.

6.1.3. Research Finding State Parity Laws Have Statistically Insignificant Effects

In contrast, some studies have found that State parity laws did not significantly improve access to mental health and substance use disorder care. For instance, a 2000 study focused on patients with mental health needs examined the impact of State parity laws on their insurance coverage, with varying specifications which defined this as insurance status, insurance generosity, and perceived access to care. Using national survey data from 1996 to 1998, the study found no statistically significant impact on insurance coverage or access to care for patients with mental health needs following the passage of State parity laws. The authors attributed this finding to several limitations of the study, including a relatively small sample size which limited the narrowness of State parity laws in terms of impact types of insurance coverage, and the significant number of individuals with mental health or substance use disorders who do not have health insurance coverage. Most significantly, while the study examined the impact of parity laws on access to insurance and care, it was not limited to behavioral health care and so the impact on those interventions may not have been statistically significantly captured.²³²

Furthermore, a 2013 study examined how State parity laws affected access to mental health care services for privately insured children and youths aged three to 17 with ASD. Using national survey data from 2005 to 2006 and adjusting for potential selection bias of States that enacted parity legislation, the study did not find evidence that State parity laws increased the utilization of mental health services for children with ASD. The authors suggested that differences in the availability of services, therapies, and treatments across States could explain this lack of impact, as these children may not benefit from the same protections and service access afforded to children with other mental health conditions under State parity laws. Additionally, the authors acknowledged limitations in their analysis, noting that the study did not provide information on the implementation of State parity

laws. They cautioned that measurement errors could arise due to the potential delayed effects associated with varying implementation timelines of the State parity laws.²³³

6.2. Research Examining the Impact of MHPAEA on Utilization

Several studies have investigated the effect MHPAEA had on utilization of treatment for mental health conditions or substance use disorders. In general, the studies have found either a small or no effect on utilization after the implementation of MHPAEA.

For instance, a 2014 study analyzed pooled data from seven Federal Employees Health Benefits (FEHB) plans, four of which contracted with carve-out plans²³⁴ before and after parity implementation, two implemented carve-out plans when parity took effect, and one was not a carve-out plan. The authors looked at annual utilization, including psychotherapy visits, medication management visits, inpatient mental health or substance use disorder days, and mental health of substance use disorder prescription fills, for three target diagnoses: bipolar disorder, major depression, and adjustment disorder. Using a difference in differences model, the authors found a 12-percent statistically significant decrease in annual psychotherapy utilization for individuals diagnosed with adjustment disorders, and a statistically significant decrease in out-of-pocket spending for enrollees across all three diagnostic categories (ranging from \$78 to \$86) following parity implementation, and found no significant change for all other metrics. The authors opine that the observed decline in psychotherapy utilization may be related to the Office of Personnel Management's encouragement that FEHB plans utilize benefit management techniques to control spending increases following parity implementation.²³⁵

²³³ Lucy A. Bilaver & Neil Jordan, *Impact of State Mental Health Parity Laws on Access to Autism Services*, 64(10) *Psychiatric Services* pp. 967–973 (2013).

²³⁴ Carve-out plans are defined as plans that only administer behavioral health benefits. (See Sarah A. Friedman, Francisca Azocar, Haiyong Xu, & Susan L. Ettner, *The Mental Health Parity and Addiction Equity Act (MHPAEA) Evaluation Study: Did Parity Differentially Affect Substance Use Disorder and Mental Health Benefits Offered by Behavioral Healthcare Carve-Out and Carve-In Plans*, 190 *Drug and Alcohol Dependence* pp. 151–158 (2018).)

²³⁵ Alisa Busch, Frank Yoon, Colleen Barry, Banessa Azzone, Sharone-Lisa Normand, Howard Goldman, & Haiden Huskamp, *The Effects of Parity on Mental Health and Substance Use Disorder Spending and Utilization: Does Diagnosis Matter?* 172(2) *American Journal of Psychiatry* pp. 180–187 (Feb. 2013).

²²⁹ Keisha T. Solomon & Kabir Dasgupta, *State Mental Health Insurance Parity Laws and College Educational Outcomes*, 86 *Journal of Health Economics* (2022).

²³⁰ The author defines “moderately distressed individuals” based on their reported levels of distress in the National Health Interview Survey. The authors categorized “distress” as follows: scores below 1 indicate no distress, 1 to 5 indicate low distress, 6 to 11 indicate moderate distress, and 12 or above indicate severe distress.

²³¹ Martin Andersen, *Heterogeneity and the Effect of Mental Health Parity Mandates on the Labor Market*, 43 *Journal of Health Economics* (2015).

²³² Roland Sturm, *State Parity Legislation and Changes in Health Insurance and Perceived Access to Care Among Individuals with Mental Illness: 1996–1998*, 3(4) *The Journal of Mental Health Policy and Economics* pp. 209–213 (2000).

Along the same lines, a 2016 study used an interrupted time series model to investigate the effect of MHPAEA on the probability of specialty behavioral health treatment, levels of utilization, and expenditures for enrollees aged 27 to 64 in group health plans between 2008 and 2013, with Optum carve-outs. The authors focused on the following outcomes: expenditures (insurer and patient), number of outpatient visits (assessment/diagnostic evaluation, individual psychotherapy, family psychotherapy, and medication management), and number of days of care (structure outpatient, day treatment, residential care, and acute inpatient care). In the post-parity period, 2011 to 2013, the effect of parity differed by type of care: the probability of using any assessment/diagnostic evaluation, medication management, of family psychotherapy visits decreased, while the probability of using structure outpatient care and inpatient care increased. Under multiple specifications and sensitivity tests, the authors found that parity had “modest to no effect on service use.” Though they did find modest evidence that costs shifted from patient to health plans.²³⁶

Similarly, a 2019 study looked at insurance claims of enrollees under age 65 with continuous enrollment in a large group, employer-sponsored fully insured health plan between January 2005 and September 2015 to analyze whether parity implementation was associated with utilization and spending changes in behavioral health services compared to medical/surgical services. Parity had a positive but small, statistically significant impact on the share of enrollees that used any outpatient substance use disorder services. Specifically, parity increased the percentage of enrollees that used any outpatient substance use disorder services by 0.023 percentage points in the first year following the implementation of MHPAEA and 0.068 percentage points by the end of 2015 relative to pre-MHPAEA levels. The authors also found that parity led to an increase in the average frequency of monthly services per user for both mental health and substance use disorder services, at a rate of 0.05 services per user for mental health services and 0.054 services per user for substance use disorder services. This

implies that people receiving services received more services, on average.²³⁷

6.3. Research Examining the Impact of MHPAEA on Spending

Research has found mixed evidence on the impact of MHPAEA on spending. Some studies did not identify a change in out-of-pocket spending following the passage of MHPAEA, whereas others found that MHPAEA increased out-of-pocket spending on substance use disorder care.

For instance, a 2017 study examined whether MHPAEA increased behavioral health expenditures and utilization among a population with substance use disorders. Using Optum’s claims and eligibility data from 2008 to 2013, the authors compared the utilization and expenditures for adults with alcohol or drug use disorders across several periods: pre-parity (2008 to 2009), transition period (2010),²³⁸ and post-parity period (2011 to 2013). They found that for carve-out plans managed by Optum, MHPAEA was associated with modest increases in total spending, plan spending, and patient out-of-pocket spending, as well as outpatient and inpatient utilization. Although the increases were mostly small in magnitude, they were evident across different types of care, potentially indicating small improvements in the accessibility to various substance use disorder treatments.²³⁹ The authors note that these results are similar to other studies, which used the same data when examining adults in carve-in plans and carve-out plans.²⁴⁰

²³⁷ Noah Mulvaney-Day, Brent Gibbons, Shums Alikhan, & Mustafa Karakus, *Mental Health Parity and Addiction Equity Act and the Use of Outpatient Behavioral Health Services in the United States, 2005–2016*, 109(3) American Journal of Public Health pp. 190–196 (2019).

²³⁸ The study defined the “transition” period as “when good-faith efforts at compliance with respect to coinsurance, copayments, combined medical-behavioral health deductibles, and quantitative treatment limits went into effect for plans renewing on a calendar-year basis.”

²³⁹ Sarah Friedman, Haiyong Xu, Jessica M. Harwood, Francisca Azocar, Brian Hurley & Susan L. Ettner, *The Mental Health Parity and Addiction Equity Act Evaluation Study: Impact on Specialty Behavioral Healthcare Utilization and Spending Among Enrollees with Substance Use Disorders*, 80 Journal of Substance Abuse Treatment pp. 67–78 (2017).

²⁴⁰ Harwood, Jessica M., Francisca Azocar, Amber Thalmayer, Haiyong Xu, Michael K. Ong, Chi-Hong Tseng, Kenneth B. Wells, Sarah Friedman, & Susan L. Ettner, *The Mental Health Parity and Addiction Equity Act Evaluation Study: Impact on Specialty Behavioral Health*

Additionally, a 2015 study examined whether MHPAEA was associated with changes in the out-of-network services for substance use disorder services. Using a 2007 to 2012 longitudinal, commercial claims database and employing an interrupted time-series design to analyze these effects, the study found that MHPAEA was associated with an increased probability of using out-of-network services at a rate of 0.0024 service users per month, an increased number of out-of-network outpatient visits at a rate of 0.0016 service users per month, and an increased average total spending on out-of-network services by \$49.81 per user per month, though it was found to have no effect on out-of-pocket spending. This result would represent a shift in expenses borne by the insurer, which might or might not be passed through to the insured through higher premiums, but the study lacked the data to assess this possibility. The authors acknowledged that the study was not able to examine the adequacy of substance use disorder provider networks, which may have influenced enrollees pursuit of out-of-network care.²⁴¹

Finally, a 2014 study examined the impact of MHPAEA on the utilization and spending of substance use disorder treatments. Using 2009 to 2010 administrative claims data from Aetna insurance, the study compared changes in outcomes among health plan enrollees one year before (2009) and one year after (2010) the implementation of MHPAEA, compared to enrollees covered by State parity laws in place prior to MHPAEA. The study found the MHPAEA was associated with a modest increase in spending on substance use disorder treatments (\$9.99 per health plan enrollee), but did not find significant changes in treatment initiation,²⁴² treatment engagement,²⁴³ or out-of-pocket spending. The authors acknowledged that these findings may not be generalizable to other insurance or population contexts, since the study

Utilization and Expenditures Among Carve-Out Enrollees, 50 Journal of Health Economics pp. 131–143 (2016).

²⁴¹ Emma E. McGinty, Susan H. Busch, Elizabeth A. Stuart, Haiden A. Huskamp, Teresa B. Gibson, Howard H. Goldman, & Colleen L. Barry, *Federal Parity Law Associated with Increased Probability of Using Out-Of-Network Substance Use Disorder Treatment Services*, 34(8) Health Affairs pp. 1331–1339 (2015).

²⁴² The study defined “treatment initiation” as the “share of enrollees with a new episode of SUD treatment who initiated treatment within 14 days of their initial diagnosis.”

²⁴³ The study defined “treatment engagement” as the “share of enrollees with a new episode of SUD treatment who receive at least two SUD services within 30 days of their initial diagnosis.”

²³⁶ Susan Ettner, Jessica Harwood, Amber Thalmayer, Michael Ong, Haiyong Xu, Michael Bresolin, Kenneth Wells, Chi-Hong Tseng, & Francisca Azocar, *The Mental Health Parity and Addiction Equity Act Evaluation Study: Impact on Specialty Behavioral Health Utilization and Expenditures Among “Carve-Out” Enrollees*, 50 Journal of Health Economics pp. 131–143 (2016).

evaluated the effects of parity on individuals insured by a single health insurer in 10 States with pre-existing State parity laws. Moreover, the study examined only the first year following MHPAEA's effective date, which may not have fully captured its implementation.²⁴⁴ As discussed in section IV.2.2, the Departments have published regulations and extensive guidance to facilitate the implementation and enforcement of MHPAEA.

7. Benefits

The Departments expect that these final rules will improve the quality of the comparative analyses performed and documented by plans and issuers required by MHPAEA, as amended by the CAA, 2021; help plans and issuers better understand and fulfill their obligations under MHPAEA; and promote greater clarity regarding differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits. By specifying more details on how to perform and document NQTL comparative analyses, the Departments expect improvements in plan and issuer compliance with the requirements for imposing NQTLs under MHPAEA, and by doing so, increased access for participants, beneficiaries and enrollees to mental health and substance use disorder services.

Thus, these final rules will generate the following economic and societal benefits for participants, beneficiaries, and enrollees:

- improved understanding of and compliance with MHPAEA by plans and issuers, resulting in better frameworks for regulators, plans, and issuers to determine whether plans and issuers are complying with MHPAEA with respect to NQTLs applicable to coverage of mental health and substance use disorder benefits,
- greater access and utilization of mental health and substance use disorder services in response to a reduction in barriers to mental health and substance use disorder coverage (the greater utilization being a cost of the rule), resulting in better health outcomes among those with mental health conditions or substance use disorders, and
- reduced adverse impacts on the families, friends, caregivers, and coworkers of people who suffer from untreated or under treated mental health

conditions or substance use disorders based on their improved access to treatment.

This analysis provides a mainly qualitative discussion of the benefits associated with these final rules, as the Departments do not have the data necessary to quantify the likely benefits associated with the additional guidance and its impact on ensuring better compliance with the rules related to NQTLs and access to mental health and substance use disorder benefits. Where possible, however, the Departments have provided estimates to illustrate some of the benefits of these final rules. The illustrative calculations address overlapping phenomena and thus are not summed due to the noteworthy potential for double-counting (moreover, for only a subset of the illustrated benefits have the associated treatment costs been quantified).

In addition, the Departments have identified several transfers that will occur due to this rulemaking, such as decreases in out-of-pocket spending and increases in premiums. These transfers are discussed in section IV.9 of this regulatory impact analysis.

The Departments requested comments and data in the proposed rules related to how the Departments might quantify these benefits. While one commenter stated that the Departments had not quantified the benefits of the proposal, they did not provide any data or recommendations on how these benefits could be quantified. Another commenter suggested that the Congressional Budget Office's (CBO) cost estimate²⁴⁵ of the CAA, 2021 may help the Departments to quantify the benefits of the proposal. However, the CBO report primarily focuses on the program cost of CAA, 2021, rather than addressing the specific impact of the additional requirements for documenting comparative analyses, and therefore the Departments are not able to utilize it for quantifying the benefits of these final rules.

7.1. Improved Understanding of and Compliance With MHPAEA by Plans and Issuers

As noted earlier, the 2022 MHPAEA Report to Congress²⁴⁶ found that none of the comparative analyses reviewed by

the Departments under the first year of the CAA, 2021, contained sufficient information and documentation from plans and issuers upon initial receipt and nearly all were similarly deficient for the 2023 MHPAEA Comparative Analysis Report to Congress.²⁴⁷ As a result, the Departments had to make numerous requests for additional information. This process is costly for plans, issuers, and the Departments, and undermines the effectiveness of MHPAEA.

These final rules will clarify and strengthen the obligations of plans and issuers under MHPAEA, thus promoting compliance, by:

- placing renewed focus on the elimination of more restrictive barriers to access to mental health and substance use disorder benefits as compared to medical/surgical benefits,
- standardizing the definitions associated with the parity analysis for NQTLs applicable to mental health and substance use disorder benefits and medical/surgical benefits,
- providing examples of the application of MHPAEA to NQTLs, and
- setting forth the content and data evaluation requirements of the NQTL comparative analyses.

These final rules will help parties better understand what plans and issuers need to do to comply with MHPAEA, reduce uncertainty about compliance status, and help plans and issuers better identify areas they need to improve upon as well as reduce the need to revise analyses upon the Departments identifying non-compliance. In the course of implementing these final rules, the Departments anticipate that parties will adjust their policies and procedures in order to come into compliance and offer better coverage of mental health and substance use benefits to participants, beneficiaries, and enrollees.

Many commenters supported modifying existing definitions and adding new ones to the MHPAEA regulations, particularly for terms such as "medical/surgical benefits," "mental health benefits," and "substance use disorder benefits." Commenters stated that these definitions would significantly improve clarity for plans and issuers. One commenter stated the proposal would clearly specify how mental health and substance use disorder benefits must be defined for MHPAEA compliance purposes, minimize situations where

²⁴⁴ Susan H. Busch, Andrew J. Epstein, Michael O. Harhay, David A. Fiellin, Hyong Un, Deane Leader Jr, & Colleen L. Barry, *The Effects of Federal Parity on Substance Use Disorder Treatment*, 20(1) *The American Journal of Managed Care* (2014).

²⁴⁵ See CBO, *Summary Estimate for Divisions M Through FF, H.R. 133, Consolidated Appropriations Act, 2021* (Pub. L. 116-260), as Enacted on December 27, 2020 (Jan. 14, 2021), https://www.cbo.gov/system/files/2021-01/PL_116-260_Summary.pdf.

²⁴⁶ 2022 MHPAEA Report to Congress, <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2022-realizing-parity-reducing-stigma-and-raising-awareness.pdf>.

²⁴⁷ 2023 MHPAEA Comparative Analysis Report to Congress, www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2023-mhpaea-comparative-analysis.pdf.

contradictions with State guidelines limit protections under MHPAEA, and ensure that plans appropriately classify mental health and substance use disorder benefits and medical/surgical benefits. The Departments acknowledge the supportive comments and agree that modifying and adding definitions, particularly for key terms like “medical/surgical benefits,” “mental health benefits,” and “substance use disorder benefits,” will enhance clarity and ensure consistent application of the MHPAEA requirements across plans and issuers, and have done so in these final rules.

Commenters also expressed support for clarifying the application of MHPAEA’s requirements to NQTLs. One commenter stated that the proposal provides more specificity for plans and issuers to assess their NQTLs applicable to mental health or substance use disorder benefits, and the information that must be included in a comparative analysis of NQTLs applicable to mental health and substance use disorder benefits and medical/surgical benefits. The commenter further stated the proposal reduces uncertainty for all parties, while providing greater clarity for consumers and other stakeholders to assess whether an NQTL is compliant with MHPAEA. Additionally, the commenter stated that the proposal provides greater clarity for insurers and patients and helps State insurance regulators better enforce existing regulations. The Departments acknowledge the supportive comments and agree that the final rules provide clarity to the statutory requirements for the regulated community and other interested parties.

However, some commenters expressed concern regarding whether certain policies and procedures would now be prohibited under MHPAEA, as interpreted through the proposed rules, if finalized. One commenter, in objecting to the proposed mathematical substantially all and predominant tests, stated that the most significant cost is not in conducting the comparative analysis, but rather in the additional expenses incurred should plans and issuers no longer be able to utilize common medical management techniques that improve cost and quality outcomes, such as prior authorization and concurrent review.

As stated earlier in this preamble, the Departments are not finalizing the proposed mathematical test for applying the substantially all and predominant tests in these final rules. These final rules also do not eliminate the use of prior authorization or other medical management NQTLs applicable to both

mental health and substance use disorder benefits and medical/surgical benefits. However, NQTLs applicable to mental health and substance use disorder benefits and medical/surgical benefits must be designed and applied in compliance with MHPAEA’s parity requirements. Moreover, as discussed earlier in this preamble, the Departments anticipate that these final rules will promote changes in network composition and medical management techniques that result in more robust mental health and substance use disorder provider networks, as well as fewer and less restrictive prior authorization requirements for individuals seeking mental health and substance use disorder treatment. While this could increase costs in some cases, there are potential offsetting benefits in other cases for the reduction in the use of medical management techniques.

7.2. Greater Access to Mental Health and Substance Use Disorder Treatments

By improving plan and issuer understanding of the requirements under MHPAEA and clarifying how comparative analyses must be performed and documented, these final rules will improve compliance. Specifically, this will ensure compliance with the design and application requirements and the relevant data evaluation requirements so that NQTLs applied to mental health and substance use disorder benefits are no more restrictive than the predominant limitation applicable to substantially all medical/surgical benefits. The Departments are of the view that this will, in turn, expand access to and utilization of mental health and substance use disorder services. These final rules will have the greatest direct benefits for individuals who currently forego treatments or cannot access specialized care for a mental health condition or substance use disorder because their plan or coverage imposes barriers to accessing benefits for coverage of these services that are greater than the barriers for accessing medical/surgical services.

The Departments do not have sufficient data to estimate how many participants, beneficiaries, and enrollees will receive treatment, or more appropriate treatment, as a result of these final rules. However, research has demonstrated that participants, beneficiaries, and enrollees experienced increased access to mental health and substance use disorder treatments following the implementation of MHPAEA. Drawing on these studies, the Departments expect that this rulemaking, in further improving

compliance with MHPAEA, will result in significant improvements in access to mental health and substance use disorder care.

For example, a 2018 study examined how MHPAEA affected the coverage of commercial health plans in the United States. The study found that between 2010²⁴⁸ and 2014, 68 percent of insurance products had expanded behavioral health coverage, and among plans that expanded services, 96 percent reported it was in part because of parity requirements.²⁴⁹ Further, a 2017 study examined the prevalence of behavioral health quantitative treatment limitations in large group health plans that utilized carve-out and carve-in services of a single service provider. While prior to implementation of MHPAEA, quantitative treatment limitations existed, following its implementation virtually all of those plans had eliminated quantitative treatment limitations.²⁵⁰ A 2019 study of claims data from both a pre-parity (January 2005 through December 2010) and post-parity period (January 2011 through September 2015), found that while MHPAEA did not appreciably increase the share of participants utilizing any outpatient mental health services, it did increase the frequency of use and total utilization of outpatient mental health and substance use disorder services of participants already receiving these services.²⁵¹ Moreover, a 2020 study of MHPAEA, using 2007 and 2011 to 2012 data from the National Survey of Children’s Health, found that among children and adolescents with family income between 150 and 400 percent of the Federal poverty level in States without prior parity laws, the enactment of MHPAEA resulted in a 2.8-percentage-point increase in mental health care utilization.²⁵²

²⁴⁸ The effective date for MHPAEA for calendar year plans is January 1, 2010. See CMS, *The Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA)* (2010).

²⁴⁹ Dominic Hodgkin, Constance M. Horgan, Maureen T. Stewart, Amity E. Quinn, Timothy B. Creedon, Sharon Reif, & Deborah W. Garnick, *Federal Parity and Access to Behavioral Health Care in Private Health Plans*, 69(4) *Psychiatric Services* pp. 396–402 (2018).

²⁵⁰ Thalmayer, Amber Gayle, Sarah A. Friedman, Francisca Azocar, Jessica M. Harwood, & Susan L. Ettner, *The Mental Health Parity and Addiction Equity Act (MHPAEA) Evaluation Study: Impact on Quantitative Treatment Limits*, 68(5) *Psychiatric Services* pp. 435–442 (2017).

²⁵¹ Norah Mulvaney-Day, Brent J. Gibbons, Shums Alikhan, & Mustafa Karakus, *Mental Health Parity and Addiction Equity Act and the Use of Outpatient Behavioral Health Services in the United States, 2005–2016*, 109(S3) *American Journal of Public Health* pp. S190–S196 (2019).

²⁵² Xiaoxue Li & Jie Ma, *Does Mental Health Parity Encourage Mental Health Utilization Among Children and Adolescents? Evidence From the 2008*

These final rules will directly benefit individuals who are currently enrolled in a plan with narrower networks, with regard to mental health and substance use disorder benefits compared to the networks for medical/surgical benefits, which prevent participants, beneficiaries, and enrollees from being able to access care from in-network providers and receive the benefits they need. A 2017 study of ACA Marketplace provider networks found that mental health networks were significantly narrower on average than primary care networks, providing less than half the share of providers practicing within a State-level market.²⁵³ A 2023 secret shopper study conducted by the Senate Committee on Finance contacted 10 providers from directories of 12 plans, making a total of 120 calls. The study found that more than 80 percent of mental health providers contacted were either unreachable, not in-network, or not accepting new patients.²⁵⁴

Ghost or phantom networks—collections of providers and facilities that are listed as being within a plan's or issuer's network but, in fact, are not available to participants, beneficiaries, and enrollees for treatment on an in-network basis—make it difficult for participants to find in-network providers.²⁵⁵ One 2020 national survey of privately insured individuals that received mental health treatment found that more than half of those patients that used a provider directory encountered inaccuracies which made them more likely to be treated by an out-of-network provider, and four times as likely to receive a surprise, out-of-network bill.²⁵⁶

In response to the Departments' proposal, numerous commenters stated that they believed the proposed rules would benefit patients, specifically by improving access to mental health and substance use disorder treatments. Several commenters stated the proposed

rules would ensure more equitable access to care by addressing burdensome administrative practices, such as NQTLs and other utilization management techniques, which negatively impact patient access to mental health and substance use disorder benefits. Additionally, many other commenters suggested that the enhanced clarity and transparency provided by the proposed rules would alleviate administrative burdens and, as such, help to streamline access to behavioral health care. The Departments acknowledge these supportive comments and agree that the final rules will increase access to mental health and substance use disorder treatments.

Given those concerns highlighted by commenters regarding challenges related to accessing mental health substance use disorder benefits, the final rules particularly highlight parity in NQTLs related to network composition as an area that requires improvement. By requiring plans and issuers to collect and evaluate relevant data on provider networks, including for network composition NQTLs, the final rules will help to ensure that individuals have more equitable access to in-network providers that are available to provide care for mental health conditions and substance use disorders. Additionally, by ensuring that plans and issuers collect and evaluate data related to NQTLs for network composition for mental health and substance use disorder benefits and medical/surgical benefits, and as necessary address material differences in access between these benefits, the Departments expect that the final rules will improve the ability of participants, beneficiaries, and enrollees to access available in-network mental health and substance use disorder providers. Thus, the final rules will reduce barriers to accessing mental health and substance use disorder care.

This discussion focuses on the benefits for participants, beneficiaries, and enrollees who were previously prevented from receiving mental health or substance use disorder treatment. For a discussion of the effects on participants, beneficiaries, and enrollees who were previously paying out-of-pocket for treatment, refer to section IV.9.1 of this regulatory impact analysis pertaining to transfers.

The implementation of the CAA, 2023 provision that sunsets the MHPAEA opt-out election is expected to reduce financial and non-financial barriers to accessing mental health and substance use disorder treatment for participants and beneficiaries of self-funded non-Federal governmental plans that elected

to opt out of requirements under MHPAEA. This is expected to result in increased access to mental health and substance use disorder care and, as discussed in more detail in the section IV.7.3, lead to better health outcomes for plan participants and beneficiaries who need mental health or substance use disorder services.

7.3. Better Health Outcomes Among Those With Mental Health Conditions and Substance Use Disorders

The Departments are of the view that by ensuring parity in medical management techniques and other NQTLs imposed by plans and issuers, the final rules will reduce barriers for participants, beneficiaries, and enrollees seeking mental health and substance use disorder care. As discussed later in this regulatory impact analysis, the removal of barriers preventing individuals from accessing mental health and substance use disorder treatment on par with medical/surgical treatment will in turn produce better patient outcomes, including potentially lives saved.

Research has demonstrated that MHPAEA has already had a positive effect on improving access to treatment. A 2016 study examining the initial effects of MHPAEA found that following implementation, prior authorization requirements were less common for behavioral health care services than in previous years.²⁵⁷ Further, removal of treatment limitations has had significant beneficial impacts in the mental health and substance use disorder space. A 2013 study, which analyzed changes in suicide rates by age groups before and after State parity laws were enacted, found that, controlling for State-specific time trends, enactment of parity laws was associated with a 5-percent decrease in suicides.²⁵⁸ It is worth noting, however, that State parity laws do not apply to most self-funded employer-sponsored health coverage, which comprise a large portion of the population in States affected by these final rules. As such, the impact of the laws in that study may have been somewhat dampened. For a more detailed description of this study, see section IV.6.1.

If, as the Departments expect, these final rules similarly increase access to mental health and substance use

Mental Health Parity and Addiction Equity Act (MHPAEA), 47(1) *The Journal of Behavioral Health Services & Research* pp. 38–53 (2020).

²⁵³ Jane M. Zhu, Yuehan Zhang, & Daniel Polsky, *Networks in ACA Marketplaces are Narrower for Mental Health Care than for Primary Care*, 36(9) *Health Affairs* pp. 1624–1631 (Sept. 2017).

²⁵⁴ Senate Committee on Finance Majority, *Majority Study Findings: Medicare Advantage Plan Directories Haunted by Ghost Networks* (2023), <https://www.finance.senate.gov/imo/media/doc/050323%20Ghost%20Network%20Hearing%20-%20Secret%20Shopper%20Study%20Report.pdf>.

²⁵⁵ GAO, *Mental Health Care: Access Challenges for Covered Consumers and Relevant Federal Efforts*, GAO–22–104597 (Mar. 2022), <https://www.gao.gov/assets/gao-22-104597.pdf>.

²⁵⁶ Susan H. Busch & Kelly A. Kyanko, *Incorrect Provider Directories Associated with Out-of-Network Mental Health Care and Outpatient Surprise Bills*, 39(6) *Health Affairs* pp. 975–983 (June 2020).

²⁵⁷ Constance M. Horgan, Dominic Hodgkin, Maureen T. Stewart, Amity Quinn, Elizabeth L. Merrick, Sharon Reif, Deborah W. Garnick, & Timothy B. Creedon, *Health Plans' Early Response to Federal Parity Legislation for Mental Health and Addiction Services*, 67(2) *Psychiatric Services* pp. 162–168 (2016).

²⁵⁸ Matthew Lang, *The Impact of Mental Health Insurance Laws on State Suicide Rates*, 22(1) *Health Economics*, pp. 73–88 (2013).

disorder care, the potential benefits could be significant. Using the suicide fatality rate for adults in 2021 from the Centers for Disease Control and Prevention (CDC) of approximately 14.1 per 100,000 persons²⁵⁹ and the 2020 Agency for Healthcare Research and Quality youth suicide fatality rate of approximately 6.3 per 100,000,²⁶⁰ and applying these rates to the numbers of individuals 12 years old and older with private health insurance,²⁶¹ suggests approximately 22,200 suicide deaths annually for adults²⁶² and 979 suicide deaths annually for children 12–17 years old.²⁶³ For illustrative purposes, the Departments assume that these final rules would have roughly 40 percent of the impact of the Lang study, or a 2-percent reduction of fatalities.²⁶⁴ As such, the Departments estimate that the final rules could help prevent 444 adult²⁶⁵ and 20 youth²⁶⁶ fatalities from suicide annually. Using the 2023 estimate of the value of a statistical life (VSL) developed by the U.S. Department of Transportation (DOT), \$13.2 million,^{267 268} this would translate into

²⁵⁹ CDC, National Center for Health Statistics, *Provisional Estimates of Suicide by Demographic Characteristics: United States, 2022*, Report No. 34 (Nov. 2023), <https://www.cdc.gov/nchs/data/vsrr/vsrr034.pdf>.

²⁶⁰ Agency for Healthcare Research and Quality, *2022 National Healthcare Quality and Disparities Report, Child and Adolescent Mental Health* (Oct. 2022), <https://www.ncbi.nlm.nih.gov/books/NBK587174/>.

²⁶¹ Based on the Departments' tabulations of adults with non-Federal employer-sponsored insurance (ESI) and/or private health insurance (15.74 million) and the number of children 12–17 with non-Federal ESI and/or private health insurance (15.5 million) off the March 2022 CPS Auxiliary Data (<https://www.dol.gov/agencies/ebsa/researchers/data/auxiliary-data>).

²⁶² The estimate is calculated as follows: 157,443,601 participants with commercial health insurance $\times$ 0.014-percent adult suicide fatality = 22,200 adult suicide fatalities.

²⁶³ The estimate is calculated as follows: 15,541,261 children aged 12–17 with private health insurance $\times$ 0.0063-percent suicide fatalities = 979 fatalities.

²⁶⁴ This estimate of a 2-percent reduction is based on the estimate of 5 percent previously cited, revised downward by 60 percent to account for the indirect impact of the final rule on access, compared to the initial introduction of mental health parity laws. See Matthew Lang, *The Impact of Mental Health Insurance Laws on State Suicide Rates*, 22(1) Health Economics, pp. 73–88 (2013).

²⁶⁵ The estimate is calculated as follows: 22,200 fatalities from suicide $\times$ 2-percent reduction in suicides = 444 fatalities prevented.

²⁶⁶ The estimate is calculated as follows: 979 fatalities from suicide $\times$ 2-percent reduction in suicides = 20 fatalities prevented.

²⁶⁷ DOT, *Departmental Guidance on Valuation of a Statistical Life in Economic Analysis*, effective May 7, 2024, <https://www.transportation.gov/office-policy/transportation-policy/revised-departmental-guidance-on-valuation-of-a-statistical-life-in-economic-analysis>.

²⁶⁸ The VSL utilized by the Departments in this analysis is one of several VSLs estimated by Federal

benefits of \$6.11 billion annually.^{269 270} The Departments recognize the uncertainty in the production of VSL benefit estimates. This uncertainty arises from a variety of assumptions that are key to the VSL estimate, such as the underlying demographic characteristics of the affected population or the differential willingness-to-pay for statistically equivalent but qualitatively different risks.²⁷¹ To account for potential sensitivity arising from such uncertainty, the Departments have conducted a sensitivity analysis of these benefits and, following guidance on VSL sensitivity analysis,²⁷² produced a lower and upper estimate of the VSL of approximately \$5.3 million and \$18.5 million, respectively.²⁷³ Utilizing this range of estimates, the Departments accordingly estimate the value of the benefits of reduced mortality arising from increased mental health treatment utilization at between \$2.5 billion and \$8.6 billion annually.²⁷⁴

These benefits further illustrate the value of receiving treatment earlier and the harms of delaying treatment. While 75 percent of mental illness onsets before age 25, individuals between age 18 and 25 have a considerably higher

agencies, all of which vary slightly in their estimated VSL. The HHS VSL in 2024 is \$13.1 million. More information on the HHS VSL can be found in *HHS Standard Values for Regulatory Analysis*, 2024 (Jan. 25, 2024) at <https://aspe.hhs.gov/sites/default/files/documents/cd2a1348ea0777b1aa918089e4965b8c/standard-ria-values.pdf>.

²⁶⁹ This estimate is calculated as follows: 444 adult fatalities prevented $\times$ 20 youth fatalities prevented $\times$ \$13,200,000 VSL = \$6,124,800,000.

²⁷⁰ Some methodological approaches to the VSL apply a distinct, and often higher, value to children. While the Departments do not utilize such an approach here, they recognize this estimate may undervalue the true benefits as the final rules' effects include a risk reduction of fatality to minor children.

²⁷¹ Individuals express a different willingness to pay to reduce the fatality risk of some deaths (those with a perceived associated morbidity, such as cancer) more than others (such as car accidents), though the risks may be equivalent. DOT guidance on the VSL suggests utilizing a single, nationwide value that does not adjust the VSL based on the nature of the risk or the underlying characteristics of the affected population but encourages a sensitivity analysis to reflect such uncertainty.

²⁷² For more information on the VSL guidance utilized, see the DOT's *Revised Departmental Guidance on Valuation of a Statistical Life in Economic Analysis*, <https://www.transportation.gov/office-policy/transportation-policy/revised-departmental-guidance-on-valuation-of-a-statistical-life-in-economic-analysis>.

²⁷³ The lower and upper bounds are estimated as 40 percent below and above the central estimate of \$13,200,000, per DOT guidance on conducting a sensitivity analysis for a VSL estimate.

²⁷⁴ These estimates are calculated as: The lower VSL estimate of \$5,280,000 $\times$ 464 fatalities prevented = \$2,447,665,113. The lower VSL estimate of \$18,480,000 $\times$ 464 fatalities prevented = \$8,566,827,999.

prevalence of serious mental illness²⁷⁵ than any other age group but the lowest rate of mental health treatment.^{276 277} Moreover, research suggesting that early symptom onset is associated with elevated risk for comorbid mental health disorders, as well as worsening health outcomes, illustrates the critical need for early mental health interventions and treatment access.^{278 279} However, the majority of adolescents with a mental health condition do not receive treatment.²⁸⁰ One review of recent changes in mental health treatment noted that “young people typically demonstrate a need for care prior to reaching the threshold for a traditional

²⁷⁵ Serious mental illness is defined as a “mental, behavioral, or emotional disorder resulting in serious functional impairment, which substantially interferes with or limits one or more major life activities.” (See National Institute of Health, *Mental Illness*, <https://www.nimh.nih.gov/health/statistics/mental-illness>)

²⁷⁶ Peter J. Uhlhaas, Christopher G. Davey, Urvakhsh Meherwan Mehta, Jai Shah, John Torous, Nicholas B. Allen, Shelli Avenevoli, Tolulope Bella-Awusah, Andrew Chanen, Eric Y. H. Chen, Christoph U. Correll, Kim Q. Do, Helen L. Fisher, Sophia Frangou, Ian B. Hickie, Matcheri S. Keshavan, Kerstin Konrad, Francis S. Lee, Cindy H. Liu, Beatriz Luna, Patrick D. McGorry, Andreas Meyer-Lindenberg, Merete Nordentoft, Dost Öngür, George C. Patton, Tomáš Paus, Ulrich Reininghaus, Akira Sawa, Michael Schoenbaum, Gunter Schumann, Vinod H. Srihari, Ezra Susser, Swapna K. Verma, T. Wilson Woo, Lawrence H. Yang, Alison R. Yung & Stephen J. Wood, *Towards a Youth Mental Health Paradigm: A Perspective and Roadmap*, *Molecular Psychiatry* 28, 3171–3181 (2023).

²⁷⁷ SAMHSA, *Key Substance Use and Mental Health Indicators in the United States: Results from the 2022 National Survey on Drug Use and Health* (2023), <https://www.samhsa.gov/data/sites/default/files/reports/rpt42731/2022-nsduh-nnr.pdf>.

²⁷⁸ Ronald C. Kessler, Patricia Berglund, Olga Demler, Robert Jin, Kathleen R. Merikangas, & Ellen E. Walters, *Lifetime Prevalence and Age-of-Onset Distributions of DSM-IV Disorders in the National Comorbidity Survey Replication*, 62(6) *Arch Gen Psychiatry* pp. 593–602 (2005).

²⁷⁹ Peter J. Uhlhaas, Christopher G. Davey, Urvakhsh Meherwan Mehta, Jai Shah, John Torous, Nicholas B. Allen, Shelli Avenevoli, Tolulope Bella-Awusah, Andrew Chanen, Eric Y.H. Chen, Christoph U. Correll, Kim Q. Do, Helen L. Fisher, Sophia Frangou, Ian B. Hickie, Matcheri S. Keshavan, Kerstin Konrad, Francis S. Lee, Cindy H. Liu, Beatriz Luna, Patrick D. McGorry, Andreas Meyer-Lindenberg, Merete Nordentoft, Dost Öngür, George C. Patton, Tomáš Paus, Ulrich Reininghaus, Akira Sawa, Michael Schoenbaum, Gunter Schumann, Vinod H. Srihari, Ezra Susser, Swapna K. Verma, T. Wilson Woo, Lawrence H. Yang, Alison R. Yung & Stephen J. Wood, *Towards a Youth Mental Health Paradigm: A Perspective and Roadmap*, *Molecular Psychiatry* 28, 3171–3181 (2023).

²⁸⁰ Kathleen Ries Merikangas, Jian-ping He, Marcy E. Burstein, Joel Swendsen, Shelli Avenevoli, Brady Case, Katholiki Georgiades, Leanne Heaton, Sonja Swanson, & Mark Olfson, *Service Utilization for Lifetime Mental Disorders in U.S. Adolescents: Results of the National Comorbidity Survey Adolescent Supplement*, 50(1) *Journal of the American Academy of Child Adolescent Psychiatry*, pp. 32–45 (2011), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4408275>.

major psychiatric diagnosis where distress, functional impairment and warning signs . . . of mental illness are present, making early intervention at this time point crucial to preventing or reducing the severity of a full-threshold disorder.”²⁸¹ Further, this review noted that early intervention is key for reducing “premature death, social isolation, poor functioning and reduced educational and vocational productivity.” In recent years, research has driven an increased interest in early intervention services for younger individuals.²⁸²

Mental health research often evaluates the benefits of mental health care in terms of a quality-adjusted life year (QALY), an assessment metric that evaluates the changes to a person’s quality of life arising from an intervention. According to the National Institute for Health and Care Excellence, one QALY “is equal to 1 year of life in perfect health.”²⁸³ In 2015 New York City launched a program called ThriveNYC, which included 54 initiatives to improve mental health, including additional screening and collaborative care. The study found that, on average, a 20-year-old who received these interventions would see an increase of 0.38 QALYs (representing a change in quality of life, with no estimation in this study of changes to length of life) relative to those who did not receive these interventions.²⁸⁴

Another study compared the cost effectiveness of early intervention to standard care for the treatment of first-episode psychosis, finding that from a societal perspective (that is, quality of life, educational attainment, and gainful employment), early intervention resulted in higher discounted QALYs and lower costs than standard care. While acknowledging that earlier interventions result in higher lifetime costs than the standard care perspective, the authors still found early intervention to be cost effective.²⁸⁵

The Departments do not anticipate the benefits to be exclusive to prevented suicides. The final rules are also expected to increase access to and utilization of behavioral health services and substance use disorder services.²⁸⁶ The 2022 NSDUH from SAMHSA indicates that 1.4 percent of adults with private health insurance reported having an OUD in the past year, while only 29 percent of those individuals indicated receiving treatment for OUD in the same year.²⁸⁷ A 2017 study utilizing claims and eligibility data from nearly 6 million enrollees found that parity resulted in a 17 percent increase in use of OUD treatment services, which illustrates a strong, positive relationship between parity and the utilization of behavioral health services.²⁸⁸ As discussed in section IV.6.1.3, there have been findings of positive or no impact of MHPAEA on the utilization of mental health and substance use disorder services. For illustrative purposes, the Departments assume that these final rules would have roughly 40 percent of the impact of the 2017 study, or an approximately 7 percent increase in OUD treatment service utilization.²⁸⁹ This would result in approximately 43,000 additional individuals receiving OUD treatment each year.²⁹⁰

²⁸⁶ Constance M. Horgan, Dominic Hodgkin, Maureen T. Stewart, Amity Quinn, Elizabeth L. Merrick, Sharon Reif, Deborah W. Garnick, & Timothy B. Creedon, *Health Plans Early Response to Federal Parity Legislation for Mental Health and Addiction Services*, 62(2) *Psychiatric Services* pp. 162–168 (2016).

²⁸⁷ SAMHSA, Center for Behavioral Health Statistics and Quality, *National Survey on Drug Use and Health, 2021 and 2022*, <https://www.samhsa.gov/data/data-we-collect/nsduh-national-survey-drug-use-and-health>.

²⁸⁸ Sarah Friedman, Haiyong Xu, Jessica M. Harwood, Francisca Azocar, Brian Hurley, & Susan L. Ettner, *The Mental Health Parity and Addiction Equity Act Evaluation Study: Impact on Specialty Behavioral Healthcare Utilization and Spending Among Enrollees with Substance Use Disorders*, 80 *Journal of Substance Abuse Treatment* pp. 67–78 (2017).

²⁸⁹ This estimate of a 7 percent reduction is based on the estimate of 17 percent previously cited, revised downward by 60 percent to account for the indirect impact of expanded parity associated with these final rules. See Sarah Friedman, Haiyong Xu, Jessica M. Harwood, Francisca Azocar, Brian Hurley, & Susan L. Ettner, *The Mental Health Parity and Addiction Equity Act Evaluation Study: Impact on Specialty Behavioral Healthcare Utilization and Spending Among Enrollees with Substance Use Disorders*, 80 *Journal of Substance Abuse Treatment* pp. 67–78 (2017).

²⁹⁰ This estimate is calculated as follows: 157,443,601 adult participants with private health insurance $\times$ 1.4 percent indicate OUD in past year = 2,125,489 adults with private health insurance and OUD. Then, 2,125,489 $\times$ 29 percent receiving treatment = 616,817 adults with OUD and private health insurance receiving treatment annually. Lastly, 616,817 $\times$ 6.98 percent increase in adults with private health insurance receiving treatment = 43,054 additional adults receiving treatment for OUD annually.

Considerable research has demonstrated the efficacy of treatment for OUD,^{291 292 293 294 295 296 297} including several recent studies that have observed the reduction of both fatal and non-fatal overdoses for people diagnosed with OUD after receiving treatment. For example, an 18-month observational study of multiple cohorts of people receiving OUD treatments across the United States between 2017 and 2021 found that following outpatient treatment for OUD, the number of patient overdoses, arrests, and drug-related hospitalizations were all reduced by over 50 percent.²⁹⁸ Similarly, a 2024 retrospective study of opioid overdose fatalities found that individuals who recently received treatment for OUD experienced approximately 34 percent to 38 percent fewer overdose deaths compared to those who did not receive treatment.²⁹⁹

²⁹¹ SAMHSA, *Medications for Opioid Use Disorder: For Healthcare and Addiction Professionals, Policymakers, Patients, and Families* (2021), <https://store.samhsa.gov/sites/default/files/pep21-02-01-002.pdf>.

²⁹² National Academies of Sciences, Engineering, and Medicine, *Medications for Opioid Use Disorder Save Lives* (2019), Washington, DC: The National Academies Press.

²⁹³ Nisha Nataraj, S. Michaela Rikard, Kun Zhang, Xinyi Jiang, Gery P. Guy Jr, Ketra Rice, Christine L. Mattson, R. Matthew Gladden, Desiree M. Mustaquim, Zachary N. Ilg, Pujia Seth, Rita K. Noonan, & Jan L. Losby, *Public Health Interventions and Overdose-Related Outcomes Among Persons with Opioid Use Disorder*, 7(4) *JAMA Network Open* (2024).

²⁹⁴ Nora D. Volkow, Thomas R. Frieden, Pamela S. Hyde, & Stephen S. Cha, *Medication-Assisted Therapies—Tackling the Opioid Overdose Epidemic*, 370(22) *New England Journal of Medicine* (2014), <https://www.nejm.org/doi/full/10.1056/NEJMp1402780>.

²⁹⁵ Robert P. Schwartz, Jan Gryczynski, Kevin E. O’Grady, Joshua M. Sharfstein, Gregory Warren, Yngvild Olsen, Shannon G. Mitchell, & Jerome H. Jaffe, *Opioid Agonist Treatments and Heroin Overdose Deaths in Baltimore, Maryland, 1995–2009*, 103(5) *American Journal of Public Health* pp. 917–922 (2013), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3670653>.

²⁹⁶ SAMHSA, *TIPS 63: Medications for Opioid Use Disorder* (2021), <https://store.samhsa.gov/sites/default/files/pep21-02-01-002.pdf>.

²⁹⁷ National Academies of Sciences, Engineering, and Medicine, *Medications for Opioid Use Disorder Save Lives*, Washington, DC: The National Academies Press (2019), <https://doi.org/10.17226/25310>.

²⁹⁸ Jill A. Dever, Marci F. Hertz, Laura J. Dunlap, John S. Richardson, Sara Beth Wolicki, Bradley B. Biggers, Mark J. Edlund, Michele K. Bohm, Didier Turcios, Xinyi Jiang, Hong Zhou, Mary E. Evans, Gery P. Guy, Jr., *The Medications for Opioid Use Disorder Study: Methods and Initial Outcomes from an 18-Month Study of Patients in Treatment for Opioid Use Disorder*, *Public Health Reports* pp. 1–10 (2024), <https://pubmed.ncbi.nlm.nih.gov/38268479/>.

²⁹⁹ Robert Heimer, Anne C. Black, Hsiuju Lin, Lauretta E. Grau, David A. Fiellin, Benjamin A. Howell, Kathryn Hawk, Gail D’Onofrio, & William C. Becker, *Receipt of Opioid Use Disorder Treatment Prior to Fatal Overdoses and*

²⁸¹ Patrick D. McGorry & Christina Mei, *Early Intervention in Youth Mental Health: Progress and Future Directions*, 21(4) *Evidence Based Mental Health* pp. 182–184 (2018).

²⁸² *Ibid.*

²⁸³ National Institute of Health and Care Excellence, *Glossary*, <https://www.nice.org.uk/glossary>.

²⁸⁴ Boshen Jiao, Zohn Rosen, Martine Bellanger, Gary Belkin, & Peter Muennig, *The Cost-Effectiveness of PHQ Screening and Collaborative Care for Depression in New York City*, *PLoS One* 12(8):e0184210 (Aug. 31, 2017), <https://pubmed.ncbi.nlm.nih.gov/28859154/>.

²⁸⁵ Saadia Sediqzadah, Allison Portnoy, Jane J. Kim, Matcheri Keshavan, & Ankur Pandya, *Cost-Effectiveness of Early Intervention in Psychosis: A Modeling Study*, 73(9) *Psychiatric Services* pp. 961–1080 (2022).

A 2021 study funded by the National Institute on Drug Abuse (NIDA) found that, across a nationally representative cohort of individuals with OUD, common treatments for OUD were associated with a reduction in the number of overdoses by 11 to 21 percent, with an average reduction of 16 percent across all treatment types.³⁰⁰ This study assessed the effects of all three FDA-approved medications for OUD in various combinations with and without the most common treatments (psychotherapy, contingency management, and overdose education and naloxone distribution).³⁰¹ Utilizing life tables, clinical data, and relevant literature on treatment outcomes, the study produced a dynamic compartmental model to analyze the effects of medications and treatments on overdoses and mortality. While it is limited by the scope and availability of relevant secondary data, the model employs parameters, robustness checks, and sensitivity analysis that sufficiently validate the empirical model.

To illustrate the potential impact of these final rules, the Departments employ this lower estimate of a 16 percent reduction in overdoses following treatment, and estimate that increased treatment for expanded OUD access and utilization could result in the prevention of approximately 730 non-fatal overdoses each year.^{302 303} Utilizing

data from the CDC estimating the average medical and non-medical cost of non-fatal overdoses,³⁰⁴ the Departments estimate the benefits of these reduced non-fatal overdoses at \$16.4 million annually.^{305 306 307}

The benefits of individuals diagnosed with an OUD receiving treatment may go beyond the benefit of reduced harms from overdoses. Mortality data of individuals diagnosed with an OUD indicate overdoses comprise approximately half of fatalities for such individuals, who are increasingly at risk of death from infectious disease, common co-morbid conditions such as liver or heart disease, accidental deaths, suicide, and other physical traumas.³⁰⁸ Research indicates that individuals with an OUD that are receiving treatment, while still at increased risk from all-

individuals receiving medication for OUD)) $\times$ 100,000 = 10,860 per 100,000 non-fatal overdose rate for those with OUD. (See Nisha S. Nataraj, Michaela Rikard, Kun Zhang, Xinyi Jiang, Gery P. Guy, Ketra Rice, Christine L. Mattson, Matthew Gladden, Desiree M. Mustaqim, Zachary N. Illg, Puja Seth, Rita K. Noonan, & Jan L. Losby, *Public Health Interventions and Overdose-Related Outcomes Among Persons with Opioid Use Disorder*, Supplement 1, eTable 9, 7(4) Substance Use and Addiction (2024).)

³⁰⁴ Non-medical costs of non-fatal overdoses are derived from work loss costs and monetized quality-adjusted life loss per injury. Medical costs of non-fatal overdoses are derived from healthcare provider payments that include inpatient, outpatient, and outpatient drug costs.

³⁰⁵ Cora Peterson, Ketra L. Rice, Dionne D. Williams, & Robert Thomas, *WISQARS Cost of Injury for Public Health Research and Practice*, 29(2) Injury Prevention (Nov. 2022).

³⁰⁶ The average cost of non-fatal overdose requiring hospitalization = \$19,256 average associated QALY non-medical cost per hospitalization + \$33,026 average associated medical cost per hospitalization = \$52,282 per non-fatal overdose hospitalization. The average cost of non-fatal overdose requiring only treatment and release = \$3,254 average associated QALY non-medical cost per treatment and release + \$9,614 associated medical cost per treatment and release = \$12,868 per non-fatal overdose requiring only treatment and release. (See Cora Peterson, Ketra L. Rice, Dionne D. Williams, & Robert Thomas, *WISQARS Cost of Injury for Public Health Research and Practice*, 29(2) Injury Prevention (Nov. 2022).)

³⁰⁷ The estimate is calculated as follows: 730 non-fatal overdoses prevented $\times$ 24.36 percent overdose hospitalization rate = 178 non-fatal overdose hospitalizations prevented. \$52,282 per non-fatal overdose hospitalization $\times$ 178 non-fatal overdose hospitalizations prevented = \$9,304,598. Additionally, 730 non-fatal overdoses $\times$ 75.64 percent overdose treatment and release rate = 552 non-fatal overdose treatment and releases prevented. \$12,868 per non-fatal overdose requiring treatment and release $\times$ 552 non-fatal overdoses requiring treatment and release = \$7,109,073. As such, the total benefit estimate related to non-fatal overdoses is calculated as: \$9,304,598 + \$7,109,073 = \$16,413,671.

³⁰⁸ Elizabeth Evans, Libo Li, Jeong Min, David Huang, Darren Urada, Lei Liu, Yih-Ing Hser, & Bohdan Nosyk, *Mortality Among Individuals Accessing Pharmacological Treatment for Opioid Dependence in California, 2006–2010*, *Addiction* 110(6): 996–1005 (June 2015).

cause mortality compared to the general population, may experience a reduced risk of mortality after receiving treatment for their OUD condition.^{309 310} One study found that mortality rates were 35 percent lower for individuals that received treatment for OUD than for those who did not receive treatment.^{311 312} This retrospective cohort study used expansive, linked public health, medical, and vital statistics data from a single State to establish a robust population cohort of individuals with OUD for which mortality was the observed outcome over approximately 45,000 person-years following an initial detox episode. While a potential limitation of observational studies is the presence of confounding variables distorting measured outcomes, the breadth of the data being utilized, which included data from insurance claims and extensive medical histories, limit this concern. The findings of the study, indicating a high all-cause and overdose-related mortality rate for individuals with OUD and resultant decline following treatment, are consistent with other research findings and, as an observational cohort study, represent a high level of evidence.^{313 314}

³⁰⁹ Marc Larochelle, Dana Bernson, Thomas Land, Thomas Stopka, Na Wang, Ziming Xuan, Sarah Bagley, Jane Liebschutz, Alexander Walley, *Medication for Opioid Use Disorder After Nonfatal Opioid Overdose and Association with Mortality: A Cohort Study*, *Ann Intern Med* 169(3): 137–145 (2018), <https://pubmed.ncbi.nlm.nih.gov/29913516/>.

³¹⁰ Yih-Ing Hser, Larissa J. Mooney, Andrew J. Saxon, Karen Miotto, Douglas S. Bell, Yuhui Zhu, Di Liang, and David Huang, *High Mortality among Patients with Opioid Use Disorder in a Large Healthcare System*, *J Addict Med* 11(4): 315–319 (2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5930020/>.

³¹¹ The reduction in all-cause mortality was calculated as the change in the crude mortality rate per 100 person-years from 1.94 (for those not receiving any treatment) to 1.27 (for those receiving either MOUD treatment, inpatient treatment, or both). Thus, the percentage change in the rates from 1.94 per 100 person-years to 1.27 per 100 person-years is approximately 35 percent.

³¹² Alexander Walley, Sara Lodi, Yijing Li, Dana Bernson, Hermik Babakhanlou-Chase, Thomas Land, & Marc R. Larochelle, *Association Between Mortality Rates and Medication and Residential Treatment After Inpatient Medically Managed Opioid Withdrawal: A Cohort Analysis*, 115(8) *Addiction* pp. 1496–1508 (Aug. 2020).

³¹³ Marc Larochelle, Dana Bernson, Thomas Land, Thomas Stopka, Na Wang, Ziming Xuan, Sarah Bagley, Jane Liebschutz, Alexander Walley, *Medication for Opioid Use Disorder After Nonfatal Opioid Overdose and Association with Mortality: A Cohort Study*, *Ann Intern Med* 169(3): 137–145 (2018), <https://pubmed.ncbi.nlm.nih.gov/29913516/>.

³¹⁴ Yih-Ing Hser, Larissa J. Mooney, Andrew J. Saxon, Karen Miotto, Douglas S. Bell, Yuhui Zhu, Di Liang, and David Huang, *High Mortality among Patients with Opioid Use Disorder in a Large Healthcare System*, *J Addict Med* 11(4): 315–319

Comparison to No Treatment in Connecticut, 2016–2017, Drug and Alcohol Dependence (2024), <https://pubmed.ncbi.nlm.nih.gov/38043226/>.

³⁰⁰ The Departments averaged the reduction in overdoses arising from four treatment outcomes against the baseline of no treatment: Medicated-Assisted Treatment (MAT) only, MAT in addition to Contingency Management (CM), MAT in addition to Psychotherapy (PT), as well as MAT in addition to both CM and PT. (See Michael Fairley, Keith Humphreys, Vilija R. Joyce, Mark Bounthavong, Jodie Trafton, Ann Combs, Elizabeth M. Oliva, Jeremy D. Goldhaber-Fiebert, Steven M. Asch, Margaret L. Brandeau, & Douglas K. Owens, *Cost-Effectiveness of Treatments for Opioid Use Disorder*, 78(7) *JAMA Psychiatry* pp. 767–777 (2021), <https://pubmed.ncbi.nlm.nih.gov/33787832/>.)

³⁰¹ Outcomes related to overdose education and naloxone distribution were not used in estimating the impacts of OUD treatment in the final rule, as naloxone is a common over-the-counter product not intended to treat OUD, but rather reverse an opioid overdose. While it may help to reduce overdoses and OUD-related fatalities, it is not a “treatment” per se and as such, is not considered when estimating the benefits of treatment.

³⁰² This estimate is calculated as follows: 43,054 additional adults receiving treatment for OUD $\times$ (10,860 per 100,000 non-fatal overdose rate for those with OUD) = 4,676 non-fatal overdoses. 4,676 non-fatal overdoses $\times$ 15.6 percent reduction = 730 non-fatal overdoses prevented.

³⁰³ The Departments utilized the nonfatal overdose rate calculated for 2023 to produce these estimates. Specifically, this calculation was derived from the data supplement, eTable 9, as (1,927,706 non-fatal overdoses in 2023 + (16,072,360 individuals with OUD in 2023 + 1,677,988

Employing this estimate of an approximately 35 percent reduction in fatalities following treatment to illustrate the potential impact of these final rules, the Departments estimate that increased treatment for expanded OUD access and utilization could result in the prevention of approximately 702 fatalities from all causes in persons receiving treatment for OUD each year.³¹⁵ The Departments have utilized the VSL, as with their estimate of the value of prevented suicides, to estimate the benefits of reduced mortality arising from increased OUD treatment utilization at \$9.3 billion annually.³¹⁶ As discussed earlier in this section, the Departments recognize some uncertainty in the production of VSL benefit estimates.³¹⁷ To account for potential sensitivity arising from such uncertainty, the Departments have conducted a sensitivity analysis of these benefits and, following guidance on VSL sensitivity analysis,³¹⁸ produced a lower and upper estimate of the VSL of approximately \$5.3 million and \$18.5 million, respectively.³¹⁹ Utilizing this range of estimates, the Departments accordingly estimate the value of the benefits of reduced mortality arising from increased OUD treatment

(2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5930020/>.

³¹⁵ This estimate is calculated as: 43,054 additional beneficiaries receiving treatment for OUD $\times$ 4.70 crude mortality rate per 100 person-years for OUD = 2,024 expected fatalities in the absence of treatment. Adjusting the crude mortality rate downward 34.7 percent to 3.07 following treatment for this group, the expected fatalities would be estimated as 43,054 additional beneficiaries receiving treatment for OUD $\times$ 3.07 crude mortality rate per 100 person-years for OUD = 1,322 expected fatalities following treatment. As such, the Departments estimate the prevented fatalities from all causes arising from OUD treatment to be: 2,024 – 1,322 = 702 prevented fatalities.

³¹⁶ This estimate is calculated as: the value of a statistical life of \$13,200,000 $\times$ 702 prevented fatalities = \$9,269,545,489.

³¹⁷ Individuals express a different willingness to pay to reduce the fatality risk of some deaths (those with a perceived associated morbidity, such as cancer) more than others (such as car accidents), though the risks may be equivalent. DOT guidance on the VSL suggests utilizing a single, nationwide value that does not adjust the VSL based on the nature of the risk or the underlying characteristics of the affected population but encourages a sensitivity analysis to reflect such uncertainty.

³¹⁸ For more information on the VSL guidance utilized, see The DOT's *Revised Departmental Guidance on Valuation of a Statistical Life in Economic Analysis*, <https://www.transportation.gov/office-policy/transportation-policy/revised-departmental-guidance-on-valuation-of-a-statistical-life-in-economic-analysis>.

³¹⁹ The lower and upper bounds are estimated as 40 percent below and above the central estimate of \$13,200,000, per DOT guidance on conducting a sensitivity analysis for a VSL estimate.

utilization at between \$3.7 billion and \$13.0 billion annually.³²⁰

Mental health and substance use disorders do not always occur in isolation, but are commonly co-occurring conditions, as individuals with substance use disorders are more likely to experience a mental health condition than the general population and nearly half of adults with serious mental illness also have a substance use disorder.³²¹ Such co-occurring conditions can significantly exacerbate the severity of symptoms as well as negative health outcomes related to these conditions.³²² Additionally, individuals with mental health conditions and substance use disorders are known to commonly experience physical co-morbidities that can significantly impact overall health and quality of life. A 2011 study indicated that over 68 percent of adults with a mental health disorder reported a comorbid medical disorder while 29 percent indicated they had another comorbid mental health condition.³²³ Human immunodeficiency virus (HIV), hepatitis, and diabetes are all more prevalent among those with substance use disorders or mental health conditions than the general population, while such physical or other mental comorbid conditions are more likely to be adversely impacted by poor disease management and treatment adherence when co-occurring with a mental health condition or substance use disorder.^{324 325 326 327 328 329} A 2022 study

³²⁰ These estimates are calculated as: The lower VSL estimate of \$5,280,000 $\times$ 702 fatalities prevented = \$3,707,818,196. The lower VSL estimate of \$18,480,000 $\times$ 702 fatalities prevented = \$12,977,363,685.

³²¹ SAMHSA, *Key Substance Use and Mental Health Indicators in the United States: Results from the 2022 National Survey on Drug Use and Health* (Nov. 2023), <https://www.samhsa.gov/data/sites/default/files/reports/rpt42731/2022-nsduh-nnr.pdf>.

³²² Beth Han, Wilson Compton, Carlos Blanco, & Lisa Colpe, *Prevalence, Treatment, and Unmet Treatment Needs of US Adults with Mental Health and Substance Use Disorders*, 36(10) *Health Affairs* pp. 1739–1747 (2017), <https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.2017.0584>.

³²³ Benjamin Druss & Elizabeth Walker, *Mental Disorders and Medical Comorbidity*, Research Synthesis Report No. 21, Robert Wood Johnson Foundation (Feb. 2011), <https://up2riverside.org/wp-content/uploads/2024/04/medical-comorbidity.pdf>.

³²⁴ Elizabeth C. Verna, Aaron Schluger, & Robert S. Brown Jr., *Opioid Epidemic and Liver Disease*, 1(3) *JHEP Report* pp. 240–255 (Sept. 2019), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7001546/pdf/main.pdf>.

³²⁵ T. Jake Liang & John W. Ward, *Hepatitis C in Injection-Drug Users—A Hidden Danger of the Opioid Epidemic*, 378(13) *New England Journal of Medicine* pp. 1169–1171 (Mar. 2018), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5993680/pdf/nihms972424.pdf>.

³²⁶ Alain K. Koyama, A. Hora, Kai McKeever Bullard, Stephen R. Benoit, Shichao Tang, & Pyone

observing the presence of comorbid conditions for inpatient hospitalizations found that 81 percent of hospitalizations for a mental health condition or substance use disorder had a co-morbid condition.³³⁰ The study also found that co-morbid conditions were associated with a longer hospitalization period, a higher cost per hospitalization, as well as increased mortality during hospitalization.³³¹

As mental health conditions and substance use disorders can make preventing, managing, and treating physical comorbidities difficult, improvements in mental health and substance use disorder outcomes may also improve overall physical health outcomes and lower healthcare costs for participants.^{332 333} Data from Evernorth Health Services, a subsidiary of Cigna, indicates that accessing mental health and substance use disorder services can result in considerable cost savings for patients diagnosed with a mental health condition and substance use disorder concern, producing a reported cost savings of between \$1,134 to \$3,321 per person over the first 27 months

Cho, *State-Specific Prevalence of Depression Among Adults With and Without Diabetes—United States, 2011–2019*, 20(70) *Preventing Chronic Disease* (Aug. 2023), https://www.cdc.gov/pcd/issues/2023/pdf/22_0407.pdf.

³²⁷ United Nations Office on Drugs and Crime, *Comorbidities in Drug Use Disorders* (Mar. 2022), https://www.unodc.org/documents/drug-prevention-and-treatment/UNODC_Comorbidities_in_drug_use_disorders.pdf.

³²⁸ National Institute on Drug Abuse, *Common Comorbidities with Substance Use Disorders Research Report* (Apr. 2020), <https://www.ncbi.nlm.nih.gov/books/NBK571451/>.

³²⁹ Stephen Magura, Andrew Rosenblum, & Chunki Fong, *Factors Associated with medication Adherence among Psychiatric Outpatients at Substance Abuse Risk*, *Open Addict J.* 4(4), 58–64 (Nov. 2011), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3526017/>.

³³⁰ Pamela Owens, Lan Liang, Marguerite Barrett, and Kathryn Fingar, *Comorbidities Associated with Adult Inpatient Stays, 2019*. Agency for Healthcare Research and Quality, Healthcare Cost and Utilization Project, Statistical Brief #303 (Dec. 2022).

³³¹ Pamela Owens, Lan Liang, Marguerite Barrett, and Kathryn Fingar, *Comorbidities Associated with Adult Inpatient Stays, 2019*. Agency for Healthcare Research and Quality, Healthcare Cost and Utilization Project, Statistical Brief #303 (Dec. 2022).

³³² United Nations Office on Drugs and Crime, *Comorbidities in Drug Use Disorders* (Mar. 2022), https://www.unodc.org/documents/drug-prevention-and-treatment/UNODC_Comorbidities_in_drug_use_disorders.pdf.

³³³ Wayne Katon, Joan Russo, Elizabeth H.B. Lin, Julie Schmittdiel, Paul Ciechanowski, Evette Ludman, Do Peterson, Bessie Young, & Michael Von Korff, *Cost-Effectiveness of a Multi-Condition Collaborative Care Intervention: A Randomized Controlled Trial*, 69(5) *Archives of General Psychiatry* (May 2012), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3840955/pdf/nihms521136.pdf>.

following diagnosis.³³⁴ Similarly, a 2012 study of patients with a mental health condition and comorbid physical health condition found that treating the underlying mental health condition yielded significant improvements in the comorbid physical conditions, resulting in increased positive health outcomes and lower long-term healthcare costs.³³⁵ The Departments, in evaluating the impacts of these final rules, anticipate that, by prohibiting inequitable barriers to coverage, the estimated improvements in mental health conditions and substance use disorders will help reduce the severity of comorbid conditions, improve related health outcomes for participants, beneficiaries, and enrollees, and as such, represent a substantial, but potentially unquantified, benefit.

7.4. Reduced Adverse Impacts on the Families, Friends, Caregivers, and Coworkers of People Who Suffer From Untreated or Poorly Managed Mental Health Conditions and Substance Use Disorders

These final rules will help employees, caregivers and their families meet their mental health and substance use disorder care needs, and thus, may improve the productivity and resulting earnings of workers dealing with mental health conditions and substance use disorder. Among adults with any mental health condition in 2022, only 50.6 percent received treatment.³³⁶ Moreover, while 19.4 percent of NSDUH respondents 12 and older were classified as needing substance use disorder treatment in 2022, only 4.6 percent of respondents 12 and older indicated that they received treatment that year.³³⁷ One survey found that more than 85 percent of individuals that did not receive their needed mental

health or substance use care reported negative impacts, including personal relationship issues, job issues and performing poorly or dropping out of school.³³⁸

The economic impact of untreated mental health conditions and substance use disorders can be significant. A 2021 study of claims data for large, self-funded health plans looked at the economic burden attributable to major depressive disorder, including the direct costs associated with treatment, suicide-related costs, and workplace costs, between 2010 and 2018. During that period, overall economic burden of adults with a major depressive disorder increased 37.9 percent (from \$236.6 billion to \$326.2 billion). While part of the cost increase can be attributed to a 12.9 percent increase in the number of adults with major depressive disorders, direct costs became a smaller share of the total costs, with workplaces costs, defined as missed work (due to injury/illness, discretionary time off and disability) and lower productivity while at work, constituting 61 percent of the costs in 2018 and increasing from \$48.3 billion in 2010 to \$70.8 billion in 2018.³³⁹ A 2015 study examined the impact of State parity laws on individuals with moderate levels of mental distress and found that State parity laws were associated with an increase in overall employment, weekly wages, and the number of hours worked per week, and attributed these changes to the increased productivity of these workers.³⁴⁰ A 2023 study critically reviewed 38 studies on the relationship between mental health and lost productivity, and found that poor mental health was associated with increased presenteeism³⁴¹ and absenteeism.³⁴²

These final rules will also have significant indirect impacts on families, friends, caregivers, and coworkers with untreated or poorly managed mental

health conditions and substance use disorders, as well as society at large. By prohibiting inequitable barriers to coverage and thereby increasing access to mental health and substance use disorder services, these final rules will lead to more people receiving treatment, reducing the burden on family members and other support systems. For example, this includes untreated maternal mental health conditions, which can lead to a reduced ability to work, increased risk of suicide, increased use of public services, and worse maternal and child health. A 2022 study of the cost of maternal mental health conditions to Texas women and their children projected costs for the 2019 birth cohort from the time of conception through 5 years postpartum to total \$2.2 billion.³⁴³ Untreated maternal mental health conditions include untreated perinatal mood and anxiety disorders, which have been found to account for approximately \$48 million in societal costs in Vermont for the average annual birth cohort from conception through 5 years postpartum, including \$12.5 million in productivity loss and \$9.4 million in non-obstetric health expenditures.³⁴⁴

The cost in missed productivity for workers with fair or poor mental health due to unplanned absences was estimated as \$47.6 billion annually in 2022.³⁴⁵ A 2022 study found that households with a family member diagnosed with a mental health disorder had lower health status scores compared to households without a mental illness diagnosis, suggesting evidence of family spillover effects on mental illness.³⁴⁶ Finally, a 2021 study estimated that the societal costs of untreated OUD was approximately \$1.02 trillion in 2017, which includes \$35 billion in health care costs and \$92 billion in lost productivity.³⁴⁷

³³⁴ Evernorth Health Services, *Behavioral Health Care Significantly Lowers Medical Care Costs* (Jan. 2023), <https://www.evernorth.com/behavioral-health-study>.

³³⁵ Wayne Katon, Joan Russo, Elizabeth H.B. Lin, Julie Schmittdiel, Paul Ciechanowski, Evette Ludman, Do Peterson, Bessie Young, & Michael Von Korff, *Cost-Effectiveness of a Multi-Condition Collaborative Care Intervention: A Randomized Controlled Trial*, 69(5) *Archives of General Psychiatry* (May 2012), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3840955/pdf/nihms521136.pdf>.

³³⁶ SAMHSA, *Key Substance Use and Mental Health Indicators in the United States: Results from the 2022 National Survey on Drug Use and Health*, Figure 62, p. 61 (Nov. 2023), <https://www.samhsa.gov/data/sites/default/files/reports/rpt42731/2022-nsduh-nnr.pdf>.

³³⁷ SAMHSA, *Key Substance Use and Mental Health Indicators in the United States: Results from the 2022 National Survey on Drug Use and Health*, Figures 54 and 55, pp. 50–51 (Nov. 2023), <https://www.samhsa.gov/data/sites/default/files/reports/rpt42731/2022-nsduh-nnr.pdf>.

³³⁸ National Council for Mental Wellbeing, *2022 Access to Care Survey Results* (May 11, 2022), <https://www.thenationalcouncil.org/wp-content/uploads/2022/05/2022-Access-To-Care-Survey-Results.pdf>.

³³⁹ Paul E. Greenberg, Andree-Anne Fournier, Tammy Sisitsky, Mark Simes, Richard Berman, Sarah H. Koenigsberg, & Ronald C. Kessler, *The Economic Burden of Adults with Major Depressive Disorder in the United States (2010 and 2018)*, 39(6) *Pharmacoeconomics* pp. 653–665 (2021).

³⁴⁰ Martin Andersen, *Heterogeneity and the Effect of Mental Health Parity Mandates on the Labor Market*, 43 *Journal of Health Economics* (2015).

³⁴¹ The study defined “presenteeism” as “decreased productivity at work.”

³⁴² Claire de Oliveira, Makeila Saka, Lauren Bone, & Rowena Jacobs, *The Role of Mental Health on Workplace Productivity: A Critical Review of the Literature*, 21(2) *Applied Health Economics and Health Policy* pp. 167–193 (2023).

³⁴³ Caroline Margiotta, Jessica Gao, So O’Neil, Divya Vohra, & Kara Zivin, *The Economic Impact of Untreated Maternal Mental Health Conditions in Texas*, 22(700) *BMC Pregnancy Childbirth* (2022).

³⁴⁴ Isabel Platt, Emma Pendl-Robinson, Eric Dehus, So O’Neil, Divya Vohra, Kara Zivin, Michael Kenny & Laura Pentenrieder, *Estimating the Costs of Untreated Perinatal Mood and Anxiety Disorders in Vermont*, *Mathematica* (May 2023), <https://www.mathematica.org/publications/societal-costs-of-perinatal-mood-and-anxiety-disorders-in-vermont>.

³⁴⁵ Dan Witters & Sangeeta Agrawal, *The Economic Cost of Poor Employee Mental Health*, Gallup Workplace (Dec. 13, 2022), <https://www.gallup.com/workplace/404174/economic-cost-poor-employee-mental-health.aspx?version=print>.

³⁴⁶ Donghoon Lee, Yeonil Kim, & Beth Devine, *Spillover Effects of Mental Health Disorders on Family Members’ Health-related Quality of Life: Evidence from a US Sample*, 42(1) *Medical Decision Making* pp. 80–93 (2022).

³⁴⁷ Curtis Florence, Feijun Luo, & Ketra Rice, *The Economic Burden of Opioid Use Disorder and Fatal*

These final rules are expected to improve access to and utilization of mental health and substance use disorder services by removing barriers to access to mental health and substance use disorder benefits caused by NQTLs. By enhancing treatment for these conditions and disorders, these final rules will likely result in reduced productivity loss or missed workdays for individuals suffering from mental health conditions or substance use disorders. Furthermore, the improved management and treatment of these conditions and disorders will potentially lead to reduced adverse impacts on the families, friends, and coworkers of those affected, as untreated or poorly managed mental health conditions and substance use disorders can have significant spillover effects on an individual's personal and professional lives.

8. Costs

These final rules aim to promote access to mental health and substance use disorder benefits by clarifying how plans and issuers must ensure that their plans and coverage are designed, as written and in operation, to comply with MHPAEA's parity requirements for mental health and substance use disorder benefits and medical/surgical benefits, and allowing them to more easily identify changes needed to bring their plans and coverage into compliance. The Departments acknowledge that plans and issuers, in revising their approach to performing and documenting their already required comparative analyses, will incur additional costs. Moreover, by removing some of the barriers to access to mental health and substance use disorder treatments caused by existing NQTLs, the Departments expect increased utilization of mental health and substance use disorder services, which will also increase costs. This collection of costs would appropriately be included in any comparison with the benefits described, and in some cases illustratively quantified, elsewhere in this regulatory impact analysis.

It is notable that the Departments are clarifying existing requirements, and only the cost burden limited to those additional content elements outlined in these final rules is a key topic discussed in the following sections.

8.1. Comment Summary

In response to the proposal, many commenters expressed concern that the Departments underestimated the burden

of collecting the required data, the burden required in conducting the proposed mathematical substantially all and predominant tests, the number of NQTLs that would need to be analyzed for each plan and issuer, and the amount of time that it would take to conduct those analyses. Commenters stated that in order to comply with the proposed rules, plans and issuers would need to purchase new data systems and hire additional staff or contractors. One commenter further stated that existing systems to provide mental health and substance use disorder benefits, such as carve out plans, would be eliminated under the proposed rule, as vendors would not be able to build networks of mental health and substance use disorder providers in alignment with networks of medical/surgical providers, as required under the proposed special rule for network composition.

Several commenters questioned the Departments' assumptions related to the number of NQTLs for which plans and issuers would need to produce comparative analyses. While the Departments assumed that issuers would impose twice as many NQTLs as plans, several commenters did not think the number of NQTLs would vary between plans and issuers. Commenters also argued that the number of NQTLs that plans and issuers would need to analyze would be roughly twice the Departments' proposed assumption for issuers, 16 NQTLs rather than 8, based on the Departments' descriptions of types of NQTLs listed in the proposed rule. Consistent with the explanation earlier in this preamble, the Departments note that they do not intend to provide an exhaustive list of NQTLs. Plans and issuers may be analyzing a fewer or greater number of NQTLs than the number of NQTLs listed in the illustrative, non-exhaustive list in these final rules.

Commenters also questioned the amount of time that it would take to conduct the NQTL comparative analyses under the proposal. While the Departments assumed that the plans and issuers preparing their own comparative analyses would incur an incremental burden of 10 hours per NQTL in the first year and 4 hours per NQTL in subsequent years, several commenters thought this was an underestimate. For instance, one commenter stated that it currently takes a team of subject matter experts, compliance officials, a project manager, and attorneys or consultants 60 hours in the first year and 12 hours in subsequent years to produce NQTL comparative analyses as required under the CAA, 2021 and current guidance. The commenter suggested that the

added requirements for the comparative analysis under these final rules could require at least an additional 60 hours per NQTL.

Another commenter estimated that the cost to issuers of fully insured plans to conduct the comparative analyses for all NQTLs is approximately between \$200,000 and \$300,000 (200 to 300 external attorney or consultant hours in addition to several hundred in-house staff hours). The commenter also reported that for large, self-funded plans, while issuers and TPAs prepare and distribute baseline comparative analysis, plans would still need to customize the comparative analysis. The commenter estimated that the cost for large self-funded plans to customize the comparative analysis and request additional information and data for all NQTLs is approximately between \$50,000 and \$150,000 (100 to 200 external attorney or consultant hours in addition to in-house staff work). The Departments are not clear whether these suggested costs represent current expenditures or projections of the added requirements for the comparative analyses. The commenter further stated that time and cost estimates for plans with behavioral carve-out vendors should be higher.

In preparing these final rules, the Departments have considered these comments and have clarified the requirements and reevaluated their estimates as appropriate. The specific adjustments to the estimates are discussed in section IV.8.4 of this regulatory impact analysis.

8.2. Commenters' Cost Estimates

As discussed earlier in this regulatory impact analysis, commenters questioned the Departments' assumptions related to the number of NQTLs imposed by plans and issuers on mental health and substance use disorder benefits and medical/surgical benefits, and the amount of time that it would take to conduct the additional requirements for producing comparative analyses and analyzing data, beyond what was required in CAA, 2021. The Departments have reviewed these comments, which include estimates made by those commenters, on the expected additional costs to prepare NQTL comparative analyses under the proposed rules. While these comments are helpful to understand the cost implications of the final rules and how they differ from the proposal, the Departments disagree with some of the inputs and underlying assumptions of these cost estimates and use different assumptions in section IV.8.4 of this regulatory impact analysis. The

commenters' cost estimates do, however, demonstrate a possible upper bound on the costs associated with these final rules.

8.2.1. Association for Behavioral Health and Wellness

The Departments considered estimates and assumptions regarding the costs to prepare the NQTL comparative analyses under the proposed rules made by the Association for Behavioral Health and Wellness (ABHW). ABHW reports that the amendments would require plans and issuers to analyze 15 NQTLs on average. They also reported that it currently takes a team of subject matter

experts, compliance officials, a project manager, and attorneys or consultants 60 hours to prepare each comparative analysis for a typical NQTL as required under the CAA, 2021 and current guidance. Thus, ABHW estimates that a comparable burden (60 hours per NQTL) is needed to review and revise the analyses under the updated requirements in the first year. In addition, they also estimate it would require 12 hours in each subsequent year to produce the comparative analyses. For the purpose of this calculation, the Departments have estimated a composite wage rate of \$167.48, which consist of attorneys,

actuaries, and data analysts.³⁴⁸ Based on these assumptions, and the Departments' estimates of affected entities, this would result in a cost burden of \$984.8 million in the first year and \$197 million in subsequent years, resulting in a 3-year average cost burden of \$459.6 million. See Table 3 for more details.

ABHW also suggested that issuers and plans would need to hire at least three full-time equivalent new staff members to help with the proposed relevant data evaluation requirements. This additional cost was not included in their cost estimates.

TABLE 3—INCREMENTAL COST TO PREPARE THE COMPARATIVE ANALYSES BASED ON THE ASSOCIATION FOR BEHAVIORAL HEALTH AND WELLNESS'S ASSUMPTIONS

	Number of entities (A)	Number of NQTLs per entity (B)	Number of hours per NQTL (C)	Total hour burden (A × B × C)	Hourly wage (D)	Cost (A × B × C × D)
First Year						
Issuers (health insurance company/State combinations)	1,467	15	60	1,320,300	\$167.48	\$221,123,844
TPAs	205	15	60	184,500	167.48	30,900,060
Self-funded plans with more than 500 participants that will conduct a comparative analysis themselves	709	15	60	638,100	167.48	106,868,988
Self-funded plans with more than 500 participants that will receive a generic comparative analysis from TPA or service providers, and will then customize it	4,076	15	30	1,834,200	167.48	307,191,816
Self-funded non-Federal governmental plans with more than 500 participants that will conduct the comparative analysis themselves	505	15	60	454,500	167.48	76,119,660
Self-funded non-Federal governmental plans with more than 500 participants that will initially receive generic comparative analyses from TPAs or service providers, and will then customize it	2,906	15	30	1,307,700	167.48	219,013,596
Plan MEWAs that are not fully insured	132	15	60	118,800	167.48	19,896,624
Non-plan MEWAs that are not fully insured	21	15	60	18,900	167.48	3,165,372
First-year Total	10,021	15		5,877,000		984,279,960
Subsequent Years						
Issuers (health insurance company/State combinations)	1,467	15	12	264,060	167.48	44,224,769
TPAs	205	15	12	36,900	167.48	6,180,012
Self-funded plans with more than 500 participants that will conduct the comparative analysis themselves	709	15	12	127,620	167.48	21,373,798
Self-funded plans with more than 500 participants that will receive a generic comparative analysis from TPAs or service providers, and will then customize it	4,076	15	6	366,840	167.48	61,438,363
Self-funded non-Federal governmental plans with more than 500 participants that will conduct the comparative analysis themselves	505	15	12	90,900	167.48	15,223,932
Self-funded non-Federal governmental plans with more than 500 participants that will initially receive generic comparative analyses from TPAs or service providers, and will then customize it	2,906	15	6	261,540	167.48	43,802,719
Plan MEWAs that are not fully insured	132	15	12	23,760	167.48	3,979,325
Non-plan MEWAs that are not fully insured	21	15	12	3,780	167.48	633,074
Subsequent Years Total	10,021	15		1,175,400		196,855,992
Total (3-year average)	10,021	15		2,742,600		459,330,648

The Departments conducted a sensitivity analysis of the assumption that 50 percent of self-funded plans and another 50 percent of self-funded non-

Federal governmental plans with more than 500 participants will receive a generic comparative analysis from TPAs or service providers, which they will

then need to customize. For every 10-percentage-point increase or decrease in the number of self-funded plans and self-funded non-Federal governmental

³⁴⁸ The wage rate of an attorney, actuary, and data analyst is, respectively, \$165.71, \$177.11, and \$159.61. (Internal DOL calculation based on 2024 labor cost data. For a description of DOL's methodology for calculating wage rates, see EBSA, *Labor Cost Inputs Used in the Employee Benefits*

Security Administration, Office of Policy and Research's Regulatory Impact Analyses and Paperwork Reduction Act Burden Calculations (June 2019), <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.) The composite wage rate is estimated in the following manner: [$\$165.71 \times (1 + 3) + \$159.61 \times (1 + 3) + \$177.61 \times (1 + 3) = \$167.48$].

plans with more than 500 participants that need to customize documentation received from TPAs or service providers, the cost would increase or decrease by \$24.6 million.³⁴⁹

8.2.2. Blue Cross Blue Shield Association

The Blue Cross Blue Shield Association (BCBSA) asked the Departments to specifically quantify the costs of preparing additional comparative analysis beyond the four priority NQTLs outlined in FAQs Part 45. BCBSA stated that based on the

number of NQTLs identified in the regulation, and the additional NQTLs identified in the preamble, the proposed rules would require plans and issuers to prepare comparative analyses for at least 17 NQTLs (7 from the preamble, and 10 from the regulation, counting those related to network composition as 3 separate NQTLs), all with the associated documentation and outcomes data.

BCBSA estimated that the cost of issuers of fully insured plans to conduct the comparative analyses for all NQTLs would range between \$200,000 and \$300,000. BCBSA also estimated the

cost for large self-funded plans that receive a generic comparative analysis from the issuer, which they then need to customize and request additional information and data for all NQTLs referenced in the proposal, is between \$50,000 and \$150,000. BCBSA did not explain if these cost estimates were for all years or were applicable to just the first year. Based on BCBSA's assumptions, and the Departments' estimates of affected entities, this will result in a lower bound cost of \$957.4 million and an upper bound cost of \$2 billion. See Table 4 for more details.

TABLE 4—ANNUAL COSTS TO CONDUCT THE COMPARATIVE ANALYSES FOR ALL NQTLs BASED ON BLUE CROSS BLUE SHIELD ASSOCIATION'S ASSUMPTIONS

	Number of entities (A)	Lower bound cost per entity (B)	Total lower bound cost (A × B)	Upper bound cost per entity (C)	Total upper bound cost (A × C)
Issuers (health insurance company/State combinations)	1,467	\$200,000	\$293,400,000	\$300,000	\$440,100,000
TPAs	205	200,000	41,000,000	300,000	61,500,000
Self-funded plans with more than 500 participants that will conduct the comparative analysis themselves	709	200,000	141,800,000	300,000	212,700,000
Self-funded plans with more than 500 participants that will receive a generic comparative analysis from TPAs or service providers, and will then customize it	4,076	50,000	203,800,000	150,000	611,400,000
Self-funded non-Federal governmental plans with more than 500 participants that will conduct the comparative analysis themselves	505	200,000	101,000,000	300,000	151,500,000
Self-funded non-Federal governmental plans with more than 500 participants that will initially receive generic comparative analyses from TPAs or service providers, and will then customize it	2,906	50,000	145,300,000	150,000	435,900,000
Plan MEWAs that are not fully insured	132	200,000	26,400,000	300,000	39,600,000
Non-plan MEWAs that are not fully insured	21	200,000	4,200,000	300,000	6,300,000
Total	10,021		956,900,000		1,959,000,000

The Departments conducted a sensitivity analysis of the assumption that 50 percent of self-funded plans and another 50 percent of self-funded non-Federal governmental plans with more than 500 participants will receive a generic comparative analysis from the issuer, and will then customize it. For every 10-percentage-point increase or decrease in the number of self-funded plans and self-funded non-Federal governmental plans with more than 500 participants that need to customize documentation received from TPAs or service providers, the cost would increase or decrease by \$34.9 million in the total lower bound cost³⁵⁰ and \$104.7 million in the total upper bound cost.³⁵¹

8.3. Final Amendments to the Existing MHPAEA Regulations (26 CFR 54.9812–1, 29 CFR 2590.712, and 45 CFR 146.136)

As part of these final rules, the Departments have added new definitions, amended existing definitions, and clarified and added new requirements for NQTLs imposed with respect to mental health or substance use disorder benefits. For example, as discussed earlier in this preamble, the final rules clarify that any condition or disorder defined by the plan or coverage as being or as not being a mental health condition or a substance use disorder must be defined consistent with generally recognized independent standards of current medical practice. To be consistent with those generally recognized independent standards of

current medical practice, these final rules state that the plan's or coverage's definition of "mental health benefits" must include all conditions covered under the plan or coverage, except for substance use disorders, that fall under any of the diagnostic categories listed in the mental, behavioral, and neurodevelopmental disorders chapter (or equivalent chapter) of the most current version of the ICD or that are listed in the most current version of the DSM. Similarly, the definition of "substance use disorder benefits" must include all disorders covered under the plan or coverage that fall under any of the diagnostic categories listed as a mental or behavioral disorder due to psychoactive substance use (or equivalent category) in the mental, behavioral, and neurodevelopmental disorders chapter (or equivalent

³⁴⁹ The Departments estimate the 10-percentage-point incremental cost by adding the total cost of self-funded plans and self-funded non-Federal governmental plans that will receive a generic comparative analysis from issuers, TPAs, or service providers and will then customize it (found in Table 3) in the first year and subsequent years, creating a 3-year average cost, and then multiplying the 3-year average cost by 10 percent.

³⁵⁰ The Departments estimate the 10-percentage-point incremental cost in the lower bound by adding the total lower bound cost of self-funded plans and self-funded non-Federal governmental plans that will initially receive a generic comparative analysis from issuers, TPAs, or service providers and will then customize it (found in Table 4) and then multiplying the sum by 10 percent.

³⁵¹ The Departments estimate the 10-percentage-point incremental cost in the upper bound adding the total upper bound cost of self-funded plans and self-funded non-Federal governmental plans that will initially receive a generic comparative analysis from issuers, TPAs, or service providers and will then customize it (found in Table 4) and then multiplying the sum by 10 percent.

chapter) of the most current version of the ICD or that are listed as a Substance-Related and Addictive Disorder (or equivalent category) in the most current version of the DSM.

Under these final rules, plans and issuers are required to collect and evaluate relevant data in a manner reasonably designed to assess the impact of the NQTL on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits. In addition, these final rules require plans and issuers to determine whether the relevant data reflect material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits and take reasonable action, as necessary to address such differences to ensure compliance, in operation, with 26 CFR 54.9812–1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4). Relevant data for all NQTLs could include, as appropriate, but are not limited to, the number and percentage of claims denials and any other data relevant to the NQTL required by State law or private accreditation standards. Additionally, for NQTLs related to network composition, relevant data could include, as appropriate, but are not limited to, in-network and out-of-network utilization rates (including data related to provider claim submissions), network adequacy metrics (including time and distance data, and data on providers accepting new patients), and provider reimbursement rates (for comparable services and as benchmarked to a reference standard).

The proposed rules would have required plans and issuers to apply the proposed mathematical substantially all and predominant tests to each NQTL applicable to mental health or substance use disorder benefits and medical/surgical benefits. As discussed earlier in this preamble, the Departments decline to finalize the proposed mathematical tests for applying the substantially all and predominant tests in these final rules. However, plans and issuers are required to collect and evaluate relevant data for NQTLs applicable to mental health and substance use disorder benefits and medical/surgical benefits under these final rules. For NQTLs related to network composition, plans and issuers must collect and evaluate relevant data in a manner reasonably designed to assess the aggregate impact of all such NQTLs on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits. Under these final rules, the Departments may specify the type, form, and manner for the

relevant data evaluation requirement in future guidance, but for some plans and issuers already subject to existing data requirements under MHPAEA, Federal transparency rules,³⁵² and State law and private accreditation standards, some of the additional data burden associated with this rulemaking will be mitigated.

These final rules could cause plans and issuers to revise their policies and procedures to remove or modify NQTLs in response to the Departments' clarifications and examples. Requirements such as covering meaningful benefits for mental health conditions and substance use disorders (determined in comparison to the benefits provided for medical conditions and surgical procedures); assessing whether the relevant data evaluated suggest that the NQTL contributes to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits; and not using or taking the steps necessary to correct, cure, or supplement the information, evidence, sources, or standards used to inform a factor or evidentiary standard that would have been biased or not objective in the absence of such steps could also cause plans and issuers to revise their policies and procedures.

For example, a 2016 study examined how private health plans responded to the 2010 interim final rules implementing MHPAEA and found that the majority of plans had eliminated quantitative treatment limitations referred to as "special annual limits" related to behavioral health treatments. The percentage of health insurance products with such limits on mental health treatments decreased from 28 percent in 2009 to 4 percent in 2010, and a similar decrease was observed for health insurance products with such limits on substance use disorder treatments (from 26 percent in 2009 to 3 percent in 2010).³⁵³ A 2019 study of claims data from both a pre-parity (January 2005 through December 2010) and post-parity period (January 2011 through September 2015), found that while MHPAEA did not appreciably increase the share of participants utilizing any outpatient mental health services, it did increase the frequency of use and total utilization of outpatient mental health and substance use

disorder services of participants already receiving these services.³⁵⁴

Plans and issuers could incur costs to implement changes associated with revising coverage and plan provisions to ensure that they comply with the requirements of these final rules or ceasing the imposition of an NQTL as directed by the Departments or an applicable State authority after a final determination of noncompliance under Code section 9812(a)(8), ERISA section 712(a)(8), or PHS Act section 2726(a)(8), or 26 CFR 54.9812–2, 29 CFR 2590.712–1, or 45 CFR 146.137, which might result in increased costs from expanded utilization of mental health and substance use disorder services. Recent data suggests that mental health and substance use disorder services account for a small portion of total health care expenditures, representing just 8.4 percent of all expenses in 2021 for individuals with private insurance.³⁵⁵ The Departments face uncertainty in quantifying these costs and did not receive public comments containing data or information to inform these estimates. As such, the Departments cannot estimate the potential increase in utilization and which services might see the largest increase in utilization.

8.3.1. Mitigation in Utilization Costs From Telehealth Expansion

As discussed in section 2 of this regulatory impact analysis, individuals seeking mental health or substance use disorder treatment often face barriers preventing them from accessing care, such as inadequate networks. Telehealth is one method of care that has the potential to improve access to treatment for mental health conditions or substance use disorders, particularly as research has documented that it can be as effective as in-person treatment.³⁵⁶

³⁵⁴ Norah Mulvaney-Day, Brent J. Gibbons, Shums Alikhan, & Mustafa Karakus, *Mental Health Parity and Addiction Equity Act and the Use of Outpatient Behavioral Health Services in the United States, 2005–2016*, 109(S3) Am J Public Health pp. S190–S196 (2019).

³⁵⁵ Agency for Healthcare Research and Quality, *Medical Expenditure Panel Survey, Total Expenditures (\$ in Millions by Condition, United States, 2016 to 2021*, <https://datatools.ahrq.gov/meps-hc?tab=medical-conditions&dash=17>.

³⁵⁶ For example, the following studies found that telehealth treatment was as effective as in-person treatment:

David Turgoose, Rachel Ashwick, & Dominic Murphy, *Systematic Review of Lessons Learned from Delivering Tele-therapy to Veterans with Post-traumatic Stress Disorder*, 24(9) Journal of Telemedicine and Telecare pp. 575–585 (2018); Nyssa Z. Bulkes, Kaley Davis, Brian Kay, & Bradley C. Riemann, *Comparing Efficacy of Telehealth to In-Person Mental Health Care in Intensive-Treatment-Seeking Adults*, 145 Journal of Psychiatric Research pp. 347–352 (2022); Jaime Moreno-Chaparro, Eliana I. Parra Esquivel, Angy Lucia Santos Quintero,

³⁵² 85 FR 72158 (Nov. 12, 2020).

³⁵³ Constance M. Horgan, Dominic Hodgkin, Maureen T. Stewart, Amity Quinn, Elizabeth L. Merrick, Sharon Reif, Deborah W. Garnick, & Timothy B. Creedon, *Health Plans' Early Response to Federal Parity Legislation for Mental Health and Addiction Services*, 67(2) Psychiatric Services pp. 162–168 (2016).

particularly when the treatment is provided through video instead of audio-only.³⁵⁷ These final rules require plans and issuers to collect and evaluate relevant data and, where the relevant data suggest that the NQTL contributes to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits in a classification, to take reasonable action, as necessary, to address the material differences to ensure compliance, in operation, with 26 CFR 54.9812–1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4). One potential reasonable action a plan or issuer could take to address material differences in access with respect to relevant data for NQTLs related to network composition may include expanding the availability of telehealth arrangements to mitigate any overall mental health and substance use disorder provider shortages in a geographic area.

The COVID–19 pandemic sparked increased demand for health care services, including behavioral health services delivered remotely. While in February 2020 telehealth claims accounted for only around 1 percent of claims pertaining to mental health or substance use disorder benefits, by April 2020 they accounted for over 50 percent of the claims and still accounted for approximately 40 percent of claims at the end of 2021.³⁵⁸ The expansion

was significantly aided by the Departments issuing guidance providing time-limited Federal flexibilities for private health plans to expand access to telehealth, which specifically included coverage of treatment for mental health conditions and substance use disorders. These Federal flexibilities included “allowing midyear plan design changes to increase telehealth coverage,” “allowing certain employers to offer coverage only for services provided via telehealth and other remote care services,” and “allowing telehealth coverage pre-deductible” for catastrophic plans and for health savings account-qualified high deductible health plans.³⁵⁹

While the COVID–19 PHE ended on May 11, 2023,³⁶⁰ many of the telehealth flexibilities it allowed were extended under the CAA, 2023 through December 31, 2024.³⁶¹ Additionally, Medicare has permanently adopted policies allowing patients to receive behavioral and mental care through telehealth within their homes,³⁶² and a survey of States indicated that, for Medicaid, “all or most expansions of behavior health providers and/or services allowed for telehealth would be maintained after the public emergency.”³⁶³ For private plans, access to telehealth for mental health and substance use disorder care will depend on plan design.

By nature, telehealth makes accessing treatment for mental health conditions and substance use disorders more convenient for many patients, particularly for those who do not have the ability, time, or means to travel to an appointment or who need care from a provider that specializes in a particular treatment that is not available in their geographic area. Despite observing similar levels of mental

illness and psychiatric disorders in urban residents, one research paper remarked that rural residents face “challenges accessing care systems due to geographic isolation, reduced access to and engagement with appropriate providers, lower socioeconomic status, generally lower levels of educational attainment, as well as reluctance to seek help due to discrimination and stigma.”³⁶⁴ An analysis of 2021 outpatient visits reported that 55 percent of patients in rural areas relied on telehealth for outpatient mental health and substance use services compared to 35 percent in urban areas.³⁶⁵ Given that 73.3 million people in the United States live in a geographic area designated as a mental health professional shortage area, of which 24.4 million resided in a rural area, telehealth is likely to continue to be a necessary means to offset provider network limitations in these areas.³⁶⁶

As with rural populations, many underserved racial, ethnic, cultural minorities, and individuals with disabilities face barriers to receiving treatment for mental health conditions and substance use disorders. These barriers may include language, stigma, or finding a therapist that understands their situation. While important in many areas of health care, many underserved populations prefer to receive treatment for mental health conditions and substance use disorders specifically from a provider with an understanding of their cultural background. A 2022 study found that there was an overall increase in the use and willingness to use video telehealth during the pandemic, with the highest levels of increase being seen among Black adults and adults with lower educational attainment. Certain communities became more willing to use telehealth, since many patients had their first telehealth experience with their trusted health care provider during the pandemic and their positive

Laura Paez, Sandra Martinez Quinto, Bayron Esteven Rojas Barrios, Juan Felipe Samudio, & Karol Madeline Romero Villareal, *Telehealth Interventions Aimed at Parents and Caregivers of Children Living in Rural Settings: A Systematic Review*, Child Care in Practice pp. 1–24 (2022); Lori Uscher-Pines, Lauren E. Riedel, Ateev Mehrotra, Sherri Rose, Alisa B. Busch, & Haiden A. Huskamp, *Many Clinicians Implement Digital Equity Strategies to Treat Opioid Use Disorder: Study Examines Clinicians’ Use of Telehealth and Digital Equity Strategies to Treat Opioid Use Disorder*, 42(2) Health Affairs pp. 182–186 (2023).

³⁵⁷ Some studies have found that a majority of clinicians and patients do not prefer audio-only telehealth to in-person care, implying that many of the benefits tied to telehealth are specifically for telehealth with video. For example:

Lori Uscher-Pines, Lauren E. Riedel, Ateev Mehrotra, Sherri Rose, Alisa B. Busch, & Haiden A. Huskamp, *Many Clinicians Implement Digital Equity Strategies to Treat Opioid Use Disorder: Study Examines Clinicians’ Use of Telehealth and Digital Equity Strategies to Treat Opioid Use Disorder*, 42(2) Health Affairs pp. 182–186 (2023); Gillian K. SteelFisher, Caitlin L. McMurtry, Hannah Caporello, Keri M. Lubell, Lisa M. Koonin, Antonio J. Neri, Eran N. Ben-Porath, Ateev Mehrotra, Ericka McGowan, Laura C. Espino, & Michael L. Barnett, *Video Telemedicine Experiences in COVID–19 Were Positive, but Physicians and Patients Prefer In-Person Care for The Future: Study Examines Patient and Physician Opinion of Telemedicine Experiences During COVID–19*, 42(4) Health Affairs pp. 575–584 (2023).

³⁵⁸ Norah Mulvaney-Day, David Dean, Jr., Kay Miller, & Jessica Camacho-Cook, *Trends in Use of Telehealth for Behavioral Health Care During the*

COVID–19 Pandemic: Considerations for Payers and Employers, 36(7) American Journal of Health Promotion pp. 1237–1241 (2022).

³⁵⁹ Congressional Research Service, *Federal Telehealth Flexibilities in Private Health Insurance During the COVID–19 Public Health Emergency*: In Brief (2023), <https://crsreports.congress.gov/product/pdf/R/R47424>.

³⁶⁰ Executive Office of the President, *Statement of Administration Policy* (Jan. 30, 2023), <https://www.whitehouse.gov/wp-content/uploads/2023/01/SAP-HR-382-H.J.-Res.-7.pdf>.

³⁶¹ Public Law 117–328 (Dec. 29, 2022).

³⁶² HHS, *Telehealth Policy Changes After the COVID–19 Public Health Emergency* (Dec. 19, 2023), <https://telehealth.hhs.gov/providers/telehealth-policy/policy-changes-after-the-covid-19-public-health-emergency#temporary-medicare-changes-through-december-31-2024>.

³⁶³ Madeline Guth, *Telehealth Delivery of Behavioral Health Care in Medicaid: Findings from a Survey of State Medicaid Programs*, KFF (Jan. 2023), <https://www.kff.org/mental-health/issue-brief/telehealth-delivery-of-behavioral-health-care-in-medicare-findings-from-a-survey-of-state-medicare-programs/>.

³⁶⁴ Dawn A. Morales, Crystal L. Barksdale, & Andrea C. Beckel-Mitchener, *A Call to Action to Address Rural Mental Health Disparities*, 4 Journal of Clinical and Translational Science pp. 463–467 (2020).

³⁶⁵ Justin Lo, Matthew Rae, Krutika Amin, Cynthia Cox, Nirmita Panchal, & Benjamin F. Miller, *Telehealth Has Played an Outsized Role Meeting Mental Health Needs During the COVID–19 Pandemic*, KFF Issue Brief (Mar. 15, 2022), <https://www.kff.org/mental-health/issue-brief/telehealth-has-played-an-outsized-role-meeting-mental-health-needs-during-the-covid-19-pandemic/>.

³⁶⁶ HHS, Health Resources and Services Administration, Bureau of Health Workforce, *Designated Health Professional Shortage Areas: Second Quarter of Fiscal year 2024 Designated HPSA Quarterly Summary* (Mar. 2024), <https://data.hrsa.gov/Default/GenerateHPSAQuarterlyReport>.

experiences eliminated their concerns with telehealth, such as concerns related to privacy or to the level of engagement of a provider through telehealth.³⁶⁷

In addition to expanding access, telehealth has also been found to improve the retention of patients receiving mental health and substance use disorder care. A 2023 retrospective cohort study of treatment-seeking patients enrolled in a substance use disorder treatment program in Ohio found that “[p]atients who received services through telehealth with video in the initial 14 days of diagnosis had a lower hazard of dropout, compared to patients receiving solely in-person services.” Moreover, when compared to in-person care, patients receiving services through either video or telephone were more likely to have higher treatment engagement, which was defined as “initiating treatment and completing at least two treatment visits within 34 days of the initiation visit.”³⁶⁸

Research has demonstrated that telehealth for medical appointments saves patients time and money.³⁶⁹ A 2021 study focused specifically on the travel cost savings associated with using tele-mental health services in a pediatric outpatient psychology clinic. The study found that patients experienced a median of 132 miles saved by not travelling to an in-person session, which translated to a median 3.5 hours saved not travelling to an in-person session and a median cost savings of \$22 per session over the course of the telehealth treatment.³⁷⁰ The benefits of telehealth

are particularly relevant for mental health and substance use disorder treatment because treatment often requires frequent sessions or appointments.

It is important to note that, while telehealth may improve access, it is not a perfect solution. For instance, it has limitations in certain segments of the population, such as individuals with limited English proficiency³⁷¹ or without access to computers or the internet.³⁷² Additionally, many individuals may prefer in-person care over telehealth. A survey published in 2023 showed that while patients have differing preferences for in-person care or telehealth, many are not able to find care that fits their preferences. Of the respondents receiving therapy, less than half were able to select whether they received in-person care or telehealth.³⁷³ Further, interviews conducted with respondents found that while many patients appreciate the convenience of telehealth, others expressed concern about the rapport between the patient and provider during telehealth. The authors cautioned that while telehealth is an attractive way to expand access to mental health care for much of the population, telehealth may not alone be sufficient for all individuals or conditions.³⁷⁴ Therefore, while telehealth may contribute significantly to the alleviation of mental health and substance use disorder provider shortages, it may not be a viable alternative for everyone.

8.4. New Regulations (26 CFR 54.9812–2, 29 CFR 2590.712–1, and 45 CFR 146.137 and 146.180)

These final rules set forth content requirements for comparative analyses

Outpatient Psychology Clinic: Therapeutic Alliance and Outcomes, 22(2) Counselling and Psychotherapy Research pp. 322–330 (2022).

³⁷¹ Jorge A. Rodriguez, Altaf Saadi, Lee H. Schwamm, David W. Bates, & Lipika Sama, *Disparities in Telehealth Use Among California Patients with Limited English Proficiency*, 40(3) Health Affairs pp. 487–495 (2021).

³⁷² United States Census Bureau, *Computer and internet Use in the United States: 2018* (2021), <https://www.census.gov/newsroom/press-releases/2021/computer-internet-use.html>.

³⁷³ The survey found that 30.6 percent of respondents were working with providers who only offered in-person care or telehealth, while 24.4 percent of respondents were working with providers who offered both modalities but chose for the patient.

³⁷⁴ Jessica Sousa, Andrew Smith, Jessica Richard, Maya Rabinowitz, Pushpa Raja, Ateev Mehrotra, Alisa B. Busch, Haideen A. Huskamp, & Lori Uscher-Pines, *Choosing or Losing in Behavioral Health: A Study of Patients' Experiences Selecting Telehealth Versus In-Person Care*, 42(9) Health Affairs pp. 1275–1282 (2023).

required by the CAA, 2021 and outline the timeframes and processes for plans and issuers to provide their comparative analyses to the Departments and applicable State authorities upon request. Under these final rules, the Departments outlined the elements that a comparative analysis must include for each NQTL (in addition to the requirements to include a written list of all NQTLs imposed under the plan or coverage). They include, as described in more detail earlier in this preamble:

- A description of the NQTL,
- Identification and definition of the factors used to design or apply the NQTL,
- A description of how factors are used in the design and application of the NQTL,
- A demonstration of comparability and stringency, as written,
- A demonstration of comparability and stringency, in operation, and
- Findings and conclusions.

However, because these elements are already required under the CAA, 2021, the cost of these final rules is more limited than the full cost of generating a comparative analysis. For instance, plans and issuers are already required under the CAA, 2021 to provide a description of the specific plan or coverage terms or other relevant terms regarding the NQTLs that applies to such plan or coverage, and a description of all the mental health and substance use disorder benefits and medical or surgical benefits to which each such term applies in each respective benefit classification.³⁷⁵ Similarly, plans and issuers are already required to identify the factors used to determine that the NQTLs will apply to mental health or substance use disorder benefits and medical or surgical benefits,³⁷⁶ and the evidentiary standards used for the factors identified, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTLs to mental health or substance use disorder benefits and medical or surgical benefits.³⁷⁷

³⁷⁵ Code section 9812(a)(8)(A)(i), ERISA section 712(a)(8)(A)(i), and PHS Act section 2726(a)(8)(A)(i).

³⁷⁶ Code section 9812(a)(8)(A)(ii), ERISA section 712(a)(8)(A)(ii), and PHS Act section 2726(a)(8)(A)(ii).

³⁷⁷ Code section 9812(a)(8)(A)(iii), ERISA section 712(a)(8)(A)(iii), and PHS Act section 2726(a)(8)(A)(iii).

³⁶⁷ Shira H. Fischer, Zachary Predmore, Elizabeth Roth, Lori Uscher-Pines, Matthew Baird, & Joshua Breslau, *Use of and Willingness to Use Video Telehealth Through the COVID–19 Pandemic: Study Examines the Use of and the Willingness to Use Video Telehealth During the COVID–19 Pandemic*, 41(11) Health Affairs pp. 1645–1651 (2022).

³⁶⁸ Danielle M. Gainer, Celeste Wong, Jared A. Embree, Nina Sardesh, Amna Amin, & Natalie Lester, *Effects of Telehealth on Dropout and Retention in Care Among Treatment-Seeking Individuals with Substance Use Disorder: A Retrospective Cohort Study*, 58(4) Substance Use & Misuse pp. 481–490 (2023).

³⁶⁹ Studies finding that telehealth has decreased travel expenses include: Josephine C. Jacobs, Jiaqi Hu, Cindie Slightam, Amy Gregory, & Donna M. Zulman, *Virtual Savings: Patient-Reported Time and Money Savings from a VA National Telehealth Tablet Initiative*, 26(8) Telemedicine and e-Health 1178–1183 (2020); Navjit W. Dullet, Estella M. Geraghty, Taylor Kaufman, Jamie L. Kisee, Jesse King, Madan Dharmar, Anthony C. Smith, & James P. Marci, *Impact of a University-Based Outpatient Telemedicine Program on Time Savings, Travel Costs, and Environmental Pollutants*, 20(4) Value in Health pp. 542–546 (2017).

³⁷⁰ William S. Frye, Lauren Gardner, & Jazmine S. Mateus, *Utilising Telemental Health in a Paediatric*

Moreover, the CAA, 2021 requires that the comparative analyses demonstrate that the processes, strategies, evidentiary standards, and other factors used to apply NQTLs to mental health and substance use disorder benefits, as written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits in the benefits classification,³⁷⁸ as well as the specific findings and conclusions reached by the plan or issuer, including any results of the analyses that indicate that the plan or coverage is or is not in compliance with MHPAEA.³⁷⁹

In their comparative analyses, plans and issuers must describe each NQTL and identify and define all the factors and evidentiary standards used to design or apply the NQTL. The plan or issuer also must describe how the factors identified are used in the design and application of the NQTL, and evaluate whether any processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, those with respect to medical/surgical benefits, both as written and in operation. The explanation of how the plan or issuer evaluates compliance, in operation, with MHPAEA must identify the relevant data collected and evaluated, and document the outcomes that resulted from the application of the NQTL to mental health or substance use disorder benefits and medical/surgical benefits. In limited circumstances where relevant data is temporarily unavailable for a newly imposed NQTL, the comparative analysis must include a detailed explanation of the lack of relevant data, the basis for the plan's or issuer's conclusion that there is a lack of relevant data, and when and how the data will become available and be collected and analyzed. Additionally, in rare instances where no data exists that can reasonably assess any relevant impact of an NQTL on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits, the plan or issuer must provide a reasoned justification as to the basis for the conclusion that there are no data that can reasonably assess the NQTL's

impact, an explanation of why the nature of the NQTL prevents the plan or issuer from reasonably measuring its impact, an explanation of what data was considered and rejected, and documentation of any additional safeguards or protocols used to ensure that the NQTL complies with MHPAEA. In the instances where there is a temporary data lag for a newly imposed NQTL or no data exists that can reasonably assess any relevant impact of an NQTL, providing this justification for the temporary data lag is likely to be less expensive than the estimated burden for doing an analysis when there is data. However, as explained earlier in this preamble, the Departments are of the view that nearly all NQTLs will have some relevant data to collect and evaluate; therefore, the Departments estimate the burden as if every plan and issuer performs the data analysis.

These final rules require additional specificity with regard to the findings and conclusion of the comparative analysis. While these final rules provide specificity for how a plan or issuer must comply with the comparative analysis requirements, they are primarily providing additional clarification and requirements with respect to the statutory content elements of a comparative analysis outlined in the CAA, 2021, so that plans and issuers can perform and document sufficient comparative analyses.

Additionally, for ERISA plans, these final rules also require the comparative analysis to include a certification by one or more named fiduciaries that they have engaged in a prudent process to select one or more qualified service providers to perform and document a comparative analysis in connection with the imposition of any NQTLs that apply to mental health and substance use disorder benefits under the plan in accordance with applicable law and regulations, and have satisfied their duty to monitor those service providers as required under part 4 of ERISA with respect to the performance and documentation of such comparative analysis. The cost to provide the certification is included in the cost estimates to prepare the comparative analysis.

In the proposed rules, the Departments estimated that, on average, plans would need to analyze four separate NQTLs and issuers would need to analyze eight NQTLs to satisfy the comparative analysis requirements.³⁸⁰

The Departments further estimated that plans and issuers preparing their own comparative analyses would incur an incremental burden of 10 hours per NQTL in the first year, with 2 hours for a general or operations manager to review the requirements and outline the changes needed for the comparative analyses and 8 hours for a business operations specialist to prepare the comparative analyses. Once the comparative analyses are performed and documented, the Departments noted that plans and issuers would need to update the analyses when making changes to the terms of the plan or coverage, including changes to the way NQTLs are applied to mental health and substance use disorder benefits, as well as medical/surgical benefits. In subsequent years, the Departments estimated that plans and issuers would incur an incremental burden of 4 hours annually per NQTL to update the analyses, with 1 hour for a general or operations manager and 3 hours for a business operations specialist.

In response to commenters' concerns that the Departments underestimated the number of NQTLs that each plan or issuer would need to provide comparative analyses for, and that plans and issuers would on average have the same number of NQTLs, the Department have revised their assumptions to 10 NQTLs for both plans and issuers. While one commenter suggested the average number of NQTLs should be more than 15 at a minimum, and another commenter noted that the proposal and guidance referenced at least 17 NQTLs, the Departments note that the number of NQTLs vary by issuer and plans and that most will not incorporate every NQTL listed in the proposal and the guidance (while some plans and issuers might incorporate others not listed). Taking into account the Departments' experience and comments received, the Departments assume 10 NQTLs but present a sensitivity analysis using 15 NQTLs.

example, if a plan applies an identical prior authorization requirement NQTL to four different benefit classifications, or to four different benefit package options in the same plan, the Departments would consider the NQTL as just one "unique" NQTL, even though it is technically four separate NQTLs. When a comparative analysis request is sent to an issuer with identical NQTLs that apply to many fully insured plans, the Departments similarly count the NQTL as one unique NQTL, even though there are technically many separate NQTLs for the different plans. The Departments acknowledge that if they instead counted each NQTL separately by benefit classification, plan, and product, irrespective of whether the NQTLs are administered in the same way in these different contexts, then the number of NQTLs would be substantially larger. This distinction may explain why the Departments' estimate of NQTLs was lower than that of commenters.

³⁷⁸ Code section 9812(a)(8)(A)(iv), ERISA section 712(a)(8)(A)(iv), and PHS Act section 2726(a)(8)(A)(iv).

³⁷⁹ Code section 9812(a)(8)(A)(v), ERISA section 712(a)(8)(A)(v), and PHS Act section 2726(a)(8)(A)(v).

³⁸⁰ The Departments generally identify a unique NQTL based on whether a specific plan or issuer has defined the NQTL using different factors or evidentiary standards than other NQTLs. For

The Departments assume that the incremental costs to collect the data and review and revise the comparative analyses will require 60 hours per NQTL in the first year and 12 hours per NQTL in subsequent years. For plan sponsors that receive a generic comparative analysis from a TPA that will require customizing to suit the plan's specific needs, the Departments assume that it will take 30 hours per NQTL in the first year and 6 hours per

NQTL in subsequent years. While plans and issuers can use other professionals to fulfill their requirements, for purposes of developing the wage estimate, the Departments assume that it will take a team of data analysts, actuaries, and attorneys to collect the data and prepare the comparative analyses, and have estimated a composite wage rate of \$167.48.³⁸¹ See Table 5 for calculations and burden totals.

The Departments conducted a sensitivity analysis of the assumption that plans and issuers would each analyze 10 NQTLs. If the Departments assume that plans and issuers analyze 15 NQTLs, the cost burden would increase by \$328.1 million in the first year and \$65.6 million in the subsequent years, resulting in a 3-year average cost increase of \$153.1 million.

TABLE 5—INCREMENTAL COST TO FULFILL THE DATA REQUIREMENTS AND PREPARE THE COMPARATIVE ANALYSES

	Number of entities	Number of NQTLs per entity	Number of hours per NQTL for data and comparative analysis	Total hour burden	Hourly wage	Cost
	(A)	(B)	(C)	(A × B × C)	(D)	(A × B × C × D)
First Year						
Issuers (health insurance company/State combinations)	1,467	10	60	880,200	\$167.48	\$147,415,896
TPAs	205	10	60	123,000	167.48	20,600,040
Self-funded plans with more than 500 participants that will conduct the comparative analysis themselves	709	10	60	425,400	167.48	71,245,992
Self-funded plans with more than 500 participants that will receive generic comparative analyses from TPAs or service providers, and will then customize it	4,076	10	30	1,222,800	167.48	204,794,544
Self-funded non-Federal governmental plans with more than 500 participants that will conduct the comparative analysis themselves	505	10	60	303,000	167.48	50,746,440
Self-funded non-Federal governmental plans with more than 500 participants that will initially receive generic comparative analyses from TPAs or service providers, and will then customize it	2,906	10	30	871,800	167.48	146,009,064
Plan MEWAs that are not fully insured	132	10	60	79,200	167.48	13,264,416
Non-plan MEWAs that are not fully insured	21	10	60	12,600	167.48	2,110,248
First-year Total	10,021			3,918,000		656,186,640
Subsequent Years						
Issuers (health insurance company/State combinations)	1,467	10	12	176,040	167.48	29,483,179
TPAs	205	10	12	24,600	167.48	4,120,008
Self-funded plans with more than 500 participants that will conduct the comparative analysis themselves	709	10	12	85,080	167.48	14,249,198
Self-funded plans with more than 500 participants that will receive generic comparative analyses from TPAs or service providers, and will then customize it	4,076	10	6	244,560	167.48	40,958,909
Self-funded non-Federal governmental plans with more than 500 participants that will conduct the comparative analysis themselves	505	10	12	60,600	167.48	10,149,288
Self-funded non-Federal governmental plans with more than 500 participants that will initially receive generic comparative analyses from TPAs or service providers, and will then customize it	2,906	10	6	174,360	167.48	29,201,813
Plan MEWAs that are not fully insured	132	10	12	15,840	167.48	2,652,883
Non-plan MEWAs that are not fully insured	21	10	6	2,520	167.48	422,050
Subsequent Years Total	10,021			783,600		131,237,328
Total (3-year average)	10,021			1,828,400		306,220,432

Additionally, plans and issuers must make the comparative analyses and other applicable information required by the CAA, 2021 available upon request to participants, beneficiaries, and enrollees in all non-grandfathered group health plans and non-grandfathered group or individual

health insurance coverage (including a provider or other person acting as a participant's, beneficiary's, or enrollee's authorized representative) in connection with an adverse benefit determination, as well as to participants and beneficiaries in plans subject to ERISA. The Departments estimate that on

average each plan or issuer will receive one request annually and that plans and issuers will annually incur a burden of 5 minutes for a clerical worker to prepare and send the comparative analyses to each requesting participant or beneficiary. The Departments received comments suggesting that this

³⁸¹ The wage rate of an attorney, actuary, and data analyst is, respectively, \$165.71, \$177.11, and \$159.61. (Internal DOL calculation based on 2024 labor cost data. For a description of DOL's methodology for calculating wage rates, see EBSA, *Labor Cost Inputs Used in the Employee Benefits*

Security Administration, Office of Policy and Research's Regulatory Impact Analyses and Paperwork Reduction Act Burden Calculations (June 2019), <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.) The composite wage rate is estimated in the following manner: [$\$165.71 \times (1 + 3) + \$159.61 \times (1 + 3) \times \$177.61 \times (1 + 3) = \$167.48$].

underestimated the demand for these analyses as well as the cost to produce them. However, after reviewing data on the number of appealed mental health or substance use disorder claims per year, which serves as a proxy for when

participants or beneficiaries would request an analysis, the Departments are of the view that this estimate is appropriate. Moreover, because plans and issuers are already responsible for preparing these analyses, the only cost

associated with providing them are the clerical ones outlined earlier in this preamble. See Table 6 for calculations and burdens totaling the cost to prepare the analysis.³⁸²

TABLE 6—COSTS TO PREPARE THE COMPARATIVE ANALYSIS UPON PARTICIPANT REQUEST

	Number of entities	Number of NQTLs per entity	Number of hours per NQTL	Total hour burden	Hourly wage	Cost
	(A)	(B)	(C)	(A × B × C)	(D)	(A × B × C × D)
Issuers (health insurance company/State combinations)	1,467	1	0.0833	122	\$65.99	\$8,051
ERISA-covered group health plans	2,129,516	1	0.0833	177,460	65.99	11,710,585
Non-Federal governmental plans	90,887	1	0.0833	7,574	65.99	499,808
Plan MEWAs that are not fully insured	132	1	0.0833	11	65.99	726
Non-plan MEWAs that are not fully insured	21	1	0.0833	2	65.99	132
Annual Total	2,222,023			185,169		12,219,302

The Departments further assume that 58.3 percent of requests will be delivered electronically, resulting in a

de minimis cost.³⁸³ The remaining 41.7 percent of requests will be mailed, at a cost of \$2.79 each.³⁸⁴ See Table 7 for

calculations and burden totaling the cost to distribute the analysis.

TABLE 7—COSTS TO DISTRIBUTE THE COMPARATIVE ANALYSIS UPON PARTICIPANT OR BENEFICIARY REQUEST

	Number of entities	Estimated page length	Paper and printing cost (per page)	Mailing cost	Cost
	(A)	(B)	(C)	(D)	[(A × B × C) + (A × D)] × 41.7 percent
Issuers (health insurance company/State combinations)	1,467	15	\$0.05	\$2.04	\$1,603
ERISA-covered Group Health Plans	2,129,516	15	0.05	2.04	2,326,581
Non-Federal Governmental Plans	90,887	15	0.05	2.04	105,741
Plan MEWAs that are not fully insured	132	15	0.05	2.04	144
Non-plan MEWAs that are not fully insured	21	15	0.05	2.04	23
Annual Total	2,222,023				2,585,169

³⁸² In Table 6, the number of ERISA-covered group health plans is calculated in the following manner: 410,581 ERISA-covered group health plans with 50 or more participants + 1,718,935 ERISA-covered fully insured, non-grandfathered plans with less than 50 participants = 2,129,516.

³⁸³ According to data from the National Telecommunications and Information Agency (NTIA), 37.4 percent of individuals age 25 and over have access to the internet at work. According to a Greenwald & Associates survey, 84 percent of plan participants find it acceptable to make electronic delivery the default option, which is used as the proxy for the number of participants who will not opt out of electronic disclosure that

are automatically enrolled (for a total of 31.4 percent receiving electronic disclosure at work). Additionally, the NTIA reports that 44.1 percent of individuals age 25 and over have access to the internet outside of work. According to a Pew Research Center survey, 61.0 percent of internet users use online banking, which is used as the proxy for the number of internet users who will affirmatively consent to receiving electronic disclosures (for a total of 26.9 percent receiving electronic disclosure outside of work). Combining the 31.4 percent who will receive electronic disclosure at work with the 26.9 percent who will receive electronic disclosure outside of work produces a total of 58.3 percent who will receive

electronic disclosure overall. See Quantria Strategies, *Improving Outcomes with Electronic Delivery of Retirement Plan Documents* (June 2015), https://www.sparkinstitute.org/content-files/improving_outcomes_with_electronic_delivery_of_retirement_plan_documents.pdf. See also Pew Research Center, *51% of U.S. Adults Bank Online* (Aug. 2013), https://www.pewresearch.org/internet/wp-content/uploads/sites/9/media/Files/Reports/2013/PIP_OnlineBanking.pdf. See also NTIA, *NTIA Data Explorer* (June 2024), <https://www.ntia.gov/data/explorer>.

³⁸⁴ The postage for a first-class mail large envelope is \$2.04 and the material cost is \$0.05 per page. Thus, \$2.04 + (\$0.05 × 15 pages) = \$2.79.

Finally, these final rules require that group health plans and health insurance issuers offering group or individual health insurance coverage must make comparative analyses available upon request to the Departments or an applicable State authority. The CAA, 2021 requires the Departments to collect no fewer than 20 comparative analyses per year, but it also provides that the Departments shall request that a group

health plan or issuer submit the comparative analyses for plans that involve potential MHPAEA violations or complaints regarding noncompliance with MHPAEA that concern NQTLs, and any other instances in which the Departments determine appropriate. Based on prior experience and current funding, DOL and HHS expect to each request 20 comparative analyses each year. To provide the Departments with

their comparative analyses and associated documentation, the Departments estimate, based on internal discussion, that it will take a total of 5 hours for plans, with 1 hour for a general or operations manager and 4 hours for a business operations specialist. See Table 8 for calculations and burden totals.

TABLE 8—COSTS OF PROVIDING COMPARATIVE ANALYSES FOR AUDITS

	Number of entities	Hour burden per entity	Total hour burden	Hourly wage	Cost
	(A)	(B)	(A × B)	(C)	(A × B × C)
General Operations Manager (Requested by HHS)	20	1	20	\$137.67	\$2,753
Business Operations Specialist (Requested by HHS)	20	4	80	114.36	9,149
General Operations Manager (Requested by DOL)	20	1	20	137.67	2,753
Business Operations Specialist (Requested by DOL)	20	4	80	114.36	9,149
Total	40		200		23,804

In the first year, group health plans and issuers will need time to familiarize themselves with these final rules to ensure that their comparative analyses

comply with all applicable requirements. The Departments assume that on average it will require 6.5 hours for an attorney to review these final

rules.³⁸⁵ See Table 9 for calculations and burden totals.

TABLE 9—COSTS FOR RULE FAMILIARIZATION

	Number of entities	Number of NQTLs per entity	Hour burden per entity	Total hour burden	Hourly wage	Cost
	(A)	(B)	(C)	(A × B × C)	(D)	(A × B × C × D)
First Year						
Issuers (health insurance company/State combinations)	1,467	1	6.5	9,536	\$165.71	\$1,580,211
TPAs	205	1	6.5	1,333	165.71	220,891
Self-funded plans with more than 500 participants that will conduct the comparative analysis themselves	709	1	6.5	4,609	165.71	763,757
Self-funded plans with more than 500 participants that will receive generic comparative analyses from TPAs or service providers, and will then customize it	4,076	1	6.5	26,494	165.71	4,390,321
Self-funded non-Federal governmental plans with more than 500 participants that will conduct the comparative analysis themselves	505	1	6.5	3,283	165.71	544,026
Self-funded non-Federal governmental plans with more than 500 participants that will initially receive generic comparative analyses from TPAs or service providers, and will then customize it	2,906	1	6.5	18,889	165.71	3,130,096
Plan MEWAs that are not fully insured	132	1	6.5	858	165.71	142,179
Non-plan MEWAs that are not fully insured	21	1	6.5	137	165.71	22,702
First-year Total	10,021			65,139		10,794,184

According to the 2022 National Health Expenditure Data, the total contribution of private employers to health insurance premiums is \$592.2 billion. The total contribution of State and local employers to health insurance

premiums is \$194.5 billion.³⁸⁶ The total health expenditure on the individual market is \$93.9 billion.³⁸⁷ In the first year, the cost to comply with these final rules is estimated to be approximately \$681.8 million,³⁸⁸ which represents 0.08

percent of total premiums in these markets. In subsequent years, the cost to comply with these final rules is estimated to be approximately \$146.1 million,³⁸⁹ which represents 0.02

³⁸⁵ The reading time is calculated based on an average 250 words per minute reading rate.

³⁸⁶ CMS, *National Health Expenditure Data*, NHE Tables—Table 24, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/nationalhealthaccountshistorical>.

³⁸⁷ CMS, *National Health Expenditure Data*, NHE Tables—Table 21, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/nationalhealthaccountshistorical>.

Reports/NationalHealthExpendData/nationalhealthaccountshistorical.

³⁸⁸ The cost is estimated as follows: \$656.2 million for collecting the data and preparing the comparative analyses + \$10.8 million for reviewing the final rules and amendments + \$12.2 million to prepare the comparative analyses upon request of participants and beneficiaries + \$2.6 million to distribute the comparative analyses to participants

and beneficiaries + \$0.02 million for audit of comparative analyses = \$681.8 million.

³⁸⁹ The cost is estimated as follows: \$131.2 million for collecting the data and preparing the comparative analyses + \$12.2 million for preparing the comparative analyses upon request of participants and beneficiaries + \$2.6 million to distribute the comparative analyses to participants and beneficiaries + \$0.02 million for audit of comparative analyses = \$146.1 million.

percent of total premiums in these markets.

In the proposed rules, HHS assumed that most of the self-funded non-Federal governmental plans that would be affected by the implementation of the CAA, 2023 provision that sunsets the MHPAEA opt-out election offered mental health and substance use disorder benefits, but that many of these plans might not be complying with MHPAEA. HHS assumed that plans would incur costs to come into compliance and noted that, in particular, some plans might remove limits on or offer more generous mental health and substance use disorder benefits, which would likely increase utilization of mental health and substance use disorder services, increasing the number of claims submitted, and the overall costs incurred by these plans. HHS also noted that plans that have opted out of requirements under MHPAEA would also need to conduct NQTL comparative analyses if they were not already doing so. HHS solicited comments on the potential costs to these plans to come into compliance with MHPAEA. Although the Departments received comments on the potential underestimation of costs related to NQTL comparative analysis requirements (refer to section IV.8.1 of this regulatory impact analysis for further discussion), HHS did not receive any comments specific to the costs associated with coming into compliance for self-funded non-Federal governmental plans. As such, HHS is unable to estimate the costs to these plans because the extent to which these

plans are currently out of compliance is unknown, and costs associated with coming into compliance are expected to vary from plan to plan.

HHS estimates that the regulatory amendments to implement a provision of the CAA, 2023 that sunsets the election option for sponsors of self-funded non-Federal governmental plans to opt out of requirements under MHPAEA eliminates the need for sponsors to submit a notice to the Federal Government regarding their plan's opt-out election, as long as the sponsors do not elect to permissibly opt out of other requirements. HHS estimates that sponsors of 185 plans will no longer submit a notice to the Federal Government regarding their plan's opt-out election. This is estimated to generate a total cost savings of approximately \$11,783 for plans (as discussed later in section V.2.5 of the Paperwork Reduction Act analysis for HHS), and cost savings of approximately \$5,200 for the Federal Government as HHS will no longer have to process the opt-out notices previously submitted by these plans.

8.5. Illustration of Cost Increases for Plans and Issuers

As discussed in the benefits section, the Departments estimate that the final rules will increase access and subsequently the utilization or frequency of use of behavioral health services. The Departments also recognize that increased service utilization will likely increase costs for plans. These costs will likely differ significantly by the type of condition and the type of treatment. The analysis

that follows provides an illustration of potential increases in costs for plans associated with depression and substance use disorder treatments.

Increasing access to mental health services is estimated to result in a significant reduction in suicides, as enumerated in section IV.7.2. While many mental health conditions and substance use disorders may increase the risk of suicide, suicide itself is an outcome that may or may not be tied directly to mental health conditions or substance use disorders. As such, it is difficult to directly tie the decrease in suicides discussed in section IV.7.2 to increased costs.

However, the most common mental health condition among those who attempt suicide, as well as one of the most highly prevalent mental health conditions in the United States, is depressive disorder.³⁹⁰ Research indicates that individuals with major depressive disorder are at an elevated risk of suicide and that approximately two-thirds have contemplated suicide.³⁹² Furthermore, major depressive disorder was the most common comorbid condition in a study of U.S. suicides, followed by substance use disorder.³⁹³ Individuals with major depressive disorder and another comorbid condition (such as a substance use disorder or anxiety disorder) are at even greater risk of suicide.³⁹⁴ Data from the 2022 NSDUH indicates that approximately 8 percent of individuals who have private health insurance experienced a major depressive episode in the past year, of whom 64 percent received treatment for depression.³⁹⁵

TABLE 10—NUMBER OF PEOPLE DIAGNOSED WITH A MAJOR DEPRESSIVE EPISODE IN THE PAST YEAR

	2021	2022
Total:		
All Ages	21,553,000	22,475,000
With Private Health Insurance	11,750,000	12,551,000
Receiving Treatment for Depression:		
All Ages	12,932,000	14,088,000
With Private Health Insurance	7,540,000	8,240,000
Not Receiving Treatment for Depression:		
All Ages	8,621,000	8,387,000
With Private Health Insurance	4,210,000	4,311,000

SAMHSA, 2022 National Survey on Drug Use and Health (Nov. 2023), <https://www.samhsa.gov/data/report/2022-nsduh-detailed-tables>.

As discussed in Section 6.1.3, MHPAEA has been found to have mixed

effects on the utilization of mental health services. A 2019 study found

that, outside of substance use disorder, MHPAEA was not associated with an

³⁹⁰ Jan Fawcett, *The Neurological Basis of Suicide* (2012).

³⁹¹ Ronald C. Kessler, Patricia Berglund, Olga Demler, Robert Jin, Kathleen R. Merikangas, & Ellen E. Walters, *Lifetime Prevalence and Age-of-Onset Distributions of DSM-IV Disorders in the National*

Comorbidity Survey Replication, 62(6) *Arch Gen Psychiatry* pp. 593–602 (2005).

³⁹² Navneet Bains & Sara Abdijadid, *Major Depressive Disorder* (2023).

³⁹³ Ian Rockett, Rockett, Ian RH, Shuhui Wang, Yinyuan Lian, & Steven Stack, *Suicide-Associated Comorbidity Among US Males and Females: A*

Multiple Cause-of-Death Analysis, 13(5) *Injury Prevention* pp. 311–315 (2007).

³⁹⁴ Navneet Bains & Sara Abdijadid, *Major Depressive Disorder* (2023).

³⁹⁵ SAMHSA, 2022 National Survey on Drug Use and Health (Nov. 2023), <https://www.samhsa.gov/data/report/2022-nsduh-detailed-tables>.

increase in new utilization of behavioral healthcare. However, the authors did find an increase in the average frequency of monthly outpatient services per user.³⁹⁶ Critically, increased frequency of mental health and OUD treatment utilization have both been associated with decreasing risks of mortality from suicide and OUD.^{397, 398}

The 2019 study also found that the average insurer cost for members receiving treatment increased following the passage of MHPAEA. According to the study, in September 2015, the last month of data considered, MHPAEA was associated with an average insurer cost increase of \$16.17 for each member receiving treatment for mental health per month.³⁹⁹

For the purposes of this analysis, it is helpful to consider this measurement in terms of the increased cost per member with depression, regardless of treatment status. To estimate a per-member cost, regardless of treatment status, the Departments scaled the estimate by the proportion of individuals who had a major depressive episode in 2015, with private insurance, and who received treatment for depression. Applying these assumptions, the Departments

estimate that in 2015, MHPAEA was associated with a \$11.15 increase in average monthly insurer spending per member with depression.⁴⁰⁰

The Departments do not have data on per-member per-month costs associated with a major depressive illness alone. Based on a 2018 Milliman report, the Departments estimate that the 2015 per-member per-month behavioral healthcare cost⁴⁰¹—including behavioral inpatient, outpatient, professional, and prescription drug costs—was \$225.10 for someone with a serious and persistent mental illness and \$116.59 on average for someone with any mental illness.⁴⁰² Milliman defines a serious and persistent mental illness as someone treated for bipolar disorder, major depression, paranoid and other psychotic disorder, or schizoaffective disorder. As costs to treat bipolar disorder, psychotic disorder, and schizoaffective disorder are likely higher than costs to treat major depression, on average, the Departments are of the view that the per-member per-month costs represent an overestimate for costs to treat major depression. Similarly, the Departments expect that the per-member per-month costs to treatment someone with any

mental illness likely represent an underestimate due to factors such as underdiagnosis, comorbidities, and delayed treatments. Additionally, the per-member per-month costs may not fully capture indirect costs or the cost of out-of-network care, further suggesting that the total costs of adequately treating mental illness are likely higher. As such, the Departments are of the view that these two measures create a reasonable range with regard to major depression.

Based on this analysis, the estimated \$11.15 increase in monthly insurer spending per-member with depression accounts for 5.0 percent of the per-member per-month costs for someone with a serious and persistent mental illness or 9.6 percent of the average cost for someone with any mental illness. In 2021, total expenditures for private insurance were \$981.2 billion, while total expenditures for private insurance for depression were \$21.0 billion.⁴⁰³ For illustrative purposes, if it is assumed that the increase in costs associated with MHPAEA had accounted for between 5.0 percent and 9.6 percent of private insurance expenditures for depression in 2021, this would account for between \$1.0 billion and \$2.0 billion of total expenditures for private insurance for depression.⁴⁰⁴

In their estimate of benefits associated with the prevention of suicide fatalities and reduced mortality from the utilization of OUD treatments, the Departments assumed that the effect of these final rules would be approximately 40 percent of the initial impact from MHPAEA. For consistency, applying this proportion to the estimated costs, the Departments estimate that these final rules would be associated with an increase cost for treatment related to depression for private insurers of between \$0.42 billion and \$0.80 billion in 2021 dollars or \$0.43 billion and \$0.84 billion in 2023 dollars.⁴⁰⁵

It is important to note that the benefits estimated in section IV.7.2 and these cost estimates do not necessarily capture the same segment. The benefits related to more frequent treatment of depression are more expansive than the estimated benefits in section IV.7.2 that only focus on suicide prevention. On the other hand, treatment for other types

³⁹⁶ Noah Mulvaney-Day, Brent Gibbons, Shums Alikhan, & Mustafa Karakus, *Mental Health Parity and Addiction Equity Act and the Use of Outpatient Behavioral Health Services in the United States, 2005–2016*, 109(3) American Journal of Public Health pp. 190–196 (2019).

³⁹⁷ Brian K. Ahmedani, Joslyn Westphal, Kirsti Autio, Farah Elsis, Edward L. Peterson, Arne Beck, Beth E. Waitzfelder, Rebecca C. Rossom, Ashli A. Owen-Smith, Frances Lynch, Christine Y. Lu, Cathrine Frank, Deepak Prabhakar, Jordan M. Braciszewski, Lisa R. Miller-Matero, Hsueh-Han Yeh, Yong Hu, Riddhi Doshi, Stephen C. Waring, & Gregory E. Simon, *Variation in Patterns of Health Care Before Suicide: A Population Case-Control Study*, 127 Prev Med. (2019), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6744956/>.

³⁹⁸ Elizabeth Evans, Libo Li, Jeong Min, David Huang, Darren Urada, Lei Liu, Yih-Ing Hser, & Bohdan Nosyk, *Mortality Among Individuals Accessing Pharmacological Treatment for Opioid Dependence in California, 2006–2010*, 110(6) Addiction pp. 996–1005 (2015), <https://pubmed.ncbi.nlm.nih.gov/25644938/>.

³⁹⁹ This is calculated by applying the coefficient estimates found in Table 2 of the study that denote the average monthly insurer spending per service user. The study includes 129 months of data, of which 57 are in the post-period. For month 57, the cost is estimated to be \$86.64 absent MHPAEA and \$102.81 with the implementation of MHPAEA. The study estimates that insurer spending per service user will continue to increase over time. However, this linear trend was established within the sample. The Department hesitates to extrapolate the linear trend outside of the sample. Additionally, the study does not include overall significant or joint significant tests of this regression. (See Noah Mulvaney-Day, Brent Gibbons, Shums Alikhan, & Mustafa Karakus, *Mental Health Parity and Addiction Equity Act and the Use of Outpatient Behavioral Health Services in the United States, 2005–2016*, 109(3) American Journal of Public Health pp. 190–196 (2019).)

⁴⁰⁰ In 2015, 9,257,000 individuals with private insurance had a major depressive episode, of which 6,381,000 received treatment for depression. (See SAMHSA, Results from the 2015 National Survey on Drug use and Health: Detailed Tables (Sept. 2016), <https://www.samhsa.gov/data/sites/default/files/NSDUH-DeT-Tabs-2015/NSDUH-DeT-Tabs-2015/NSDUH-DeT-Tabs-2015.pdf>.) This represents approximately 69 percent. As such, the Departments estimate the per-member cost increase as: \$16.17 per member receiving treatment $\times$ 69 percent of members with depression receiving treatment = \$11.15 per member with depression (regardless of treatment status).

⁴⁰¹ This cost estimate is calculated from costs incurred by both the participant and the insurer, similar to expenditures used elsewhere in this analysis, such as the Medical Expenditure Panel Survey Household Component (MEPS-HC).

⁴⁰² Melek (2018) uses 2015 claims data and apply annual cost trends to estimate 2017 values. The report states that they use an annual cost trend of 10 percent to behavioral health care and 12 percent to behavioral prescription costs. For someone with a serious and persistent mental illness, the report estimates that the per-member per-month cost was \$119.00 for behavioral health care (*i.e.* behavioral inpatient, outpatient, professional care) and \$159.00 for behavioral prescriptions, resulting in a total cost of \$178.00. The weighted average per-member per-month cost of having any mental illness, the report estimates a cost of \$55.08 for behavioral health care and \$89.14 for behavioral prescriptions, resulting in a total of \$142.22. Discounting the behavioral health care and behavioral prescription costs by the respective annual cost trend, results in an estimate of a per-member per-month cost of \$225.10 for someone with a serious and persistent mental illness and \$116.59 on average for someone with any mental illness. (See Stephen Melek, Douglas Norris, Jordan Paulus, Katherine Matthews, Alexandra Weaver, & Stoddard Davenport, *Potential Economic Impact of Integrated Medical-Behavioral Healthcare*, Milliman Research Report (Jan. 2018))

⁴⁰³ Agency for Healthcare Research and Quality, *Total Expenditures (\$ in Millions by Condition and Source of Payment, United States, 2021*, Medical Expenditure Panel Survey.

⁴⁰⁴ This is estimated as: \$21.02 billion $\times$ 5.0 percent (9.6 percent) = \$1.0 billion (\$2.0 billion).

⁴⁰⁵ The estimates in 2023 dollars are estimated using the Consumer Price Index (CPI) medical care cost.

of mental health conditions or substance use disorders may also contribute to the decreased prevalence of suicides, the cost of which is not considered in this illustration.

Additionally, the Departments estimate that the final rules will increase the utilization of substance use disorder services (specifically, OUD), resulting in significant benefits arising from decreased mortality related to substance use disorders. These benefits would arise from approximately 40,000 additional individuals receiving treatment each year. As recent research indicates that cost of treatment for OUD is approximately \$13,500, the Departments estimate that the increased service utilization for OUD would result in an additional cost of approximately \$579 million annually.^{406 407 408}

9. Transfers

Achieving parity in coverage of mental health and substance use disorder benefits has the potential to change the spending patterns of plans and issuers, increase premiums and contributions, and change the utilization patterns of participants, beneficiaries, and enrollees. The Departments recognize these as transfers among participants, beneficiaries, and enrollees; plans and issuers; and mental health and substance use disorder providers and facilities. Specifically, the Departments expect these final rules will result in:

- transfers from plans and issuers to participants, beneficiaries, and enrollees caused by lower out-of-pocket spending;
- transfers from participants, beneficiaries, and enrollees to plans and issuers caused by higher premiums; and
- transfers between primary care providers and mental health and substance use disorder providers for the treatment of mental health and substance use disorders resulting from the anticipated shift of participants, beneficiaries, and enrollees choosing to obtain such treatment from a specialist instead of a primary care provider.

The following sections are primarily qualitative discussions of transfers that the Departments expect to occur due to these final rules. Where possible, the Departments have referenced studies with quantitative results that help indicate the potential magnitude of these transfers. The Departments requested comment or data in the proposal on how large these transfers might be but did not receive any comments.

9.1. Transfers From Plans and Issuers to Participants, Beneficiaries, and Enrollees Caused by Lower Out-of-Pocket Spending

As discussed in section IV.7.2 of this regulatory impact analysis, these final rules are expected to increase access to mental health and substance use disorder treatments by improving plan and issuer compliance with the requirements under MHPAEA. This will help ensure that NQTLs are no more restrictive for mental health and substance use disorder benefits than the predominant limitations applicable to substantially all medical/surgical benefits. For individuals who were previously prevented from accessing care because it was not covered by their plan or coverage in a manner that violated these final rules, improved access to treatment is a benefit. However, for individuals who previously resorted to out-of-network treatment, expanded coverage of treatment—resulting in more access to in-network providers or facilities—will result in a transfer from plans and issuers to participants, beneficiaries, and enrollees.

Currently, it is more common for individuals to rely on out-of-network care for mental health and substance use disorder treatment than for medical/surgical treatment. One study found that patients received out-of-network care 3.5 times more often for behavioral health clinician office visits than for medical and surgical clinician office visits (13.4 percent vs. 3.8 percent). Further, the study found that when comparing specialist care, patients received out-of-network care 8.9 times more often for psychiatrist office visits (15.3 percent vs. 1.7 percent) and 10.6 times more often for psychologist office visits (18.2 percent vs. 1.7 percent) than for medical and surgical specialist physicians.⁴⁰⁹

Receiving out-of-network treatment is costly, and research has found that mental health parity decreases out-of-pocket spending on treatment. For example, a 2013 study that examined the impact of the 2001 parity directive in the FEHB Program found that annual out-of-pocket spending for FEHB enrollees diagnosed with bipolar disorder, major depression, or adjustment disorder decreased by between \$78 and \$86, roughly between 11 percent and 18 percent of average total out-of-pocket spending for enrollees with one of these diagnoses, as compared to before the parity directive.⁴¹⁰

A 2018 study compared commercially insured children ages 3 to 18 years in 2008 who were continuously enrolled in plans newly subject to parity under MHPAEA to children continuously enrolled in plans never subject to MHPAEA. The study found that children with mental health conditions who were enrolled in plans subject to parity had, on average, \$140 lower annual out-of-pocket mental health spending than expected compared to the comparison group. The study further found that children at or above the 85th percentile in total mental health spending who were enrolled in plans subject to MHPAEA had, on average, \$234 lower annual out-of-pocket mental health spending than those in the comparison group.⁴¹¹

A 2019 study examined the impact of MHPAEA on mental health services spending in a commercially insured population diagnosed with mental health disorders and found that MHPAEA resulted in a decrease in the mean out-of-pocket spending per mental health outpatient visit.⁴¹² Additionally, a 2017 study that examined expenditures of patients receiving behavioral health treatment following the implementation of MHPAEA found that the out-of-pocket expenditure for

⁴¹⁰ Before the parity directive, average out-of-pocket spending was \$787 for someone with bipolar disorder, \$563 for someone with major depression, and \$428 for someone with adjustment disorder. See Alisa B. Busch, Frank Yoon, Colleen L. Barry, Vanessa Azzone, Sharon-Lise T. Normand, Howard H. Goldman, & Haiden A. Huskamp, *The Effects of Parity on Mental Health and Substance Use Disorder Spending and Utilization: Does Diagnosis Matter?*, 170(2) *The American Journal of Psychiatry* p. 180 (2013).

⁴¹¹ Alene Kennedy-Hendricks, Andrew J. Epstein, Elizabeth A. Stuart, Rebecca L. Haffajee, Emma E. McGinty, Alisa B. Busch, Haiden A. Huskamp, & Colleen L. Barry, *Federal Parity and Spending for Mental Illness*, 142(2) *Pediatrics* (2018).

⁴¹² Rebecca L. Haffajee, Michelle M. Mello, Fang Zhang, Alisa B. Busch, Alan M. Zaslavsky, & J. Frank Wharam, *Association of Federal Mental Health Parity Legislation with Health Care Use and Spending Among High Utilizers of Services*, 57(4) *Medical Care* p. 245.

⁴⁰⁶ Mengyao Li, Cora Peterson, Likang Xu, Christina A. Mikosz, & Feijun Luo, *Medical Costs of Substance Use Disorders in the US Employer-Sponsored Insurance Population*, 6(1) *JAMA Netw Open* (2023), <https://pubmed.ncbi.nlm.nih.gov/36692881/>.

⁴⁰⁷ The OUD treatment cost estimate of \$11,871 has been adjusted using the CPI for medical care cost to 2023 dollars. See Mengyao Li, Cora Peterson, Likang Xu, Christina A. Mikosz, & Feijun Luo, *Medical Costs of Substance Use Disorders in the US Employer-Sponsored Insurance Population*, 6(1) *JAMA Netw Open* (2023), <https://pubmed.ncbi.nlm.nih.gov/36692881/>.

⁴⁰⁸ \$13,448 OUD treatment cost × 43,054 additional persons receiving treatment = \$578,990,192.

⁴⁰⁹ Tami L. Mark & William Parish, *Behavioral Health Parity—Pervasive Disparities in Access to In-Network Care Continue*, RTI International (Apr. 2024), <https://dpjh8al9zd3a4.cloudfront.net/publication/behavioral-health-parity-pervasive-disparities-access-network-care-continue/fulltext.pdf>.

patients had decreased and the total expenditure for health plans had increased, with no significant impact on health care utilization, suggesting that the costs had shifted from patients to health plans.⁴¹³

According to the 2019 MEPS–HC, private insurance covered \$33.87 billion of expenditures for treatment of mental health disorders among adults ages 18 and older⁴¹⁴ while all individuals paid \$15.62 billion out-of-pocket.⁴¹⁵ As discussed throughout this analysis, there are many reasons someone might seek care out-of-network or pay out-of-pocket for treatment, such as limited coverage from the issuer or plan, difficulty finding a network provider, or long wait times to see an in-network provider. The Departments acknowledge that these final rules will not address all the reasons that individuals pay out-of-pocket for treatment, and there is significant uncertainty in how these final rules will affect out-of-network spending.

Accordingly, the Departments do not know what proportion of total out-of-pocket spending experienced in the past will be covered by group health plans and health insurance coverage following the applicability of these final rules. However, to illustrate the potential scale of transfers from participants, beneficiaries, and enrollees to plans under this rulemaking, the Departments reference a 2020 study of in-network versus out-of-network psychotherapy employer-sponsored insurance claims which found in-network cost sharing was, on average, \$24.41 less than out-of-network cost-sharing for psychotherapy claims.⁴¹⁶ Utilizing tabulations from the MEPS–HC on events, such as office and outpatient visits for mental, behavioral, or neurological conditions, there were 530.7 million of these medical events in

2021 for individuals 65 and under with private insurance.⁴¹⁷ Applying the initial out-of-network rates of 13.4 percent from the Marsh and Parish paper would translate into 71.1 million out-of-network claims, which is 9 percentage points higher for mental health and substance use disorders than for medical/surgical treatments.⁴¹⁸ It is assumed that, under these final rules, the out-of-network utilization rates for mental health and substance use disorder benefits fall by just 10 percent to 12.1 percent of claims, this would still represent a transfer from plans and issuers to participants and beneficiaries of \$168.4 million annually in lower cost-sharing.⁴¹⁹

9.2. Transfers From Participants, Beneficiaries, and Enrollees to Plans and Issuers Caused by Higher Premiums

These final rules might also result in a transfer from participants, beneficiaries, and enrollees to plans and issuers in the form of higher premiums. By limiting the ability of plans and issuers to avoid costs of certain mental health and substance use disorder treatments while increasing access to and utilization of these services, these final rules might cause plans and issuers to increase premiums and change cost-sharing requirements (for example, by raising deductibles) to offset these costs. Similarly, plans and issuers might reduce the number of NQTLs employed and increase premiums in order to offset the costs of participants, beneficiaries, and enrollees utilizing more mental health and substance use disorder benefits.

Many studies attempt to isolate the changes in health costs associated with implementing parity requirements. One 2005 study by the Society of Actuaries on State mental health parity laws found that “overall health care costs increased minimally and in some cases were even reduced.”⁴²⁰ As discussed

earlier in section IV.8 of this regulatory impact analysis, by removing some of the barriers to access to mental health and substance use disorder treatments caused by existing NQTLs, the Departments expect that the final rules will result in increased utilization of mental health and substance use disorder services, which could increase costs, including premiums. However, as discussed in section IV.7.3 of this regulatory impact analysis, better access to mental health and substance use disorder services can lead to better health outcomes and prevent costly interventions, which may reduce overall health care costs and premiums in the long-term. Thus, the Departments anticipate that these final rules will have a minimal impact on premiums, but there may be instances in which plans and issuers may impose higher premiums.

The Departments requested comments or data on this transfer in the proposal. A few commenters stated that the proposal would hinder the ability of plans to utilize common medical management techniques that improve cost and quality outcomes, such as prior authorization. As a result, commenters stated there would be an increase in premiums for participants, beneficiaries, and enrollees. However, as discussed previously, these final rules do not finalize the substantially all and predominant mathematical tests for NQTLs as proposed. The final rules also do not eliminate the use of prior authorization or other medical management, but the Departments emphasize that they must be designed and applied in parity as required by law.

9.3. Transfers Between Primary Care Providers and Mental Health and Substance Use Disorder Providers

These final rules may result in a transfer from primary care providers to mental health and substance use disorder providers. More specifically, with improved in-network access to mental health and substance use disorder providers, patients may be more likely to seek treatment from a behavioral health specialist rather than a primary care provider.

For example, a 2012 study that examined the impact of Oregon’s 2007 parity law on the choice of provider found that the law was associated with a slight increase in the likelihood of patients seeking care “with masters-level specialists, and relatively little change for generalist physicians,

⁴¹³ Susan L. Ettner, Jessica M. Harwood, Amber Thalmer, Michael K. Ong, Haiyong Xu, Michael J. Bresolin, Kenneth B. Wells, Chi-Hong Tseng, & Francisca Azocar, *The Mental Health Parity and Addiction Equity Act Evaluation Study: Impact on Specialty Behavioral Health Utilization and Expenditures Among “Carve-Out” Enrollees*, 50 *Journal of Health Economics* pp. 131–143 (2016).

⁴¹⁴ As defined in the MEPS–HC, mental disorders include anxiety, depression, bipolar disorder, schizophrenia, obsessive-compulsive disorder, attention-deficit and/or hyperactivity disorder, substance use disorder, and other mental and neurodevelopmental illnesses.

⁴¹⁵ Anita Soni, *Healthcare Expenditures for Treatment of Mental Disorders: Estimates for Adults Ages 18 and Older, U.S. Civilian Noninstitutionalized Population, 2019*, Agency for Healthcare Research and Quality, Statistical Brief #539 (Feb. 2022), https://meps.ahrq.gov/data_files/publications/st539/stat539.pdf.

⁴¹⁶ Nicole M. Benson & Zirui Song, *Prices and Cost Sharing for Psychotherapy In Network Versus Out Of Network in the United States*, 39(7) *Health Affairs* pp. 1210–1218 (2020).

⁴¹⁷ Agency for Healthcare Research and Quality, *Number of Events in Thousands by Condition and Insurance Coverage, United States, 2021*, Medical Expenditure Panel Survey, <https://datatools.ahrq.gov/meps-hc?tab=medical-conditions&=17>.

⁴¹⁸ Tami L. Mark & William Parish, *Behavioral Health Parity—Pervasive Disparities in Access to In-Network Care Continue*, RTI International (Apr. 2024), <https://dpjh8al9zd3a4.cloudfront.net/publication/behavioral-health-parity-pervasive-disparities-access-network-care-continue/fulltext.pdf>.

⁴¹⁹ This estimate is calculated as follows: 530.7 million medical events × change in share that are out-of-network (13.4 percent – 12.1 percent) × \$24.41 = \$168.4 million.

⁴²⁰ Steve Melek, *The Cost of Mental Health Parity*, Health Section News, Issue 49 (2005), as presented to the Society of Actuaries, [https://www.soa.org/globalassets/assets/library/newsletters/health-](https://www.soa.org/globalassets/assets/library/newsletters/health-section-news/2005/march/hsn-2005-iss49-melek-b.pdf)

[section-news/2005/march/hsn-2005-iss49-melek-b.pdf](https://www.soa.org/globalassets/assets/library/newsletters/health-section-news/2005/march/hsn-2005-iss49-melek-b.pdf).

psychiatrists, and psychologists,” leading to a shift in the use of nonphysician specialists and away from generalist physicians.⁴²¹ Further, a 2020 study compared mental health outpatient visits of adults in the period between 2008 and 2011 to the period between 2012 and 2015 using data from the MEPS–HC. Between the two time periods, the study found that the percentage of adults who visited only primary care non-physicians, such as physician assistants and nurse practitioners, increased by about 4 percent, whereas the percentage of adults who visited only primary care physicians decreased by about 2 percent.⁴²² The findings of these papers suggest that the final rules may lead to a slight shift in the use of nonphysician specialists, and away from generalist physicians.

9.4. Transfers Associated With the Implementation of the CAA, 2023 Provision That Sunsets the MHPAEA Opt-Out Election for Self-Funded Non-Federal Governmental Plans

HHS anticipates that the rules implementing the CAA, 2023 provision that sunsets the MHPAEA opt-out election for self-funded non-Federal governmental plans will have similar effects as the other provisions examined in this section IV.9 of the regulatory impact analysis. These final rules are generally expected to lead to improved coverage of and lower cost-sharing requirements for mental health and substance use disorder benefits for participants and beneficiaries of self-funded non-Federal governmental plans. This will lead to lower out-of-pocket costs for plan participants and beneficiaries who receive mental health or substance use disorder services, which will be a transfer from self-funded non-Federal governmental plans to participants and beneficiaries.

On the other hand, as noted in section IV.8.2 of this regulatory impact analysis, if the final rules cause plans to remove limits on or offer more generous mental health and substance use disorder benefits, utilization of mental health and substance use disorder services may increase, which may cause in the number of claims submitted, the

number of claims paid, and the overall costs incurred by plans to also increase. This, in turn, might lead to higher contributions and/or deductibles for plan participants, which may seem to be a transfer from plan participants to self-funded non-Federal governmental plans, but is instead an indication of the societal cost presented in section IV.8 of this regulatory impact analysis (and who bears it).

10. Uncertainty

It is unclear what percentage of plans and issuers impose greater burdens on mental health and substance use disorder benefits than on medical/surgical benefits. This frequency may differ among small and large plans and issuers. The Departments’ experience in enforcing MHPAEA shows that plans and issuers are not in full compliance with MHPAEA, although the extent across all plans and issuers is not known. As documented in the fiscal year (FY) 2022 MHPAEA Enforcement Fact Sheet, DOL closed investigations on 145 health plans, with 86 of them subject to MHPAEA, in fiscal year 2022. Of these closed investigations, EBSA cited 18 MHPAEA violations in 11 investigations.⁴²³

One commenter stated that the new requirements of the comparative analyses would require plans to make significant changes to their benefits design and NQTL compliance structure, which could result in more restrictions on medical/surgical benefits and/or higher premiums. The commenter did not provide any data or evidence. The Departments note that there is no evidence from previous parity requirements that such actions led to the implementation of new NQTLs, particularly to medical/surgical benefits, and impacted cost sharing, medical management provisions, or medical/surgical coverage.

There is also the possibility that some plans and issuers will stop offering mental health and substance use disorder benefits. In 2010, 2 percent of employers reported discontinuing their coverage of both mental health and substance use disorder treatments or only substance use disorder treatments since MHPAEA was passed.⁴²⁴ Nevertheless, as discussed in section IV.9.1 of this regulatory impact analysis,

the Departments anticipate that these final rules will expand the level of coverage for mental health and substance use disorder benefits, which will result in reduced out-of-pocket spending for plan participants, beneficiaries, and enrollees.

Another commenter also stated that the proposed rules would largely eliminate behavioral health carve-out vendors as a business model, because such vendors would not be able to build networks in complete alignment with medical/surgical disorder networks, as required under the proposed network composition NQTL rule. In response, the Departments note that similar claims—that MHPAEA would eliminate behavioral health carve-outs—were made when MHPAEA was first enacted in 2008. Furthermore, studies have found that the number of carve-out plans have increased since the enactment of MHPAEA. A 2016 study examined the impact of MHPAEA on carve-out plans and found that MHPAEA “led to a proliferation of plans and heterogeneity in benefit design in the post-parity period among employer groups choosing to retain the carve-out model for their behavioral health coverage.” The study also found no evidence that carve-out plans dropped coverage altogether for behavioral health treatments.⁴²⁵ A 2020 study also observing the impact of MHPAEA on carve-out plans found that “post-MHPAEA, the number of carve-out plans increased relative to carve-ins” and that MHPAEA was associated with lower copayments and out-of-network coinsurance for emergency room and outpatient services. The findings suggest that MHPAEA led to more generous benefits for carve-out plans. However, the authors also noted an increase in deductibles and in-network outpatient coinsurance, suggesting that some patients experienced higher out-of-pocket costs.⁴²⁶ Nevertheless, these studies suggest that the purported issues referenced by commenters were surmountable.

Additionally, the Departments note that they are not finalizing the proposed

⁴²¹ John K. McConnell, Samuel HN Gast, & Benton H. McFarland, *The Effect of Comprehensive Behavioral Health Parity on Choice of Provider*, 50(6) Medical Care p. 527.

⁴²² The study did not find a statistically significant change in visits to specialty mental health providers. See Hayley D. Germack, Coleman Drake, Julie M. Donohue, Ezra Golberstein, & Susan H. Busch, *National Trends in Outpatient Mental Health Service Use Among Adults Between 2008 and 2015*, 71 Psychiatric Services 11 pp. 1127–1135 (2020).

⁴²³ EBSA, FY 2022 MHPAEA Enforcement Fact Sheet, <https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/mental-health-parity/mhpaea-enforcement-2022>.

⁴²⁴ GAO, *Mental Health and Substance Use: Employers’ Insurance Coverage Maintained or Enhanced Since Parity Act, but Effect of Coverage on Enrollees Varied*, GAO–12–63 (Nov. 2011), <https://www.gao.gov/assets/gao-12-63.pdf>.

⁴²⁵ Susan L. Ettner, Jessica M. Harwood, Amber Thalmayer, Michael K. Ong, Haiyong Xu, & Michael J. Bresolin, *The Mental Health Parity and Addiction Equity Act Evaluation Study: Impact on Specialty Behavioral Health Utilization and Expenditures among “Carve-Out” Enrollees*, 50 Journal of Health Economics pp. 131–143 (2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5127782>.

⁴²⁶ Sarah Friedman, Haiyong Xu, Francisca Azocar, & Susan L. Ettner, *Carve-out Plan Financial Requirements Associated with National Behavioral Health Parity*, 55(6) Health Services Research pp. 924–931 (2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7704471/>.

special rule for NQTLs related to network composition, and are instead including language in these final rules to explain how plans and issuers are expected to comply with the relevant data evaluation requirements with respect to those NQTLs. Under these final rules, material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits (including for NQTLs related to network composition) will not be treated as a violation; instead, plans and issuers must take reasonable action, as necessary, to address any material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits, and document those actions in their comparative analyses.

Further, there may be some possible societal spillover effects which may occur as a result of these final rules such as improving public safety in the long-term from an increase in access to mental health and substance use disorder treatments. For example, a 2017 study examined the effect of State parity laws for substance use disorder treatments on fatal traffic accidents and found that enactment of State parity laws were associated with reduced annual total traffic fatality rates from 4.1 percent to 5.4 percent.⁴²⁷ Furthermore, a 2021 study which examined the impact of State parity laws on crime between 1994 and 2010 found that the enactment of State parity laws was associated with a reduction of violent crimes by 5 percent to 7 percent and that the resulting lower crime rates were associated with an annual savings of \$3 billion.⁴²⁸ These studies suggest that the benefits of these final rules may go beyond the listed benefits discussed in this regulatory impact analysis.

The Departments face uncertainty in estimating the magnitude of savings for participants, beneficiaries, and enrollees. The Departments requested comments and data in the proposal related to how the Departments may quantify the impact in out-of-pocket spending from these rules, but did not receive any comments.

Additionally, HHS is unable to precisely forecast how many participants and beneficiaries will be affected by the amendments to

implement the CAA, 2023 provision that sunsets the MHPAEA opt-out election for self-funded non-Federal governmental plans, as plan sponsors that have elected to opt out of requirements under MHPAEA were not required to report that information to HHS as part of their opt-out filings. See section IV.5.3 of this regulatory impact analysis for further discussion on the affected participants and beneficiaries.

It is possible that some self-funded non-Federal governmental plans will stop offering mental health and substance use disorder benefits in response to the final rules. However, HHS is unable to estimate the potential number of self-funded non-Federal governmental plans that might do so. It is also possible that some self-funded non-Federal governmental plans might increase the financial requirements and treatment limitations that apply to medical/surgical benefits in response to this provision, to ensure that financial requirements and treatment limitations applicable to mental health and substance use disorder benefits comply with MHPAEA and its implementing regulations. HHS anticipates that this is a less likely outcome of these amendments.

HHS solicited comments on the potential number of self-funded non-Federal governmental plans that might stop offering mental health and substance use disorder benefits, as well as the potential number of self-funded non-Federal governmental plans that might increase financial requirements and treatment limitations for medical/surgical benefits in response to the proposed amendments. HHS also solicited comments on the potential number of participants and beneficiaries that might be affected by these potential plan changes. HHS did not receive any comments that provided this information.

11. Alternatives

In addition to the regulatory approach outlined in these final rules, the Departments considered alternatives when developing policy regarding the implementation of MHPAEA. The Departments considered not expressly incorporating the statutory requirement that NQTLs be no more restrictive for mental health and substance use disorder benefits than for medical/surgical benefits. However, as described earlier in this preamble, it is clear that plans and issuers too often fail to consider the impact of their NQTLs on access to mental health and substance use disorder benefits before designing and applying NQTLs, in a manner that is consistent with MHPAEA's

fundamental purpose. While the Departments have seen some improvements in response to their reviews of plans' and issuers' comparative analyses under the CAA, 2021 requirements, they have primarily seen a great deal of confusion about the application of the current regulation to NQTLs and about the parity obligation generally. Based on the experience with plans' and issuers' attempts to comply with the existing regulations and guidance and the CAA, 2021, the Departments have concluded that the existing MHPAEA regulations failed to sufficiently focus attention on the obligation to ensure that NQTLs, and associated processes, strategies, evidentiary standards, and other factors avoid placing disparate burdens on participants', beneficiaries', and enrollees' access to mental health and substance use disorder benefits as compared to medical/surgical benefits. Accordingly, the Departments are of the view that these final rules will be beneficial to participants, beneficiaries, and enrollees, as plans and issuers revise their policies and remove or amend NQTLs that are inconsistent with MHPAEA.

The Departments also considered not requiring plans and issuers to use specific data elements in designing and applying NQTLs and preparing their comparative analyses or to provide the data to the Departments upon request. However, during their review of comparative analyses as part of their reporting requirements to Congress, the Departments found that many plans and issuers did not initially provide sufficient information to demonstrate compliance of an NQTL as written, in operation, or both. It is often difficult to assess compliance in operation without such data. By requiring the consideration, use, and production of this data, the regulation will improve the review of plans' and issuers' policies and processes, and improved parity outcomes for participants, beneficiaries, and enrollees.

12. Conclusion

The Departments expect that these final rules will provide plans and issuers with a better understanding of the requirements of MHPAEA and improve how they measure, analyze, document, and demonstrate parity with regard to NQTLs. The Departments are of the view that these final rules will help plans and issuers produce NQTL comparative analyses that meet the requirements of the CAA, 2021, resulting in improved access to and coverage of mental health and substance use disorder treatments, which should

⁴²⁷ Ioana Popovici, Johanna Catherine Maclean, & Michael T. French, *The Effects of Health Insurance Parity Laws for Substance Use Disorder Treatment on Traffic Fatalities: Evidence of Unintended Benefits*, National Bureau of Economic Research (2017), https://www.nber.org/system/files/working_papers/w23388/revisions/w23388.rev0.pdf?sy=388.

⁴²⁸ Keshob Sharma, *Do Mental Health Parity Laws Reduce Crime?*, working paper (Nov. 14, 2021).

ultimately result in better health outcomes among those with mental health conditions and substance use disorders.

V. Paperwork Reduction Act

1. Paperwork Reduction Act— *Departments of Labor and the Treasury*

In accordance with the Paperwork Reduction Act of 1995 (PRA 95) (44 U.S.C. 3506(c)(2)(A)), the Departments solicited comments concerning the information collection requests (ICRs) included in the proposed rules. At the same time, the Departments also submitted ICRs to OMB, in accordance with 44 U.S.C. 3507(d).

The Departments received comments that specifically addressed the paperwork burden analysis of the ICRs contained in the proposed rules. Many commenters expressed concern that the Departments underestimated the burden of collecting the required data, the burden required in conducting the substantially all and predominant variation analysis, the number of NQTLs that would need to be analyzed for each plan and issuer, and the amount of time that it would take to conduct those analyses. The Departments reviewed these public comments in developing the paperwork burden analysis discussed here.

The changes made by these final rules affect the existing OMB control number, 1210–0138. A copy of the ICR for OMB Control Number 1210–0138 may be obtained by contacting the PRA addressee listed in the following sentence or at www.RegInfo.gov. For additional information contact, U.S. Department of Labor, Employee Benefits Security Administration, Office of Research and Analysis, Attention: PRA Officer, 200 Constitution Avenue NW, Room N–5718, Washington, DC 20210; or send to ebbsa.opr@dol.gov.

1.1. Final Amendments to Existing MHPAEA Regulations (26 CFR 54.9812–1; 29 CFR 2590.712)

These final rules add new definitions, amend existing definitions, specify new requirements related to NQTLs, including by prohibiting discriminatory factors and evidentiary standards, amend existing examples illustrating the rules for NQTLs, and add new examples illustrating the rules for NQTLs, providing clarity to interested parties. The final rules also specify that the way a plan or issuer defines mental health benefits, substance use disorder benefits, and medical/surgical benefits must be consistent with generally recognized independent standards of current medical practice and add more

specificity as to what conditions or disorders plans and issuers must treat as mental health conditions, substance use disorders, and medical conditions and surgical procedures. The final rules also require that plans and issuers provide meaningful benefits for covered mental health conditions or substance use disorders in each classification in which meaningful medical/surgical benefits are provided. Additionally, these final rules require plans and issuers to collect and evaluate relevant data in a manner reasonably designed to assess the impact of the NQTL on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits. Where the relevant data suggest that the NQTL contributes to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits in a classification, plans and issuers are required to take reasonable action, as necessary, to address the material differences to ensure compliance, in operation, with 26 CFR 54.9812–1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4). These final rules provide guidance for how to comply with the relevant data evaluation requirements in limited circumstances where data is initially and temporarily unavailable for new and newly imposed NQTLs and where no data exists that can reasonably measure any relevant impact of the NQTL on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits. In those instances, the plan or issuer must include specific information in their comparative analyses, as explained earlier in this preamble. However, as explained earlier in this preamble, the Departments are of the view that nearly all NQTLs will have some relevant data to collect and evaluate; therefore, the Departments estimate the burden as if every plan and issuer performs the data analysis.

1.2. New Regulation (26 CFR 54.9812–2; 29 CFR 2590.712–1)

These final rules set more specific content and data requirements for the NQTL comparative analyses required by MHPAEA as amended by the CAA, 2021, clarify when the comparative analyses need to be performed, and outline the timeframes and process for plans and issuers to provide their comparative analyses to the Departments or applicable State authority upon request.

For the purpose of this analysis, it is assumed that health insurance issuers will fulfill the data request for fully insured group health plans. This burden

is accounted for under HHS' OMB Control number 0938–1393 and is discussed later in this document. It is also assumed that TPAs and other service providers will fulfill the requirements for the vast majority of self-funded group health plans.

1.3. Burden Estimates for Final Rules Requirements

The final rules will affect self-funded plans and MEWAs. The Departments estimate that 709 self-funded plans with 500 or more participants will prepare the comparative analysis and data themselves. The Departments also estimate that 4,076 self-funded plans with 500 or more participants will receive a generic comparative analysis from their TPA or other service provider, which they will subsequently customize to suit their specific needs. Finally, the Departments estimate that 132 plan MEWAs and 21 non-plan MEWAs that are not fully insured will provide assistance to plans in collecting and analyzing the data, and generating the comparative analyses. For more information on how the number of each type of entity is estimated, please refer to the Affected Entities section of the regulatory impact analysis.

Non-grandfathered, fully insured ERISA plans with less than 50 participants that are subject to MHPAEA under the EHB requirements of the ACA are likely to have their issuers prepare their comparative analyses. Issuers can take advantage of economies of scale by preparing the required documents for those plans purchasing coverage. HHS has jurisdiction over issuers in States that substantially fail to enforce MHPAEA's requirements and therefore is accounting for this portion of the burden in its analysis, in addition to the burden related to non-Federal governmental plans. Accordingly, this analysis considers only the burden associated with ERISA self-funded group health plans, which are under the jurisdiction of the DOL and the Treasury.

These final rules require that a plan or issuer perform and document a comparative analysis of each NQTL applicable to mental health and substance use disorder benefits. In the proposed rules, the Departments estimated that, on average, plans would need to analyze four separate NQTLs and issuers would need to analyze eight NQTLs to satisfy their additional comparative analysis requirements. The Departments further estimated that plans and issuers preparing their own comparative analyses would incur a burden of 20 hours per NQTL in the first year, with 4 hours for a general or

operations manager to review the requirements and outline the changes needed for the comparative analyses and 16 hours for a business operations specialist to prepare the comparative analyses. Once the comparative analyses are performed and documented, the Departments estimated that plans and issuers would need to update the analyses when making changes to the terms of the plan or coverage, including changes to the way NQTLs are applied to mental health and substance use disorder benefits as well as medical and surgical benefits. In subsequent years, the Departments estimated plans would incur a burden of 10 hours annually per NQTL to update the analyses, with 2 hours for a general or operations manager and 8 hours for a business operations specialist.

In response to commenters' concerns that the Departments underestimated the number of NQTLs that each plan or issuer would need to create comparative analyses for, and that plans and issuers would on average have the same number NQTLs, the Departments have revised their assumptions to 10 NQTLs for both plans and issuers. One commenter proposed the average number of NQTLs should be more than 15 at a minimum, while another noted that there were at least 15 NQTLs referenced in the proposed rules and other guidance. However, given that the number of NQTLs vary by issuer and plan, that most plans will not have every NQTL referenced in the proposed rules and other guidance (although some might have more), and that NQTLs can be counted as an umbrella group, the Departments assume 10 NQTLs.

The Departments assume that collecting the data, and reviewing and revising the comparative analyses would require 60 hours per NQTL in the first year and 12 hours per NQTL in subsequent years. For plans that receive a generic comparative analysis that will require customizing to suit the plan's specific needs, the Departments assume that it will take 30 hours per NQTL in the first year and 6 hours per NQTL in subsequent years. While plans and issuers can use other professionals to fulfill their requirements, for purposes of developing the wage estimate, the Departments assume that it will take a team of data analysts, actuaries, and attorneys to collect the data and prepare the comparative analyses and have estimated a composite wage rate of \$167.48.⁴²⁹ See Table 11 for calculations and burden totals.

TABLE 11—HOURLY BURDEN TO FULFILL THE DATA REQUIREMENTS AND PREPARE THE COMPARATIVE ANALYSES

	Number of entities	Number of NQTLs per entity	Number of hours per NQTL for data and comparative analysis	Total hour burden	Hourly wage	Equivalent cost of hour burden
	(A)	(B)	(C)	(A × B × C)	(D)	E (A × B × C × D)
First Year						
TPAs	103	10	60	61,800	\$167.48	\$10,350,264
Self-funded plans with more than 500 participants that will conduct the comparative analysis themselves	709	10	60	425,400	167.48	71,245,992
Self-funded plans with more than 500 participants that will receive generic comparative analyses from TPAs or service providers, and will then customize it	4,076	10	30	1,222,800	167.48	204,794,544
Plan MEWAs that are not fully insured	132	10	60	79,200	167.48	13,264,416
Non-plan MEWAs that are not fully insured	21	10	60	12,600	167.48	2,110,248
First-year Total	5,041			1,801,800		301,765,464
Subsequent Years						
TPAs	103	10	12	12,360	167.48	2,070,053
Self-funded plans with more than 500 participants that will conduct the comparative analysis themselves	709	10	12	85,080	167.48	14,249,198
Self-funded plans with more than 500 participants that will receive generic comparative analyses from TPAs or service providers, and will then customize it	4,076	10	6	244,560	167.48	40,958,909
Plan MEWAs that are not fully insured	132	10	12	15,840	167.48	2,652,883
Non-plan MEWAs that are not fully insured	21	10	12	2,520	167.48	422,050
Subsequent Years Total	5,041			360,360		60,353,093
Total (3-year average)	5,041			840,840		140,823,883

These final rules also require that group health plans offering group health insurance coverage must make a comparative analysis available upon request by the Departments. The CAA, 2021 requires the Departments to collect no fewer than 20 comparative analyses

per year, but it also provides that the Departments shall request that a group health plan or issuer submit the comparative analyses for plans that involve potential MHPAEA violations or complaints regarding noncompliance with MHPAEA that concern NQTLs,

and any other instances in which the Departments determine appropriate. Based on its prior experience and current funding, DOL expects to request 20 comparative analyses each year. See Table 12 for calculations and burden totals.

⁴²⁹ The wage rate of an attorney, actuary, and data analyst is, respectively, \$165.71, \$177.11, and \$159.61. (Internal DOL calculation based on 2024 labor cost data. For a description of DOL's methodology for calculating wage rates, see EBSA, *Labor Cost Inputs Used in the Employee Benefits*

Security Administration, Office of Policy and Research's Regulatory Impact Analyses and Paperwork Reduction Act Burden Calculations (June 2019), <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.) The composite wage rate is estimated in the following manner: [$\$165.71 \times (1 + 3) + \$159.61 \times (1 + 3) \times \$177.61 \times (1 + 3) = \$167.48$].

These final rules also require plans and issuers to make the comparative analyses and other applicable information required by the CAA, 2021 available upon request to participants, beneficiaries, and enrollees in all non-grandfathered group health plans and non-grandfathered group or individual health insurance coverage (including a provider or other person acting as a participant's, beneficiary's, or enrollee's authorized representative) in connection with an adverse benefit determination, as well as to participants and beneficiaries in plans subject to ERISA.

The Departments estimate that each plan will receive one request per covered health plan annually and that plans will annually incur a burden of 5 minutes for a clerical worker to prepare and send the comparative analyses to each requesting participant or beneficiary. DOL also assumes that 58.3 percent of requests will be delivered electronically, resulting in a de minimis cost.⁴³⁰ The remaining 41.7 percent of requests will be mailed at a cost of \$2.79.⁴³¹ See Table 12 for calculations and burden totals.

1.4. Recordkeeping Requirement

The Departments posit that plans and issuers already maintain records as part of their regular business practices. Further, ERISA section 107 includes a general 6-year retention requirement. For these reasons, the Departments estimate a minimal additional burden. The Departments estimate that, on average, any additional recordkeeping requirements will take clerical personnel 5 minutes annually. See Table 12 for calculations and burden totals.

TABLE 12—HOUR AND COST BURDEN OF OTHER REQUIREMENTS

	Number of response	Number of hours per responses	Total hour burden	Wage rate	Hour equivalent of cost burden	Mailing cost per response	Cost burden
	(A)	(B)	(A × B)	(C)	(A × B × C)	(D)	(A × D × 41.7 percent)
Business operations specialists prepare comparative analysis for audits	20	1	20	137.67	2,753	0	0
General operation managers prepare comparative analysis for audits	20	4	80	114.36	9,149	0	0
Clerical workers prepare and distribute comparative analyses upon participant request	2,129,516	0.083	177,460	65.99	11,710,585	2.79	2,477,543
Clerical workers maintain recordkeeping	2,129,516	0.083	177,460	65.99	11,710,585	0	0
Total	2,129,536		355,020		23,433,073		2,477,543

1.5. Overall Summary

In summary, the total burden associated with these final rules has a 3-year average hour burden of 1,195,860 hours with an equivalent cost of \$164,256,956 and a cost burden of \$2,477,543.

A summary of paperwork burden estimates follows:

Type of Review: Revision.

Agency: Employee Benefits Security Administration, U.S. Department of Labor; Internal Revenue Service, U.S. Department of the Treasury.

Title: MHPAEA Notices.

OMB Control Number: 1210–0138.

Affected Public: Businesses or other for-profits, Not-for-profit institutions.

Estimated Number of Respondents: 123,1752.

Estimated Number of Annual Responses: 123,1752.

Frequency of Response: Annual.

Estimated Total Annual Burden Hours: 1,195,860 (597,930 for DOL, 597,930 for Treasury).

Estimated Total Annual Burden Cost: \$2,477,543 (\$1,238,771 for DOL, \$1,238,771 for Treasury).

2. Paperwork Reduction Act—Department of HHS

In accordance with the Paperwork Reduction Act of 1995 (PRA 95) (44 U.S.C. 3506(c)(2)(A)), the Department solicited comments concerning the ICRs included in the proposed rules. At the same time, the Departments also submitted ICRs to OMB, in accordance with 44 U.S.C. 3507(d).

The Departments received comments that specifically addressed the paperwork burden analysis of the ICRs contained in the proposed rules. Many commenters expressed concern that the Departments underestimated the burden of collecting the required data, the burden of conducting the substantially all and predominant variation analysis, the number of NQTLs that would need to be analyzed for each plan and issuer, and the amount of time that it would take to conduct those analyses. The

Departments reviewed these public comments in developing the paperwork burden analysis discussed here.

The changes made by these final rules affect the existing OMB control number, 0938–1393. HHS will update the information collection to account for the burden related to the provisions in these final rules.

2.1. Final Amendments to Existing MHPAEA Regulations (45 CFR 146.136)

The amendments to the existing MHPAEA regulations in these final rules add new definitions, amend existing definitions, clarify the rules for NQTLs, including by prohibiting discriminatory factors and evidentiary standards, amend existing examples illustrating the rules for NQTLs, and add new examples illustrating the rules for NQTLs, providing clarity to the regulated community. The amendments also clarify that whether a condition or disorder is defined by the plan or issuer as being a mental health condition or a substance use disorder for purposes of

⁴³⁰ According to data from NTIA, 37.4 percent of individuals aged 25 and over have access to the internet at work. According to a Greenwald & Associates survey, 84 percent of plan participants find it acceptable to make electronic delivery the default option, which is used as the proxy for the number of participants who will not opt out of electronic disclosure that are automatically enrolled (for a total of 31.4 percent receiving electronic

disclosure at work). Additionally, the NTIA reports that 44.1 percent of individuals aged 25 and over have access to the internet outside of work. According to a Pew Research Center survey, 61.0 percent of internet users use online banking, which is used as the proxy for the number of internet users who will affirmatively consent to receiving electronic disclosures (for a total of 26.9 percent receiving electronic disclosure outside of work).

Combining the 31.4 percent who will receive electronic disclosure at work with the 26.9 percent who will receive electronic disclosure outside of work produces a total of 58.3 percent who will receive electronic disclosure overall.

⁴³¹ The postage for a first-class mail large envelope letter is \$2.04 and the material cost is \$0.05 per page. Thus, \$2.04 + (\$0.05 × 15 pages) = \$2.79.

MHPAEA must be consistent with generally recognized independent standards of current medical practice. The final rules also require that plans and issuers provide meaningful benefits for covered mental health conditions or substance use disorders in each classification in which meaningful medical/surgical benefits are provided.

These final rules also require plans and issuers to collect and evaluate relevant data in a manner reasonably designed to assess the impact of the NQTL on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits. Relevant data for the majority of NQTLs could include, as appropriate, but are not limited to, the number and percentage of claims denials and any other data relevant to the NQTL required by State law or private accreditation standards. Additionally, relevant data for NQTLs related to network composition could include, as appropriate, but are not limited to, in-network and out-of-network utilization rates (including data related to provider claim submissions), network adequacy metrics (including time and distance data, and data on providers accepting new patients), and provider reimbursement rates (for comparable services and as benchmarked to a reference standard).

2.2. New Regulations (45 CFR 146.137)

These final rules set forth more specific content and data requirements for the NQTL comparative analyses required by MHPAEA as amended by the CAA, 2021, clarify when the comparative analyses need to be performed, and outline the timeframes and process for plans and issuers to provide their comparative analyses to the Departments or an applicable State authority upon request.

These final rules provide guidance for how to comply with the relevant data evaluation requirements in limited circumstances where data is initially and temporarily unavailable for new and newly imposed NQTLs and where no data exists that can reasonably measure any relevant impact of the NQTL on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits. In those instances, the plan or issuer must include specific information in their comparative analyses, as explained earlier in this preamble. In such instances, providing this justification is likely to be less expensive than the estimated burden for doing an analysis when there is data. However, as explained earlier in this preamble, the Departments are of the

view that nearly all NQTLs will have some relevant data to collect and evaluate; therefore, the Departments estimate the burden as if every plan and issuer performs the data analysis.

As discussed earlier in this preamble, HHS enforces applicable provisions of Title XXVII of the PHS Act, including the provisions added by MHPAEA, with respect to health insurance issuers offering group and individual health insurance coverage in States that elect not to enforce or fail to substantially enforce MHPAEA or another PHS Act provision. HHS is therefore accounting for this portion of the burden in its analysis, in addition to accounting for the burden on sponsors of self-funded non-Federal governmental plans.

2.3. Burden Estimates for Final Requirements

These final rules will affect issuers, TPAs, and self-funded non-Federal governmental plans. Health insurance issuers offering individual or group health insurance coverage usually have multiple products offered in multiple States. HHS estimates a total of 479 health insurance companies offering individual or group health insurance coverage nationwide, with a total of 1,467 issuers (health insurance company/State combinations). In addition, there are an estimated 205 TPAs that provide services to group health plans, particularly for self-funded plans where TPAs often establish provider networks and adjudicate claims, which will be impacted by these final rules. Furthermore, sponsors of self-funded non-Federal governmental plans will be affected by these final rules. HHS estimates that out of the estimated 32,901 self-funded non-Federal governmental plans, 505 self-funded non-Federal governmental plans with 500 or more participants will prepare the comparative analysis and data themselves, and 2,906 self-funded non-Federal governmental plans with 500 or more participants will receive a generic comparative analysis from their TPA, which they will subsequently customize to suit their specific needs. For more information on how the number of each type of entity is estimated, please refer to section IV.5.2 of the regulatory impact analysis.

These final rules require that a plan or issuer perform and document a comparative analysis of each NQTL applicable to mental health and substance use disorder benefits. In the proposed rules, the Departments estimated that, on average, plans would need to analyze four separate NQTLs and issuers would need to analyze eight NQTLs to satisfy their additional

comparative analysis requirements. The Departments further estimated that plans and issuers preparing their own comparative analyses would incur a burden of 20 hours per NQTL in the first year, with 4 hours for a general or operations manager to review the requirements and outline the changes needed for the comparative analyses and 16 hours for a business operations specialist to prepare the comparative analyses. Once the comparative analyses are performed and documented, plans and issuers would need to update the analyses when making changes to the terms of the plan or coverage, including changes to the way NQTLs are applied to mental health and substance use disorder benefits, as well as medical and surgical benefits. In subsequent years, the Departments estimated plans would incur a burden of 10 hours annually per NQTL to update the analyses, with 2 hours for a general or operations manager and 8 hours for a business operations specialist.

In response to commenters' concerns that the Departments underestimated the number of NQTLs that each plan or issuer would need to create comparative analyses for, and that plans and issuers would on average have the same number NQTLs, the Departments have revised their assumptions to 10 NQTLs for both plans and issuers. One commenter proposed the average number of NQTLs should be more than 15 at a minimum, while another noted that there were at least 15 NQTLs referenced in the proposed rules and other guidance. However, because the number of NQTLs varies by issuer and plan, most plans will not have every NQTL referenced in the rules or guidance (although some might use more), and NQTLs can be counted as an umbrella group, the Departments assume 10 NQTLs.

The Departments assume that collecting the data, and reviewing and revising the comparative analyses will require 60 hours per NQTL in the first year and 12 hours per NQTL in subsequent years. For plan sponsors that receive a generic comparative analysis from a TPA that will require customizing to suit the plan's specific needs, the Departments assume that it will take 30 hours per NQTL in the first year and 6 hours per NQTL in subsequent years. While plans and issuers can use other professionals to fulfill their requirements, for purposes of developing the wage estimate, the Departments assume that it will take a team of data analysts, actuaries, and attorneys to collect the data and prepare the comparative analyses, and have estimated a composite wage rate of

\$167.48.⁴³² See Table 13 for calculations and burden totals.

TABLE 13—HOURLY BURDEN TO FULFILL THE DATA REQUIREMENTS AND PREPARE THE COMPARATIVE ANALYSES

	Number of entities	Number of NQTLs per entity	Number of hours per NQTL for data and comparative analysis	Total hour burden	Hourly wage	Equivalent cost of hour burden
	(A)	(B)	(C)	(A × B × C)	(D)	E (A × B × C × D)
First Year						
Issuers (health insurance company/State combinations)	1,467	10	60	880,200	\$167.48	\$147,415,896
TPAs	103	10	60	61,800	167.48	10,350,264
Self-funded non-Federal governmental plans with more than 500 participants that will conduct the comparative analysis themselves	505	10	60	303,000	167.48	50,746,440
Self-funded non-Federal governmental plans with more than 500 participants that will receive a generic comparative analysis from TPAs or service providers, and will then customize it	2,906	10	30	871,800	167.48	146,009,064
First-year Total	4,981			2,116,800		354,521,664
Subsequent Years						
Issuers	1,467	10	12	176,040	167.48	29,483,179
TPAs	103	10	12	12,360	167.48	2,070,053
Self-funded non-Federal governmental plans with more than 500 participants that will conduct the comparative analysis themselves	505	10	12	60,600	167.48	10,149,288
Self-funded non-Federal governmental plans with more than 500 participants that will receive a generic comparative analysis from TPAs or service providers, and will then customize it	2,906	10	6	174,360	167.48	29,201,813
Subsequent Years Total	4,981			423,360		70,904,333
Total (3-year average)	4,981			987,840		165,443,443

These final rules require that plans or issuers make their comparative analyses available upon request to the Departments. The CAA, 2021 requires the Departments to collect not fewer than 20 comparative analyses per year, but it also provides that the Departments shall request that a plan or issuer submit the comparative analyses for plans that involve potential MHPAEA violations or complaints regarding noncompliance with MHPAEA that concern NQTLs, and any other instances in which the Departments determine appropriate. HHS expects to request at least 20 comparative analyses each year. See Table 14 for calculations and burden totals.

These final rules also require plans and issuers to make the comparative analyses and other applicable

information required by the CAA, 2021 available upon request to participants, beneficiaries, and enrollees in all non-grandfathered group health plans and non-grandfathered group or individual health insurance coverage (including a provider or other person acting as a participant's, beneficiary's, or enrollee's authorized representative) in connection with an adverse benefit determination, as well as to participants and beneficiaries in plans subject to ERISA. HHS estimates that each non-Federal governmental plan and each issuer will receive one request annually and that plans and issuers will annually incur a burden of 5 minutes for a clerical worker to prepare and send the comparative analyses to each requesting participant, beneficiary, or enrollee. HHS also assumes that 58.3 percent of requests will be delivered electronically,

resulting in a de minimis cost.⁴³³ The remaining 41.7 percent of requests will be mailed.⁴³⁴ The annual cost burden to mail the comparative analyses to the participants and beneficiaries will therefore be approximately \$107,500. See Table 14 for calculations and burden totals.

2.4. Recordkeeping Requirement

HHS posits that plans and issuers already maintain records as part of their regular business practices. HHS therefore estimates a minimal additional burden associated with these final rules. HHS estimates that each non-Federal governmental plan and issuer will annually incur a burden of 5 minutes, on average. See Table 14 for calculations and burden totals.

HHS will revise the information collection approved under OMB Control

⁴³² The wage rate of an attorney, actuary, and data analyst is, respectively, \$165.71, \$177.11, and \$159.61. (Internal DOL calculation based on 2024 labor cost data. For a description of DOL's methodology for calculating wage rates, see EBSA, *Labor Cost Inputs Used in the Employee Benefits Security Administration, Office of Policy and Research's Regulatory Impact Analyses and Paperwork Reduction Act Burden Calculations* (June 2019), <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>.) The composite wage rate is estimated in

the following manner: $[\$165.71 \times (1 + 3) + \$159.61 \times (1 + 3) \times \$177.61 \times (1 + 3) = \$167.48]$.

⁴³³ According to data from NTIA, 37.4 percent of individuals aged 25 and over have access to the internet at work. According to a Greenwald & Associates survey, 84 percent of plan participants find it acceptable to make electronic delivery the default option, which is used as the proxy for the number of participants who will not opt out of electronic disclosure that are automatically enrolled (for a total of 31.4 percent receiving electronic disclosure at work). Additionally, the NTIA reports that 44.1 percent of individuals aged 25 and over have access to the internet outside of work.

According to a Pew Research Center survey, 61.0 percent of internet users use online banking, which is used as the proxy for the number of internet users who will affirmatively consent to receiving electronic disclosures (for a total of 26.9 percent receiving electronic disclosure outside of work). Combining the 31.4 percent who will receive electronic disclosure at work with the 26.9 percent who will receive electronic disclosure outside of work produces a total of 58.3 percent who will receive electronic disclosure overall.

⁴³⁴ The postage for a first-class mail large envelope is \$2.04 and the material cost is \$0.05 per page. Thus, $\$2.04 + (\$0.05 \times 15 \text{ pages}) = \$2.79$.

Number 0938–1393 to account for this burden.⁴³⁵

TABLE 14—HOURLY AND COST BURDEN OF OTHER REQUIREMENTS

	Number of responses (A)	Number of hours per response (B)	Total hour burden (A × B)	Wage rate (C)	Hour equivalent of cost burden (A × B × C)	Mailing cost per response (D)	Cost burden (A × D × 41.7 percent)
Business operations specialists prepare comparative analysis for audits	20	4	80	\$114.36	\$9,149	\$0	\$0
General operation managers prepare comparative analysis for audits	20	1	20	137.67	2,753	0	0
Clerical workers prepare comparative analyses upon participant request	92,354	0.083	7,696	65.99	507,859	2.79	107,477
Clerical workers maintain recordkeeping	92,354	0.083	7,696	65.99	507,859	0	0
Total	92,374		15,492		1,027,620		107,477

2.5. ICRs Regarding the Self-Funded Non-Federal Governmental Plan Opt-Out Provisions (45 CFR 146.180)

2.5.1. Notice to Federal Government of Self-Funded Non-Federal Governmental Plan Opt-Out: Plan Burden Reduction—Preparation and Processing of Opt-Out Election Notice

The regulatory amendments to implement a provision in the CAA, 2023 that sunsets the election option for sponsors of self-funded non-Federal governmental plans to opt out of requirements under MHPAEA eliminate the need for sponsors to submit a notice to the Federal Government regarding their plan's opt-out election (or, for sponsors of multiple plans, their plans' opt-out elections), as long as the sponsors do not elect to permissibly opt out of other requirements.⁴³⁶ HHS estimates that sponsors of 185 plans will no longer need to submit a notice to the Federal Government regarding their plan's opt-out election. HHS estimates that for each self-funded non-Federal governmental plan whose sponsor has elected to opt out of the requirements, a compensation and benefits manager will need 15 minutes annually to fill out and electronically submit the model notification form to HHS.⁴³⁷ See Table 14 for calculations and cost savings.

These amendments also generate cost savings for the Federal Government, as HHS will no longer have to process the opt-out notices submitted by plan sponsors. The processing of the opt-out notices is performed by an HHS employee. The average labor rate for the employee who completes this task, which includes the locality pay adjustment for the area of Washington-Baltimore-Arlington, and the cost of fringe benefits and other indirect costs, is \$113.04 per hour for a GS–13, step 1 employee.⁴³⁸ HHS estimates that on average it takes an HHS employee 15 minutes to process an opt-out notice submitted by a plan sponsor. See Table 15 for calculations and cost savings.

2.5.2. Notice to Plan Participants of Self-Funded Non-Federal Governmental Plan Opt-Out: Plan Burden Reduction—Preparation and Processing of Opt-Out Election Notice

The regulatory amendments to implement the provision in the CAA, 2023 that sunsets the election option for sponsors of self-funded non-Federal governmental plans to opt out of requirements under MHPAEA also eliminate the need for those sponsors to prepare and disseminate an opt-out notice to plan participants regarding their plan sponsors' opt-out election, as

long as the sponsors do not elect to permissibly opt out of other requirements. HHS estimates that sponsors of 185 plans will no longer need to prepare and disseminate an opt-out notice to plan participants. HHS estimates that for each self-funded non-Federal governmental plan whose sponsor has elected to opt out of the requirements under MHPAEA, an administrative assistant will need 15 minutes to develop and update the HHS standardized disclosure statement annually. Further, self-funded non-Federal governmental plan sponsors will no longer be required to print and mail the opt-out notice to plan participants and will therefore no longer incur costs associated with this requirement. As noted earlier in section IV.5.2 of the regulatory impact analysis, HHS estimates that there are approximately 261 participants in each self-funded non-Federal governmental plan, and therefore approximately 48,285 notices⁴³⁹ will no longer have to be printed and mailed. See Table 15 for calculations and cost savings.

The burden related to HIPAA opt-outs is currently approved under OMB Control Number 0938–0702.⁴⁴⁰ HHS will update the information collection to account for this burden reduction.

⁴³⁵ CMS–10773, *Non-Quantitative Treatment Limitation Analyses and Compliance Under MHPAEA*.

⁴³⁶ Based on the HIPAA opt-out filings, sponsors of 46 self-funded non-Federal governmental plans permissibly opt out of other requirements (standards relating to benefits for mothers and newborns, required coverage for reconstructive surgery following mastectomies, and/or coverage of

dependent students on medically necessary leave of absence).

⁴³⁷ This includes the time required by the individual signing the certification to conduct a thorough review of the election contents.

⁴³⁸ See Office of Personnel Management, 2024 *General Schedule (GS) Locality Pay Tables*, https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2024/DCB_h.pdf.

⁴³⁹ This estimate is calculated as follows: 185 plans × 261 participants per plan on average = 48,285 notices in total.

⁴⁴⁰ CMS–10430, *Information Collection Requirements for Compliance with Individual and Group Market Reforms under Title XXVII of the Public Health Service Act*.

TABLE 15—COST SAVINGS OF PREPARING AND DISTRIBUTING OPT-OUT ELECTION NOTICE

	Number of responses (A)	Number of hours per entity (B)	Total hour burden (A × B)	Wage rate (C)	Mailing cost per response (D)	Cost savings (A × B × C) or (A × D)
General operation managers preparing and processing of opt-out election notice to Federal Government	185	0.25	46	\$131.14		\$6,032
Clerical workers preparing and processing of opt-out election notice to plan participants	185	0.25	46	42.58		1,959
Clerical workers distributing opt-out election notice to plan participants	48,285				\$0.05	2,414
Total	48,470		92			10,405

2.6. Overall Summary

In summary, the total new burden imposed by these final rules regarding NQTL comparative analyses and compliance, has a 3-year average hour burden of approximately 1,003,332 hours with an equivalent cost of approximately \$166,471,063 and a total cost burden of approximately \$107,447. The final amendments to implement the CAA, 2023 provision that sunsets the MHPAEA opt-out election for sponsors of self-funded non-Federal governmental plans will result in an annual burden reduction of approximately 92 hours with an equivalent annual cost savings of approximately \$7,991 and total cost savings of approximately \$10,405.

A summary of the change in paperwork burden estimates follows:

Type of Review: Revision.

Agency: Centers for Medicare & Medicaid Services, U.S. Department of Health and Human Services.

Title: Non-Quantitative Treatment Limitation Analyses and Compliance Under MHPAEA.

OMB Control Number: 0938–1393.

Affected Public: Businesses or other for-profits, Not-for-profit institutions, State, Local, or Tribal Governments.

Estimated Number of Respondents: 92,457.

Estimated Number of Annual Responses: 189,709.

Frequency of Response: Annual.

Estimated Total Annual Burden Hours: 1,003,332.

Estimated Total Annual Burden Cost: \$107,447.

Title: Requirements for Compliance with Individual and Group Market Reforms under Title XXVII of the Public Health Service Act.

OMB Control Number: 0938–0702.

Affected Public: State, Local, or Tribal Governments.

Estimated Number of Respondents: (185).

Estimated Number of Annual Responses: (185).

Frequency of Response: Annual.

Estimated Total Annual Burden Hours: (92).

Estimated Total Annual Burden Cost: (\$2,414).

Note: Numbers in parentheses denote a burden reduction.

VI. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA)⁴⁴¹ 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 604⁴⁴² of the RFA requires the agency to present a final regulatory flexibility analysis of these final rules.

The Departments certify that these final rules will not have a significant impact on a substantial number of small entities. The Departments have prepared the following justification for this determination.

1. Need for and Objectives of the Rule

As documented in the 2022 MHPAEA Report to Congress and the 2023 MHPAEA Comparative Analysis Report to Congress,⁴⁴³ the Departments found that none of the NQTL comparative analyses they reviewed upon initial receipt contained sufficient information and documentation.

These final rules clarify existing definitions, add new definitions of key terms, and provide additional examples

of the application of MHPAEA to NQTLs to improve the understanding and ability of the regulated community to comply with MHPAEA. The final rules also clarify that plan and issuer definitions of conditions or disorders as mental health conditions and substance use disorders must be consistent with generally recognized independent standards of current medical practice and add more specificity as to what plans and issuers must treat as mental health conditions or substance use disorders. The final rules also require that plans and issuers must provide meaningful benefits for covered mental health conditions or substance use disorders in each such classification in which medical/surgical benefits are provided. These final rules also require plans and issuers to collect and evaluate relevant data in a manner reasonably designed to assess the impact of the NQTL on access to mental health and substance use disorder benefits and medical/surgical benefits. Relevant data for the majority of NQTLs could include, as appropriate, but are not limited to, the number and percentage of claims denials and any other data relevant to the NQTL as required by State law or private accreditation standards. Additionally, for NQTLs related to network composition, relevant data could include, as appropriate, but are not limited to, in-network and out-of-network utilization rates (including data related to provider claim submissions), network adequacy metrics (including time and distance data, and data on providers accepting new patients), and provider reimbursement rates (for comparable services and as benchmarked to a reference standard). Under these final rules, the Departments may specify the type, form, and manner for the relevant data evaluation requirements in future guidance, which will allow the Departments to adjust the data requirements as needed to account for enforcement experience and industry trends.

These final rules also set more specific content requirements for

⁴⁴¹ 5 U.S.C. 601 *et seq.* (1980).

⁴⁴² 5 U.S.C. 604 (1980).

⁴⁴³ 2022 MHPAEA Report to Congress, <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2022-realizing-parity-reducing-stigma-and-raising-awareness.pdf>; 2023 MHPAEA Comparative Analysis Report to Congress, www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2023-mhpaea-comparative-analysis.pdf.

comparative analyses required by the CAA, 2021, clarify when a comparative analysis needs to be performed and for which NQTLs, and outline the process for plans and issuers to provide their comparative analyses to the Departments upon request.

The Departments expect that these final rules will result in plans and issuers having a better understanding of the MHPAEA requirements for NQTLs. These final rules will also improve the manner in which parity is measured, compared, and demonstrated by plans and issuers. The Departments are of the view that these final rules will improve the compliance of plans and issuers with these requirements, resulting in greater parity in access to benefits for mental health conditions and substance use disorders as compared with medical/surgical benefits, as intended by MHPAEA.

Additionally, in these final rules, HHS finalizes regulatory amendments to implement a provision in the CAA, 2023 that sunsets the election option for sponsors of self-funded non-Federal governmental plans to opt out of requirements under MHPAEA. HHS is of the view that these regulatory amendments will ultimately increase access to mental health and substance use disorder services, and increase parity of benefits for such services as compared to benefits for medical/surgical services by requiring self-funded non-Federal governmental plans that had previously opted out to come into compliance with the requirements under MHPAEA.

2. Affected Small Entities

For purposes of analysis under the RFA, the Departments consider employee benefit plans with fewer than 100 participants to be small entities. The basis of this definition is found in section 104(a)(2) of ERISA, which permits the Secretary of Labor to prescribe simplified annual reports for plans that cover fewer than 100 participants. Under section 104(a)(3) of ERISA, the Secretary of Labor may also provide for exemptions or simplified annual reporting and disclosure for welfare benefit plans. Under the authority of section 104(a)(3), DOL 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 cover fewer than 100 participants and satisfy certain requirements. While some large employers have small plans, small plans

are maintained generally by small employers. Thus, the Departments are of the view that assessing the impact of these final rules on small plans is an appropriate substitute for evaluating the effect on small entities. The definition of small entity considered appropriate for this purpose differs, however, from the definition of small business based on size standards (revenue or number of employees) issued by the Small Business Administration (SBA) under the Small Business Act.

As discussed in section IV.5.2 of the regulatory impact analysis, these final rules will affect nearly all small ERISA-covered group health plans, including fully insured group health plans and self-funded group health plans, as well as small health insurance issuers and non-Federal governmental plans. The Departments estimate that these final rules will affect approximately 106,000 fully insured plans with 50 to 100 participants,⁴⁴⁴ and approximately 1,719,000 fully insured, non-grandfathered plans with less than 50 participants.⁴⁴⁵

The Departments also estimate that approximately 25,300 self-funded plans with less than 100 participants will be affected by these final rules.⁴⁴⁶ Additionally, the Departments estimate that approximately 18,000 self-funded non-Federal governmental plans with less than 100 participants will also be affected by these final rules.⁴⁴⁷ The

⁴⁴⁴ The Departments estimate that there are 140,998 ERISA-covered group health plans with 50 to 100 participants based on the MEPS-IC and the 2020 County Business Patterns from the Census Bureau. The Departments also estimate that 75 percent of ERISA-covered group health plans with 50 to 100 participants are fully insured based on assumptions referencing these same data. Thus, the Departments have calculated the number of fully insured plans with 50 to 100 participants in the following manner: 140,998 ERISA-covered group health plans with 50 to 100 participants $\times$ 75 percent = 105,749.

⁴⁴⁵ The Departments estimate that there are 2,465,483 ERISA-covered group health plans with less than 50 participants based on data from the 2022 MEPS-IC and the 2020 County Business Patterns from the Census Bureau. The Departments also estimate that 83 percent of group health plans with less than 50 participants are fully insured based on data from the 2022 MEPS-IC. The 2020 KFF Employer Health Benefits Survey reported that in 2020, 16 percent of firms offering health benefits offered at least one grandfathered health plan; therefore, the Departments assume the percent of firms offering at least one non-grandfathered health plan is 84 percent (100 percent – 16 percent). KFF, *2020 Employer Health Benefits Survey* (Oct. 8, 2020), <https://files.kff.org/attachment/Report-Employer-Health-Benefits-2020-Annual-Survey.pdf>. Thus, the Departments have calculated the number of fully insured, non-grandfathered plans with less than 50 participants in the following manner: 2,465,483 small ERISA-covered group health plans $\times$ 83 percent $\times$ 84 percent = 1,718,935.

⁴⁴⁶ Estimates based on the 2021 Form 5500 data.

⁴⁴⁷ Based on the 2022 Census of Governments, there are 90,887 non-Federal governmental plans.

Departments assume that these small, self-funded plans will receive assistance with the comparative analyses and data requirements from TPAs or other service providers involved with the plan. Due to many small plans using identical insurance products, these small plans are not expected to be significantly impacted as costs are spread across many small plans.

As discussed in section IV.5.1 of the regulatory impact analysis, these final rules will also affect health insurance issuers. The Departments estimate that these final rules will affect 479 health insurance companies nationwide that provide mental health and substance use disorder benefits in the group and individual health insurance markets, with a total of 1,467 issuers (health insurance company/State combinations).⁴⁴⁸

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.⁴⁴⁹ The Departments expect that few, if any, health insurance companies underwriting health insurance policies fall below these size thresholds. Based on data from MLR annual report submissions for the 2022 MLR reporting year, approximately 87 out of 487 health insurance companies (of which 479 are impacted by these final rules) had total premium revenue of \$47 million or less.⁴⁵⁰ However, it should be noted that at least 76 percent of these small companies belong to larger holding groups that may not be small, and many,

Based on the 2022 MEPS-IC, the Departments estimate that 36.2 percent of non-Federal governmental plans are self-funded. Thus, 90,887 plans $\times$ 36.2 percent = 32,901 self-funded non-Federal governmental plans. Based on the 2021 Form 5500 data, the Departments estimate that 54.6 percent of self-funded health plans with less than 100 participants have filed the Form 5500. The Departments use the percent of self-funded health plans with less than 100 participants that have filed a Form 5500 as a proxy for the percent of self-funded non-Federal governmental plans with less than 100 participants. Thus, 32,901 self-funded non-Federal governmental plans $\times$ 54.6 percent = 17,964 self-funded non-Federal governmental plans with less than 100 participants.

⁴⁴⁸ The Departments' estimate of the number of health insurance issuers are based on MLR reports submitted by issuers for the 2022 reporting year. CMS, *Medical Loss Ratio Data and System Resources* (2022), <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr>.

⁴⁴⁹ SBA, *Table of Size Standards*, <https://www.sba.gov/document/support-table-size-standards>, as of March 2023.

⁴⁵⁰ CMS, *Medical Loss Ratio Data and System Resources* (2022), <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html>.

if not all, of these companies are likely to have non-health lines of business that would result in their revenues exceeding \$47 million.

The amendments to implement the CAA, 2023 provision that sunsets the MHPAEA opt-out election will affect sponsors of self-funded non-Federal governmental plans, some of which might be small entities. As noted in section IV.8.4 of the regulatory impact analysis, the extent to which these plans are out of compliance is unknown, and the costs for them to come into compliance are expected to vary from plan to plan. HHS solicited comments in the proposal on the number of small entities that would be impacted by the implementation of the sunset provision and the potential effects on small entities. HHS did not receive any comments on these estimates.

2.1. Amendments to Existing MHPAEA Regulation (26 CFR 54.9812–1, 29 CFR 2590.712, and 45 CFR 146.136)

These final rules clarify existing definitions, add new definitions, generally ensure that the NQTLs applicable to mental health and substance use disorder benefits are generally no more restrictive than the predominant NQTLs applied to substantially all medical/surgical benefits, and provide additional examples of the application of MHPAEA to NQTLs to improve the understanding and ability of the regulated community to comply with MHPAEA. These final rules also clarify that mental health benefits and substance use disorder benefits must be defined to be consistent with generally recognized independent standards of current medical practice and add more specificity as to what plans and issuers must define as mental health conditions or substance use disorders. The final rules also require that plans and issuers must provide meaningful benefits for covered mental health conditions or substance use disorders in each classification in which medical/surgical benefits are provided. These final rules also require plans and issuers to collect and evaluate relevant data and include an analysis of the data as part of each comparative analysis. The Departments are of the view that plans and issuers will incur costs in collecting, preparing, and analyzing the data.

The Departments are of the view that the final amendments might cause small plans and issuers to revise their policies and remove treatment limitations. Therefore, small plans and issuers could incur costs to revise plan provisions, which may result in increased costs from expanded utilization of mental

health and substance use disorder services. The Departments face uncertainty in quantifying these costs as they cannot estimate the increase in utilization and which services may see the largest increase in utilization.

2.2. New Regulations (26 CFR 54.9812–2, 29 CFR 2590.712–1, and 45 CFR 146.137 and 146.180)

These final rules codify existing guidance, set more specific content requirements for comparative analyses required by the CAA, 2021, and outline the timeframes and process for plans and issuers to provide their comparative analyses to the Departments upon request. Participants and beneficiaries in ERISA plans may also request a copy of comparative analyses at any time, and all participants, beneficiaries, and enrollees may request a comparative analysis in connection with an adverse benefit determination. Additionally, in these final rules, HHS finalizes regulatory amendments to implement the provision in the CAA, 2023 that sunsets the election option for self-funded non-Federal governmental plans to opt out of requirements under MHPAEA.

In the first year, the Departments estimate that TPAs, MEWAs, issuers, and self-funded group health plans, most if not all of which are large entities, will conduct the comparative analysis themselves will incur an incremental per-entity cost of approximately \$101,600 associated with these final rules. The Departments also estimate an incremental per-entity cost of \$51,300 in the first year for self-funded group health plans that will receive a generic comparative analysis from their TPA or other service provider and subsequently will customize to suit their specific needs.

In the subsequent years, the Departments estimate that TPAs, MEWAs, issuers, and self-funded group health plans that will conduct the comparative analysis themselves, will incur an incremental per-entity cost of approximately \$20,100 associated with these final rules and amendments. The Departments also estimate an incremental per-entity cost of \$10,100 in subsequent years for self-funded group health plans that will receive a generic comparative analysis from their TPA or other service provider and subsequently will customize it to suit their specific needs.

The Departments note that these per-entity costs are average costs, and these costs are expected to vary by plan or issuer depending on the number of NQTL analyses performed.

3. Comment Summary

In the proposal, commenters expressed concerns that the Departments underestimated the burden of collecting the required data and performing the comparative analyses. One commenter stated that small plans lack access to aggregated claims data. The same commenter suggested that the proposal was burdensome, since it required information that was beyond the possession of small plans. The commenter contended that small employers may decide to stop offering health coverage altogether in favor of having their employees purchase their own individual health insurance coverage through the ACA Exchange, stating that the penalties under the ACA for employers not offering coverage may be preferable compared to the costly requirements under the proposal. The Departments note that there are no such penalties that apply to small employers. The commenter also did not provide any data or evidence.

Another commenter stated that there is a limited market of vendors for conducting the comparative analyses, mentioning that these services could cost upwards of \$100,000. The same commenter expressed concern that the proposal's comparative analysis requirements would disproportionately consume the health benefits budget of plan sponsors, potentially causing small employers to discontinue offering mental health and substance use disorder benefits. The Departments note that while there is a possibility that some plans and issuers will stop offering mental health and substance use disorder benefits, the Departments anticipate that these final rules will expand the level of coverage for mental health and substance use disorder benefits, which will result in reduced out-of-pocket spending for plan participants, beneficiaries, and enrollees. The Departments also note that the commenter did not cite any data or evidence.

Furthermore, another commenter was concerned that the proposal would disrupt the operations of plans, by forcing plans to change their network composition and eliminate the use of common medical management techniques. The same commenter stated that the burden would fall on small plans, since they may have insufficient resources to cope with this unanticipated cost burden. The commenter did not provide any data or evidence to support these assertions. As discussed earlier in this preamble, these final rules do not eliminate the use of prior authorization or other medical

management techniques, but emphasize that they must be developed and used in parity as required by law.

Finally, the Departments did not receive any comments from the Chief Counsel for Advocacy of SBA.

4. Duplicate, Overlapping, or Relevant Federal Rules

There are no duplicate, overlapping, or relevant Federal rules.

VII. Special Analyses—Department of the Treasury

Under the Memorandum of Agreement, Review of Treasury Regulations under Executive Order 12866 (June 9, 2023), tax regulatory actions issued by the Internal Revenue Service (IRS) are not subject to the requirements of section 6 of Executive Order 12866, as amended. Therefore, a regulatory impact analysis is not required. As required by section 7805(f) of the Code, these regulations were submitted to the Chief Counsel for Advocacy of SBA for comment on their impact on small business.

VIII. 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.⁴⁵¹ For purposes of the UMRA, this rulemaking is expected to have such an impact. For the purposes of this rulemaking, the regulatory impact analysis shall meet the UMRA obligations.

IX. 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.⁴⁵² 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 these final rules.

In the Departments’ view, these final rules have federalism implications because they will have direct effects on the States, on the relationship between the Federal Government and the States, and on the distribution of power and responsibilities among various levels of government. These final rules could also have federalism implications because the Departments remove the reference to State guidelines in the definitions of medical/surgical benefits, mental health benefits, and substance use disorder benefits, and amend these definitions to provide that any condition or procedure defined by the plan or coverage as being or not being a mental health condition or substance use disorder, respectively, must be defined to be consistent with generally recognized independent standards of current medical practice, which for purposes of these final rules are all conditions or disorders under the relevant chapters of the ICD or DSM. Finally, these final rules have federalism implications because the implementation of the CAA, 2023 provision that sunsets the election option for sponsors of self-funded non-Federal governmental plans to opt out of requirements under MHPAEA will require State and local government sponsors of self-funded non-Federal governmental plans that currently opt out of requirements under MHPAEA to come into compliance.

In general, through section 514, ERISA supersedes State laws to the extent that they relate to any covered employee benefit plan, and preserves State laws that regulate insurance, banking, or securities. While ERISA prohibits States from regulating a plan as an insurance or investment company or bank, the preemption provisions of section 731 of ERISA and section 2724 of the PHS Act (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that the MHPAEA requirements are not to be “construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with individual or group health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement” of MHPAEA. The conference report accompanying HIPAA indicates that this is intended to be the “narrowest” preemption of State laws. *See* Conf. Rep. No. 104–736, pg. 205, reprinted in 1996 U.S. Code Cong. & Admin. News 2018.

States may continue to apply State law requirements except to the extent that such requirements prevent the application of the MHPAEA requirements that are the subject of this rulemaking. State insurance laws that are more stringent than the Federal requirements are unlikely to “prevent the application of” MHPAEA and be preempted. Accordingly, States have significant latitude to impose requirements on health insurance issuers that are more restrictive than the Federal law.

Throughout the process of developing these final rules, to the extent feasible within the specific preemption provisions of HIPAA as it applies to MHPAEA, the Departments have attempted to balance the States’ interests in regulating health insurance issuers, and Congress’ intent to provide uniform minimum protections to consumers in every State. By doing so, it is the Departments’ view that they have complied with the requirements of Executive Order 13132.

X. Congressional Review Act

In accordance with Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act, 5 U.S.C. 801 *et seq.*), OIRA has determined that this rule meets the criteria set forth in 5 U.S.C. 804(2). Accordingly, a report containing a copy of the rule along with other specified information has been submitted to each House of the Congress and to the Comptroller General.

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 146

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 147

Aged, Citizenship and naturalization, Civil rights, Health care, Health insurance, Individuals with disabilities, Intergovernmental relations, Reporting

⁴⁵¹ 2 U.S.C. 1501 *et seq.* (1995).

⁴⁵² *Federalism*, 64 FR 153 (Aug. 4, 1999).

and recordkeeping requirements, Sex discrimination.

Douglas W. O'Donnell,

Deputy Commissioner, Internal Revenue Service.

Aviva Aron-Dine,

Acting Assistant Secretary (Tax Policy), Department of the Treasury.

Lisa M. Gomez,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Xavier Becerra,

Secretary, Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

Accordingly, the Treasury Department and the IRS amend 26 CFR part 54 as follows:

PART 54—PENSION EXCISE TAXES

■ **Paragraph 1.** The authority citation for part 54 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Amend § 54.9812–1 by:

■ a. Redesignating paragraph (a) as paragraph (a)(2) and adding paragraphs (a) heading and (a)(1);

■ b. In newly redesignated paragraph (a)(2):

■ i. Revising the introductory text;

■ ii. Adding the definitions of “DSM,” “Evidentiary standards,” “Factors,” and “ICD” in alphabetical order;

■ iii. Revising the definitions of “Medical/surgical benefits” and “Mental health benefits”;

■ iv. Adding the definitions of “Processes” and “Strategies” in alphabetical order; and

■ v. Revising the definitions of “Substance use disorder benefits” and “Treatment limitations”;

■ c. Revising paragraphs (c)(1)(ii), (c)(2)(i), (c)(2)(ii)(A) introductory text, (c)(2)(ii)(C), and (c)(3)(i)(A), (C), and (D);

■ d. In paragraph (c)(3)(iii), adding introductory text;

■ e. Revising paragraphs (c)(3)(iii)(A) and (B), (c)(3)(iv), (c)(4), (d)(3), (e)(4), and (i)(1); and

■ f. Adding paragraph (j).

The revisions and additions read as follows:

§ 54.9812–1 Parity in mental health and substance use disorder benefits.

(a) *Purpose and meaning of terms—* (1) *Purpose.* This section and § 54.9812–2 set forth rules to ensure parity in aggregate lifetime and annual dollar limits, financial requirements, and

quantitative and nonquantitative treatment limitations between mental health and substance use disorder benefits and medical/surgical benefits, as required under Code section 9812. A fundamental purpose of Code section 9812, this section, and § 54.9812–2 is to ensure that participants and beneficiaries in a group health plan that offers mental health or substance use disorder benefits are not subject to more restrictive aggregate lifetime or annual dollar limits, financial requirements, or treatment limitations with respect to those benefits than the predominant dollar limits, financial requirements, or treatment limitations that are applied to substantially all medical/surgical benefits covered by the plan in the same classification, as further provided in this section and § 54.9812–2. Accordingly, in complying with the provisions of Code section 9812, this section, and § 54.9812–2, plans must not design or apply financial requirements and treatment limitations that impose a greater burden on access (that is, are more restrictive) to mental health or substance use disorder benefits under the plan than they impose on access to medical/surgical benefits in the same classification of benefits. The provisions of Code section 9812, this section, and § 54.9812–2 should be interpreted in a manner that is consistent with the purpose described in this paragraph (a)(1).

(2) *Meaning of terms.* For purposes of this section and § 54.9812–2, except where the context clearly indicates otherwise, the following terms have the meanings indicated:

* * * * *

DSM means the American Psychiatric Association’s Diagnostic and Statistical Manual of Mental Disorders. For the purpose of this definition, the most current version of the DSM as of November 22, 2024, is the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision published in March 2022. A subsequent version of the DSM published after November 22, 2024, will be considered the most current version beginning on the first day of the plan year that is one year after the date the subsequent version is published.

Evidentiary standards are any evidence, sources, or standards that a group health plan considered or relied upon in designing or applying a factor with respect to a nonquantitative treatment limitation, including specific benchmarks or thresholds. Evidentiary standards may be empirical, statistical, or clinical in nature, and include: sources acquired or originating from an

objective third party, such as recognized medical literature, professional standards and protocols (which may include comparative effectiveness studies and clinical trials), published research studies, payment rates for items and services (such as publicly available databases of the “usual, customary and reasonable” rates paid for items and services), and clinical treatment guidelines; internal plan data, such as claims or utilization data or criteria for assuring a sufficient mix and number of network providers; and benchmarks or thresholds, such as measures of excessive utilization, cost levels, time or distance standards, or network participation percentage thresholds.

Factors are all information, including processes and strategies (but not evidentiary standards), that a group health plan considered or relied upon to design a nonquantitative treatment limitation, or to determine whether or how the nonquantitative treatment limitation applies to benefits under the plan. Examples of factors include, but are not limited to: provider discretion in determining a diagnosis or type or length of treatment; clinical efficacy of any proposed treatment or service; licensing and accreditation of providers; claim types with a high percentage of fraud; quality measures; treatment outcomes; severity or chronicity of condition; variability in the cost of an episode of treatment; high cost growth; variability in cost and quality; elasticity of demand; and geographic location.

* * * * *

ICD means the World Health Organization’s International Classification of Diseases adopted by the Department of Health and Human Services through 45 CFR 162.1002. For the purpose of this definition, the most current version of the ICD as of November 22, 2024, is the International Classification of Diseases, 10th Revision, Clinical Modification adopted for the period beginning on October 1, 2015. Any subsequent version of the ICD adopted through 45 CFR 162.1002 after November 22, 2024, will be considered the most current version beginning on the first day of the plan year that is one year after the date the subsequent version is adopted.

Medical/surgical benefits means benefits with respect to items or services for medical conditions or surgical procedures, as defined under the terms of the group health plan and in accordance with applicable Federal and State law, but does not include mental health benefits or substance use disorder benefits. Notwithstanding the

preceding sentence, any condition or procedure defined by the plan as being or as not being a medical condition or surgical procedure must be defined consistent with generally recognized independent standards of current medical practice (for example, the most current version of the ICD). To the extent generally recognized independent standards of current medical practice do not address whether a condition or procedure is a medical condition or surgical procedure, plans may define the condition or procedure in accordance with applicable Federal and State law.

Mental health benefits means benefits with respect to items or services for mental health conditions, as defined under the terms of the group health plan and in accordance with applicable Federal and State law, but does not include medical/surgical benefits or substance use disorder benefits. Notwithstanding the preceding sentence, any condition defined by the plan as being or as not being a mental health condition must be defined consistent with generally recognized independent standards of current medical practice. For the purpose of this definition, to be consistent with generally recognized independent standards of current medical practice, the definition must include all conditions covered under the plan, except for substance use disorders, that fall under any of the diagnostic categories listed in the mental, behavioral, and neurodevelopmental disorders chapter (or equivalent chapter) of the most current version of the ICD or that are listed in the most current version of the DSM. To the extent generally recognized independent standards of current medical practice do not address whether a condition is a mental health condition, plans may define the condition in accordance with applicable Federal and State law.

Processes are actions, steps, or procedures that a group health plan uses to apply a nonquantitative treatment limitation, including actions, steps, or procedures established by the plan as requirements in order for a participant or beneficiary to access benefits, including through actions by a participant's or beneficiary's authorized representative or a provider or facility. Examples of processes include, but are not limited to: procedures to submit information to authorize coverage for an item or service prior to receiving the benefit or while treatment is ongoing (including requirements for peer or expert clinical review of that information); provider referral

requirements that are used to determine when and how a participant or beneficiary may access certain services; and the development and approval of a treatment plan used in a concurrent review process to determine whether a specific request should be granted or denied. Processes also include the specific procedures used by staff or other representatives of a plan (or the service provider of a plan) to administer the application of nonquantitative treatment limitations, such as how a panel of staff members applies the nonquantitative treatment limitation (including the qualifications of staff involved, number of staff members allocated, and time allocated), consultations with panels of experts in applying the nonquantitative treatment limitation, and the degree of reviewer discretion in adhering to criteria hierarchy when applying a nonquantitative treatment limitation.

Strategies are practices, methods, or internal metrics that a plan considers, reviews, or uses to design a nonquantitative treatment limitation. Examples of strategies include, but are not limited to: the development of the clinical rationale used in approving or denying benefits; the method of determining whether and how to deviate from generally accepted standards of care in concurrent reviews; the selection of information deemed reasonably necessary to make medical necessity determinations; reliance on treatment guidelines or guidelines provided by third-party organizations in the design of a nonquantitative treatment limitation; and rationales used in selecting and adopting certain threshold amounts to apply a nonquantitative treatment limitation, professional standards and protocols to determine utilization management standards, and fee schedules used to determine provider reimbursement rates, used as part of a nonquantitative treatment limitation. Strategies also include the method of creating and determining the composition of the staff or other representatives of a plan (or the service provider of a plan) that deliberates, or otherwise makes decisions, on the design of nonquantitative treatment limitations, including the plan's methods for making decisions related to the qualifications of staff involved, number of staff members allocated, and time allocated; breadth of sources and evidence considered; consultations with panels of experts in designing the nonquantitative treatment limitation; and the composition of the panels used to design a nonquantitative treatment limitation.

Substance use disorder benefits means benefits with respect to items or services for substance use disorders, as defined under the terms of the group health plan and in accordance with applicable Federal and State law, but does not include medical/surgical benefits or mental health benefits. Notwithstanding the preceding sentence, any disorder defined by the plan as being or as not being a substance use disorder must be defined consistent with generally recognized independent standards of current medical practice. For the purpose of this definition, to be consistent with generally recognized independent standards of current medical practice, the definition must include all disorders covered under the plan that fall under any of the diagnostic categories listed as a mental or behavioral disorder due to psychoactive substance use (or equivalent category) in the mental, behavioral, and neurodevelopmental disorders chapter (or equivalent chapter) of the most current version of the ICD or that are listed as a Substance-Related and Addictive Disorder (or equivalent category) in the most current version of the DSM. To the extent generally recognized independent standards of current medical practice do not address whether a disorder is a substance use disorder, plans may define the disorder in accordance with applicable Federal and State law.

Treatment limitations include limits on benefits based on the frequency of treatment, number of visits, days of coverage, days in a waiting period, or other similar limits on the scope or duration of treatment. Treatment limitations include both quantitative treatment limitations, which are expressed numerically (such as 50 outpatient visits per year), and nonquantitative treatment limitations (such as standards related to network composition), which otherwise limit the scope or duration of benefits for treatment under a plan. (See paragraph (c)(4)(ii) of this section for an illustrative, non-exhaustive list of nonquantitative treatment limitations.) A complete exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation for purposes of this definition.

- * * * * *
- (c) * * *
- (1) * * *

(ii) *Type of financial requirement or treatment limitation.* When reference is made in this paragraph (c) to a type of financial requirement or treatment limitation, the reference to type means its nature. Different types of financial

requirements include deductibles, copayments, coinsurance, and out-of-pocket maximums. Different types of quantitative treatment limitations include annual, episode, and lifetime day and visit limits. See paragraph (c)(4)(ii) of this section for an illustrative, non-exhaustive list of nonquantitative treatment limitations.

* * * * *

(2) * * *

(i) *General rule.* A group health plan that provides both medical/surgical benefits and mental health or substance use disorder benefits may not apply any financial requirement or treatment limitation to mental health or substance use disorder benefits in any classification that is more restrictive than the predominant financial requirement or treatment limitation of that type applied to substantially all medical/surgical benefits in the same classification. Whether a financial requirement or treatment limitation is a predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in a classification is determined separately for each type of financial requirement or treatment limitation. A plan may not impose any financial requirement or treatment limitation that is applicable only with respect to mental health or substance use disorder benefits and not to any medical/surgical benefits in the same benefit classification. The application of the rules of this paragraph (c)(2) to financial requirements and quantitative treatment limitations is addressed in paragraph (c)(3) of this section; the application of the rules of this paragraph (c)(2) to nonquantitative treatment limitations is addressed in paragraph (c)(4) of this section.

(ii) * * *

(A) *In general.* If a plan provides any benefits for a mental health condition or substance use disorder in any classification of benefits described in this paragraph (c)(2)(ii), it must provide meaningful benefits for that mental health condition or substance use disorder in every classification in which medical/surgical benefits are provided. For purposes of this paragraph (c)(2)(ii)(A), whether the benefits provided are meaningful benefits is determined in comparison to the benefits provided for medical conditions and surgical procedures in the classification and requires, at a minimum, coverage of benefits for that condition or disorder in each classification in which the plan provides benefits for one or more medical conditions or surgical

procedures. A plan does not provide meaningful benefits under this paragraph (c)(2)(ii)(A) unless it provides benefits for a core treatment for that condition or disorder in each classification in which the plan provides benefits for a core treatment for one or more medical conditions or surgical procedures. For purposes of this paragraph (c)(2)(ii)(A), a core treatment for a condition or disorder is a standard treatment or course of treatment, therapy, service, or intervention indicated by generally recognized independent standards of current medical practice. If there is no core treatment for a covered mental health condition or substance use disorder with respect to a classification, the plan is not required to provide benefits for a core treatment for such condition or disorder in that classification (but must provide benefits for such condition or disorder in every classification in which medical/surgical benefits are provided). In determining the classification in which a particular benefit belongs, a plan must apply the same standards to medical/surgical benefits and to mental health or substance use disorder benefits. To the extent that a plan provides benefits in a classification and imposes any separate financial requirement or treatment limitation (or separate level of a financial requirement or treatment limitation) for benefits in the classification, the rules of this paragraph (c) apply separately with respect to that classification for all financial requirements or treatment limitations (illustrated in examples in paragraph (c)(2)(ii)(C) of this section). The following classifications of benefits are the only classifications used in applying the rules of this paragraph (c), in addition to the permissible sub-classifications described in paragraph (c)(3)(iii) of this section:

* * * * *

(C) *Examples.* The rules of this paragraph (c)(2)(ii) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits. With regard to the examples in this paragraph (c)(2)(ii)(C), references to any particular core treatment are included for illustrative purposes only. Plans must consult generally recognized independent standards of current medical practice to determine the applicable core treatment, therapy, service, or intervention for any covered condition or disorder.

(1) *Example 1—(i) Facts.* A group health plan offers inpatient and outpatient benefits and does not contract with a network of providers. The plan imposes a \$500 deductible on all benefits. For inpatient medical/surgical benefits, the plan imposes a coinsurance requirement. For outpatient medical/surgical benefits, the plan imposes copayments. The plan imposes no other financial requirements or treatment limitations.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(1) (*Example 1*), because the plan has no network of providers, all benefits provided are out-of-network. Because inpatient, out-of-network medical/surgical benefits are subject to separate financial requirements from outpatient, out-of-network medical/surgical benefits, the rules of this paragraph (c) apply separately with respect to any financial requirements and treatment limitations, including the deductible, in each classification.

(2) *Example 2—(i) Facts.* A plan imposes a \$500 deductible on all benefits. The plan has no network of providers. The plan generally imposes a 20 percent coinsurance requirement with respect to all benefits, without distinguishing among inpatient, outpatient, emergency care, or prescription drug benefits. The plan imposes no other financial requirements or treatment limitations.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(2) (*Example 2*), because the plan does not impose separate financial requirements (or treatment limitations) based on classification, the rules of this paragraph (c) apply with respect to the deductible and the coinsurance across all benefits.

(3) *Example 3—(i) Facts.* Same facts as in paragraph (c)(2)(ii)(C)(2)(i) of this section (*Example 2*), except the plan exempts emergency care benefits from the 20 percent coinsurance requirement. The plan imposes no other financial requirements or treatment limitations.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(3) (*Example 3*), because the plan imposes separate financial requirements based on classifications, the rules of this paragraph (c) apply with respect to the deductible and the coinsurance separately for benefits in the emergency care classification and all other benefits.

(4) *Example 4—(i) Facts.* Same facts as in paragraph (c)(2)(ii)(C)(2)(i) of this section (*Example 2*), except the plan also imposes a preauthorization requirement for all inpatient treatment in order for benefits to be paid. No such requirement applies to outpatient treatment.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(4) (*Example 4*), because the plan has no network of providers, all benefits provided are out-of-network. Because the plan imposes a separate treatment limitation based on classifications, the rules of this paragraph (c) apply with respect to the deductible and coinsurance separately for inpatient, out-of-network benefits and all other benefits.

(5) *Example 5—(i) Facts.* A plan covers treatment for autism spectrum disorder (ASD), a mental health condition, and covers outpatient, out-of-network developmental

screenings for ASD but excludes all other benefits for outpatient treatment for ASD, including applied behavior analysis (ABA) therapy, when provided on an out-of-network basis. The plan generally covers the full range of outpatient treatments (including core treatments) and treatment settings for medical conditions and surgical procedures when provided on an out-of-network basis. Under the generally recognized independent standards of current medical practice consulted by the plan, developmental screenings alone do not constitute a core treatment for ASD.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(5) (*Example 5*), the plan violates the rules of this paragraph (c)(2)(ii). Although the plan covers benefits for ASD, in the outpatient, out-of-network classification, it only covers developmental screenings, so it does not cover a core treatment for ASD in the classification. Because the plan generally covers the full range of medical/surgical benefits including a core treatment for one or more medical conditions or surgical procedures in the classification, it fails to provide meaningful benefits for treatment of ASD in the classification.

(6) *Example 6—(i) Facts.* Same facts as in paragraph (c)(2)(ii)(C)(5) of this section (*Example 5*), except that the plan is an HMO that does not cover the full range of medical/surgical benefits, including a core treatment for any medical conditions or surgical procedures in the outpatient, out-of-network classification (except as required under Code sections 9816 and 9817), but covers benefits for medical conditions and surgical procedures in the inpatient, in-network; outpatient, in-network; emergency care; and prescription drug classifications.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(6) (*Example 6*), the plan does not violate the rules of this paragraph (c)(2)(ii). Because the plan does not provide meaningful benefits, including for a core treatment for any medical condition or surgical procedure in the outpatient, out-of-network classification (except as required under Code sections 9816 and 9817), the plan is not required to provide meaningful benefits for any mental health conditions or substance use disorders in that classification. Nevertheless, the plan must provide meaningful benefits for each mental health condition and substance use disorder for which the plan provides benefits in every classification in which meaningful medical/surgical benefits are provided, as required under paragraph (c)(2)(ii)(A) of this section. This example does not address whether the plan has complied with other applicable requirements of this section in excluding coverage of ABA therapy in the outpatient, out-of-network classification.

(7) *Example 7—(i) Facts.* A plan provides extensive benefits, including for core treatments for many medical conditions and surgical procedures in the outpatient, in-network classification, including nutrition counseling for diabetes and obesity. The plan also generally covers diagnosis and treatment for eating disorders, which are mental health conditions, including coverage for nutrition counseling to treat eating disorders in the outpatient, in-network classification.

Nutrition counseling is a core treatment for eating disorders, in accordance with generally recognized independent standards of current medical practice consulted by the plan.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(7) (*Example 7*), the plan does not violate the rules of this paragraph (c)(2)(ii). The coverage of diagnosis and treatment for eating disorders, including nutrition counseling, in the outpatient, in-network classification results in the plan providing meaningful benefits for the treatment of eating disorders in the classification, as determined in comparison to the benefits provided for medical conditions or surgical procedures in the classification.

(8) *Example 8—(i) Facts.* A plan provides extensive benefits for the core treatments for many medical conditions and surgical procedures in the outpatient, in-network and prescription drug classifications. The plan provides coverage for diagnosis and treatment for opioid use disorder, a substance use disorder, in the outpatient, in-network classification, by covering counseling and behavioral therapies and, in the prescription drug classification, by covering medications to treat opioid use disorder (MOUD). Counseling and behavioral therapies and MOUD, in combination, are one of the core treatments for opioid use disorder, in accordance with generally recognized independent standards of current medical practice consulted by the plan.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(8) (*Example 8*), the plan does not violate the rules of this paragraph (c)(2)(ii). The coverage of counseling and behavioral therapies and MOUD, in combination, in the outpatient, in-network classification and prescription drug classification, respectively, results in the plan providing meaningful benefits for the treatment of opioid use disorder in the outpatient, in-network and prescription drug classifications.

(3) * * *

(i) * * *

(A) *Substantially all.* For purposes of this paragraph (c)(3), a type of financial requirement or quantitative treatment limitation is considered to apply to substantially all medical/surgical benefits in a classification of benefits if it applies to at least two-thirds of all medical/surgical benefits in that classification. (For purposes of this paragraph (c)(3)(i)(A), benefits expressed as subject to a zero level of a type of financial requirement are treated as benefits not subject to that type of financial requirement, and benefits expressed as subject to a quantitative treatment limitation that is unlimited are treated as benefits not subject to that type of quantitative treatment limitation.) If a type of financial requirement or quantitative treatment limitation does not apply to at least two-thirds of all medical/surgical benefits in a classification, then that type cannot be applied to mental health or substance

use disorder benefits in that classification.

* * * * *

(C) *Portion based on plan payments.* For purposes of this paragraph (c)(3), the determination of the portion of medical/surgical benefits in a classification of benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation) is based on the dollar amount of all plan payments for medical/surgical benefits in the classification expected to be paid under the plan for the plan year (or for the portion of the plan year after a change in plan benefits that affects the applicability of the financial requirement or quantitative treatment limitation).

(D) *Clarifications for certain threshold requirements.* For any deductible, the dollar amount of plan payments includes all plan payments with respect to claims that would be subject to the deductible if it had not been satisfied. For any out-of-pocket maximum, the dollar amount of plan payments includes all plan payments associated with out-of-pocket payments that are taken into account towards the out-of-pocket maximum as well as all plan payments associated with out-of-pocket payments that would have been made towards the out-of-pocket maximum if it had not been satisfied. The rules of this paragraph (c)(3)(i)(D) apply for any other thresholds at which the rate of plan payment changes. (See also PHS Act section 2707 and Affordable Care Act section 1302(c), which establish annual limitations on out-of-pocket maximums for all non-grandfathered health plans.)

* * * * *

(iii) *Special rules.* Unless specifically permitted under this paragraph (c)(3)(iii), sub-classifications are not permitted when applying the rules of paragraph (c)(3) of this section.

(A) *Multi-tiered prescription drug benefits.* If a plan applies different levels of financial requirements to different tiers of prescription drug benefits based on reasonable factors determined in accordance with the rules in paragraph (c)(4) of this section (relating to requirements for nonquantitative treatment limitations) and without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits, the plan satisfies the parity requirements of this paragraph (c) with respect to prescription drug benefits. Reasonable factors include cost,

efficacy, generic versus brand name, and mail order versus pharmacy pick-up.

(B) *Multiple network tiers.* If a plan provides benefits through multiple tiers of in-network providers (such as an in-network tier of preferred providers with more generous cost-sharing to participants than a separate in-network tier of participating providers), the plan may divide its benefits furnished on an in-network basis into sub-classifications that reflect network tiers, if the tiering is based on reasonable factors determined in accordance with the rules in paragraph (c)(4) of this section (such as quality, performance, and market standards) and without regard to

whether a provider provides services with respect to medical/surgical benefits or mental health or substance use disorder benefits. After the sub-classifications are established, the plan may not impose any financial requirement or treatment limitation on mental health or substance use disorder benefits in any sub-classification that is more restrictive than the predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in the sub-classification using the methodology set forth in paragraph (c)(3)(i) of this section.

* * * * *

(iv) *Examples.* The rules of paragraphs (c)(3)(i) through (iii) of this section are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

(A) *Example 1—(1) Facts.* (i) For inpatient, out-of-network medical/surgical benefits, a group health plan imposes five levels of coinsurance. Using a reasonable method, the plan projects its payments for the upcoming year as follows:

TABLE 1 TO PARAGRAPH (c)(3)(iv)(A)(1)(i)

Coinurance rate	0%	10%	15%	20%	30%	Total
Projected payments	\$200x	\$100x	\$450x	\$100x	\$150x	\$1,000x
Percent of total plan costs	20%	10%	45%	10%	15%	
Percent subject to coinsurance level	N/A	12.5% (100x/800x)	56.25% (450x/800x)	12.5% (100x/800x)	18.75% (150x/800x)	

(ii) The plan projects plan costs of \$800x to be subject to coinsurance (\$100x + \$450x + \$100x + \$150x = \$800x). Thus, 80 percent (\$800x/\$1,000x) of the benefits are projected to be subject to coinsurance, and 56.25 percent of the benefits subject to coinsurance are projected to be subject to the 15 percent coinsurance level.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(A) (*Example 1*), the two-thirds

threshold of the substantially all standard is met for coinsurance because 80 percent of all inpatient, out-of-network medical/surgical benefits are subject to coinsurance. Moreover, the 15 percent coinsurance is the predominant level because it is applicable to more than one-half of inpatient, out-of-network medical/surgical benefits subject to the coinsurance requirement. The plan may not impose any level of coinsurance with

respect to inpatient, out-of-network mental health or substance use disorder benefits that is more restrictive than the 15 percent level of coinsurance.

(B) *Example 2—(1) Facts.* (i) For outpatient, in-network medical/surgical benefits, a plan imposes five different copayment levels. Using a reasonable method, the plan projects payments for the upcoming year as follows:

TABLE 2 TO PARAGRAPH (c)(3)(iv)(B)(1)(i)

Copayment amount	\$0	\$10	\$15	\$20	\$50	Total
Projected payments	\$200x	\$200x	\$200x	\$300x	\$100x	\$1,000x
Percent of total plan costs	20%	20%	20%	30%	10%	
Percent subject to copayments	N/A	25% (200x/800x)	25% (200x/800x)	37.5% (300x/800x)	12.5% (100x/800x)	

(ii) The plan projects plan costs of \$800x to be subject to copayments (\$200x + \$200x + \$300x + \$100x = \$800x). Thus, 80 percent (\$800x/\$1,000x) of the benefits are projected to be subject to a copayment.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(B) (*Example 2*), the two-thirds threshold of the substantially all standard is met for copayments because 80 percent of all outpatient, in-network medical/surgical benefits are subject to a copayment. Moreover, there is no single level that applies to more than one-half of medical/surgical benefits in the classification subject to a copayment (for the \$10 copayment, 25%; for the \$15 copayment, 25%; for the \$20 copayment, 37.5%; and for the \$50 copayment, 12.5%). The plan can combine any levels of copayment, including the highest levels, to determine the predominant level that can be applied to mental health or substance use disorder benefits. If the plan combines the highest levels of copayment, the combined projected payments for the two highest copayment levels, the \$50 copayment and the \$20 copayment, are not more than one-half of the outpatient, in-network medical/surgical benefits subject to a copayment because they are exactly one-half

(\$300x + \$100x = \$400x; \$400x/\$800x = 50%). The combined projected payments for the three highest copayment levels—the \$50 copayment, the \$20 copayment, and the \$15 copayment—are more than one-half of the outpatient, in-network medical/surgical benefits subject to the copayments (\$100x + \$300x + \$200x = \$600x; \$600x/\$800x = 75%). Thus, the plan may not impose any copayment on outpatient, in-network mental health or substance use disorder benefits that is more restrictive than the least restrictive copayment in the combination, the \$15 copayment.

(C) *Example 3—(1) Facts.* A plan imposes a \$250 deductible on all medical/surgical benefits for self-only coverage and a \$500 deductible on all medical/surgical benefits for family coverage. The plan has no network of providers. For all medical/surgical benefits, the plan imposes a coinsurance requirement. The plan imposes no other financial requirements or treatment limitations.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(C) (*Example 3*), because the plan has no network of providers, all benefits are provided out-of-network. Because self-only and family coverage are subject to different

deductibles, whether the deductible applies to substantially all medical/surgical benefits is determined separately for self-only medical/surgical benefits and family medical/surgical benefits. Because the coinsurance is applied without regard to coverage units, the predominant coinsurance that applies to substantially all medical/surgical benefits is determined without regard to coverage units.

(D) *Example 4—(1) Facts.* A plan applies the following financial requirements for prescription drug benefits. The requirements are applied without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits. Moreover, the process for certifying a particular drug as “generic”, “preferred brand name”, “non-preferred brand name”, or “specialty” complies with the rules of paragraph (c)(4) of this section (relating to requirements for nonquantitative treatment limitations).

TABLE 3 TO PARAGRAPH (c)(3)(iv)(D)(1)

	Tier 1	Tier 2	Tier 3	Tier 4
Tier description	Generic drugs	Preferred brand name drugs.	Non-preferred brand name drugs (which may have Tier 1 or Tier 2 alternatives).	Specialty drugs.
Percent paid by plan	90%	80%	60%	50%.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(D) (*Example 4*), the financial requirements that apply to prescription drug benefits are applied without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits; the process for certifying drugs in different tiers complies with paragraph (c)(4) of this section; and the bases for establishing different levels or types of financial requirements are reasonable. The financial requirements applied to prescription drug benefits do not violate the parity requirements of this paragraph (c)(3).

(E) *Example 5—(1) Facts.* A plan has two tiers of network of providers: a preferred provider tier and a participating provider tier. Providers are placed in either the preferred tier or participating tier based on reasonable factors determined in accordance with the rules in paragraph (c)(4) of this section, such as accreditation, quality and performance measures (including customer feedback), and relative reimbursement rates. Furthermore, provider tier placement is determined without regard to whether a provider specializes in the treatment of mental health conditions or substance use disorders, or medical/surgical conditions. The plan divides the in-network classifications into two sub-classifications (in-network/preferred and in-network/participating). The plan does not impose any financial requirement or treatment limitation on mental health or substance use disorder benefits in either of these sub-classifications that is more restrictive than the predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in each sub-classification.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(E) (*Example 5*), the division of in-network benefits into sub-classifications that reflect the preferred and participating provider tiers does not violate the parity requirements of this paragraph (c)(3).

(F) *Example 6—(1) Facts.* With respect to outpatient, in-network benefits, a plan imposes a \$25 copayment for office visits and a 20 percent coinsurance requirement for outpatient surgery. The plan divides the outpatient, in-network classification into two sub-classifications (in-network office visits and all other outpatient, in-network items and services). The plan does not impose any financial requirement or quantitative treatment limitation on mental health or substance use disorder benefits in either of these sub-classifications that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in each sub-classification.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(F) (*Example 6*), the division of outpatient, in-network benefits into sub-classifications for office visits and all other outpatient, in-network items and services does not violate the parity requirements of this paragraph (c)(3).

(G) *Example 7—(1) Facts.* Same facts as in paragraph (c)(3)(iv)(F)(1) of this section (*Example 6*), but for purposes of determining parity, the plan divides the outpatient, in-network classification into outpatient, in-network generalists and outpatient, in-network specialists.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(G) (*Example 7*), the division of outpatient, in-network benefits into any sub-classifications other than office visits and all other outpatient items and services violates the requirements of paragraph (c)(3)(iii)(C) of this section.

* * * * *

(4) *Nonquantitative treatment limitations.* Consistent with paragraph (a)(1) of this section, a group health plan may not impose any nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in any classification that is more restrictive, as written or in operation, than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification. For purposes of this paragraph (c)(4), a nonquantitative treatment limitation is more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification if the plan fails to meet the requirements of paragraph (c)(4)(i) or (iii) of this section. In such a case, the plan will be considered to violate Code section 9812(a)(3)(A)(ii), and the nonquantitative treatment limitation may not be imposed by the plan with respect to mental health or substance use disorder benefits in the classification.

(i) *Requirements related to design and application of a nonquantitative treatment limitation—(A) In general.* A plan may not impose a nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in any classification unless, under the terms of the plan, as written and in operation, any processes,

strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the limitation with respect to medical/surgical benefits in the classification.

(B) *Prohibition on discriminatory factors and evidentiary standards.* For purposes of determining comparability and stringency under paragraph (c)(4)(i)(A) of this section, a plan may not rely upon discriminatory factors or evidentiary standards to design a nonquantitative treatment limitation to be imposed on mental health or substance use disorder benefits. A factor or evidentiary standard is discriminatory if the information, evidence, sources, or standards on which the factor or evidentiary standard are based are biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits.

(7) Information, evidence, sources, or standards are considered to be biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits if, based on all the relevant facts and circumstances, the information, evidence, sources, or standards systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits. For purposes of this paragraph (c)(4)(i)(B)(1), relevant facts and circumstances may include, but are not limited to, the reliability of the source of the information, evidence, sources, or standards, including any underlying data; the independence of the information, evidence, sources, and standards relied upon; the analyses and methodologies employed to select the information and the consistency of their application; and any known safeguards deployed to prevent reliance on skewed data or metrics. Information, evidence,

sources, or standards are not considered biased or not objective for this purpose if the plan has taken the steps necessary to correct, cure, or supplement any information, evidence, sources, or standards that would have been biased or not objective in the absence of such steps.

(2) For purposes of this paragraph (c)(4)(i)(B), historical plan data or other historical information from a time when the plan was not subject to Code section 9812 or was not in compliance with Code section 9812 are considered to be biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits, if the historical plan data or other historical information systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits, and the plan has not taken the steps necessary to correct, cure, or supplement the data or information.

(3) For purposes of this paragraph (c)(4)(i)(B), generally recognized independent professional medical or clinical standards and carefully circumscribed measures reasonably and appropriately designed to detect or prevent and prove fraud and abuse that minimize the negative impact on access to appropriate mental health and substance use disorder benefits are not information, evidence, sources, or standards that are biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits. However, plans must comply with the other requirements in this paragraph (c)(4), as applicable, with respect to such standards or measures that are used as the basis for a factor or evidentiary standard used to design or apply a nonquantitative treatment limitation.

(ii) *Illustrative, non-exhaustive list of nonquantitative treatment limitations.* Nonquantitative treatment limitations include—

(A) Medical management standards (such as prior authorization) limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative;

(B) Formulary design for prescription drugs;

(C) For plans with multiple network tiers (such as preferred providers and participating providers), network tier design;

(D) Standards related to network composition, including but not limited

to, standards for provider and facility admission to participate in a network or for continued network participation, including methods for determining reimbursement rates, credentialing standards, and procedures for ensuring the network includes an adequate number of each category of provider and facility to provide services under the plan;

(E) Plan methods for determining out-of-network rates, such as allowed amounts; usual, customary, and reasonable charges; or application of other external benchmarks for out-of-network rates;

(F) Refusal to pay for higher-cost therapies until it can be shown that a lower-cost therapy is not effective (also known as fail-first policies or step therapy protocols);

(G) Exclusions based on failure to complete a course of treatment; and

(H) Restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits for services provided under the plan.

(iii) *Required use of outcomes data—*
(A) *In general.* To ensure that a nonquantitative treatment limitation applicable to mental health or substance use disorder benefits in a classification, in operation, is no more restrictive than the predominant nonquantitative treatment limitation applied to substantially all medical/surgical benefits in the classification, a plan must collect and evaluate relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits and carefully consider the impact as part of the plan's evaluation. As part of its evaluation, the plan may not disregard relevant outcomes data that it knows or reasonably should know suggest that a nonquantitative treatment limitation is associated with material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits. The Secretary, jointly with the Secretary of Labor and the Secretary of Health and Human Services, may specify in guidance the type, form, and manner of collection and evaluation for the data required under this paragraph (c)(4)(iii)(A).

(1) *Relevant data generally.* For purposes of this paragraph (c)(4)(iii)(A), relevant data could include, as appropriate, but are not limited to, the number and percentage of claims denials and any other data relevant to the nonquantitative treatment limitation

required by State law or private accreditation standards.

(2) *Relevant data for nonquantitative treatment limitations related to network composition.* In addition to the relevant data set forth in paragraph (c)(4)(iii)(A)(1) of this section, relevant data for nonquantitative treatment limitations related to network composition could include, as appropriate, but are not limited to, in-network and out-of-network utilization rates (including data related to provider claim submissions), network adequacy metrics (including time and distance data, and data on providers accepting new patients), and provider reimbursement rates (for comparable services and as benchmarked to a reference standard).

(3) *Unavailability of data.* (i) If a plan newly imposes a nonquantitative treatment limitation for which relevant data is initially temporarily unavailable and the plan therefore cannot comply with this paragraph (c)(4)(iii)(A), the plan must include in its comparative analysis, as required under § 54.9812–2(c)(5)(i)(C), a detailed explanation of the lack of relevant data, the basis for the plan's conclusion that there is a lack of relevant data, and when and how the data will become available and be collected and analyzed. Such a plan also must comply with this paragraph (c)(4)(iii)(A) as soon as practicable once relevant data becomes available.

(ii) If a plan imposes a nonquantitative treatment limitation for which no data exist that can reasonably assess any relevant impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits, the plan must include in its comparative analysis, as required under § 54.9812–2(c)(5)(i)(D), a reasoned justification as to the basis for the conclusion that there are no data that can reasonably assess the nonquantitative treatment limitation's impact, why the nature of the nonquantitative treatment limitation prevents the plan from reasonably measuring its impact, an explanation of what data was considered and rejected, and documentation of any additional safeguards or protocols used to ensure the nonquantitative treatment limitation complies with this section. If a plan becomes aware of data that can reasonably assess any relevant impact of the nonquantitative treatment limitation, the plan must comply with this paragraph (c)(4)(iii)(A) as soon as practicable.

(iii) Consistent with paragraph (a)(1) of this section, paragraphs

(c)(4)(iii)(A)(3)(i) and (ii) of this section shall only apply in very limited circumstances and, where applicable, shall be construed narrowly.

(B) *Material differences.* To the extent the relevant data evaluated under paragraph (c)(4)(iii)(A) of this section suggest that the nonquantitative treatment limitation contributes to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits in a classification, such differences will be considered a strong indicator that the plan violates this paragraph (c)(4).

(1) Where the relevant data suggest that the nonquantitative treatment limitation contributes to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits in a classification, the plan must take reasonable action, as necessary, to address the material differences to ensure compliance, in operation, with this paragraph (c)(4) and must document the actions that have been or are being taken by the plan to address material differences in access to mental health or substance use disorder benefits, as compared to medical/surgical benefits, as required by § 54.9812–2(c)(5)(iv).

(2) For purposes of this paragraph (c)(4)(iii)(B), relevant data are considered to suggest that the nonquantitative treatment limitation contributes to material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits if, based on all relevant facts and circumstances, and taking into account the considerations outlined in this paragraph (c)(4)(iii)(B)(2), the difference in the data suggests that the nonquantitative treatment limitation is likely to have a negative impact on access to mental health or substance use disorder benefits as compared to medical/surgical benefits.

(i) Relevant facts and circumstances, for purposes of this paragraph (c)(4)(iii)(B)(2), may include, but are not limited to, the terms of the nonquantitative treatment limitation at issue, the quality or limitations of the data, causal explanations and analyses, evidence as to the recurring or non-recurring nature of the results, and the magnitude of any disparities.

(ii) Differences in access to mental health or substance use disorder benefits attributable to generally recognized independent professional medical or clinical standards or carefully circumscribed measures reasonably and appropriately designed

to detect or prevent and prove fraud and abuse that minimize the negative impact on access to appropriate mental health and substance use disorder benefits, which are used as the basis for a factor or evidentiary standard used to design or apply a nonquantitative treatment limitation, are not considered to be material for purposes of this paragraph (c)(4)(iii)(B). To the extent a plan attributes any differences in access to the application of such standards or measures, the plan must explain the bases for that conclusion in the documentation prepared under § 54.9812–2(c)(5)(iv)(A).

(C) *Nonquantitative treatment limitations related to network composition.* For purposes of applying paragraph (c)(4)(iii)(A) of this section with respect to nonquantitative treatment limitations related to network composition, a plan must collect and evaluate relevant data in a manner reasonably designed to assess the aggregate impact of all such nonquantitative treatment limitations on access to mental health and substance use disorder benefits and medical/surgical benefits. Examples of possible actions that a plan could take to comply with the requirement under paragraph (c)(4)(iii)(B)(1) of this section to take reasonable action, as necessary, to address any material differences in access with respect to nonquantitative treatment limitations related to network composition, to ensure compliance with this paragraph (c)(4), include, but are not limited to:

(1) Strengthening efforts to recruit and encourage a broad range of available mental health and substance use disorder providers and facilities to join the plan's network of providers, including taking actions to increase compensation or other inducements, streamline credentialing processes, or contact providers reimbursed for items and services provided on an out-of-network basis to offer participation in the network;

(2) Expanding the availability of telehealth arrangements to mitigate any overall mental health and substance use disorder provider shortages in a geographic area;

(3) Providing additional outreach and assistance to participants and beneficiaries enrolled in the plan to assist them in finding available in-network mental health and substance use disorder providers and facilities; and

(4) Ensuring that provider directories are accurate and reliable.

(iv) *Prohibition on separate nonquantitative treatment limitations applicable only to mental health or*

substance use disorder benefits.

Consistent with paragraph (c)(2)(i) of this section, a group health plan may not apply any nonquantitative treatment limitation that is applicable only with respect to mental health or substance use disorder benefits and does not apply with respect to any medical/surgical benefits in the same benefit classification.

(v) *Effect of final determination of noncompliance under § 54.9812–2.* (A) If a group health plan receives a final determination from the Secretary that the plan is not in compliance with the requirements of Code section 9812(a)(8) or § 54.9812–2 with respect to a nonquantitative treatment limitation, the nonquantitative treatment limitation violates this paragraph (c)(4) and the Secretary may direct the plan not to impose the nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in the relevant classification, unless and until the plan demonstrates to the Secretary compliance with the requirements of this section or takes appropriate action to remedy the violation.

(B) A determination by the Secretary of whether to require cessation of a nonquantitative treatment limitation under this paragraph (c)(4)(v) will be based on an evaluation of the relevant facts and circumstances involved in the specific final determination and the nature of the underlying nonquantitative treatment limitation and will take into account the interest of plan participants and beneficiaries and feedback from the plan.

(vi) *Examples.* The rules of this paragraph (c)(4) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

(A) *Example 1 (not comparable and more stringent factors for reimbursement rate methodology, in operation)—(1) Facts.* A plan's reimbursement rate methodology for outpatient, in-network providers is based on a variety of factors. As written, for mental health, substance use disorder, and medical/surgical benefits, all reimbursement rates for physicians and non-physician practitioners for the same Current Procedural Terminology (CPT) code are based on a combination of factors, such as the nature of the service, duration of the service, intensity and specialization of training, provider licensure and type, number of providers qualified to provide the service in a given geographic area, and market need (demand). In operation, the plan utilizes an additional strategy to further reduce reimbursement rates for mental health and substance use disorder non-physician providers from those

paid to mental health and substance use disorder physicians by the same percentage for every CPT code, but does not apply the same reductions for non-physician medical/surgical providers.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(A) (*Example 1*), the plan violates the rules of this paragraph (c)(4). Because the plan reimburses non-physician providers of mental health and substance use disorder services by reducing their reimbursement rate from the rate for physician providers of mental health and substance use disorder services by the same percentage for every CPT code but does not apply the same reductions to non-physician providers of medical/surgical services from the rate for physician providers of medical/surgical services, in operation, the factors used in designing and applying the nonquantitative treatment limitation to mental health and substance use disorder benefits in the outpatient, in-network classification are not comparable to, and are applied more stringently than, the factors used in designing and applying the limitation with respect to medical/surgical benefits in the same classification. As a result, the nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in the outpatient, in-network classification is more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification.

(B) *Example 2 (strategy for exclusion for experimental or investigative treatment more stringently applied to ABA therapy in operation)*—(1) *Facts.* A plan, as written, generally excludes coverage for all treatments that are experimental or investigative for both medical/surgical benefits and mental health and substance use disorder benefits in the outpatient, in-network classification. As a result, the plan generally excludes, as experimental, a treatment or procedure when no professionally recognized treatment guidelines include the treatment or procedure as a clinically appropriate standard of care for the condition or disorder and fewer than two randomized controlled trials are available to support the treatment's use with respect to the given condition or disorder. The plan provides benefits for the treatment of ASD, which is a mental health condition, but, in operation, the plan excludes coverage for ABA therapy to treat children with ASD, deeming it experimental. More than one professionally recognized treatment guideline defines clinically appropriate standards of care for ASD and more than two randomized controlled trials are available to support the use of ABA therapy as one intervention to treat certain children with ASD.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(B) (*Example 2*), the plan violates the rules of this paragraph (c)(4). As written, the plan excludes coverage of experimental treatment of medical conditions and surgical procedures, mental health conditions, and substance use disorders when no professionally recognized treatment guidelines define clinically appropriate standards of care for the condition or

disorder as including the treatment or procedure at issue, and fewer than two randomized controlled trials are available to support the treatment's use with respect to the given condition or procedure. However, in operation, the plan deviates from this strategy with respect to ABA therapy because more than one professionally recognized treatment guideline defines clinically appropriate standards of care for ASD as including ABA therapy to treat certain children with ASD and more than two randomized controlled trials are available to support the use of ABA therapy to treat certain children with ASD. Therefore, in operation, the strategy used to design the nonquantitative treatment limitation for benefits for the treatment of ASD, which is a mental health condition, in the outpatient, in-network classification is not comparable to, and is applied more stringently than, the strategy used to design the nonquantitative treatment limitation for medical/surgical benefits in the same classification. As a result, the nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in the outpatient, in-network classification is more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification.

(C) *Example 3 (step therapy protocol with exception for severe or irreversible consequences, discriminatory factor)*—(1) *Facts.* A plan's written terms include a step therapy protocol that requires participants and beneficiaries who are prescribed certain drugs to try and fail a generic or preferred brand name drug before the plan will cover the drug originally prescribed by a participant's or beneficiary's attending provider. The plan provides an exception to this protocol that was developed solely based on a methodology developed by an external third-party organization. The third-party organization's methodology, which is not based on a generally recognized independent professional medical or clinical standard, identifies instances in which a delay in treatment with a drug prescribed for a medical condition or surgical procedure could result in either severe or irreversible consequences. However, with respect to a drug prescribed for a mental health condition or a substance use disorder, the third-party organization's methodology only identifies instances in which a delay in treatment could result in both severe and irreversible consequences, and the plan does not take any steps to correct, cure, or supplement the methodology.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(C) (*Example 3*), the plan violates the rules of paragraph (c)(4)(i)(B) of this section. The source upon which the factor used to apply the step therapy protocol is based is biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits because it addresses instances in which a delay in treatment with a drug prescribed for a medical condition or surgical procedure could result in either severe or irreversible consequences, but only addresses instances

in which a delay in treatment with a drug prescribed for a mental health condition or substance use disorder could result in both severe and irreversible consequences, and the plan fails to take the steps necessary to correct, cure, or supplement the methodology so that it is not biased and is objective. Based on the relevant facts and circumstances, this source systematically disfavors access or is specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits. Therefore, the factor used to apply the step therapy protocol is discriminatory for purposes of determining comparability and stringency under paragraph (c)(4)(i)(A) of this section, and may not be relied upon by the plan.

(D) *Example 4 (use of historical plan data and plan steps to correct, cure, or supplement)*—(1) *Facts.* A plan's methodology for calculating provider reimbursement rates relies only on historical plan data on total plan spending for each specialty, divided between mental health and substance use disorder providers and medical/surgical providers, from a time when the plan was not subject to Code section 9812. The plan has used these historical plan data for many years to establish base reimbursement rates in all provider specialties for which it provides medical/surgical, mental health, and substance use disorder benefits in the inpatient, in-network classification. In evaluating the use of these historical plan data in the design of the methodology for calculating provider reimbursement rates, the plan determined, based on all the relevant facts and circumstances, that the historical plan data systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits. To ensure this information about historical reimbursement rates is not biased and is objective, the plan supplements its methodology to develop the base reimbursement rates for mental health and substance use disorder providers in accordance with additional information, evidence, sources, and standards that reflect the increased demand for mental health and substance use disorder benefits in the inpatient, in-network classification and to attract sufficient mental health and substance use disorder providers to the network, so that the relevant facts and circumstances indicate the supplemented information, evidence, sources, or standards do not systematically disfavor access and are not specifically designed to disfavor access to mental health and substance use disorder benefits as compared to medical/surgical benefits.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(D) (*Example 4*), the plan does not violate the rules of paragraph (c)(4)(i)(B) of this section with respect to the plan's methodology for calculating provider reimbursement rates in the inpatient, in-network classification. The relevant facts and circumstances indicate that the plan's use of only historical plan data to design its methodology for calculating provider reimbursement rates in the inpatient, in-network classification would otherwise be

considered to be biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits under paragraph (c)(4)(i)(B)(2) of this section, since the historical data systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits. However, the plan took the steps necessary to supplement the information, evidence, sources, and standards to reasonably reflect the increased demand for mental health and substance use disorder benefits in the inpatient, in-network classification, and adjust the methodology to increase reimbursement rates for those benefits, thereby ensuring that the information, evidence, sources, and standards relied upon by the plan for this purpose are not biased and are objective. Therefore, the factors and evidentiary standards used to design the plan's methodology for calculating provider reimbursement rates in the inpatient, in-network classification are not discriminatory.

(E) *Example 5 (generally recognized independent professional medical or clinical standards and more stringent prior authorization requirement in operation)*—(1) *Facts.* The provisions of a plan state that it relies on, and does not deviate from, generally recognized independent professional medical or clinical standards to inform the factor used to design prior authorization requirements for both medical/surgical and mental health and substance use disorder benefits in the prescription drug classification. The generally recognized independent professional medical standard for treatment of opioid use disorder that the plan utilizes—in this case, the American Society of Addiction Medicine national practice guidelines—does not support prior authorization every 30 days for buprenorphine/naloxone. However, in operation, the plan requires prior authorization for buprenorphine/naloxone combination for treatment of opioid use disorder, every 30 days, which is inconsistent with the generally recognized independent professional medical standard on which the factor used to design the limitation is based. The plan's factor used to design prior authorization requirements for medical/surgical benefits in the prescription drug classification relies on, and does not deviate from, generally recognized independent professional medical or clinical standards.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(E) (*Example 5*), the plan violates the rules of this paragraph (c)(4). The American Society of Addiction Medicine national practice guidelines on which the factor used to design prior authorization requirements for substance use disorder benefits is based are generally recognized independent professional medical or clinical standards that are not considered to be biased or not objective in a manner that discriminates against mental health and substance use disorder benefits under paragraph (c)(4)(i)(B)(3) of this section. However, the plan must comply with other requirements in this paragraph (c)(4), as applicable, with

respect to such standards or measures that are used as the basis for a factor or evidentiary standard used to design or apply a nonquantitative treatment limitation. In operation, the plan's factor used to design and apply prior authorization requirements with respect to substance use disorder benefits is not comparable to, and is applied more stringently than, the same factor used to design and apply prior authorization requirements for medical/surgical benefits, because the factor relies on, and does not deviate from, generally recognized independent professional medical or clinical standards for medical/surgical benefits, but deviates from the relevant guidelines for substance use disorder benefits. As a result, the nonquantitative treatment limitation with respect to substance use disorder benefits in the prescription drug classification is more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification.

(F) *Example 6 (plan claims no data exist to reasonably assess impact of nonquantitative treatment limitation on access; medical necessity criteria)*—(1) *Facts.* A plan approves or denies claims for mental health and substance use disorder benefits and for medical/surgical benefits in the inpatient, in-network and outpatient, in-network classifications based on medical necessity criteria. The plan states in its comparative analysis that no data exist that can reasonably assess any relevant impact of the medical necessity criteria nonquantitative treatment limitation on relevant outcomes related to access to mental health or substance use disorder benefits as compared to the plan's medical necessity criteria nonquantitative treatment limitation's impact on relevant outcomes related to access to medical/surgical benefits in the relevant classifications, without further explanation.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(F) (*Example 6*), the plan violates this paragraph (c)(4). The plan does not comply with paragraph (c)(4)(iii)(A)(3)(ii) of this section because the plan did not include in its comparative analysis, as required under § 54.9812–2(c)(5)(i)(D), a reasoned justification as to the basis for its conclusion that there are no data that can reasonably assess the nonquantitative treatment limitation's impact, an explanation of why the nature of the nonquantitative treatment limitation prevents the plan from reasonably measuring its impact, an explanation of what data was considered and rejected, and documentation of any additional safeguards or protocols used to ensure the nonquantitative treatment limitation complies with this paragraph (c)(4). Data that could reasonably assess the medical necessity criteria nonquantitative treatment limitation's impact might include, for example, the number and percentage of claims denials, or the number and percentage of claims that were approved for a lower level of care than the level requested on the initial claim. Therefore, because the plan has not collected and evaluated relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitation on relevant outcomes related to

access to mental health and substance use disorder benefits and medical/surgical benefits in the relevant classifications, the plan violates the requirements of paragraph (c)(4)(iii) of this section, and violates the requirements under § 54.9812–2(c)(5)(i)(D) because it did not include sufficient information in its comparative analysis with respect to the lack of relevant data.

(G) *Example 7 (concurrent review data collection; no material difference in access)*—(1) *Facts.* A plan follows a written process to apply a concurrent review nonquantitative treatment limitation to all medical/surgical benefits and mental health and substance use disorder benefits within the inpatient, in-network classification. Under this process, a first-level review is conducted in every instance in which concurrent review applies and an authorization request is approved by the first-level reviewer only if the clinical information submitted by the facility meets the plan's criteria for a continued stay. If the first-level reviewer is unable to approve the authorization request because the clinical information submitted by the facility does not meet the plan's criteria for a continued stay, it is sent to a second-level reviewer who will either approve or deny the request. The plan collects relevant data, including the number of referrals to second-level review, and the number of denials of claims for medical/surgical benefits and mental health and substance use disorder benefits subject to concurrent review as compared to the total number of claims subject to concurrent review, in the inpatient, in-network classification. The plan also collects and evaluates the number of denied claims for medical/surgical benefits and mental health and substance use disorder benefits that are overturned on appeal in the inpatient, in-network classification. The plan evaluates the relevant data and determines that, based on the relevant facts and circumstances, the data do not suggest that the concurrent review nonquantitative treatment limitation contributes to material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits in the classification. Upon requesting the plan's comparative analysis for the concurrent review nonquantitative treatment limitation and reviewing the relevant data, the Secretary does not request additional data and agrees that the data do not suggest material differences in access.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(G) (*Example 7*), the plan does not violate the rules of paragraph (c)(4)(iii) of this section. The plan collected and evaluated relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits and considered the impact as part of its evaluation. Because the relevant data evaluated do not suggest that the nonquantitative treatment limitation contributes to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits in the inpatient, in-network classification, under paragraph (c)(4)(iii)(B) of this section, there is no strong indicator that the plan violates this paragraph (c)(4).

(H) *Example 8 (material difference in access for prior authorization requirement with reasonable action)*—(1) *Facts.* A plan requires prior authorization that a treatment is medically necessary for all inpatient, in-network medical/surgical benefits and for all inpatient, in-network mental health and substance use disorder benefits. The plan collects and evaluates relevant data in a manner reasonably designed to assess the impact of the prior authorization requirement on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits in the inpatient, in-network classification. The plan's written process for prior authorization states that the plan approves inpatient, in-network benefits for medical conditions and surgical procedures and mental health and substance use disorder benefits for periods of 1, 3, and 7 days, after which a treatment plan must be submitted by the patient's attending provider and approved by the plan. Approvals for mental health and substance use disorder benefits are most commonly given only for 1 day, after which a treatment plan must be submitted by the patient's attending provider and approved by the plan. The relevant data show that approvals for 7 days are most common for medical conditions and surgical procedures under this plan. Based on all the relevant facts and circumstances, the difference in the relevant data suggests that the nonquantitative treatment limitation is likely to have a negative impact on access to mental health and substance use disorder benefits as compared to medical/surgical benefits. Therefore, the data suggest that the nonquantitative treatment limitation contributes to material differences in access. To address these material differences in access, the plan consults more recent medical guidelines to update the factors that inform its medical necessity nonquantitative treatment limitations. Based on this review, the plan modifies the limitation so that inpatient, in-network prior authorization requests for mental health or substance use disorder benefits are approved for similar periods to what is approved for medical/surgical benefits. The plan includes documentation of this action as part of its comparative analysis.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(H) (*Example 8*), the plan does not violate the rules of paragraph (c)(4)(iii) of this section. While relevant data for the plan's prior authorization requirements suggested that the nonquantitative treatment limitation contributes to material differences in access to mental health and substance use disorder benefits as compared to inpatient, in-network medical/surgical benefits under paragraph (c)(4)(iii)(B) of this section, the plan has taken reasonable action, as necessary, to ensure compliance, in operation, with this paragraph (c)(4) by updating the factors that inform its prior authorization nonquantitative treatment limitation for inpatient, in-network mental health and substance use disorder benefits so that these benefits are approved for similar periods to what is approved for medical/surgical benefits. The plan also documents its action taken to address material differences in

access to inpatient, in-network benefits as required by paragraph (c)(4)(iii)(B)(1) of this section.

(I) *Example 9 (differences attributable to generally recognized independent professional medical or clinical standards)*—(1) *Facts.* A group health plan develops a medical management requirement for all inpatient, out-of-network benefits for both medical/surgical benefits and mental health and substance use disorder benefits to ensure treatment is medically necessary. The factors and evidentiary standards used to design and apply the medical management requirement rely on independent professional medical or clinical standards that are generally recognized by health care providers and facilities in relevant clinical specialties. The processes, strategies, evidentiary standards, and other factors used in designing and applying the medical management requirement to mental health and substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the requirement with respect to medical/surgical benefits. The plan collects and evaluates relevant data in a manner reasonably designed to assess the impact of the medical management nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits, and considers the impact as part of the plan's evaluation, as required by paragraph (c)(4)(iii)(A) of this section. Within the inpatient, out-of-network classification, the application of the medical management requirement results in a higher percentage of denials for mental health and substance use disorder claims than medical/surgical claims, because the benefits were found to be medically necessary for a lower percentage of mental health and substance use disorder claims. The plan correctly determines that these differences in access are attributable to the generally recognized independent professional medical or clinical standards used as the basis for the factors and evidentiary standards used to design or apply the limitation and adequately explains the bases for that conclusion as part of its comparative analysis.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(I) (*Example 9*), the plan does not violate the rules of this paragraph (c)(4). Generally recognized independent professional medical or clinical standards of care are not considered to be information, evidence, sources, or standards that are biased and not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits, and the plan otherwise complies with the requirements in paragraph (c)(4)(i) of this section. Additionally, the plan does not violate paragraph (c)(4)(iii) of this section because it has collected and evaluated relevant data, the differences in access are attributable to the generally recognized independent professional medical or clinical standards that are used as the basis for the factors and evidentiary standards used to design or apply the medical management nonquantitative

treatment limitation, and the plan explains the bases for this conclusion in its comparative analysis. As a result, the nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in the inpatient, out-of-network classification is no more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification.

(J) *Example 10 (material differences in access for standards for provider admission to a network with reasonable action)*—(1) *Facts.* A plan applies nonquantitative treatment limitations related to network composition in the inpatient, in-network and outpatient, in-network classifications. The plan's networks are constructed by separate service providers for medical/surgical benefits and mental health and substance use disorder benefits. The processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitations related to network composition for mental health or substance use disorder benefits in the outpatient, in-network and inpatient, in-network classifications are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitations with respect to medical/surgical benefits in the classifications, as required under paragraph (c)(4)(i) of this section. In order to ensure, in operation, that the nonquantitative treatment limitations are no more restrictive than the predominant nonquantitative treatment limitations applied to substantially all medical/surgical benefits in the classification, the plan collects and evaluates relevant data in a manner reasonably designed to assess the aggregate impact of all the nonquantitative treatment limitations related to network composition on relevant outcomes related to access to mental health and substance use disorder benefits as compared with access to medical/surgical benefits and considers the impact as part of the plan's evaluation. The plan considers relevant data that is known, or reasonably should be known, including metrics relating to the time and distance from plan participants and beneficiaries to network providers in rural and urban regions; the number of network providers accepting new patients; the proportions of mental health and substance use disorder and medical/surgical providers and facilities that provide services in rural and urban regions who are in the plan's network; provider reimbursement rates (for comparable services and benchmarked to a reference standard, as appropriate); and in-network and out-of-network utilization rates (including data related to the dollar value and number of provider claims submissions). The plan determines that the relevant data suggest that the nonquantitative treatment limitations in the aggregate contribute to material differences in access to mental health and substance use disorder benefits compared to medical/surgical benefits in the classifications because, based on all the relevant facts and circumstances, the

differences in the data suggest that the nonquantitative treatment limitations related to network composition are likely to have a negative impact on access to mental health or substance use disorder benefits as compared to medical/surgical benefits. The plan takes reasonable actions, as necessary, to address the material differences in access, to ensure compliance, in operation, with this paragraph (c)(4), by strengthening its efforts to recruit and encourage a broad range of available providers and facilities to join the plan's network of providers, including by taking actions to increase compensation and other inducements, streamline credentialing processes, contact providers reimbursed for items and services provided on an out-of-network basis to offer participation in the network, and develop a process to monitor the effects of such efforts; expanding the availability of telehealth arrangements to mitigate overall provider shortages in certain geographic areas; providing additional outreach and assistance to participants and beneficiaries enrolled in the plan to assist them in finding available in-network providers and facilities; and ensuring that the plan's provider directories are accurate and reliable. The plan documents the efforts that it has taken to address the material differences in access that the data revealed, and the plan includes the documentation as part of its comparative analysis submission.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(J) (*Example 10*), the plan does not violate the rules of this paragraph (c)(4). The plan's nonquantitative treatment limitations related to network composition comply with the rules of paragraph (c)(4)(i) of this section. Additionally, the plan collects and evaluates relevant data, as required under paragraph (c)(4)(iii)(A) of this section, in a manner reasonably designed to assess the aggregate impact of all such nonquantitative treatment limitations on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits, as required under paragraph (c)(4)(iii)(C) of this section. While the data suggest that the nonquantitative treatment limitations contribute to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, the plan has taken reasonable action, as necessary, to ensure compliance with this paragraph (c)(4). The plan also documents the actions that have been and are being taken by the plan to address material differences as required by § 54.9812–21(c)(5)(iv). As a result, the network composition nonquantitative treatment limitations with respect to mental health or substance use disorder benefits in the inpatient, in-network and outpatient, in-network classifications are no more restrictive than the predominant nonquantitative treatment limitations that apply to substantially all medical/surgical benefits in the same classifications.

(K) *Example 11 (separate EAP exhaustion treatment limitation applicable only to mental health or substance use disorder benefits)*—(1) *Facts.* An employer maintains both a major medical plan and an employee assistance program (EAP). The EAP provides, among other benefits, a limited number of

mental health or substance use disorder counseling sessions, which, together with other benefits provided by the EAP, are not significant benefits in the nature of medical care. Participants are eligible for mental health or substance use disorder benefits under the major medical plan only after exhausting the counseling sessions provided by the EAP. No similar exhaustion requirement applies with respect to medical/surgical benefits provided under the major medical plan.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(K) (*Example 11*), the requirement that limits eligibility for mental health and substance use disorder benefits under the major medical plan until EAP benefits are exhausted is a nonquantitative treatment limitation subject to the parity requirements of this paragraph (c)(4). Because the limitation does not apply to medical/surgical benefits, it is a separate nonquantitative treatment limitation applicable only to mental health and substance use disorder benefits that violates paragraph (c)(4)(iv) of this section. Additionally, this EAP would not qualify as excepted benefits under § 54.9831–1(c)(3)(vi)(B)(1) because participants in the major medical plan are required to use and exhaust benefits under the EAP (making the EAP a gatekeeper) before an individual is eligible for benefits under the plan.

(L) *Example 12 (separate exclusion for treatment in a residential facility applicable only to mental health and substance use disorder benefits)*—(1) *Facts.* A plan generally covers inpatient, in-network and inpatient, out-of-network treatment without any limitations on setting, including skilled nursing facilities and rehabilitation hospitals, provided other medical necessity standards are satisfied. The plan has an exclusion for treatment at residential facilities, which the plan defines as an inpatient benefit for mental health and substance use disorder benefits. This exclusion was not generated through any broader nonquantitative treatment limitation (such as medical necessity or other clinical guideline).

(2) *Conclusion.* In this paragraph (c)(4)(vi)(L) (*Example 12*), the plan violates the rules of paragraph (c)(4)(iv) of this section. The exclusion of treatment at residential facilities is a separate nonquantitative treatment limitation applicable only to mental health and substance use disorder benefits in the inpatient, in-network and inpatient, out-of-network classifications because the plan does not apply a comparable exclusion with respect to any medical/surgical benefits in the same benefit classification.

(M) *Example 13 (impermissible nonquantitative treatment limitation imposed following a final determination of noncompliance and direction by the Secretary)*—(1) *Facts.* Following an initial request by the Secretary for a plan's comparative analysis of the plan's exclusion of mental health and substance use disorder benefits for failure to complete a course of treatment in the inpatient, in-network classification under § 54.9812–2(d), the plan submits a comparative analysis for the nonquantitative treatment limitation. After

review of the comparative analysis, as well as additional information submitted by the plan after the Secretary determines that the plan has not submitted sufficient information to be responsive to the request, the Secretary makes an initial determination that the comparative analysis fails to demonstrate that the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the inpatient, in-network classification are comparable to, and applied no more stringently than, those used in designing and applying the limitation to medical/surgical benefits in the classification. Under § 54.9812–2(d)(3), the plan submits a corrective action plan and additional comparative analyses within 45 calendar days after the initial determination. However, the corrective action plan does not alter or eliminate the exclusion or alter the processes, strategies, evidentiary standards, and other factors used in designing and applying the exclusion. Moreover, the additional comparative analysis still does not include sufficient information. The Secretary then determines that the additional comparative analyses do not demonstrate compliance with the requirements of this paragraph (c)(4). Accordingly, the plan receives a final determination of noncompliance with Code section 9812(a)(8) and § 54.9812–2 from the Secretary, which concludes that the plan did not demonstrate compliance through the comparative analysis process. After considering the relevant facts and circumstances, and considering the interests of plan participants and beneficiaries, as well as feedback from the plan, the Secretary directs the plan not to impose the nonquantitative treatment limitation by a certain date, unless and until the plan demonstrates compliance to the Secretary or takes appropriate action to remedy the violation. The plan makes no changes to its plan terms by that date and continues to impose the exclusion of benefits for failure to complete a course of treatment in the inpatient, in-network classification.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(M) (*Example 13*), by continuing to impose the exclusion of mental health and substance use disorder benefits for failure to complete a course of treatment in the inpatient, in-network classification after the Secretary directs the plan not to impose this nonquantitative treatment limitation, the plan violates the requirements of paragraph (c)(4)(v) of this section.

* * * * *

(3) *Provisions of other law.* Compliance with the disclosure requirements in paragraphs (d)(1) and (2) of this section is not determinative of compliance with any other provision of applicable Federal or State law. In particular, in addition to those disclosure requirements, provisions of other applicable law require disclosure of information relevant to medical/surgical, mental health, and substance use disorder benefits. For example,

ERISA section 104 and 29 CFR 2520.104b–1 provide that, for plans subject to ERISA, instruments under which the plan is established or operated must generally be furnished to plan participants within 30 days of request. Instruments under which the plan is established or operated include documents with information on medical necessity criteria for both medical/surgical benefits and mental health and substance use disorder benefits; the processes, strategies, evidentiary standards, and other factors used to apply a nonquantitative treatment limitation with respect to medical/surgical benefits and mental health or substance use disorder benefits under the plan; and the comparative analyses and other applicable information required by § 54.9812–2. In addition, 29 CFR 2560.503–1 and § 54.9815–2719 set forth rules regarding claims and appeals, including the right of claimants (or their authorized representative) who have received an adverse benefit determination (or a final internal adverse benefit determination) to be provided, upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant to the claimant's claim for benefits. This includes documents with information on medical necessity criteria for both medical/surgical benefits and mental health and substance use disorder benefits, as well as the processes, strategies, evidentiary standards, and other factors used to apply a nonquantitative treatment limitation with respect to medical/surgical benefits and mental health or substance use disorder benefits under the plan and the comparative analyses and other applicable information required by § 54.9812–2.

(e) * * *

(4) *Coordination with EHB requirements.* Nothing in paragraph (f) or (g) of this section or § 54.9812–2(g) changes the requirements of 45 CFR 147.150 and 156.115 providing that a health insurance issuer offering non-grandfathered health insurance coverage in the individual or small group market that is required to provide mental health and substance use disorder services, including behavioral health treatment services, as part of essential health benefits required under 45 CFR 156.110(a)(5) and 156.115(a), must comply with the requirements under section 2726 of the Public Health Service Act and its implementing regulations at 45 CFR 146.136 and 146.137 to satisfy the requirement to provide coverage for mental health and substance use disorder services,

including behavioral health treatment, as part of essential health benefits.

* * * * *

(i) * * *

(1) *In general.* Except as provided in paragraph (i)(2) of this section—

(i) This section applies to group health plans on the first day of the first plan year beginning on or after January 1, 2025, except that the requirements of paragraphs (c)(2)(ii)(A), (c)(4)(i)(B), and (c)(4)(iii) of this section apply on the first day of the first plan year beginning on or after January 1, 2026.

(ii) Until the applicability date in paragraph (i)(1)(i) of this section, plans are required to continue to comply with 26 CFR 54.9812–1, revised as of April 1, 2022.

* * * * *

(j) *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 or the application of the provision to persons not similarly situated or to dissimilar circumstances.

■ **Par. 3.** Add § 54.9812–2 to read as follows:

§ 54.9812–2 Nonquantitative treatment limitation comparative analysis requirements.

(a) *Meaning of terms.* Unless otherwise stated in this section, the terms of this section have the meanings indicated in § 54.9812–1(a)(2).

(b) *In general.* In the case of a group health plan that provides both medical/surgical benefits and mental health or substance use disorder benefits and that imposes any nonquantitative treatment limitation on mental health or substance use disorder benefits, the plan must perform and document a comparative analysis of the design and application of each nonquantitative treatment limitation applicable to mental health or substance use disorder benefits. Each comparative analysis must comply with the content requirements of paragraph (c) of this section and be made available to the Secretary, upon request, in the manner required by paragraphs (d) and (e) of this section.

(c) *Comparative analysis content requirements.* With respect to each nonquantitative treatment limitation applicable to mental health or substance use disorder benefits under a group

health plan, the comparative analysis performed by the plan must include, at minimum, the elements specified in this paragraph (c). In addition to the comparative analysis for each nonquantitative treatment limitation, each plan must prepare and make available to the Secretary, upon request, a written list of all nonquantitative treatment limitations imposed under the plan.

(1) *Description of the nonquantitative treatment limitation.* The comparative analysis must include, with respect to the nonquantitative treatment limitation that is the subject of the comparative analysis:

(i) Identification of the nonquantitative treatment limitation, including the specific terms of the plan or other relevant terms regarding the nonquantitative treatment limitation, the policies or guidelines (internal or external) in which the nonquantitative treatment limitation appears or is described, and the applicable sections of any other relevant documents, such as provider contracts, that describe the nonquantitative treatment limitation;

(ii) Identification of all mental health or substance use disorder benefits and medical/surgical benefits to which the nonquantitative treatment limitation applies, including a list of which benefits are considered mental health or substance use disorder benefits and which benefits are considered medical/surgical benefits; and

(iii) A description of which benefits are included in each classification set forth in § 54.9812–1(c)(2)(ii)(A).

(2) *Identification and definition of the factors and evidentiary standards used to design or apply the nonquantitative treatment limitation.* The comparative analysis must include, with respect to every factor considered or relied upon to design the nonquantitative treatment limitation or apply the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits:

(i) Identification of every factor considered or relied upon, as well as the evidentiary standards considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived, in determining which mental health or substance use disorder benefits and which medical/surgical benefits are subject to the nonquantitative treatment limitation; and

(ii) A definition of each factor, including:

(A) A detailed description of the factor;

(B) A description of each evidentiary standard used to design or apply each

factor (and the source of each evidentiary standard) identified under paragraph (c)(2)(i) of this section; and

(C) A description of any steps the plan has taken to correct, cure, or supplement any information, evidence, sources, or standards that would otherwise have been considered biased or not objective under § 54.9812–1(c)(4)(i)(B)(1) in the absence of such steps.

(3) *Description of how factors are used in the design and application of the nonquantitative treatment limitation.* The comparative analysis must include a description of how each factor identified and defined under paragraph (c)(2) of this section is used in the design or application of the nonquantitative treatment limitation to mental health and substance use disorder benefits and medical/surgical benefits in a classification, including:

(i) A detailed explanation of how each factor identified and defined in paragraph (c)(2) of this section is used to determine which mental health or substance use disorder benefits and which medical/surgical benefits are subject to the nonquantitative treatment limitation;

(ii) An explanation of the evidentiary standards or other information or sources (if any) considered or relied upon in designing or applying the factors or relied upon in designing and applying the nonquantitative treatment limitation, including in the determination of whether and how mental health or substance use disorder benefits or medical/surgical benefits are subject to the nonquantitative treatment limitation;

(iii) If the application of the factor depends on specific decisions made in the administration of benefits, the nature of the decisions, the timing of the decisions, and the professional designations and qualifications of each decision maker;

(iv) If more than one factor is identified and defined in paragraph (c)(2) of this section, an explanation of:

(A) How all of the factors relate to each other;

(B) The order in which all the factors are applied, including when they are applied;

(C) Whether and how any factors are given more weight than others; and

(D) The reasons for the ordering or weighting of the factors; and

(v) Any deviations or variations from a factor, its applicability, or its definition (including the evidentiary standards used to define the factor and the information or sources from which each evidentiary standard was derived), such as how the factor is used

differently to apply the nonquantitative treatment limitation to mental health or substance use disorder benefits as compared to medical/surgical benefits, and a description of how the plan establishes such deviations or variations.

(4) *Demonstration of comparability and stringency as written.* The comparative analysis must evaluate whether, in any classification, under the terms of the plan as written, any processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation with respect to medical/surgical benefits. The comparative analysis must include, with respect to the nonquantitative treatment limitation and the factors used in designing and applying the nonquantitative treatment limitation:

(i) Documentation of each factor identified and defined in paragraph (c)(2) of this section that was applied to determine whether the nonquantitative treatment limitation applies to mental health or substance use disorder benefits and medical/surgical benefits in a classification, including, as relevant:

(A) Quantitative data, calculations, or other analyses showing whether, in each classification in which the nonquantitative treatment limitation applies, mental health or substance use disorder benefits and medical/surgical benefits met or did not meet any applicable threshold identified in the relevant evidentiary standard to determine that the nonquantitative treatment limitation would or would not apply; and

(B) Records maintained by the plan documenting the consideration and application of all factors and evidentiary standards, as well as the results of their application;

(ii) In each classification in which the nonquantitative treatment limitation applies to mental health or substance use disorder benefits, a comparison of how the nonquantitative treatment limitation, as written, is designed and applied to mental health or substance use disorder benefits and to medical/surgical benefits, including the specific provisions of any forms, checklists, procedure manuals, or other documentation used in designing and applying the nonquantitative treatment limitation or that address the

application of the nonquantitative treatment limitation;

(iii) Documentation demonstrating how the factors are comparably applied, as written, to mental health or substance use disorder benefits and medical/surgical benefits in each classification, to determine which benefits are subject to the nonquantitative treatment limitation; and

(iv) An explanation of the reasons for any deviations or variations in the application of a factor used to apply the nonquantitative treatment limitation, or the application of the nonquantitative treatment limitation, to mental health or substance use disorder benefits as compared to medical/surgical benefits, and how the plan establishes such deviations or variations, including:

(A) In the definition of the factors, the evidentiary standards used to define the factors, and the sources from which the evidentiary standards were derived;

(B) In the design of the factors or evidentiary standards; or

(C) In the application or design of the nonquantitative treatment limitation.

(5) *Demonstration of comparability and stringency in operation.* The comparative analysis must evaluate whether, in any classification, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the limitation with respect to medical/surgical benefits. The comparative analysis must include, with respect to the nonquantitative treatment limitation and the factors used in designing and applying the nonquantitative treatment limitation:

(i) A comprehensive explanation of how the plan evaluates whether, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation with respect to medical/surgical benefits, including:

(A) An explanation of any methodology and underlying data used to demonstrate the application of the nonquantitative treatment limitation, in operation;

(B) The sample period, inputs used in any calculations, definitions of terms used, and any criteria used to select the mental health or substance use disorder benefits and medical/surgical benefits to which the nonquantitative treatment limitation is applicable;

(C) With respect to a nonquantitative treatment limitation for which relevant data is temporarily unavailable as described in § 54.9812–1(c)(4)(iii)(A)(3)(i), a detailed explanation of the lack of relevant data, the basis for the plan's conclusion that there is a lack of relevant data, and when and how the data will become available and be collected and analyzed; and

(D) With respect to a nonquantitative treatment limitation for which no data exist that can reasonably assess any relevant impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits as described in § 54.9812–1(c)(4)(iii)(A)(3)(ii), a reasoned justification as to the basis for the conclusion that there are no data that can reasonably assess the nonquantitative treatment limitation's impact, an explanation of why the nature of the nonquantitative treatment limitation prevents the plan from reasonably measuring its impact, an explanation of what data was considered and rejected, and documentation of any additional safeguards or protocols used to ensure that the nonquantitative treatment limitation complies with § 54.9812–1(c)(4);

(ii) Identification of the relevant data collected and evaluated, as required under § 54.9812–1(c)(4)(iii)(A);

(iii) Documentation of the outcomes that resulted from the application of the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits, including:

(A) The evaluation of relevant data as required under § 54.9812–1(c)(4)(iii)(A); and

(B) A reasoned justification and analysis that explains why the plan concluded that any differences in the relevant data do or do not suggest the nonquantitative treatment limitation contributes to material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits, in accordance with § 54.9812–1(c)(4)(iii)(B)(2);

(iv) A detailed explanation of any material differences in access demonstrated by the outcomes

evaluated under paragraph (c)(5)(iii) of this section, including:

(A) A reasoned explanation of any material differences in access that are not attributable to differences in the comparability or relative stringency of the nonquantitative treatment limitation as applied to mental health or substance use disorder benefits and medical/surgical benefits (including any considerations beyond a plan's control that contribute to the existence of material differences) and a detailed explanation of the bases for concluding that material differences are not attributable to differences in the comparability or relative stringency of the nonquantitative treatment limitation; and

(B) To the extent differences in access to mental health or substance use disorder benefits are attributable to generally recognized independent professional medical or clinical standards or carefully circumscribed measures reasonably and appropriately designed to detect or prevent and prove fraud and abuse that minimize the negative impact on access to appropriate mental health and substance use disorder benefits, and such standards or measures are used as the basis for a factor or evidentiary standard used to design or apply a nonquantitative treatment limitation, documentation explaining how any such differences are attributable to those standards or measures, as required in § 54.9812–1(c)(4)(iii)(B)(2)(ii); and

(v) A discussion of the actions that have been or are being taken by the plan to address any material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits, including the actions the plan has taken or is taking under § 54.9812–1(c)(4)(iii)(B)(1) to address material differences to comply, in operation, with § 54.9812–1(c)(4), including, as applicable:

(A) A reasoned explanation of any material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits that persist despite reasonable actions that have been or are being taken; and

(B) For a plan designing and applying one or more nonquantitative treatment limitations related to network composition, a discussion of the actions that have been or are being taken to address material differences in access to in-network mental health and substance use disorder benefits as compared to in-network medical/surgical benefits, including those listed in § 54.9812–1(c)(4)(iii)(C).

(6) *Findings and conclusions.* The comparative analysis must address the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits within each classification, and the relative stringency of their application, both as written and in operation, and include:

(i) Any findings or conclusions indicating that the plan is or is not (or might or might not be) in compliance with the requirements of § 54.9812–1(c)(4), including any additional actions the plan has taken or intends to take to address any potential areas of concern or noncompliance;

(ii) A reasoned and detailed discussion of the findings and conclusions described in paragraph (c)(6)(i) of this section;

(iii) Citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions described in paragraph (c)(6)(i) of this section not otherwise discussed in the comparative analysis;

(iv) The date the analysis is completed and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis; and

(v) If the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan to be an expert, an assessment of each expert's qualifications and the extent to which the plan ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of the nonquantitative treatment limitation applicable to both mental health or substance use disorder benefits and medical/surgical benefits.

(d) *Requirements related to submission of comparative analyses to the Secretary upon request—*(1) *Initial request by the Secretary for comparative analysis.* A group health plan must make the comparative analysis required by paragraph (b) of this section available and submit it to the Secretary within 10 business days of receipt of a request from the Secretary (or an additional period of time specified by the Secretary).

(2) *Additional information required after a comparative analysis is deemed to be insufficient.* In instances in which the Secretary determines that the plan has not submitted sufficient information under paragraph (d)(1) of this section for the Secretary to determine whether the

comparative analysis required in paragraph (b) of this section complies with paragraph (c) of this section or whether the plan complies with § 54.9812–1(c)(4), the Secretary will specify to the plan the additional information the plan must submit to the Secretary to be responsive to the request under paragraph (d)(1). Any such information must be provided to the Secretary by the plan within 10 business days after the Secretary specifies the additional information to be submitted (or an additional period of time specified by the Secretary).

(3) *Initial determination of noncompliance, required action, and corrective action plan.* In instances in which the Secretary reviewed the comparative analysis submitted under paragraph (d)(1) of this section and any additional information submitted under paragraph (d)(2) of this section, and made an initial determination that the plan is not in compliance with the requirements of § 54.9812–1(c)(4) or this section, the plan must respond to the initial determination by the Secretary and specify the actions the plan will take to bring the plan into compliance, and provide to the Secretary additional comparative analyses meeting the requirements of paragraph (c) of this section that demonstrate compliance with § 54.9812–1(c)(4), not later than 45 calendar days after the Secretary's initial determination that the plan is not in compliance.

(4) *Requirement to notify participants and beneficiaries of final determination of noncompliance—(i) In general.* If the Secretary makes a final determination of noncompliance, the plan must notify all participants and beneficiaries enrolled in the plan that the plan has been determined to not be in compliance with the requirements of § 54.9812–1(c)(4) or this section with respect to such plan. Such notice must be provided within 7 business days of receipt of the final determination of noncompliance, and the plan must provide a copy of the notice to the Secretary, any service provider involved in the claims process, and any fiduciary responsible for deciding benefit claims within the same timeframe.

(ii) *Content of notice.* The notice to participants and beneficiaries required in paragraph (d)(4)(i) of this section shall be written in a manner calculated to be understood by the average plan participant and must include, in plain language, the following information in a standalone notice:

(A) The following statement prominently displayed on the first page, in no less than 14-point font: “Attention! The Department of the

Treasury has determined that [insert the name of group health plan] is not in compliance with the Mental Health Parity and Addiction Equity Act.”;

(B) A summary of changes the plan has made as part of its corrective action plan specified to the Secretary following the initial determination of noncompliance, including an explanation of any opportunity for a participant or beneficiary to have a claim for benefits submitted or reprocessed;

(C) A summary of the Secretary's final determination that the plan is not in compliance with § 54.9812–1(c)(4) or this section, including any provisions or practices identified as being in violation of § 54.9812–1(c)(4) or this section, additional corrective actions identified by the Secretary in the final determination notice, and information on how participants and beneficiaries can obtain from the plan a copy of the final determination of noncompliance;

(D) Any additional actions the plan is taking to come into compliance with § 54.9812–1(c)(4) or this section, when the plan will take such actions, and a clear and accurate statement explaining whether the Secretary has concurred with those actions; and

(E) Contact information for questions and complaints, and a statement explaining how participants and beneficiaries can obtain more information about the notice, including:

(1) The plan's phone number and an email or web portal address; and

(2) The Employee Benefits Security Administration's phone number and email or web portal address.

(iii) *Manner of notice.* The plan must make the notice required under paragraph (d)(4)(i) of this section available in paper form, or electronically (such as by email or an internet posting) if:

(A) The format is readily accessible;

(B) The notice is provided in paper form free of charge upon request; and

(C) In a case in which the electronic form is an internet posting, the plan timely notifies the participant or beneficiary in paper form (such as a postcard) or email, that the documents are available on the internet, provides the internet address, includes the statement required in paragraph (d)(4)(ii)(A) of this section, and notifies the participant or beneficiary that the documents are available in paper form upon request.

(e) *Requests for a copy of a comparative analysis.* In addition to making a comparative analysis available upon request to the Secretary, a plan must make available a copy of the comparative analysis required by

paragraph (b) of this section when requested by:

(1) Any applicable State authority; and

(2) A participant or beneficiary (including a provider or other person acting as a participant's or beneficiary's authorized representative) who has received an adverse benefit determination related to mental health or substance use disorder benefits.

(f) *Rule of construction.* Nothing in this section or § 54.9812–1 shall be construed to prevent the Secretary from acting within the scope of existing authorities to address violations of § 54.9812–1 or this section.

(g) *Applicability.* The provisions of this section apply to group health plans described in § 54.9812–1(e), to the extent the plan is not exempt under § 54.9812–1(f) or (g), on the first day of the first plan year beginning on or after January 1, 2025, except the requirements of paragraphs (c)(2)(ii)(C), (c)(5)(i)(C) and (D), and (c)(5)(ii) through (v) of this section apply on the first day of the first plan year beginning on or after January 1, 2026.

(h) *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 or the application of the provision to persons not similarly situated or to dissimilar circumstances.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Chapter XXV

For the reasons set forth in the preamble, the Department of Labor amends 29 CFR part 2590 as set forth below:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 4. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a–n, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029;

Division M, Pub. L. 113–235, 128 Stat. 2130; Pub. L. 116–260, 134 Stat. 1182; Secretary of Labor’s Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

- 5. Amend § 2590.712 by:
 - a. Redesignating paragraph (a) as paragraph (a)(2) and adding paragraphs (a) heading and (a)(1);
 - b. In newly redesignated paragraph (a)(2):
 - i. Revising the introductory text;
 - ii. Adding the definitions of “DSM,” “Evidentiary standards,” “Factors,” and “ICD” in alphabetical order;
 - iii. Revising the definitions of “Medical/surgical benefits” and “Mental health benefits”;
 - iv. Adding the definitions of “Processes” and “Strategies” in alphabetical order; and
 - v. Revising the definitions of “Substance use disorder benefits” and “Treatment limitations”;
 - c. Revising paragraphs (c)(1)(ii), (c)(2)(i), (c)(2)(ii)(A) introductory text, (c)(2)(ii)(C), and (c)(3)(i)(A), (C), and (D);
 - d. In paragraph (c)(3)(iii), adding introductory text;
 - e. Revising paragraphs (c)(3)(iii)(A) and (B), (c)(3)(iv), (c)(4), (d)(3), (e)(4), and (i)(1); and
 - f. Adding paragraph (j).

The revisions and additions read as follows:

§ 2590.712 Parity in mental health and substance use disorder benefits.

(a) *Purpose and meaning of terms—*

(1) *Purpose.* This section and § 2590.712–1 set forth rules to ensure parity in aggregate lifetime and annual dollar limits, financial requirements, and quantitative and nonquantitative treatment limitations between mental health and substance use disorder benefits and medical/surgical benefits, as required under ERISA section 712. A fundamental purpose of ERISA section 712, this section, and § 2590.712–1 is to ensure that participants and beneficiaries in a group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) that offers mental health or substance use disorder benefits are not subject to more restrictive aggregate lifetime or annual dollar limits, financial requirements, or treatment limitations with respect to those benefits than the predominant dollar limits, financial requirements, or treatment limitations that are applied to substantially all medical/surgical benefits covered by the plan or coverage in the same classification, as further provided in this section and § 2590.712–1. Accordingly, in complying with the provisions of ERISA section 712, this section, and § 2590.712–1, plans and

issuers must not design or apply financial requirements and treatment limitations that impose a greater burden on access (that is, are more restrictive) to mental health or substance use disorder benefits under the plan or coverage than they impose on access to medical/surgical benefits in the same classification of benefits. The provisions of ERISA section 712, this section, and § 2590.712–1 should be interpreted in a manner that is consistent with the purpose described in this paragraph (a)(1).

(2) *Meaning of terms.* For purposes of this section and § 2590.712–1, except where the context clearly indicates otherwise, the following terms have the meanings indicated:

* * * * *

DSM means the American Psychiatric Association’s Diagnostic and Statistical Manual of Mental Disorders. For the purpose of this definition, the most current version of the DSM as of November 22, 2024, is the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision published in March 2022. A subsequent version of the DSM published after November 22, 2024, will be considered the most current version beginning on the first day of the plan year that is one year after the date the subsequent version is published.

Evidentiary standards are any evidence, sources, or standards that a group health plan (or health insurance issuer offering coverage in connection with such a plan) considered or relied upon in designing or applying a factor with respect to a nonquantitative treatment limitation, including specific benchmarks or thresholds. Evidentiary standards may be empirical, statistical, or clinical in nature, and include: sources acquired or originating from an objective third party, such as recognized medical literature, professional standards and protocols (which may include comparative effectiveness studies and clinical trials), published research studies, payment rates for items and services (such as publicly available databases of the “usual, customary and reasonable” rates paid for items and services), and clinical treatment guidelines; internal plan or issuer data, such as claims or utilization data or criteria for assuring a sufficient mix and number of network providers; and benchmarks or thresholds, such as measures of excessive utilization, cost levels, time or distance standards, or network participation percentage thresholds.

Factors are all information, including processes and strategies (but not

evidentiary standards), that a group health plan (or health insurance issuer offering coverage in connection with such a plan) considered or relied upon to design a nonquantitative treatment limitation, or to determine whether or how the nonquantitative treatment limitation applies to benefits under the plan or coverage. Examples of factors include, but are not limited to: provider discretion in determining a diagnosis or type or length of treatment; clinical efficacy of any proposed treatment or service; licensing and accreditation of providers; claim types with a high percentage of fraud; quality measures; treatment outcomes; severity or chronicity of condition; variability in the cost of an episode of treatment; high cost growth; variability in cost and quality; elasticity of demand; and geographic location.

* * * * *

ICD means the World Health Organization’s International Classification of Diseases adopted by the Department of Health and Human Services through 45 CFR 162.1002. For the purpose of this definition, the most current version of the ICD as of November 22, 2024, is the International Classification of Diseases, 10th Revision, Clinical Modification adopted for the period beginning on October 1, 2015. Any subsequent version of the ICD adopted through 45 CFR 162.1002 after November 22, 2024, will be considered the most current version beginning on the first day of the plan year that is one year after the date the subsequent version is adopted.

Medical/surgical benefits means benefits with respect to items or services for medical conditions or surgical procedures, as defined under the terms of the group health plan (or health insurance coverage offered by an issuer in connection with such a plan) and in accordance with applicable Federal and State law, but does not include mental health benefits or substance use disorder benefits. Notwithstanding the preceding sentence, any condition or procedure defined by the plan or coverage as being or as not being a medical condition or surgical procedure must be defined consistent with generally recognized independent standards of current medical practice (for example, the most current version of the ICD). To the extent generally recognized independent standards of current medical practice do not address whether a condition or procedure is a medical condition or surgical procedure, plans and issuers may define the condition or procedure in

accordance with applicable Federal and State law.

Mental health benefits means benefits with respect to items or services for mental health conditions, as defined under the terms of the group health plan (or health insurance coverage offered by an issuer in connection with such a plan) and in accordance with applicable Federal and State law, but does not include medical/surgical benefits or substance use disorder benefits. Notwithstanding the preceding sentence, any condition defined by the plan or coverage as being or as not being a mental health condition must be defined consistent with generally recognized independent standards of current medical practice. For the purpose of this definition, to be consistent with generally recognized independent standards of current medical practice, the definition must include all conditions covered under the plan or coverage, except for substance use disorders, that fall under any of the diagnostic categories listed in the mental, behavioral, and neurodevelopmental disorders chapter (or equivalent chapter) of the most current version of the ICD or that are listed in the most current version of the DSM. To the extent generally recognized independent standards of current medical practice do not address whether a condition is a mental health condition, plans and issuers may define the condition in accordance with applicable Federal and State law.

Processes are actions, steps, or procedures that a group health plan (or health insurance issuer offering coverage in connection with such a plan) uses to apply a nonquantitative treatment limitation, including actions, steps, or procedures established by the plan or issuer as requirements in order for a participant or beneficiary to access benefits, including through actions by a participant's or beneficiary's authorized representative or a provider or facility. Examples of processes include, but are not limited to: procedures to submit information to authorize coverage for an item or service prior to receiving the benefit or while treatment is ongoing (including requirements for peer or expert clinical review of that information); provider referral requirements that are used to determine when and how a participant or beneficiary may access certain services; and the development and approval of a treatment plan used in a concurrent review process to determine whether a specific request should be granted or denied. Processes also include the specific procedures used by staff or other representatives of a plan or issuer

(or the service provider of a plan or issuer) to administer the application of nonquantitative treatment limitations, such as how a panel of staff members applies the nonquantitative treatment limitation (including the qualifications of staff involved, number of staff members allocated, and time allocated), consultations with panels of experts in applying the nonquantitative treatment limitation, and the degree of reviewer discretion in adhering to criteria hierarchy when applying a nonquantitative treatment limitation.

Strategies are practices, methods, or internal metrics that a plan (or health insurance issuer offering coverage in connection with such a plan) considers, reviews, or uses to design a nonquantitative treatment limitation. Examples of strategies include, but are not limited to: the development of the clinical rationale used in approving or denying benefits; the method of determining whether and how to deviate from generally accepted standards of care in concurrent reviews; the selection of information deemed reasonably necessary to make medical necessity determinations; reliance on treatment guidelines or guidelines provided by third-party organizations in the design of a nonquantitative treatment limitation; and rationales used in selecting and adopting certain threshold amounts to apply a nonquantitative treatment limitation, professional standards and protocols to determine utilization management standards, and fee schedules used to determine provider reimbursement rates, used as part of a nonquantitative treatment limitation. Strategies also include the method of creating and determining the composition of the staff or other representatives of a plan or issuer (or the service provider of a plan or issuer) that deliberates, or otherwise makes decisions, on the design of nonquantitative treatment limitations, including the plan's or issuer's methods for making decisions related to the qualifications of staff involved, number of staff members allocated, and time allocated; breadth of sources and evidence considered; consultations with panels of experts in designing the nonquantitative treatment limitation; and the composition of the panels used to design a nonquantitative treatment limitation.

Substance use disorder benefits means benefits with respect to items or services for substance use disorders, as defined under the terms of the group health plan (or health insurance coverage offered by an issuer in connection with such a plan) and in accordance with applicable Federal and

State law, but does not include medical/surgical benefits or mental health benefits. Notwithstanding the preceding sentence, any disorder defined by the plan or coverage as being or as not being a substance use disorder must be defined consistent with generally recognized independent standards of current medical practice. For the purpose of this definition, to be consistent with generally recognized independent standards of current medical practice, the definition must include all disorders covered under the plan or coverage that fall under any of the diagnostic categories listed as a mental or behavioral disorder due to psychoactive substance use (or equivalent category) in the mental, behavioral, and neurodevelopmental disorders chapter (or equivalent chapter) of the most current version of the ICD or that are listed as a Substance-Related and Addictive Disorder (or equivalent category) in the most current version of the DSM. To the extent generally recognized independent standards of current medical practice do not address whether a disorder is a substance use disorder, plans and issuers may define the disorder in accordance with applicable Federal and State law.

Treatment limitations include limits on benefits based on the frequency of treatment, number of visits, days of coverage, days in a waiting period, or other similar limits on the scope or duration of treatment. Treatment limitations include both quantitative treatment limitations, which are expressed numerically (such as 50 outpatient visits per year), and nonquantitative treatment limitations (such as standards related to network composition), which otherwise limit the scope or duration of benefits for treatment under a plan or coverage. (See paragraph (c)(4)(ii) of this section for an illustrative, non-exhaustive list of nonquantitative treatment limitations.) A complete exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation for purposes of this definition.

* * * * *

(c) * * *

(1) * * *

(ii) *Type of financial requirement or treatment limitation.* When reference is made in this paragraph (c) to a type of financial requirement or treatment limitation, the reference to type means its nature. Different types of financial requirements include deductibles, copayments, coinsurance, and out-of-pocket maximums. Different types of quantitative treatment limitations

include annual, episode, and lifetime day and visit limits. See paragraph (c)(4)(ii) of this section for an illustrative, non-exhaustive list of nonquantitative treatment limitations.

* * * * *

(2) * * *

(i) *General rule.* A group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) that provides both medical/surgical benefits and mental health or substance use disorder benefits may not apply any financial requirement or treatment limitation to mental health or substance use disorder benefits in any classification that is more restrictive than the predominant financial requirement or treatment limitation of that type applied to substantially all medical/surgical benefits in the same classification. Whether a financial requirement or treatment limitation is a predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in a classification is determined separately for each type of financial requirement or treatment limitation. A plan or issuer may not impose any financial requirement or treatment limitation that is applicable only with respect to mental health or substance use disorder benefits and not to any medical/surgical benefits in the same benefit classification. The application of the rules of this paragraph (c)(2) to financial requirements and quantitative treatment limitations is addressed in paragraph (c)(3) of this section; the application of the rules of this paragraph (c)(2) to nonquantitative treatment limitations is addressed in paragraph (c)(4) of this section.

(ii) * * *

(A) *In general.* If a plan (or health insurance coverage) provides any benefits for a mental health condition or substance use disorder in any classification of benefits described in this paragraph (c)(2)(ii), it must provide meaningful benefits for that mental health condition or substance use disorder in every classification in which medical/surgical benefits are provided. For purposes of this paragraph (c)(2)(ii)(A), whether the benefits provided are meaningful benefits is determined in comparison to the benefits provided for medical conditions and surgical procedures in the classification and requires, at a minimum, coverage of benefits for that condition or disorder in each classification in which the plan (or coverage) provides benefits for one or more medical conditions or surgical procedures. A plan (or coverage) does

not provide meaningful benefits under this paragraph (c)(2)(ii)(A) unless it provides benefits for a core treatment for that condition or disorder in each classification in which the plan (or coverage) provides benefits for a core treatment for one or more medical conditions or surgical procedures. For purposes of this paragraph (c)(2)(ii)(A), a core treatment for a condition or disorder is a standard treatment or course of treatment, therapy, service, or intervention indicated by generally recognized independent standards of current medical practice. If there is no core treatment for a covered mental health condition or substance use disorder with respect to a classification, the plan (or coverage) is not required to provide benefits for a core treatment for such condition or disorder in that classification (but must provide benefits for such condition or disorder in every classification in which medical/surgical benefits are provided). In determining the classification in which a particular benefit belongs, a plan (or health insurance issuer) must apply the same standards to medical/surgical benefits and to mental health or substance use disorder benefits. To the extent that a plan (or health insurance coverage) provides benefits in a classification and imposes any separate financial requirement or treatment limitation (or separate level of a financial requirement or treatment limitation) for benefits in the classification, the rules of this paragraph (c) apply separately with respect to that classification for all financial requirements or treatment limitations (illustrated in examples in paragraph (c)(2)(ii)(C) of this section). The following classifications of benefits are the only classifications used in applying the rules of this paragraph (c), in addition to the permissible sub-classifications described in paragraph (c)(3)(iii) of this section:

* * * * *

(C) *Examples.* The rules of this paragraph (c)(2)(ii) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits. With regard to the examples in this paragraph (c)(2)(ii)(C), references to any particular core treatment are included for illustrative purposes only. Plans and issuers must consult generally recognized independent standards of current medical practice to determine the applicable core treatment, therapy, service, or intervention for any covered condition or disorder.

(1) *Example 1—(i) Facts.* A group health plan offers inpatient and outpatient benefits and does not contract with a network of providers. The plan imposes a \$500 deductible on all benefits. For inpatient medical/surgical benefits, the plan imposes a coinsurance requirement. For outpatient medical/surgical benefits, the plan imposes copayments. The plan imposes no other financial requirements or treatment limitations.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(1) (*Example 1*), because the plan has no network of providers, all benefits provided are out-of-network. Because inpatient, out-of-network medical/surgical benefits are subject to separate financial requirements from outpatient, out-of-network medical/surgical benefits, the rules of this paragraph (c) apply separately with respect to any financial requirements and treatment limitations, including the deductible, in each classification.

(2) *Example 2—(i) Facts.* A plan imposes a \$500 deductible on all benefits. The plan has no network of providers. The plan generally imposes a 20 percent coinsurance requirement with respect to all benefits, without distinguishing among inpatient, outpatient, emergency care, or prescription drug benefits. The plan imposes no other financial requirements or treatment limitations.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(2) (*Example 2*), because the plan does not impose separate financial requirements (or treatment limitations) based on classification, the rules of this paragraph (c) apply with respect to the deductible and the coinsurance across all benefits.

(3) *Example 3—(i) Facts.* Same facts as in paragraph (c)(2)(ii)(C)(2)(i) of this section (*Example 2*), except the plan exempts emergency care benefits from the 20 percent coinsurance requirement. The plan imposes no other financial requirements or treatment limitations.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(3) (*Example 3*), because the plan imposes separate financial requirements based on classifications, the rules of this paragraph (c) apply with respect to the deductible and the coinsurance separately for benefits in the emergency care classification and all other benefits.

(4) *Example 4—(i) Facts.* Same facts as in paragraph (c)(2)(ii)(C)(2)(i) of this section (*Example 2*), except the plan also imposes a preauthorization requirement for all inpatient treatment in order for benefits to be paid. No such requirement applies to outpatient treatment.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(4) (*Example 4*), because the plan has no network of providers, all benefits provided are out-of-network. Because the plan imposes a separate treatment limitation based on classifications, the rules of this paragraph (c) apply with respect to the deductible and coinsurance separately for inpatient, out-of-network benefits and all other benefits.

(5) *Example 5—(i) Facts.* A plan covers treatment for autism spectrum disorder (ASD), a mental health condition, and covers outpatient, out-of-network developmental

screenings for ASD but excludes all other benefits for outpatient treatment for ASD, including applied behavior analysis (ABA) therapy, when provided on an out-of-network basis. The plan generally covers the full range of outpatient treatments (including core treatments) and treatment settings for medical conditions and surgical procedures when provided on an out-of-network basis. Under the generally recognized independent standards of current medical practice consulted by the plan, developmental screenings alone do not constitute a core treatment for ASD.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(5) (*Example 5*), the plan violates the rules of this paragraph (c)(2)(ii). Although the plan covers benefits for ASD in the outpatient, out-of-network classification, it only covers developmental screenings, so it does not cover a core treatment for ASD in the classification. Because the plan generally covers the full range of medical/surgical benefits, including a core treatment for one or more medical conditions or surgical procedures in the classification, it fails to provide meaningful benefits for treatment of ASD in the classification.

(6) *Example 6—(i) Facts.* Same facts as in paragraph (c)(2)(ii)(C)(5) of this section (*Example 5*), except that the plan is an HMO that does not cover the full range of medical/surgical benefits, including a core treatment for any medical conditions or surgical procedures in the outpatient, out-of-network classification (except as required under ERISA sections 716 and 717), but covers benefits for medical conditions and surgical procedures in the inpatient, in-network; outpatient, in-network; emergency care; and prescription drug classifications.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(6) (*Example 6*), the plan does not violate the rules of this paragraph (c)(2)(ii). Because the plan does not provide meaningful benefits, including for a core treatment for any medical condition or surgical procedure in the outpatient, out-of-network classification (except as required under ERISA sections 716 and 717), the plan is not required to provide meaningful benefits for any mental health conditions or substance use disorders in that classification. Nevertheless, the plan must provide meaningful benefits for each mental health condition and substance use disorder for which the plan provides benefits in every classification in which meaningful medical/surgical benefits are provided as required under paragraph (c)(2)(ii)(A) of this section. This example does not address whether the plan has complied with other applicable requirements of this section in excluding coverage of ABA therapy in the outpatient, out-of-network classification.

(7) *Example 7—(i) Facts.* A plan provides extensive benefits, including for core treatments for many medical conditions and surgical procedures in the outpatient, in-network classification, including nutrition counseling for diabetes and obesity. The plan also generally covers diagnosis and treatment for eating disorders, which are mental health conditions, including coverage for nutrition counseling to treat eating disorders in the outpatient, in-network classification.

Nutrition counseling is a core treatment for eating disorders, in accordance with generally recognized independent standards of current medical practice consulted by the plan.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(7) (*Example 7*), the plan does not violate the rules of this paragraph (c)(2)(ii). The coverage of diagnosis and treatment for eating disorders, including nutrition counseling, in the outpatient, in-network classification results in the plan providing meaningful benefits for the treatment of eating disorders in the classification, as determined in comparison to the benefits provided for medical conditions or surgical procedures in the classification.

(8) *Example 8—(i) Facts.* A plan provides extensive benefits for the core treatments for many medical conditions and surgical procedures in the outpatient, in-network and prescription drug classifications. The plan provides coverage for diagnosis and treatment for opioid use disorder, a substance use disorder, in the outpatient, in-network classification, by covering counseling and behavioral therapies and, in the prescription drug classification, by covering medications to treat opioid use disorder (MOUD). Counseling and behavioral therapies and MOUD, in combination, are one of the core treatments for opioid use disorder, in accordance with generally recognized independent standards of current medical practice consulted by the plan.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(8) (*Example 8*), the plan does not violate the rules of this paragraph (c)(2)(ii). The coverage of counseling and behavioral therapies and MOUD, in combination, in the outpatient, in-network classification and prescription drug classification, respectively, results in the plan providing meaningful benefits for the treatment of opioid use disorder in the outpatient, in-network and prescription drug classifications.

(3) * * *

(i) * * *

(A) *Substantially all.* For purposes of this paragraph (c)(3), a type of financial requirement or quantitative treatment limitation is considered to apply to substantially all medical/surgical benefits in a classification of benefits if it applies to at least two-thirds of all medical/surgical benefits in that classification. (For purposes of this paragraph (c)(3)(i)(A), benefits expressed as subject to a zero level of a type of financial requirement are treated as benefits not subject to that type of financial requirement, and benefits expressed as subject to a quantitative treatment limitation that is unlimited are treated as benefits not subject to that type of quantitative treatment limitation.) If a type of financial requirement or quantitative treatment limitation does not apply to at least two-thirds of all medical/surgical benefits in a classification, then that type cannot be applied to mental health or substance

use disorder benefits in that classification.

* * * * *

(C) *Portion based on plan payments.* For purposes of this paragraph (c)(3), the determination of the portion of medical/surgical benefits in a classification of benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation) is based on the dollar amount of all plan payments for medical/surgical benefits in the classification expected to be paid under the plan for the plan year (or for the portion of the plan year after a change in plan benefits that affects the applicability of the financial requirement or quantitative treatment limitation).

(D) *Clarifications for certain threshold requirements.* For any deductible, the dollar amount of plan payments includes all plan payments with respect to claims that would be subject to the deductible if it had not been satisfied. For any out-of-pocket maximum, the dollar amount of plan payments includes all plan payments associated with out-of-pocket payments that are taken into account towards the out-of-pocket maximum as well as all plan payments associated with out-of-pocket payments that would have been made towards the out-of-pocket maximum if it had not been satisfied. The rules of this paragraph (c)(3)(i)(D) apply for any other thresholds at which the rate of plan payment changes. (See also PHS Act section 2707 and Affordable Care Act section 1302(c), which establish annual limitations on out-of-pocket maximums for all non-grandfathered health plans.)

* * * * *

(iii) *Special rules.* Unless specifically permitted under this paragraph (c)(3)(iii), sub-classifications are not permitted when applying the rules of paragraph (c)(3) of this section.

(A) *Multi-tiered prescription drug benefits.* If a plan (or health insurance coverage) applies different levels of financial requirements to different tiers of prescription drug benefits based on reasonable factors determined in accordance with the rules in paragraph (c)(4) of this section (relating to requirements for nonquantitative treatment limitations) and without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits, the plan (or health insurance coverage) satisfies the parity requirements of this paragraph (c) with

respect to prescription drug benefits. Reasonable factors include cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up.

(B) *Multiple network tiers.* If a plan (or health insurance coverage) provides benefits through multiple tiers of in-network providers (such as an in-network tier of preferred providers with more generous cost-sharing to participants than a separate in-network tier of participating providers), the plan may divide its benefits furnished on an in-network basis into sub-classifications that reflect network tiers, if the tiering is based on reasonable factors determined in accordance with the rules in paragraph (c)(4) of this section (such

as quality, performance, and market standards) and without regard to whether a provider provides services with respect to medical/surgical benefits or mental health or substance use disorder benefits. After the sub-classifications are established, the plan or issuer may not impose any financial requirement or treatment limitation on mental health or substance use disorder benefits in any sub-classification that is more restrictive than the predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in the sub-classification using the methodology set

forth in paragraph (c)(3)(i) of this section.

* * * * *

(iv) *Examples.* The rules of paragraphs (c)(3)(i) through (iii) of this section are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

(A) *Example 1—(1) Facts.* (i) For inpatient, out-of-network medical/surgical benefits, a group health plan imposes five levels of coinsurance. Using a reasonable method, the plan projects its payments for the upcoming year as follows:

TABLE 1 TO PARAGRAPH (c)(3)(iv)(A)(1)(i)

Coinurance rate	0%	10%	15%	20%	30%	Total.
Projected payments	\$200x	\$100x	\$450x	\$100x	\$150x	\$1,000x.
Percent of total plan costs	20%	10%	45%	10%	15%	
Percent subject to coinsurance level	N/A	12.5% (100x/800x)	56.25% (450x/800x)	12.5% (100x/800x)	18.75% (150x/800x).	

(ii) The plan projects plan costs of \$800x to be subject to coinsurance (\$100x + \$450x + \$100x + \$150x = \$800x). Thus, 80 percent (\$800x/\$1,000x) of the benefits are projected to be subject to coinsurance, and 56.25 percent of the benefits subject to coinsurance are projected to be subject to the 15 percent coinsurance level.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(A) (*Example 1*), the two-thirds

threshold of the substantially all standard is met for coinsurance because 80 percent of all inpatient, out-of-network medical/surgical benefits are subject to coinsurance. Moreover, the 15 percent coinsurance is the predominant level because it is applicable to more than one-half of inpatient, out-of-network medical/surgical benefits subject to the coinsurance requirement. The plan may not impose any level of coinsurance with

respect to inpatient, out-of-network mental health or substance use disorder benefits that is more restrictive than the 15 percent level of coinsurance.

(B) *Example 2—(1) Facts.* (i) For outpatient, in-network medical/surgical benefits, a plan imposes five different copayment levels. Using a reasonable method, the plan projects payments for the upcoming year as follows:

TABLE 2 TO PARAGRAPH (c)(3)(iv)(B)(1)(i)

Copayment amount	\$0	\$10	\$15	\$20	\$50	Total.
Projected payments	\$200x	\$200x	\$200x	\$300x	\$100x	\$1,000x.
Percent of total plan costs	20%	20%	20%	30%	10%	
Percent subject to copayments	N/A	25% (200x/800x)	25% (200x/800x)	37.5% (300x/800x)	12.5% (100x/800x).	

(ii) The plan projects plan costs of \$800x to be subject to copayments (\$200x + \$200x + \$300x + \$100x = \$800x). Thus, 80 percent (\$800x/\$1,000x) of the benefits are projected to be subject to a copayment.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(B) (*Example 2*), the two-thirds threshold of the substantially all standard is met for copayments because 80 percent of all outpatient, in-network medical/surgical benefits are subject to a copayment. Moreover, there is no single level that applies to more than one-half of medical/surgical benefits in the classification subject to a copayment (for the \$10 copayment, 25%; for the \$15 copayment, 25%; for the \$20 copayment, 37.5%; and for the \$50 copayment, 12.5%). The plan can combine any levels of copayment, including the highest levels, to determine the predominant level that can be applied to mental health or substance use disorder benefits. If the plan combines the highest levels of copayment, the combined projected payments for the two highest copayment levels, the \$50 copayment and the \$20 copayment, are not more than one-half of the outpatient, in-network medical/surgical benefits subject to a

copayment because they are exactly one-half (\$300x + \$100x = \$400x; \$400x/\$800x = 50%). The combined projected payments for the three highest copayment levels—the \$50 copayment, the \$20 copayment, and the \$15 copayment—are more than one-half of the outpatient, in-network medical/surgical benefits subject to the copayments (\$100x + \$300x + \$200x = \$600x; \$600x/\$800x = 75%). Thus, the plan may not impose any copayment on outpatient, in-network mental health or substance use disorder benefits that is more restrictive than the least restrictive copayment in the combination, the \$15 copayment.

(C) *Example 3—(1) Facts.* A plan imposes a \$250 deductible on all medical/surgical benefits for self-only coverage and a \$500 deductible on all medical/surgical benefits for family coverage. The plan has no network of providers. For all medical/surgical benefits, the plan imposes a coinsurance requirement. The plan imposes no other financial requirements or treatment limitations.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(C) (*Example 3*), because the plan has no network of providers, all benefits are

provided out-of-network. Because self-only and family coverage are subject to different deductibles, whether the deductible applies to substantially all medical/surgical benefits is determined separately for self-only medical/surgical benefits and family medical/surgical benefits. Because the coinsurance is applied without regard to coverage units, the predominant coinsurance that applies to substantially all medical/surgical benefits is determined without regard to coverage units.

(D) *Example 4—(1) Facts.* A plan applies the following financial requirements for prescription drug benefits. The requirements are applied without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits. Moreover, the process for certifying a particular drug as “generic”, “preferred brand name”, “non-preferred brand name”, or “specialty” complies with the rules of paragraph (c)(4) of this section (relating to requirements for nonquantitative treatment limitations).

TABLE 3 TO PARAGRAPH (c)(3)(iv)(D)(1)

	Tier 1	Tier 2	Tier 3	Tier 4
Tier description	Generic drugs	Preferred brand name drugs.	Non-preferred brand name drugs (which may have Tier 1 or Tier 2 alternatives).	Specialty drugs.
Percent paid by plan	90%	80%	60%	50%.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(D) (*Example 4*), the financial requirements that apply to prescription drug benefits are applied without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits; the process for certifying drugs in different tiers complies with paragraph (c)(4) of this section; and the bases for establishing different levels or types of financial requirements are reasonable. The financial requirements applied to prescription drug benefits do not violate the parity requirements of this paragraph (c)(3).

(E) *Example 5—(1) Facts.* A plan has two tiers of network of providers: a preferred provider tier and a participating provider tier. Providers are placed in either the preferred tier or participating tier based on reasonable factors determined in accordance with the rules in paragraph (c)(4) of this section, such as accreditation, quality and performance measures (including customer feedback), and relative reimbursement rates. Furthermore, provider tier placement is determined without regard to whether a provider specializes in the treatment of mental health conditions or substance use disorders, or medical/surgical conditions. The plan divides the in-network classifications into two sub-classifications (in-network/preferred and in-network/participating). The plan does not impose any financial requirement or treatment limitation on mental health or substance use disorder benefits in either of these sub-classifications that is more restrictive than the predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in each sub-classification.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(E) (*Example 5*), the division of in-network benefits into sub-classifications that reflect the preferred and participating provider tiers does not violate the parity requirements of this paragraph (c)(3).

(F) *Example 6—(1) Facts.* With respect to outpatient, in-network benefits, a plan imposes a \$25 copayment for office visits and a 20 percent coinsurance requirement for outpatient surgery. The plan divides the outpatient, in-network classification into two sub-classifications (in-network office visits and all other outpatient, in-network items and services). The plan or issuer does not impose any financial requirement or quantitative treatment limitation on mental health or substance use disorder benefits in either of these sub-classifications that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in each sub-classification.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(F) (*Example 6*), the division of outpatient, in-network benefits into sub-classifications for office visits and all other outpatient, in-network items and services does not violate the parity requirements of this paragraph (c)(3).

(G) *Example 7—(1) Facts.* Same facts as in paragraph (c)(3)(iv)(F)(1) of this section (*Example 6*), but for purposes of determining parity, the plan divides the outpatient, in-network classification into outpatient, in-network generalists and outpatient, in-network specialists.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(G) (*Example 7*), the division of outpatient, in-network benefits into any sub-classifications other than office visits and all other outpatient items and services violates the requirements of paragraph (c)(3)(iii)(C) of this section.

* * * * *

(4) *Nonquantitative treatment limitations.* Consistent with paragraph (a)(1) of this section, a group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) may not impose any nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in any classification that is more restrictive, as written or in operation, than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification. For purposes of this paragraph (c)(4), a nonquantitative treatment limitation is more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification if the plan or issuer fails to meet the requirements of paragraph (c)(4)(i) or (iii) of this section. In such a case, the plan (or health insurance coverage) will be considered to violate ERISA section 712(a)(3)(A)(ii), and the nonquantitative treatment limitation may not be imposed by the plan (or health insurance coverage) with respect to mental health or substance use disorder benefits in the classification.

(i) *Requirements related to design and application of a nonquantitative treatment limitation—(A) In general.* A plan (or health insurance coverage) may not impose a nonquantitative treatment limitation with respect to mental health

or substance use disorder benefits in any classification unless, under the terms of the plan (or health insurance coverage), as written and in operation, any processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the limitation with respect to medical/surgical benefits in the classification.

(B) *Prohibition on discriminatory factors and evidentiary standards.* For purposes of determining comparability and stringency under paragraph (c)(4)(i)(A) of this section, a plan (or health insurance coverage) may not rely upon discriminatory factors or evidentiary standards to design a nonquantitative treatment limitation to be imposed on mental health or substance use disorder benefits. A factor or evidentiary standard is discriminatory if the information, evidence, sources, or standards on which the factor or evidentiary standard are based are biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits.

(7) Information, evidence, sources, or standards are considered to be biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits if, based on all the relevant facts and circumstances, the information, evidence, sources, or standards systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits. For purposes of this paragraph (c)(4)(i)(B)(1), relevant facts and circumstances may include, but are not limited to, the reliability of the source of the information, evidence, sources, or standards, including any underlying data; the independence of the information, evidence, sources, and

standards relied upon; the analyses and methodologies employed to select the information and the consistency of their application; and any known safeguards deployed to prevent reliance on skewed data or metrics. Information, evidence, sources, or standards are not considered biased or not objective for this purpose if the plan or issuer has taken the steps necessary to correct, cure, or supplement any information, evidence, sources, or standards that would have been biased or not objective in the absence of such steps.

(2) For purposes of this paragraph (c)(4)(i)(B), historical plan data or other historical information from a time when the plan or coverage was not subject to ERISA section 712 or was not in compliance with ERISA section 712 are considered to be biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits, if the historical plan data or other historical information systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits, and the plan or issuer has not taken the steps necessary to correct, cure, or supplement the data or information.

(3) For purposes of this paragraph (c)(4)(i)(B), generally recognized independent professional medical or clinical standards and carefully circumscribed measures reasonably and appropriately designed to detect or prevent and prove fraud and abuse that minimize the negative impact on access to appropriate mental health and substance use disorder benefits are not information, evidence, sources, or standards that are biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits. However, plans and issuers must comply with the other requirements in this paragraph (c)(4), as applicable, with respect to such standards or measures that are used as the basis for a factor or evidentiary standard used to design or apply a nonquantitative treatment limitation.

(ii) *Illustrative, non-exhaustive list of nonquantitative treatment limitations.* Nonquantitative treatment limitations include—

(A) Medical management standards (such as prior authorization) limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative;

(B) Formulary design for prescription drugs;

(C) For plans with multiple network tiers (such as preferred providers and participating providers), network tier design;

(D) Standards related to network composition, including but not limited to, standards for provider and facility admission to participate in a network or for continued network participation, including methods for determining reimbursement rates, credentialing standards, and procedures for ensuring the network includes an adequate number of each category of provider and facility to provide services under the plan or coverage;

(E) Plan or issuer methods for determining out-of-network rates, such as allowed amounts; usual, customary, and reasonable charges; or application of other external benchmarks for out-of-network rates;

(F) Refusal to pay for higher-cost therapies until it can be shown that a lower-cost therapy is not effective (also known as fail-first policies or step therapy protocols);

(G) Exclusions based on failure to complete a course of treatment; and

(H) Restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits for services provided under the plan or coverage.

(iii) *Required use of outcomes data—*
(A) *In general.* To ensure that a nonquantitative treatment limitation applicable to mental health or substance use disorder benefits in a classification, in operation, is no more restrictive than the predominant nonquantitative treatment limitation applied to substantially all medical/surgical benefits in the classification, a plan or issuer must collect and evaluate relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits and carefully consider the impact as part of the plan's or issuer's evaluation. As part of its evaluation, the plan or issuer may not disregard relevant outcomes data that it knows or reasonably should know suggest that a nonquantitative treatment limitation is associated with material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits. The Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services, may specify in guidance the type, form, and manner of

collection and evaluation for the data required under this paragraph (c)(4)(iii)(A).

(1) *Relevant data generally.* For purposes of this paragraph (c)(4)(iii)(A), relevant data could include, as appropriate, but are not limited to, the number and percentage of claims denials and any other data relevant to the nonquantitative treatment limitation required by State law or private accreditation standards.

(2) *Relevant data for nonquantitative treatment limitations related to network composition.* In addition to the relevant data set forth in paragraph (c)(4)(iii)(A)(1) of this section, relevant data for nonquantitative treatment limitations related to network composition could include, as appropriate, but are not limited to, in-network and out-of-network utilization rates (including data related to provider claim submissions), network adequacy metrics (including time and distance data, and data on providers accepting new patients), and provider reimbursement rates (for comparable services and as benchmarked to a reference standard).

(3) *Unavailability of data.* (i) If a plan or issuer newly imposes a nonquantitative treatment limitation for which relevant data is initially temporarily unavailable and the plan or issuer therefore cannot comply with this paragraph (c)(4)(iii)(A), the plan or issuer must include in its comparative analysis, as required under § 2590.712–1(c)(5)(i)(C), a detailed explanation of the lack of relevant data, the basis for the plan's or issuer's conclusion that there is a lack of relevant data, and when and how the data will become available and be collected and analyzed. Such a plan or issuer also must comply with this paragraph (c)(4)(iii)(A) as soon as practicable once relevant data becomes available.

(ii) If a plan or issuer imposes a nonquantitative treatment limitation for which no data exist that can reasonably assess any relevant impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits, the plan or issuer must include in its comparative analysis, as required under § 2590.712–1(c)(5)(i)(D), a reasoned justification as to the basis for the conclusion that there are no data that can reasonably assess the nonquantitative treatment limitation's impact, why the nature of the nonquantitative treatment limitation prevents the plan or issuer from reasonably measuring its impact, an explanation of what data was

considered and rejected, and documentation of any additional safeguards or protocols used to ensure the nonquantitative treatment limitation complies with this section. If a plan or issuer becomes aware of data that can reasonably assess any relevant impact of the nonquantitative treatment limitation, the plan or issuer must comply with this paragraph (c)(4)(iii)(A) as soon as practicable.

(iii) Consistent with paragraph (a)(1) of this section, paragraphs (c)(4)(iii)(A)(3)(i) and (ii) of this section shall only apply in very limited circumstances and, where applicable, shall be construed narrowly.

(B) *Material differences.* To the extent the relevant data evaluated under paragraph (c)(4)(iii)(A) of this section suggest that the nonquantitative treatment limitation contributes to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits in a classification, such differences will be considered a strong indicator that the plan or issuer violates this paragraph (c)(4).

(1) Where the relevant data suggest that the nonquantitative treatment limitation contributes to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits in a classification, the plan or issuer must take reasonable action, as necessary, to address the material differences to ensure compliance, in operation, with this paragraph (c)(4) and must document the actions that have been or are being taken by the plan or issuer to address material differences in access to mental health or substance use disorder benefits, as compared to medical/surgical benefits, as required by § 2590.712–1(c)(5)(iv).

(2) For purposes of this paragraph (c)(4)(iii)(B), relevant data are considered to suggest that the nonquantitative treatment limitation contributes to material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits if, based on all relevant facts and circumstances, and taking into account the considerations outlined in this paragraph (c)(4)(iii)(B)(2), the difference in the data suggests that the nonquantitative treatment limitation is likely to have a negative impact on access to mental health or substance use disorder benefits as compared to medical/surgical benefits.

(i) Relevant facts and circumstances, for purposes of this paragraph (c)(4)(iii)(B)(2), may include, but are not limited to, the terms of the

nonquantitative treatment limitation at issue, the quality or limitations of the data, causal explanations and analyses, evidence as to the recurring or non-recurring nature of the results, and the magnitude of any disparities.

(ii) Differences in access to mental health or substance use disorder benefits attributable to generally recognized independent professional medical or clinical standards or carefully circumscribed measures reasonably and appropriately designed to detect or prevent and prove fraud and abuse that minimize the negative impact on access to appropriate mental health and substance use disorder benefits, which are used as the basis for a factor or evidentiary standard used to design or apply a nonquantitative treatment limitation, are not considered to be material for purposes of this paragraph (c)(4)(iii)(B). To the extent a plan or issuer attributes any differences in access to the application of such standards or measures, the plan or issuer must explain the bases for that conclusion in the documentation prepared under § 2590.712–1(c)(5)(iv)(A).

(C) *Nonquantitative treatment limitations related to network composition.* For purposes of applying paragraph (c)(4)(iii)(A) of this section with respect to nonquantitative treatment limitations related to network composition, a plan or issuer must collect and evaluate relevant data in a manner reasonably designed to assess the aggregate impact of all such nonquantitative treatment limitations on access to mental health and substance use disorder benefits and medical/surgical benefits. Examples of possible actions that a plan or issuer could take to comply with the requirement under paragraph (c)(4)(iii)(B)(1) of this section to take reasonable action, as necessary, to address any material differences in access with respect to nonquantitative treatment limitations related to network composition, to ensure compliance with this paragraph (c)(4), include, but are not limited to:

(1) Strengthening efforts to recruit and encourage a broad range of available mental health and substance use disorder providers and facilities to join the plan's or issuer's network of providers, including taking actions to increase compensation or other inducements, streamline credentialing processes, or contact providers reimbursed for items and services provided on an out-of-network basis to offer participation in the network;

(2) Expanding the availability of telehealth arrangements to mitigate any overall mental health and substance use

disorder provider shortages in a geographic area;

(3) Providing additional outreach and assistance to participants and beneficiaries enrolled in the plan or coverage to assist them in finding available in-network mental health and substance use disorder providers and facilities; and

(4) Ensuring that provider directories are accurate and reliable.

(iv) *Prohibition on separate nonquantitative treatment limitations applicable only to mental health or substance use disorder benefits.*

Consistent with paragraph (c)(2)(i) of this section, a group health plan (or health insurance coverage offered by an issuer in connection with such a plan) may not apply any nonquantitative treatment limitation that is applicable only with respect to mental health or substance use disorder benefits and does not apply with respect to any medical/surgical benefits in the same benefit classification.

(v) *Effect of final determination of noncompliance under § 2590.712–1.* (A) If a group health plan (or health insurance issuer offering coverage in connection with a group health plan) receives a final determination from the Secretary that the plan or issuer is not in compliance with the requirements of ERISA section 712(a)(8) or § 2590.712–1 with respect to a nonquantitative treatment limitation, the nonquantitative treatment limitation violates this paragraph (c)(4) and the Secretary may direct the plan or issuer not to impose the nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in the relevant classification, unless and until the plan or issuer demonstrates to the Secretary compliance with the requirements of this section or takes appropriate action to remedy the violation.

(B) A determination by the Secretary of whether to require cessation of a nonquantitative treatment limitation under this paragraph (c)(4)(v) will be based on an evaluation of the relevant facts and circumstances involved in the specific final determination and the nature of the underlying nonquantitative treatment limitation and will take into account the interest of plan participants and beneficiaries and feedback from the plan or issuer.

(vi) *Examples.* The rules of this paragraph (c)(4) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

(A) *Example 1 (not comparable and more stringent factors for reimbursement rate methodology, in operation)*—(1) *Facts.* A plan's reimbursement rate methodology for outpatient, in-network providers is based on a variety of factors. As written, for mental health, substance use disorder, and medical/surgical benefits, all reimbursement rates for physicians and non-physician practitioners for the same Current Procedural Terminology (CPT) code are based on a combination of factors, such as the nature of the service, duration of the service, intensity and specialization of training, provider licensure and type, number of providers qualified to provide the service in a given geographic area, and market need (demand). In operation, the plan utilizes an additional strategy to further reduce reimbursement rates for mental health and substance use disorder non-physician providers from those paid to mental health and substance use disorder physicians by the same percentage for every CPT code, but does not apply the same reductions for non-physician medical/surgical providers.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(A) (*Example 1*), the plan violates the rules of this paragraph (c)(4). Because the plan reimburses non-physician providers of mental health and substance use disorder services by reducing their reimbursement rate from the rate for physician providers of mental health and substance use disorder services by the same percentage for every CPT code but does not apply the same reductions to non-physician providers of medical/surgical services from the rate for physician providers of medical/surgical services, in operation, the factors used in designing and applying the nonquantitative treatment limitation to mental health and substance use disorder benefits in the outpatient, in-network classification are not comparable to, and are applied more stringently than, the factors used in designing and applying the limitation with respect to medical/surgical benefits in the same classification. As a result, the nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in the outpatient, in-network classification is more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification.

(B) *Example 2 (strategy for exclusion for experimental or investigative treatment more stringently applied to ABA therapy in operation)*—(1) *Facts.* A plan, as written, generally excludes coverage for all treatments that are experimental or investigative for both medical/surgical benefits and mental health and substance use disorder benefits in the outpatient, in-network classification. As a result, the plan generally excludes, as experimental, a treatment or procedure when no professionally recognized treatment guidelines include the treatment or procedure as a clinically appropriate standard of care for the condition or disorder and fewer than two randomized controlled trials are available to support the treatment's use with respect to the given condition or disorder. The plan provides benefits for the

treatment of ASD, which is a mental health condition, but, in operation, the plan excludes coverage for ABA therapy to treat children with ASD, deeming it experimental. More than one professionally recognized treatment guideline defines clinically appropriate standards of care for ASD and more than two randomized controlled trials are available to support the use of ABA therapy as one intervention to treat certain children with ASD.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(B) (*Example 2*), the plan violates the rules of this paragraph (c)(4). As written, the plan excludes coverage of experimental treatment of medical conditions and surgical procedures, mental health conditions, and substance use disorders when no professionally recognized treatment guidelines define clinically appropriate standards of care for the condition or disorder as including the treatment or procedure at issue, and fewer than two randomized controlled trials are available to support the treatment's use with respect to the given condition or procedure. However, in operation, the plan deviates from this strategy with respect to ABA therapy because more than one professionally recognized treatment guideline defines clinically appropriate standards of care for ASD as including ABA therapy to treat certain children with ASD and more than two randomized controlled trials are available to support the use of ABA therapy to treat certain children with ASD. Therefore, in operation, the strategy used to design the nonquantitative treatment limitation for benefits for the treatment of ASD, which is a mental health condition, in the outpatient, in-network classification is not comparable to, and is applied more stringently than, the strategy used to design the nonquantitative treatment limitation for medical/surgical benefits in the same classification. As a result, the nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in the outpatient, in-network classification is more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification.

(C) *Example 3 (step therapy protocol with exception for severe or irreversible consequences, discriminatory factor)*—(1) *Facts.* A plan's written terms include a step therapy protocol that requires participants and beneficiaries who are prescribed certain drugs to try and fail a generic or preferred brand name drug before the plan will cover the drug originally prescribed by a participant's or beneficiary's attending provider. The plan provides an exception to this protocol that was developed solely based on a methodology developed by an external third-party organization. The third-party organization's methodology, which is not based on a generally recognized independent professional medical or clinical standard, identifies instances in which a delay in treatment with a drug prescribed for a medical condition or surgical procedure could result in either severe or irreversible consequences. However, with respect to a drug prescribed for a mental health condition

or a substance use disorder, the third-party organization's methodology only identifies instances in which a delay in treatment could result in both severe and irreversible consequences, and the plan does not take any steps to correct, cure, or supplement the methodology.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(C) (*Example 3*), the plan violates the rules of paragraph (c)(4)(i)(B) of this section. The source upon which the factor used to apply the step therapy protocol is based is biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits because it addresses instances in which a delay in treatment with a drug prescribed for a medical condition or surgical procedure could result in either severe or irreversible consequences, but only addresses instances in which a delay in treatment with a drug prescribed for a mental health condition or substance use disorder could result in both severe and irreversible consequences, and the plan fails to take the steps necessary to correct, cure, or supplement the methodology so that it is not biased and is objective. Based on the relevant facts and circumstances, this source systematically disfavors access or is specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits. Therefore, the factor used to apply the step therapy protocol is discriminatory for purposes of determining comparability and stringency under paragraph (c)(4)(i)(A) of this section, and may not be relied upon by the plan.

(D) *Example 4 (use of historical plan data and plan steps to correct, cure, or supplement)*—(1) *Facts.* A plan's methodology for calculating provider reimbursement rates relies only on historical plan data on total plan spending for each specialty, divided between mental health and substance use disorder providers and medical/surgical providers, from a time when the plan was not subject to ERISA section 712. The plan has used these historical plan data for many years to establish base reimbursement rates in all provider specialties for which it provides medical/surgical, mental health, and substance use disorder benefits in the inpatient, in-network classification. In evaluating the use of these historical plan data in the design of the methodology for calculating provider reimbursement rates, the plan determined, based on all the relevant facts and circumstances, that the historical plan data systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits. To ensure this information about historical reimbursement rates is not biased and is objective, the plan supplements its methodology to develop the base reimbursement rates for mental health and substance use disorder providers in accordance with additional information, evidence, sources, and standards that reflect the increased demand for mental health and substance use disorder benefits in the inpatient, in-network classification and to

attract sufficient mental health and substance use disorder providers to the network, so that the relevant facts and circumstances indicate the supplemented information, evidence, sources, or standards do not systematically disfavor access and are not specifically designed to disfavor access to mental health and substance use disorder benefits as compared to medical/surgical benefits.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(D) (*Example 4*), the plan does not violate the rules of paragraph (c)(4)(i)(B) of this section with respect to the plan's methodology for calculating provider reimbursement rates in the inpatient, in-network classification. The relevant facts and circumstances indicate that the plan's use of only historical plan data to design its methodology for calculating provider reimbursement rates in the inpatient, in-network classification would otherwise be considered to be biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits under paragraph (c)(4)(i)(B)(2) of this section, since the historical data systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits. However, the plan took the steps necessary to supplement the information, evidence, sources, and standards to reasonably reflect the increased demand for mental health and substance use disorder benefits in the inpatient, in-network classification, and adjust the methodology to increase reimbursement rates for those benefits, thereby ensuring that the information, evidence, sources, and standards relied upon by the plan for this purpose are not biased and are objective. Therefore, the factors and evidentiary standards used to design the plan's methodology for calculating provider reimbursement rates in the inpatient, in-network classification are not discriminatory.

(E) *Example 5 (generally recognized independent professional medical or clinical standards and more stringent prior authorization requirement in operation)—(1) Facts.* The provisions of a plan state that it relies on, and does not deviate from, generally recognized independent professional medical or clinical standards to inform the factor used to design prior authorization requirements for both medical/surgical and mental health and substance use disorder benefits in the prescription drug classification. The generally recognized independent professional medical standard for treatment of opioid use disorder that the plan utilizes—in this case, the American Society of Addiction Medicine national practice guidelines—does not support prior authorization every 30 days for buprenorphine/naloxone. However, in operation, the plan requires prior authorization for buprenorphine/naloxone combination for treatment of opioid use disorder, every 30 days, which is inconsistent with the generally recognized independent professional medical standard on which the factor used to design the limitation is based. The plan's factor used to design prior authorization requirements for

medical/surgical benefits in the prescription drug classification relies on, and does not deviate from, generally recognized independent professional medical or clinical standards.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(E) (*Example 5*), the plan violates the rules of this paragraph (c)(4). The American Society of Addiction Medicine national practice guidelines on which the factor used to design prior authorization requirements for substance use disorder benefits is based are generally recognized independent professional medical or clinical standards that are not considered to be biased or not objective in a manner that discriminates against mental health and substance use disorder benefits under paragraph (c)(4)(i)(B)(3) of this section. However, the plan must comply with other requirements in this paragraph (c)(4), as applicable, with respect to such standards or measures that are used as the basis for a factor or evidentiary standard used to design or apply a nonquantitative treatment limitation. In operation, the plan's factor used to design and apply prior authorization requirements with respect to substance use disorder benefits is not comparable to, and is applied more stringently than, the same factor used to design and apply prior authorization requirements for medical/surgical benefits, because the factor relies on, and does not deviate from, generally recognized independent professional medical or clinical standards for medical/surgical benefits, but deviates from the relevant guidelines for substance use disorder benefits. As a result, the nonquantitative treatment limitation with respect to substance use disorder benefits in the prescription drug classification is more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification.

(F) *Example 6 (plan claims no data exist to reasonably assess impact of nonquantitative treatment limitation on access; medical necessity criteria)—(1) Facts.* A plan approves or denies claims for mental health and substance use disorder benefits and for medical/surgical benefits in the inpatient, in-network and outpatient, in-network classifications based on medical necessity criteria. The plan states in its comparative analysis that no data exist that can reasonably assess any relevant impact of the medical necessity criteria nonquantitative treatment limitation on relevant outcomes related to access to mental health or substance use disorder benefits as compared to the plan's medical necessity criteria nonquantitative treatment limitation's impact on relevant outcomes related to access to medical/surgical benefits in the relevant classifications, without further explanation.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(F) (*Example 6*), the plan violates this paragraph (c)(4). The plan does not comply with paragraph (c)(4)(iii)(A)(3)(ii) of this section because the plan did not include in its comparative analysis, as required under § 2590.712–1(c)(5)(i)(D), a reasoned justification as to the basis for its conclusion that there are no data that can reasonably assess the nonquantitative treatment

limitation's impact, an explanation of why the nature of the nonquantitative treatment limitation prevents the plan from reasonably measuring its impact, an explanation of what data was considered and rejected, and documentation of any additional safeguards or protocols used to ensure the nonquantitative treatment limitation complies with this paragraph (c)(4). Data that could reasonably assess the medical necessity criteria nonquantitative treatment limitation's impact might include, for example, the number and percentage of claims denials, or the number and percentage of claims that were approved for a lower level of care than the level requested on the initial claim. Therefore, because the plan has not collected and evaluated relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits in the relevant classifications, the plan violates the requirements of paragraph (c)(4)(iii) of this section, and violates the requirements under § 2590.712–1(c)(5)(i)(D) because it did not include sufficient information in its comparative analysis with respect to the lack of relevant data.

(G) *Example 7 (concurrent review data collection; no material difference in access)—(1) Facts.* A plan follows a written process to apply a concurrent review nonquantitative treatment limitation to all medical/surgical benefits and mental health and substance use disorder benefits within the inpatient, in-network classification. Under this process, a first-level review is conducted in every instance in which concurrent review applies and an authorization request is approved by the first-level reviewer only if the clinical information submitted by the facility meets the plan's criteria for a continued stay. If the first-level reviewer is unable to approve the authorization request because the clinical information submitted by the facility does not meet the plan's criteria for a continued stay, it is sent to a second-level reviewer who will either approve or deny the request. The plan collects relevant data, including the number of referrals to second-level review, and the number of denials of claims for medical/surgical benefits and mental health and substance use disorder benefits subject to concurrent review as compared to the total number of claims subject to concurrent review, in the inpatient, in-network classification. The plan also collects and evaluates the number of denied claims for medical/surgical benefits and mental health and substance use disorder benefits that are overturned on appeal in the inpatient, in-network classification. The plan evaluates the relevant data and determines that, based on the relevant facts and circumstances, the data do not suggest that the concurrent review nonquantitative treatment limitation contributes to material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits in the classification. Upon requesting the plan's comparative analysis for the concurrent review nonquantitative treatment limitation and reviewing the relevant data, the Secretary does not request additional data

and agrees that the data do not suggest material differences in access.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(G) (*Example 7*), the plan does not violate the rules of paragraph (c)(4)(iii) of this section. The plan collected and evaluated relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits and considered the impact as part of its evaluation. Because the relevant data evaluated do not suggest that the nonquantitative treatment limitation contributes to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits in the inpatient, in-network classification, under paragraph (c)(4)(iii)(B) of this section, there is no strong indicator that the plan violates this paragraph (c)(4).

(H) *Example 8 (material difference in access for prior authorization requirement with reasonable action)—(1) Facts.* A plan requires prior authorization that a treatment is medically necessary for all inpatient, in-network medical/surgical benefits and for all inpatient, in-network mental health and substance use disorder benefits. The plan collects and evaluates relevant data in a manner reasonably designed to assess the impact of the prior authorization requirement on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits in the inpatient, in-network classification. The plan's written process for prior authorization states that the plan approves inpatient, in-network benefits for medical conditions and surgical procedures and mental health and substance use disorder benefits for periods of 1, 3, and 7 days, after which a treatment plan must be submitted by the patient's attending provider and approved by the plan. Approvals for mental health and substance use disorder benefits are most commonly given only for 1 day, after which a treatment plan must be submitted by the patient's attending provider and approved by the plan. The relevant data show that approvals for 7 days are most common for medical conditions and surgical procedures under this plan. Based on all the relevant facts and circumstances, the difference in the relevant data suggests that the nonquantitative treatment limitation is likely to have a negative impact on access to mental health and substance use disorder benefits as compared to medical/surgical benefits. Therefore, the data suggest that the nonquantitative treatment limitation contributes to material differences in access. To address these material differences in access, the plan consults more recent medical guidelines to update the factors that inform its medical necessity nonquantitative treatment limitations. Based on this review, the plan modifies the limitation so that inpatient, in-network prior authorization requests for mental health or substance use disorder benefits are approved for similar periods to what is approved for medical/surgical benefits. The plan includes documentation of this action as part of its comparative analysis.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(H) (*Example 8*), the plan does not violate the rules of paragraph (c)(4)(iii) of this section. While relevant data for the plan's prior authorization requirements suggested that the nonquantitative treatment limitation contributes to material differences in access to mental health and substance use disorder benefits as compared to inpatient, in-network medical/surgical benefits under paragraph (c)(4)(iii)(B) of this section, the plan has taken reasonable action, as necessary, to ensure compliance, in operation, with this paragraph (c)(4) by updating the factors that inform its prior authorization nonquantitative treatment limitation for inpatient, in-network mental health and substance use disorder benefits so that these benefits are approved for similar periods to what is approved for medical/surgical benefits. The plan also documents its action taken to address material differences in access to inpatient, in-network benefits as required by paragraph (c)(4)(iii)(B)(1) of this section.

(I) *Example 9 (differences attributable to generally recognized independent professional medical or clinical standards)—(1) Facts.* A group health plan develops a medical management requirement for all inpatient, out-of-network benefits for both medical/surgical benefits and mental health and substance use disorder benefits to ensure treatment is medically necessary. The factors and evidentiary standards used to design and apply the medical management requirement rely on independent professional medical or clinical standards that are generally recognized by health care providers and facilities in relevant clinical specialties. The processes, strategies, evidentiary standards, and other factors used in designing and applying the medical management requirement to mental health and substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the requirement with respect to medical/surgical benefits. The plan collects and evaluates relevant data in a manner reasonably designed to assess the impact of the medical management nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits, and considers the impact as part of the plan's evaluation, as required by paragraph (c)(4)(iii)(A) of this section. Within the inpatient, out-of-network classification, the application of the medical management requirement results in a higher percentage of denials for mental health and substance use disorder claims than medical/surgical claims, because the benefits were found to be medically necessary for a lower percentage of mental health and substance use disorder claims. The plan correctly determines that these differences in access are attributable to the generally recognized independent professional medical or clinical standards used as the basis for the factors and evidentiary standards used to design or apply the limitation and adequately explains the bases for that conclusion as part of its comparative analysis.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(I) (*Example 9*), the plan does not violate the rules of this paragraph (c)(4). Generally recognized independent professional medical or clinical standards of care are not considered to be information, evidence, sources, or standards that are biased and not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits, and the plan otherwise complies with the requirements in paragraph (c)(4)(i) of this section. Additionally, the plan does not violate paragraph (c)(4)(iii) of this section because it has collected and evaluated relevant data, the differences in access are attributable to the generally recognized independent professional medical or clinical standards that are used as the basis for the factors and evidentiary standards used to design or apply the medical management nonquantitative treatment limitation, and the plan explains the bases for this conclusion in its comparative analysis. As a result, the nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in the inpatient, out-of-network classification is no more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification.

(J) *Example 10 (material differences in access for standards for provider admission to a network with reasonable action)—(1) Facts.* A plan applies nonquantitative treatment limitations related to network composition in the inpatient, in-network and outpatient, in-network classifications. The plan's networks are constructed by separate service providers for medical/surgical benefits and mental health and substance use disorder benefits. The processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitations related to network composition for mental health or substance use disorder benefits in the outpatient, in-network and inpatient, in-network classifications are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitations with respect to medical/surgical benefits in the classifications, as required under paragraph (c)(4)(i) of this section. In order to ensure, in operation, that the nonquantitative treatment limitations are no more restrictive than the predominant nonquantitative treatment limitations applied to substantially all medical/surgical benefits in the classification, the plan collects and evaluates relevant data in a manner reasonably designed to assess the aggregate impact of all the nonquantitative treatment limitations related to network composition on relevant outcomes related to access to mental health and substance use disorder benefits as compared with access to medical/surgical benefits and considers the impact as part of the plan's evaluation. The plan considers relevant data that is known, or reasonably should be known, including metrics relating to the time and distance from

plan participants and beneficiaries to network providers in rural and urban regions; the number of network providers accepting new patients; the proportions of mental health and substance use disorder and medical/surgical providers and facilities that provide services in rural and urban regions who are in the plan's network; provider reimbursement rates (for comparable services and benchmarked to a reference standard, as appropriate); and in-network and out-of-network utilization rates (including data related to the dollar value and number of provider claims submissions). The plan determines that the relevant data suggest that the nonquantitative treatment limitations in the aggregate contribute to material differences in access to mental health and substance use disorder benefits compared to medical/surgical benefits in the classifications because, based on all the relevant facts and circumstances, the differences in the data suggest that the nonquantitative treatment limitations related to network composition are likely to have a negative impact on access to mental health or substance use disorder benefits as compared to medical/surgical benefits. The plan takes reasonable actions, as necessary, to address the material differences in access, to ensure compliance, in operation, with this paragraph (c)(4), by strengthening its efforts to recruit and encourage a broad range of available providers and facilities to join the plan's network of providers, including by taking actions to increase compensation and other inducements, streamline credentialing processes, contact providers reimbursed for items and services provided on an out-of-network basis to offer participation in the network, and develop a process to monitor the effects of such efforts; expanding the availability of telehealth arrangements to mitigate overall provider shortages in certain geographic areas; providing additional outreach and assistance to participants and beneficiaries enrolled in the plan to assist them in finding available in-network providers and facilities; and ensuring that the plan's provider directories are accurate and reliable. The plan documents the efforts that it has taken to address the material differences in access that the data revealed, and the plan includes the documentation as part of its comparative analysis submission.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(J) (*Example 10*), the plan does not violate the rules of this paragraph (c)(4). The plan's nonquantitative treatment limitations related to network composition comply with the rules of paragraph (c)(4)(i) of this section. Additionally, the plan collects and evaluates relevant data, as required under paragraph (c)(4)(iii)(A) of this section, in a manner reasonably designed to assess the aggregate impact of all such nonquantitative treatment limitations on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits, as required under paragraph (c)(4)(iii)(C) of this section. While the data suggest that the nonquantitative treatment limitations contribute to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, the plan has taken

reasonable action, as necessary, to ensure compliance with this paragraph (c)(4). The plan also documents the actions that have been and are being taken by the plan to address material differences as required by § 2590.712–1(c)(5)(iv). As a result, the network composition nonquantitative treatment limitations with respect to mental health or substance use disorder benefits in the inpatient, in-network and outpatient, in-network classifications are no more restrictive than the predominant nonquantitative treatment limitations that apply to substantially all medical/surgical benefits in the same classifications.

(K) *Example 11 (separate EAP exhaustion treatment limitation applicable only to mental health or substance use disorder benefits)*—(1) *Facts.* An employer maintains both a major medical plan and an employee assistance program (EAP). The EAP provides, among other benefits, a limited number of mental health or substance use disorder counseling sessions, which, together with other benefits provided by the EAP, are not significant benefits in the nature of medical care. Participants are eligible for mental health or substance use disorder benefits under the major medical plan only after exhausting the counseling sessions provided by the EAP. No similar exhaustion requirement applies with respect to medical/surgical benefits provided under the major medical plan.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(K) (*Example 11*), the requirement that limits eligibility for mental health and substance use disorder benefits under the major medical plan until EAP benefits are exhausted is a nonquantitative treatment limitation subject to the parity requirements of this paragraph (c)(4). Because the limitation does not apply to medical/surgical benefits, it is a separate nonquantitative treatment limitation applicable only to mental health and substance use disorder benefits that violates paragraph (c)(4)(iv) of this section. Additionally, this EAP would not qualify as excepted benefits under § 2590.732(c)(3)(vi)(B)(1) because participants in the major medical plan are required to use and exhaust benefits under the EAP (making the EAP a gatekeeper) before an individual is eligible for benefits under the plan.

(L) *Example 12 (separate exclusion for treatment in a residential facility applicable only to mental health and substance use disorder benefits)*—(1) *Facts.* A plan generally covers inpatient, in-network and inpatient, out-of-network treatment without any limitations on setting, including skilled nursing facilities and rehabilitation hospitals, provided other medical necessity standards are satisfied. The plan has an exclusion for treatment at residential facilities, which the plan defines as an inpatient benefit for mental health and substance use disorder benefits. This exclusion was not generated through any broader nonquantitative treatment limitation (such as medical necessity or other clinical guideline).

(2) *Conclusion.* In this paragraph (c)(4)(vi)(L) (*Example 12*), the plan violates the rules of paragraph (c)(4)(iv) of this section. The exclusion of treatment at

residential facilities is a separate nonquantitative treatment limitation applicable only to mental health and substance use disorder benefits in the inpatient, in-network and inpatient, out-of-network classifications because the plan does not apply a comparable exclusion with respect to any medical/surgical benefits in the same benefit classification.

(M) *Example 13 (impermissible nonquantitative treatment limitation imposed following a final determination of noncompliance and direction by the Secretary)*—(1) *Facts.* Following an initial request by the Secretary for a plan's comparative analysis of the plan's exclusion of mental health and substance use disorder benefits for failure to complete a course of treatment in the inpatient, in-network classification under § 2590.712–1(d), the plan submits a comparative analysis for the nonquantitative treatment limitation. After review of the comparative analysis, as well as additional information submitted by the plan after the Secretary determines that the plan has not submitted sufficient information to be responsive to the request, the Secretary makes an initial determination that the comparative analysis fails to demonstrate that the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the inpatient, in-network classification are comparable to, and applied no more stringently than, those used in designing and applying the limitation to medical/surgical benefits in the classification. Under § 2590.712–1(d)(3), the plan submits a corrective action plan and additional comparative analyses within 45 calendar days after the initial determination. However, the corrective action plan does not alter or eliminate the exclusion or alter the processes, strategies, evidentiary standards, and other factors used in designing and applying the exclusion. Moreover, the additional comparative analysis still does not include sufficient information. The Secretary then determines that the additional comparative analyses do not demonstrate compliance with the requirements of this paragraph (c)(4). Accordingly, the plan receives a final determination of noncompliance with ERISA section 712(a)(8) and § 2590.712–1 from the Secretary, which concludes that the plan did not demonstrate compliance through the comparative analysis process. After considering the relevant facts and circumstances, and considering the interests of plan participants and beneficiaries, as well as feedback from the plan, the Secretary directs the plan not to impose the nonquantitative treatment limitation by a certain date, unless and until the plan demonstrates compliance to the Secretary or takes appropriate action to remedy the violation. The plan makes no changes to its plan terms by that date and continues to impose the exclusion of benefits for failure to complete a course of treatment in the inpatient, in-network classification.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(M) (*Example 13*), by continuing to impose the exclusion of mental health and

substance use disorder benefits for failure to complete a course of treatment in the inpatient, in-network classification after the Secretary directs the plan not to impose this nonquantitative treatment limitation, the plan violates the requirements of paragraph (c)(4)(v) of this section.

* * * * *

(d) * * *

(3) *Provisions of other law.*

Compliance with the disclosure requirements in paragraphs (d)(1) and (2) of this section is not determinative of compliance with any other provision of applicable Federal or State law. In particular, in addition to those disclosure requirements, provisions of other applicable law require disclosure of information relevant to medical/surgical, mental health, and substance use disorder benefits. For example, ERISA section 104 and § 2520.104b–1 of this chapter provide that, for plans subject to ERISA, instruments under which the plan is established or operated must generally be furnished to plan participants within 30 days of request. Instruments under which the plan is established or operated include documents with information on medical necessity criteria for both medical/surgical benefits and mental health and substance use disorder benefits; the processes, strategies, evidentiary standards, and other factors used to apply a nonquantitative treatment limitation with respect to medical/surgical benefits and mental health or substance use disorder benefits under the plan; and the comparative analyses and other applicable information required by § 2590.712–1. In addition, § 2560.503–1 of this chapter and § 2590.715–2719 set forth rules regarding claims and appeals, including the right of claimants (or their authorized representative) who have received an adverse benefit determination (or a final internal adverse benefit determination) to be provided, upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant to the claimant's claim for benefits. This includes documents with information on medical necessity criteria for both medical/surgical benefits and mental health and substance use disorder benefits, as well as the processes, strategies, evidentiary standards, and other factors used to apply a nonquantitative treatment limitation with respect to medical/surgical benefits and mental health or substance use disorder benefits under the plan and the comparative analyses and other applicable information required by § 2590.712–1.

(e) * * *

(4) *Coordination with EHB requirements.* Nothing in paragraph (f) or (g) of this section or § 2590.712–1(g) changes the requirements of 45 CFR 147.150 and 156.115 providing that a health insurance issuer offering non-grandfathered health insurance coverage in the individual or small group market that is required to provide mental health and substance use disorder services, including behavioral health treatment services, as part of essential health benefits required under 45 CFR 156.110(a)(5) and 156.115(a), must comply with the requirements under section 2726 of the Public Health Service Act and its implementing regulations at 45 CFR 146.136 and 146.137 to satisfy the requirement to provide coverage for mental health and substance use disorder services, including behavioral health treatment, as part of essential health benefits.

* * * * *

(i) * * *

(1) *In general.* Except as provided in paragraph (i)(2) of this section—

(i) This section applies to group health plans and health insurance issuers offering group health insurance coverage on the first day of the first plan year beginning on or after January 1, 2025, except that the requirements of paragraphs (c)(2)(ii)(A), (c)(4)(i)(B), and (c)(4)(iii) of this section apply on the first day of the first plan year beginning on or after January 1, 2026.

(ii) Until the applicability date in paragraph (i)(1)(i) of this section, plans and issuers are required to continue to comply with 29 CFR 2590.712, revised as of July 1, 2022.

* * * * *

(j) *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 or the application of the provision to persons not similarly situated or to dissimilar circumstances.

■ 6. Add § 2590.712–1 to read as follows:

§ 2590.712–1 Nonquantitative treatment limitation comparative analysis requirements.

(a) *Meaning of terms.* Unless otherwise stated in this section, the terms of this section have the meanings indicated in § 2590.712(a)(2).

(b) *In general.* In the case of a group health plan (or health insurance issuer offering coverage in connection with a group health plan) that provides both medical/surgical benefits and mental health or substance use disorder benefits and that imposes any nonquantitative treatment limitation on mental health or substance use disorder benefits, the plan or issuer must perform and document a comparative analysis of the design and application of each nonquantitative treatment limitation applicable to mental health or substance use disorder benefits. Each comparative analysis must comply with the content requirements of paragraph (c) of this section and be made available to the Secretary, upon request, in the manner required by paragraphs (d) and (e) of this section.

(c) *Comparative analysis content requirements.* With respect to each nonquantitative treatment limitation applicable to mental health or substance use disorder benefits under a group health plan (or health insurance coverage offered in connection with a group health plan), the comparative analysis performed by the plan or issuer must include, at minimum, the elements specified in this paragraph (c). In addition to the comparative analysis for each nonquantitative treatment limitation, each plan or issuer must prepare and make available to the Secretary, upon request, a written list of all nonquantitative treatment limitations imposed under the plan or coverage, which must be provided to the named fiduciaries of the plan who are required to include a certification as part of each comparative analysis, as required under paragraph (c)(6)(vi) of this section.

(1) *Description of the nonquantitative treatment limitation.* The comparative analysis must include, with respect to the nonquantitative treatment limitation that is the subject of the comparative analysis:

(i) Identification of the nonquantitative treatment limitation, including the specific terms of the plan or coverage or other relevant terms regarding the nonquantitative treatment limitation, the policies or guidelines (internal or external) in which the nonquantitative treatment limitation appears or is described, and the applicable sections of any other relevant documents, such as provider contracts, that describe the nonquantitative treatment limitation;

(ii) Identification of all mental health or substance use disorder benefits and medical/surgical benefits to which the nonquantitative treatment limitation applies, including a list of which benefits are considered mental health or

substance use disorder benefits and which benefits are considered medical/surgical benefits; and

(iii) A description of which benefits are included in each classification set forth in § 2590.712(c)(2)(ii)(A).

(2) *Identification and definition of the factors and evidentiary standards used to design or apply the nonquantitative treatment limitation.* The comparative analysis must include, with respect to every factor considered or relied upon to design the nonquantitative treatment limitation or apply the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits:

(i) Identification of every factor considered or relied upon, as well as the evidentiary standards considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived, in determining which mental health or substance use disorder benefits and which medical/surgical benefits are subject to the nonquantitative treatment limitation; and

(ii) A definition of each factor, including:

(A) A detailed description of the factor;

(B) A description of each evidentiary standard used to design or apply each factor (and the source of each evidentiary standard) identified under paragraph (c)(2)(i) of this section; and

(C) A description of any steps the plan or issuer has taken to correct, cure, or supplement any information, evidence, sources, or standards that would otherwise have been considered biased or not objective under § 2590.712(c)(4)(i)(B)(1) in the absence of such steps.

(3) *Description of how factors are used in the design and application of the nonquantitative treatment limitation.* The comparative analysis must include a description of how each factor identified and defined under paragraph (c)(2) of this section is used in the design or application of the nonquantitative treatment limitation to mental health and substance use disorder benefits and medical/surgical benefits in a classification, including:

(i) A detailed explanation of how each factor identified and defined in paragraph (c)(2) of this section is used to determine which mental health or substance use disorder benefits and which medical/surgical benefits are subject to the nonquantitative treatment limitation;

(ii) An explanation of the evidentiary standards or other information or sources (if any) considered or relied upon in designing or applying the

factors or relied upon in designing and applying the nonquantitative treatment limitation, including in the determination of whether and how mental health or substance use disorder benefits or medical/surgical benefits are subject to the nonquantitative treatment limitation;

(iii) If the application of the factor depends on specific decisions made in the administration of benefits, the nature of the decisions, the timing of the decisions, and the professional designations and qualifications of each decision maker;

(iv) If more than one factor is identified and defined in paragraph (c)(2) of this section, an explanation of:

(A) How all of the factors relate to each other;

(B) The order in which all the factors are applied, including when they are applied;

(C) Whether and how any factors are given more weight than others; and

(D) The reasons for the ordering or weighting of the factors; and

(v) Any deviations or variations from a factor, its applicability, or its definition (including the evidentiary standards used to define the factor and the information or sources from which each evidentiary standard was derived), such as how the factor is used differently to apply the nonquantitative treatment limitation to mental health or substance use disorder benefits as compared to medical/surgical benefits, and a description of how the plan or issuer establishes such deviations or variations.

(4) *Demonstration of comparability and stringency as written.* The comparative analysis must evaluate whether, in any classification, under the terms of the plan (or health insurance coverage) as written, any processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation with respect to medical/surgical benefits. The comparative analysis must include, with respect to the nonquantitative treatment limitation and the factors used in designing and applying the nonquantitative treatment limitation:

(i) Documentation of each factor identified and defined in paragraph (c)(2) of this section that was applied to determine whether the nonquantitative treatment limitation applies to mental

health or substance use disorder benefits and medical/surgical benefits in a classification, including, as relevant:

(A) Quantitative data, calculations, or other analyses showing whether, in each classification in which the nonquantitative treatment limitation applies, mental health or substance use disorder benefits and medical/surgical benefits met or did not meet any applicable threshold identified in the relevant evidentiary standard to determine that the nonquantitative treatment limitation would or would not apply; and

(B) Records maintained by the plan or issuer documenting the consideration and application of all factors and evidentiary standards, as well as the results of their application;

(ii) In each classification in which the nonquantitative treatment limitation applies to mental health or substance use disorder benefits, a comparison of how the nonquantitative treatment limitation, as written, is designed and applied to mental health or substance use disorder benefits and to medical/surgical benefits, including the specific provisions of any forms, checklists, procedure manuals, or other documentation used in designing and applying the nonquantitative treatment limitation or that address the application of the nonquantitative treatment limitation;

(iii) Documentation demonstrating how the factors are comparably applied, as written, to mental health or substance use disorder benefits and medical/surgical benefits in each classification, to determine which benefits are subject to the nonquantitative treatment limitation; and

(iv) An explanation of the reasons for any deviations or variations in the application of a factor used to apply the nonquantitative treatment limitation, or the application of the nonquantitative treatment limitation, to mental health or substance use disorder benefits as compared to medical/surgical benefits, and how the plan or issuer establishes such deviations or variations, including:

(A) In the definition of the factors, the evidentiary standards used to define the factors, and the sources from which the evidentiary standards were derived;

(B) In the design of the factors or evidentiary standards; or

(C) In the application or design of the nonquantitative treatment limitation.

(5) *Demonstration of comparability and stringency in operation.* The comparative analysis must evaluate whether, in any classification, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the

nonquantitative treatment limitation to mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the limitation with respect to medical/surgical benefits. The comparative analysis must include, with respect to the nonquantitative treatment limitation and the factors used in designing and applying the nonquantitative treatment limitation:

(i) A comprehensive explanation of how the plan or issuer evaluates whether, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation with respect to medical/surgical benefits, including:

(A) An explanation of any methodology and underlying data used to demonstrate the application of the nonquantitative treatment limitation, in operation;

(B) The sample period, inputs used in any calculations, definitions of terms used, and any criteria used to select the mental health or substance use disorder benefits and medical/surgical benefits to which the nonquantitative treatment limitation is applicable;

(C) With respect to a nonquantitative treatment limitation for which relevant data is temporarily unavailable as described in § 2590.712(c)(4)(iii)(A)(3)(i), a detailed explanation of the lack of relevant data, the basis for the plan's or issuer's conclusion that there is a lack of relevant data, and when and how the data will become available and be collected and analyzed; and

(D) With respect to a nonquantitative treatment limitation for which no data exist that can reasonably assess any relevant impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits as described in

§ 2590.712(c)(4)(iii)(A)(3)(ii), a reasoned justification as to the basis for the conclusion that there are no data that can reasonably assess the nonquantitative treatment limitation's impact, an explanation of why the nature of the nonquantitative treatment limitation prevents the plan or issuer

from reasonably measuring its impact, an explanation of what data was considered and rejected, and documentation of any additional safeguards or protocols used to ensure that the nonquantitative treatment limitation complies with § 2590.712(c)(4);

(ii) Identification of the relevant data collected and evaluated, as required under § 2590.712(c)(4)(iii)(A);

(iii) Documentation of the outcomes that resulted from the application of the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits, including:

(A) The evaluation of relevant data as required under § 2590.712(c)(4)(iii)(A); and

(B) A reasoned justification and analysis that explains why the plan or issuer concluded that any differences in the relevant data do or do not suggest the nonquantitative treatment limitation contributes to material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits, in accordance with § 2590.712(c)(4)(iii)(B)(2);

(iv) A detailed explanation of any material differences in access demonstrated by the outcomes evaluated under paragraph (c)(5)(iii) of this section, including:

(A) A reasoned explanation of any material differences in access that are not attributable to differences in the comparability or relative stringency of the nonquantitative treatment limitation as applied to mental health or substance use disorder benefits and medical/surgical benefits (including any considerations beyond a plan's or issuer's control that contribute to the existence of material differences) and a detailed explanation of the bases for concluding that material differences are not attributable to differences in the comparability or relative stringency of the nonquantitative treatment limitation; and

(B) To the extent differences in access to mental health or substance use disorder benefits are attributable to generally recognized independent professional medical or clinical standards or carefully circumscribed measures reasonably and appropriately designed to detect or prevent and prove fraud and abuse that minimize the negative impact on access to appropriate mental health and substance use disorder benefits, and such standards or measures are used as the basis for a factor or evidentiary standard used to design or apply a nonquantitative treatment limitation, documentation explaining how any such differences are

attributable to those standards or measures, as required in § 2590.712(c)(4)(iii)(B)(2)(ii); and

(v) A discussion of the actions that have been or are being taken by the plan or issuer to address any material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits, including the actions the plan or issuer has taken or is taking under § 2590.712(c)(4)(iii)(B)(1) to address material differences to comply, in operation, with § 2590.712(c)(4), including, as applicable:

(A) A reasoned explanation of any material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits that persist despite reasonable actions that have been or are being taken; and

(B) For a plan or issuer designing and applying one or more nonquantitative treatment limitations related to network composition, a discussion of the actions that have been or are being taken to address material differences in access to in-network mental health and substance use disorder benefits as compared to in-network medical/surgical benefits, including those listed in § 2590.712(c)(4)(iii)(C).

(6) *Findings and conclusions.* The comparative analysis must address the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits within each classification, and the relative stringency of their application, both as written and in operation, and include:

(i) Any findings or conclusions indicating that the plan or coverage is or is not (or might or might not be) in compliance with the requirements of § 2590.712(c)(4), including any additional actions the plan or issuer has taken or intends to take to address any potential areas of concern or noncompliance;

(ii) A reasoned and detailed discussion of the findings and conclusions described in paragraph (c)(6)(i) of this section;

(iii) Citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions described in paragraph (c)(6)(i) of this section not otherwise discussed in the comparative analysis;

(iv) The date the analysis is completed and the title and credentials of all relevant persons who participated

in the performance and documentation of the comparative analysis;

(v) If the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan or issuer to be an expert, an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of the nonquantitative treatment limitation applicable to both mental health or substance use disorder benefits and medical/surgical benefits; and

(vi) A certification by one or more named fiduciaries that they have engaged in a prudent process to select one or more qualified service providers to perform and document a comparative analysis in connection with the imposition of any nonquantitative treatment limitations that apply to mental health and substance use disorder benefits under the plan in accordance with applicable law and regulations, and have satisfied their duty to monitor those service providers as required under part 4 of ERISA with respect to the performance and documentation of such comparative analysis.

(d) *Requirements related to submission of comparative analyses to the Secretary upon request*—(1) *Initial request by the Secretary for comparative analysis.* A group health plan (or health insurance issuer offering coverage in connection with a group health plan) must make the comparative analysis required by paragraph (b) of this section available and submit it to the Secretary within 10 business days of receipt of a request from the Secretary (or an additional period of time specified by the Secretary).

(2) *Additional information required after a comparative analysis is deemed to be insufficient.* In instances in which the Secretary determines that the plan or issuer has not submitted sufficient information under paragraph (d)(1) of this section for the Secretary to determine whether the comparative analysis required in paragraph (b) of this section complies with paragraph (c) of this section or whether the plan or issuer complies with § 2590.712(c)(4), the Secretary will specify to the plan or issuer the additional information the plan or issuer must submit to the Secretary to be responsive to the request under paragraph (d)(1). Any such information must be provided to the Secretary by the plan or issuer within 10 business days after the Secretary specifies the additional information to

be submitted (or an additional period of time specified by the Secretary).

(3) *Initial determination of noncompliance, required action, and corrective action plan.* In instances in which the Secretary reviewed the comparative analysis submitted under paragraph (d)(1) of this section and any additional information submitted under paragraph (d)(2) of this section, and made an initial determination that the plan or issuer is not in compliance with the requirements of § 2590.712(c)(4) or this section, the plan or issuer must respond to the initial determination by the Secretary and specify the actions the plan or issuer will take to bring the plan or coverage into compliance, and provide to the Secretary additional comparative analyses meeting the requirements of paragraph (c) of this section that demonstrate compliance with § 2590.712(c)(4), not later than 45 calendar days after the Secretary's initial determination that the plan or issuer is not in compliance.

(4) *Requirement to notify participants and beneficiaries of final determination of noncompliance*—(i) *In general.* If the Secretary makes a final determination of noncompliance, the plan or issuer must notify all participants and beneficiaries enrolled in the plan or coverage that the plan or issuer has been determined to not be in compliance with the requirements of § 2590.712(c)(4) or this section with respect to such plan or coverage. Such notice must be provided within 7 business days of receipt of the final determination of noncompliance, and the plan or issuer must provide a copy of the notice to the Secretary, any service provider involved in the claims process, and any fiduciary responsible for deciding benefit claims within the same timeframe.

(ii) *Content of notice.* The notice to participants and beneficiaries required in paragraph (d)(4)(i) of this section shall be written in a manner calculated to be understood by the average plan participant and must include, in plain language, the following information in a standalone notice:

(A) The following statement prominently displayed on the first page, in no less than 14-point font: "Attention! The Department of Labor has determined that [insert the name of group health plan or health insurance issuer] is not in compliance with the Mental Health Parity and Addiction Equity Act.";

(B) A summary of changes the plan or issuer has made as part of its corrective action plan specified to the Secretary following the initial determination of noncompliance, including an explanation of any opportunity for a

participant or beneficiary to have a claim for benefits submitted or reprocessed;

(C) A summary of the Secretary's final determination that the plan or issuer is not in compliance with § 2590.712(c)(4) or this section, including any provisions or practices identified as being in violation of § 2590.712(c)(4) or this section, additional corrective actions identified by the Secretary in the final determination notice, and information on how participants and beneficiaries can obtain from the plan or issuer a copy of the final determination of noncompliance;

(D) Any additional actions the plan or issuer is taking to come into compliance with § 2590.712(c)(4) or this section, when the plan or issuer will take such actions, and a clear and accurate statement explaining whether the Secretary has concurred with those actions; and

(E) Contact information for questions and complaints, and a statement explaining how participants and beneficiaries can obtain more information about the notice, including:

(1) The plan's or issuer's phone number and an email or web portal address; and

(2) The Employee Benefits Security Administration's phone number and email or web portal address.

(iii) *Manner of notice.* The plan or issuer must make the notice required under paragraph (d)(4)(i) of this section available in paper form, or electronically (such as by email or an internet posting) if:

(A) The format is readily accessible;

(B) The notice is provided in paper form free of charge upon request; and

(C) In a case in which the electronic form is an internet posting, the plan or issuer timely notifies the participant or beneficiary in paper form (such as a postcard) or email, that the documents are available on the internet, provides the internet address, includes the statement required in paragraph (d)(4)(ii)(A) of this section, and notifies the participant or beneficiary that the documents are available in paper form upon request.

(e) *Requests for a copy of a comparative analysis.* In addition to making a comparative analysis available upon request to the Secretary, a plan or issuer must make available a copy of the comparative analysis required by paragraph (b) of this section when requested by:

(1) Any applicable State authority;

(2) A participant or beneficiary (including a provider or other person acting as a participant's or beneficiary's authorized representative) who has

received an adverse benefit determination related to mental health or substance use disorder benefits; and

(3) Participants and beneficiaries, who may request the comparative analysis at any time under ERISA section 104.

(f) *Rule of construction.* Nothing in this section or § 2590.712 shall be construed to prevent the Secretary from acting within the scope of existing authorities to address violations of § 2590.712 or this section.

(g) *Applicability.* The provisions of this section apply to group health plans and health insurance issuers offering group health insurance coverage described in § 2590.712(e), to the extent the plan or issuer is not exempt under § 2590.712(f) or (g), on the first day of the first plan year beginning on or after January 1, 2025, except the requirements of paragraphs (c)(2)(ii)(C), (c)(5)(i)(C) and (D), and (c)(5)(ii) through (v) of this section apply on the first day of the first plan year beginning on or after January 1, 2026.

(h) *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 or the application of the provision to persons not similarly situated or to dissimilar circumstances.

Department of Health and Human Services

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR parts 146 and 147 as set forth below:

PART 146—REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKET

■ 7. The authority citation for part 146 continues to read as follows:

Authority: 42 U.S.C. 300gg–1 through 300gg–5, 300gg–11 through 300gg–23, 300gg–91, and 300gg–92.

■ 8. Amend § 146.136 by:

■ a. Redesignating paragraph (a) as paragraph (a)(2) and adding paragraphs (a) heading and (a)(1);

■ b. In newly redesignated paragraph (a)(2):

■ i. Revising the introductory text;

■ ii. Adding the definitions of “DSM,” “Evidentiary standards,” “Factors,” and “ICD” in alphabetical order;

■ iii. Revising the definitions of “Medical/surgical benefits” and “Mental health benefits”;

■ iv. Adding the definitions of “Processes” and “Strategies” in alphabetical order; and

■ v. Revising the definitions of “Substance use disorder benefits” and “Treatment limitations”;

■ c. Revising paragraphs (c)(1)(ii), (c)(2)(i), (c)(2)(ii)(A) introductory text, (c)(2)(ii)(C), and (c)(3)(i)(A), (C), and (D);

■ d. In paragraph (c)(3)(iii), adding introductory text;

■ e. Revising paragraphs (c)(3)(iii)(A) and (B), (c)(3)(iv), (c)(4), (d)(3), (e)(4), and (i)(1); and

■ f. Adding paragraph (j).

The revisions and additions read as follows:

§ 146.136 Parity in mental health and substance use disorder benefits.

(a) *Purpose and meaning of terms—*

(1) *Purpose.* This section and § 146.137 set forth rules to ensure parity in aggregate lifetime and annual dollar limits, financial requirements, and quantitative and nonquantitative treatment limitations between mental health and substance use disorder benefits and medical/surgical benefits, as required under PHS Act section 2726. A fundamental purpose of PHS Act section 2726, this section, and § 146.137 is to ensure that participants and beneficiaries in a group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) that offers mental health or substance use disorder benefits are not subject to more restrictive aggregate lifetime or annual dollar limits, financial requirements, or treatment limitations with respect to those benefits than the predominant dollar limits, financial requirements, or treatment limitations that are applied to substantially all medical/surgical benefits covered by the plan or coverage in the same classification, as further provided in this section and § 146.137. Accordingly, in complying with the provisions of PHS Act section 2726, this section, and § 146.137, plans and issuers must not design or apply financial requirements and treatment limitations that impose a greater burden on access (that is, are more restrictive) to mental health or substance use disorder benefits under the plan or coverage than they impose on access to medical/surgical benefits in the same classification of benefits. The provisions of PHS Act section 2726, this section, and § 146.137 should be interpreted in a manner that is consistent with the purpose described in this paragraph (a)(1).

(2) *Meaning of terms.* For purposes of this section and § 146.137, except where the context clearly indicates otherwise, the following terms have the meanings indicated:

* * * * *

DSM means the American Psychiatric Association’s Diagnostic and Statistical Manual of Mental Disorders. For the purpose of this definition, the most current version of the DSM as of November 22, 2024, is the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision published in March 2022. A subsequent version of the DSM published after November 22, 2024, will be considered the most current version beginning on the first day of the plan year that is one year after the date the subsequent version is published.

Evidentiary standards are any evidence, sources, or standards that a group health plan (or health insurance issuer offering coverage in connection with such a plan) considered or relied upon in designing or applying a factor with respect to a nonquantitative treatment limitation, including specific benchmarks or thresholds. Evidentiary standards may be empirical, statistical, or clinical in nature, and include: sources acquired or originating from an objective third party, such as recognized medical literature, professional standards and protocols (which may include comparative effectiveness studies and clinical trials), published research studies, payment rates for items and services (such as publicly available databases of the “usual, customary and reasonable” rates paid for items and services), and clinical treatment guidelines; internal plan or issuer data, such as claims or utilization data or criteria for assuring a sufficient mix and number of network providers; and benchmarks or thresholds, such as measures of excessive utilization, cost levels, time or distance standards, or network participation percentage thresholds.

Factors are all information, including processes and strategies (but not evidentiary standards), that a group health plan (or health insurance issuer offering coverage in connection with such a plan) considered or relied upon to design a nonquantitative treatment limitation, or to determine whether or how the nonquantitative treatment limitation applies to benefits under the plan or coverage. Examples of factors include, but are not limited to: provider discretion in determining a diagnosis or type or length of treatment; clinical efficacy of any proposed treatment or service; licensing and accreditation of

providers; claim types with a high percentage of fraud; quality measures; treatment outcomes; severity or chronicity of condition; variability in the cost of an episode of treatment; high cost growth; variability in cost and quality; elasticity of demand; and geographic location.

* * * * *

ICD means the World Health Organization's International Classification of Diseases adopted by the Department of Health and Human Services through § 162.1002 of this subtitle. For the purpose of this definition, the most current version of the ICD as of November 22, 2024, is the International Classification of Diseases, 10th Revision, Clinical Modification adopted for the period beginning on October 1, 2015. Any subsequent version of the ICD adopted through § 162.1002 of this subtitle after November 22, 2024, will be considered the most current version beginning on the first day of the plan year that is one year after the date the subsequent version is adopted.

Medical/surgical benefits means benefits with respect to items or services for medical conditions or surgical procedures, as defined under the terms of the group health plan (or health insurance coverage offered by an issuer in connection with such a plan) and in accordance with applicable Federal and State law, but does not include mental health benefits or substance use disorder benefits. Notwithstanding the preceding sentence, any condition or procedure defined by the plan or coverage as being or as not being a medical condition or surgical procedure must be defined consistent with generally recognized independent standards of current medical practice (for example, the most current version of the ICD). To the extent generally recognized independent standards of current medical practice do not address whether a condition or procedure is a medical condition or surgical procedure, plans and issuers may define the condition or procedure in accordance with applicable Federal and State law.

Mental health benefits means benefits with respect to items or services for mental health conditions, as defined under the terms of the group health plan (or health insurance coverage offered by an issuer in connection with such a plan) and in accordance with applicable Federal and State law, but does not include medical/surgical benefits or substance use disorder benefits. Notwithstanding the preceding sentence, any condition defined by the

plan or coverage as being or as not being a mental health condition must be defined consistent with generally recognized independent standards of current medical practice. For the purpose of this definition, to be consistent with generally recognized independent standards of current medical practice, the definition must include all conditions covered under the plan or coverage, except for substance use disorders, that fall under any of the diagnostic categories listed in the mental, behavioral, and neurodevelopmental disorders chapter (or equivalent chapter) of the most current version of the ICD or that are listed in the most current version of the DSM. To the extent generally recognized independent standards of current medical practice do not address whether a condition is a mental health condition, plans and issuers may define the condition in accordance with applicable Federal and State law.

Processes are actions, steps, or procedures that a group health plan (or health insurance issuer offering coverage in connection with such a plan) uses to apply a nonquantitative treatment limitation, including actions, steps, or procedures established by the plan or issuer as requirements in order for a participant or beneficiary to access benefits, including through actions by a participant's or beneficiary's authorized representative or a provider or facility. Examples of processes include, but are not limited to: procedures to submit information to authorize coverage for an item or service prior to receiving the benefit or while treatment is ongoing (including requirements for peer or expert clinical review of that information); provider referral requirements that are used to determine when and how a participant or beneficiary may access certain services; and the development and approval of a treatment plan used in a concurrent review process to determine whether a specific request should be granted or denied. Processes also include the specific procedures used by staff or other representatives of a plan or issuer (or the service provider of a plan or issuer) to administer the application of nonquantitative treatment limitations, such as how a panel of staff members applies the nonquantitative treatment limitation (including the qualifications of staff involved, number of staff members allocated, and time allocated), consultations with panels of experts in applying the nonquantitative treatment limitation, and the degree of reviewer discretion in adhering to criteria

hierarchy when applying a nonquantitative treatment limitation.

Strategies are practices, methods, or internal metrics that a plan (or health insurance issuer offering coverage in connection with such a plan) considers, reviews, or uses to design a nonquantitative treatment limitation. Examples of strategies include, but are not limited to: the development of the clinical rationale used in approving or denying benefits; the method of determining whether and how to deviate from generally accepted standards of care in concurrent reviews; the selection of information deemed reasonably necessary to make medical necessity determinations; reliance on treatment guidelines or guidelines provided by third-party organizations in the design of a nonquantitative treatment limitation; and rationales used in selecting and adopting certain threshold amounts to apply a nonquantitative treatment limitation, professional standards and protocols to determine utilization management standards, and fee schedules used to determine provider reimbursement rates, used as part of a nonquantitative treatment limitation. Strategies also include the method of creating and determining the composition of the staff or other representatives of a plan or issuer (or the service provider of a plan or issuer) that deliberates, or otherwise makes decisions, on the design of nonquantitative treatment limitations, including the plan's or issuer's methods for making decisions related to the qualifications of staff involved, number of staff members allocated, and time allocated; breadth of sources and evidence considered; consultations with panels of experts in designing the nonquantitative treatment limitation; and the composition of the panels used to design a nonquantitative treatment limitation.

Substance use disorder benefits means benefits with respect to items or services for substance use disorders, as defined under the terms of the group health plan (or health insurance coverage offered by an issuer in connection with such a plan) and in accordance with applicable Federal and State law, but does not include medical/surgical benefits or mental health benefits. Notwithstanding the preceding sentence, any disorder defined by the plan or coverage as being or as not being a substance use disorder must be defined consistent with generally recognized independent standards of current medical practice. For the purpose of this definition, to be consistent with generally recognized independent standards of current

medical practice, the definition must include all disorders covered under the plan or coverage that fall under any of the diagnostic categories listed as a mental or behavioral disorder due to psychoactive substance use (or equivalent category) in the mental, behavioral, and neurodevelopmental disorders chapter (or equivalent chapter) of the most current version of the ICD or that are listed as a Substance-Related and Addictive Disorder (or equivalent category) in the most current version of the DSM. To the extent generally recognized independent standards of current medical practice do not address whether a disorder is a substance use disorder, plans and issuers may define the disorder in accordance with applicable Federal and State law.

Treatment limitations include limits on benefits based on the frequency of treatment, number of visits, days of coverage, days in a waiting period, or other similar limits on the scope or duration of treatment. Treatment limitations include both quantitative treatment limitations, which are expressed numerically (such as 50 outpatient visits per year), and nonquantitative treatment limitations (such as standards related to network composition), which otherwise limit the scope or duration of benefits for treatment under a plan or coverage. (See paragraph (c)(4)(ii) of this section for an illustrative, non-exhaustive list of nonquantitative treatment limitations.) A complete exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation for purposes of this definition.

* * * * *

(c) * * *

(1) * * *

(ii) *Type of financial requirement or treatment limitation.* When reference is made in this paragraph (c) to a type of financial requirement or treatment limitation, the reference to type means its nature. Different types of financial requirements include deductibles, copayments, coinsurance, and out-of-pocket maximums. Different types of quantitative treatment limitations include annual, episode, and lifetime day and visit limits. See paragraph (c)(4)(ii) of this section for an illustrative, non-exhaustive list of nonquantitative treatment limitations.

* * * * *

(2) * * *

(i) *General rule.* A group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) that provides both medical/surgical benefits and mental health or

substance use disorder benefits may not apply any financial requirement or treatment limitation to mental health or substance use disorder benefits in any classification that is more restrictive than the predominant financial requirement or treatment limitation of that type applied to substantially all medical/surgical benefits in the same classification. Whether a financial requirement or treatment limitation is a predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in a classification is determined separately for each type of financial requirement or treatment limitation. A plan or issuer may not impose any financial requirement or treatment limitation that is applicable only with respect to mental health or substance use disorder benefits and not to any medical/surgical benefits in the same benefit classification. The application of the rules of this paragraph (c)(2) to financial requirements and quantitative treatment limitations is addressed in paragraph (c)(3) of this section; the application of the rules of this paragraph (c)(2) to nonquantitative treatment limitations is addressed in paragraph (c)(4) of this section.

(ii) * * *

(A) *In general.* If a plan (or health insurance coverage) provides any benefits for a mental health condition or substance use disorder in any classification of benefits described in this paragraph (c)(2)(ii), it must provide meaningful benefits for that mental health condition or substance use disorder in every classification in which medical/surgical benefits are provided. For purposes of this paragraph (c)(2)(ii)(A), whether the benefits provided are meaningful benefits is determined in comparison to the benefits provided for medical conditions and surgical procedures in the classification and requires, at a minimum, coverage of benefits for that condition or disorder in each classification in which the plan (or coverage) provides benefits for one or more medical conditions or surgical procedures. A plan (or coverage) does not provide meaningful benefits under this paragraph (c)(2)(ii)(A) unless it provides benefits for a core treatment for that condition or disorder in each classification in which the plan (or coverage) provides benefits for a core treatment for one or more medical conditions or surgical procedures. For purposes of this paragraph (c)(2)(ii)(A), a core treatment for a condition or disorder is a standard treatment or course of treatment, therapy, service, or intervention indicated by generally

recognized independent standards of current medical practice. If there is no core treatment for a covered mental health condition or substance use disorder with respect to a classification, the plan (or coverage) is not required to provide benefits for a core treatment for such condition or disorder in that classification (but must provide benefits for such condition or disorder in every classification in which medical/surgical benefits are provided). In determining the classification in which a particular benefit belongs, a plan (or health insurance issuer) must apply the same standards to medical/surgical benefits and to mental health or substance use disorder benefits. To the extent that a plan (or health insurance coverage) provides benefits in a classification and imposes any separate financial requirement or treatment limitation (or separate level of a financial requirement or treatment limitation) for benefits in the classification, the rules of this paragraph (c) apply separately with respect to that classification for all financial requirements or treatment limitations (illustrated in examples in paragraph (c)(2)(ii)(C) of this section). The following classifications of benefits are the only classifications used in applying the rules of this paragraph (c), in addition to the permissible subclassifications described in paragraph (c)(3)(iii) of this section:

* * * * *

(C) *Examples.* The rules of this paragraph (c)(2)(ii) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits. With regard to the examples in this paragraph (c)(2)(ii)(C), references to any particular core treatment are included for illustrative purposes only. Plans and issuers must consult generally recognized independent standards of current medical practice to determine the applicable core treatment, therapy, service, or intervention for any covered condition or disorder.

(1) *Example 1—(i) Facts.* A group health plan offers inpatient and outpatient benefits and does not contract with a network of providers. The plan imposes a \$500 deductible on all benefits. For inpatient medical/surgical benefits, the plan imposes a coinsurance requirement. For outpatient medical/surgical benefits, the plan imposes copayments. The plan imposes no other financial requirements or treatment limitations.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(1) (*Example 1*), because the plan has no network of providers, all benefits provided are out-of-network. Because

inpatient, out-of-network medical/surgical benefits are subject to separate financial requirements from outpatient, out-of-network medical/surgical benefits, the rules of this paragraph (c) apply separately with respect to any financial requirements and treatment limitations, including the deductible, in each classification.

(2) *Example 2—(i) Facts.* A plan imposes a \$500 deductible on all benefits. The plan has no network of providers. The plan generally imposes a 20 percent coinsurance requirement with respect to all benefits, without distinguishing among inpatient, outpatient, emergency care, or prescription drug benefits. The plan imposes no other financial requirements or treatment limitations.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(2) (*Example 2*), because the plan does not impose separate financial requirements (or treatment limitations) based on classification, the rules of this paragraph (c) apply with respect to the deductible and the coinsurance across all benefits.

(3) *Example 3—(i) Facts.* Same facts as in paragraph (c)(2)(ii)(C)(2)(i) of this section (*Example 2*), except the plan exempts emergency care benefits from the 20 percent coinsurance requirement. The plan imposes no other financial requirements or treatment limitations.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(3) (*Example 3*), because the plan imposes separate financial requirements based on classifications, the rules of this paragraph (c) apply with respect to the deductible and the coinsurance separately for benefits in the emergency care classification and all other benefits.

(4) *Example 4—(i) Facts.* Same facts as in paragraph (c)(2)(ii)(C)(2)(i) of this section (*Example 2*), except the plan also imposes a preauthorization requirement for all inpatient treatment in order for benefits to be paid. No such requirement applies to outpatient treatment.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(4) (*Example 4*), because the plan has no network of providers, all benefits provided are out-of-network. Because the plan imposes a separate treatment limitation based on classifications, the rules of this paragraph (c) apply with respect to the deductible and coinsurance separately for inpatient, out-of-network benefits and all other benefits.

(5) *Example 5—(i) Facts.* A plan covers treatment for autism spectrum disorder (ASD), a mental health condition, and covers outpatient, out-of-network developmental screenings for ASD but excludes all other benefits for outpatient treatment for ASD, including applied behavior analysis (ABA) therapy, when provided on an out-of-network basis. The plan generally covers the full range of outpatient treatments (including core treatments) and treatment settings for medical conditions and surgical procedures when provided on an out-of-network basis. Under the generally recognized independent standards of current medical practice consulted by the plan, developmental screenings alone do not constitute a core treatment for ASD.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(5) (*Example 5*), the plan violates

the rules of this paragraph (c)(2)(ii). Although the plan covers benefits for ASD in the outpatient, out-of-network classification, it only covers developmental screenings, so it does not cover a core treatment for ASD in the classification. Because the plan generally covers the full range of medical/surgical benefits, including a core treatment for one or more medical conditions or surgical procedures in the classification, it fails to provide meaningful benefits for treatment of ASD in the classification.

(6) *Example 6—(i) Facts.* Same facts as in paragraph (c)(2)(ii)(C)(5) of this section (*Example 5*), except that the plan is an HMO that does not cover the full range of medical/surgical benefits including a core treatment for any medical conditions or surgical procedures in the outpatient, out-of-network classification (except as required under PHS Act sections 2799A–1 and 2799A–2), but covers benefits for medical conditions and surgical procedures in the inpatient, in-network; outpatient, in-network; emergency care; and prescription drug classifications.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(6) (*Example 6*), the plan does not violate the rules of this paragraph (c)(2)(ii). Because the plan does not provide meaningful benefits including for a core treatment for any medical condition or surgical procedure in the outpatient, out-of-network classification (except as required under PHS Act sections 2799A–1 and 2799A–2), the plan is not required to provide meaningful benefits for any mental health conditions or substance use disorders in that classification. Nevertheless, the plan must provide meaningful benefits for each mental health condition and substance use disorder for which the plan provides benefits in every classification in which meaningful medical/surgical benefits are provided as required under paragraph (c)(2)(ii)(A) of this section. This example does not address whether the plan has complied with other applicable requirements of this section in excluding coverage of ABA therapy in the outpatient, out-of-network classification.

(7) *Example 7—(i) Facts.* A plan provides extensive benefits, including for core treatments for many medical conditions and surgical procedures in the outpatient, in-network classification, including nutrition counseling for diabetes and obesity. The plan also generally covers diagnosis and treatment for eating disorders, which are mental health conditions, including coverage for nutrition counseling to treat eating disorders in the outpatient, in-network classification. Nutrition counseling is a core treatment for eating disorders, in accordance with generally recognized independent standards of current medical practice consulted by the plan.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(7) (*Example 7*), the plan does not violate the rules of this paragraph (c)(2)(ii). The coverage of diagnosis and treatment for eating disorders, including nutrition counseling, in the outpatient, in-network classification results in the plan providing meaningful benefits for the treatment of eating disorders in the classification, as determined in comparison to the benefits provided for medical conditions or surgical procedures in the classification.

(8) *Example 8—(i) Facts.* A plan provides extensive benefits for the core treatments for many medical conditions and surgical procedures in the outpatient, in-network and prescription drug classifications. The plan provides coverage for diagnosis and treatment for opioid use disorder, a substance use disorder, in the outpatient, in-network classification, by covering counseling and behavioral therapies and, in the prescription drug classification, by covering medications to treat opioid use disorder (MOUD). Counseling and behavioral therapies and MOUD, in combination, are one of the core treatments for opioid use disorder, in accordance with generally recognized independent standards of current medical practice consulted by the plan.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(8) (*Example 8*), the plan does not violate the rules of this paragraph (c)(2)(ii). The coverage of counseling and behavioral therapies and MOUD, in combination, in the outpatient, in-network classification and prescription drug classification, respectively, results in the plan providing meaningful benefits for the treatment of opioid use disorder in the outpatient, in-network and prescription drug classifications.

(3) * * *

(i) * * *

(A) *Substantially all.* For purposes of this paragraph (c)(3), a type of financial requirement or quantitative treatment limitation is considered to apply to substantially all medical/surgical benefits in a classification of benefits if it applies to at least two-thirds of all medical/surgical benefits in that classification. (For purposes of this paragraph (c)(3)(i)(A), benefits expressed as subject to a zero level of a type of financial requirement are treated as benefits not subject to that type of financial requirement, and benefits expressed as subject to a quantitative treatment limitation that is unlimited are treated as benefits not subject to that type of quantitative treatment limitation.) If a type of financial requirement or quantitative treatment limitation does not apply to at least two-thirds of all medical/surgical benefits in a classification, then that type cannot be applied to mental health or substance use disorder benefits in that classification.

* * * * *

(C) *Portion based on plan payments.* For purposes of this paragraph (c)(3), the determination of the portion of medical/surgical benefits in a classification of benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation) is based on the dollar amount of all plan payments for medical/surgical benefits in the classification expected to be paid under the plan for the plan year (or for

the portion of the plan year after a change in plan benefits that affects the applicability of the financial requirement or quantitative treatment limitation).

(D) *Clarifications for certain threshold requirements.* For any deductible, the dollar amount of plan payments includes all plan payments with respect to claims that would be subject to the deductible if it had not been satisfied. For any out-of-pocket maximum, the dollar amount of plan payments includes all plan payments associated with out-of-pocket payments that are taken into account towards the out-of-pocket maximum as well as all plan payments associated with out-of-pocket payments that would have been made towards the out-of-pocket maximum if it had not been satisfied. The rules of this paragraph (c)(3)(i)(D) apply for any other thresholds at which the rate of plan payment changes. (See also PHS Act section 2707 and Affordable Care Act section 1302(c), which establish annual limitations on out-of-pocket maximums for all non-grandfathered health plans.)

* * * * *

(iii) *Special rules.* Unless specifically permitted under this paragraph (c)(3)(iii), sub-classifications are not permitted when applying the rules of paragraph (c)(3) of this section.

(A) *Multi-tiered prescription drug benefits.* If a plan (or health insurance coverage) applies different levels of financial requirements to different tiers of prescription drug benefits based on reasonable factors determined in accordance with the rules in paragraph (c)(4) of this section (relating to requirements for nonquantitative treatment limitations) and without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits, the plan (or health insurance coverage) satisfies the parity requirements of this paragraph (c) with respect to prescription drug benefits. Reasonable factors include cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up.

(B) *Multiple network tiers.* If a plan (or health insurance coverage) provides benefits through multiple tiers of in-network providers (such as an in-network tier of preferred providers with more generous cost-sharing to participants than a separate in-network tier of participating providers), the plan may divide its benefits furnished on an in-network basis into sub-classifications that reflect network tiers, if the tiering is based on reasonable factors determined in accordance with the rules in paragraph (c)(4) of this section (such

as quality, performance, and market standards) and without regard to whether a provider provides services with respect to medical/surgical benefits or mental health or substance use disorder benefits. After the sub-classifications are established, the plan or issuer may not impose any financial requirement or treatment limitation on mental health or substance use disorder benefits in any sub-classification that is more restrictive than the predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in the sub-classification using the methodology set forth in paragraph (c)(3)(i) of this section.

* * * * *

(iv) *Examples.* The rules of paragraphs (c)(3)(i) through (iii) of this section are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

(A) *Example 1—(1) Facts.* (i) For inpatient, out-of-network medical/surgical benefits, a group health plan imposes five levels of coinsurance. Using a reasonable method, the plan projects its payments for the upcoming year as follows:

TABLE 1 TO PARAGRAPH (c)(3)(iv)(A)(1)(i)

Coinurance rate	0%	10%	15%	20%	30%	Total.
Projected payments	\$200x	\$100x	\$450x	\$100x	\$150x	\$1,000x.
Percent of total plan costs	20%	10%	45%	10%	15%	
Percent subject to coinsurance level	N/A	12.5% (100x/800x)	56.25% (450x/800x)	12.5% (100x/800x)	18.75% (150x/800x).	

(ii) The plan projects plan costs of \$800x to be subject to coinsurance (\$100x + \$450x + \$100x + \$150x = \$800x). Thus, 80 percent (\$800x/\$1,000x) of the benefits are projected to be subject to coinsurance, and 56.25 percent of the benefits subject to coinsurance are projected to be subject to the 15 percent coinsurance level.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(A) (*Example 1*), the two-thirds

threshold of the substantially all standard is met for coinsurance because 80 percent of all inpatient, out-of-network medical/surgical benefits are subject to coinsurance. Moreover, the 15 percent coinsurance is the predominant level because it is applicable to more than one-half of inpatient, out-of-network medical/surgical benefits subject to the coinsurance requirement. The plan may not impose any level of coinsurance with

respect to inpatient, out-of-network mental health or substance use disorder benefits that is more restrictive than the 15 percent level of coinsurance.

(B) *Example 2—(1) Facts.* (i) For outpatient, in-network medical/surgical benefits, a plan imposes five different copayment levels. Using a reasonable method, the plan projects payments for the upcoming year as follows:

TABLE 2 TO PARAGRAPH (c)(3)(iv)(B)(1)(i)

Copayment amount	\$0	\$10	\$15	\$20	\$50	Total.
Projected payments	\$200x	\$200x	\$200x	\$300x	\$100x	\$1,000x.
Percent of total plan costs	20%	20%	20%	30%	10%	
Percent subject to copayments	N/A	25% (200x/800x)	25% (200x/800x)	37.5% (300x/800x)	12.5% (100x/800x).	

(ii) The plan projects plan costs of \$800x to be subject to copayments (\$200x + \$200x + \$300x + \$100x = \$800x). Thus, 80 percent (\$800x/\$1,000x) of the benefits are projected to be subject to a copayment.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(B) (*Example 2*), the two-thirds threshold of the substantially all standard is met for copayments because 80 percent of all

outpatient, in-network medical/surgical benefits are subject to a copayment. Moreover, there is no single level that applies to more than one-half of medical/surgical benefits in the classification subject to a copayment (for the \$10 copayment, 25%; for the \$15 copayment, 25%; for the \$20 copayment, 37.5%; and for the \$50 copayment, 12.5%). The plan can combine

any levels of copayment, including the highest levels, to determine the predominant level that can be applied to mental health or substance use disorder benefits. If the plan combines the highest levels of copayment, the combined projected payments for the two highest copayment levels, the \$50 copayment and the \$20 copayment, are not more than one-half of the outpatient, in-network

medical/surgical benefits subject to a copayment because they are exactly one-half (\$300x + \$100x = \$400x; \$400x/\$800x = 50%). The combined projected payments for the three highest copayment levels—the \$50 copayment, the \$20 copayment, and the \$15 copayment—are more than one-half of the outpatient, in-network medical/surgical benefits subject to the copayments (\$100x + \$300x + \$200x = \$600x; \$600x/\$800x = 75%). Thus, the plan may not impose any copayment on outpatient, in-network mental health or substance use disorder benefits that is more restrictive than the least restrictive copayment in the combination, the \$15 copayment.

(C) *Example 3—(1) Facts.* A plan imposes a \$250 deductible on all medical/surgical benefits for self-only coverage and a \$500

deductible on all medical/surgical benefits for family coverage. The plan has no network of providers. For all medical/surgical benefits, the plan imposes a coinsurance requirement. The plan imposes no other financial requirements or treatment limitations.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(C) (*Example 3*), because the plan has no network of providers, all benefits are provided out-of-network. Because self-only and family coverage are subject to different deductibles, whether the deductible applies to substantially all medical/surgical benefits is determined separately for self-only medical/surgical benefits and family medical/surgical benefits. Because the coinsurance is applied without regard to coverage units, the predominant coinsurance

that applies to substantially all medical/surgical benefits is determined without regard to coverage units.

(D) *Example 4—(1) Facts.* A plan applies the following financial requirements for prescription drug benefits. The requirements are applied without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits. Moreover, the process for certifying a particular drug as “generic”, “preferred brand name”, “non-preferred brand name”, or “specialty” complies with the rules of paragraph (c)(4) of this section (relating to requirements for nonquantitative treatment limitations).

TABLE 3 TO PARAGRAPH (c)(3)(iv)(D)(1)

	Tier 1	Tier 2	Tier 3	Tier 4
Tier description	Generic drugs	Preferred brand name drugs ..	Non-preferred brand name drugs (which may have Tier 1 or Tier 2 alternatives).	Specialty drugs.
Percent paid by plan	90%	80%	60%	50%.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(D) (*Example 4*), the financial requirements that apply to prescription drug benefits are applied without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits; the process for certifying drugs in different tiers complies with paragraph (c)(4) of this section; and the bases for establishing different levels or types of financial requirements are reasonable. The financial requirements applied to prescription drug benefits do not violate the parity requirements of this paragraph (c)(3).

(E) *Example 5—(1) Facts.* A plan has two tiers of network of providers: a preferred provider tier and a participating provider tier. Providers are placed in either the preferred tier or participating tier based on reasonable factors determined in accordance with the rules in paragraph (c)(4) of this section, such as accreditation, quality and performance measures (including customer feedback), and relative reimbursement rates. Furthermore, provider tier placement is determined without regard to whether a provider specializes in the treatment of mental health conditions or substance use disorders, or medical/surgical conditions. The plan divides the in-network classifications into two sub-classifications (in-network/preferred and in-network/participating). The plan does not impose any financial requirement or treatment limitation on mental health or substance use disorder benefits in either of these sub-classifications that is more restrictive than the predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in each sub-classification.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(E) (*Example 5*), the division of in-network benefits into sub-classifications that reflect the preferred and participating provider tiers does not violate the parity requirements of this paragraph (c)(3).

(F) *Example 6—(1) Facts.* With respect to outpatient, in-network benefits, a plan imposes a \$25 copayment for office visits and a 20 percent coinsurance requirement for outpatient surgery. The plan divides the outpatient, in-network classification into two sub-classifications (in-network office visits and all other outpatient, in-network items and services). The plan or issuer does not impose any financial requirement or quantitative treatment limitation on mental health or substance use disorder benefits in either of these sub-classifications that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in each sub-classification.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(F) (*Example 6*), the division of outpatient, in-network benefits into sub-classifications for office visits and all other outpatient, in-network items and services does not violate the parity requirements of this paragraph (c)(3).

(G) *Example 7—(1) Facts.* Same facts as in paragraph (c)(3)(iv)(F)(1) of this section (*Example 6*), but for purposes of determining parity, the plan divides the outpatient, in-network classification into outpatient, in-network generalists and outpatient, in-network specialists.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(G) (*Example 7*), the division of outpatient, in-network benefits into any sub-classifications other than office visits and all other outpatient items and services violates the requirements of paragraph (c)(3)(iii)(C) of this section.

* * * * *

(4) *Nonquantitative treatment limitations.* Consistent with paragraph (a)(1) of this section, a group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) may not impose any nonquantitative treatment limitation

with respect to mental health or substance use disorder benefits in any classification that is more restrictive, as written or in operation, than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification. For purposes of this paragraph (c)(4), a nonquantitative treatment limitation is more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification if the plan or issuer fails to meet the requirements of paragraph (c)(4)(i) or (iii) of this section. In such a case, the plan (or health insurance coverage) will be considered to violate PHS Act section 2726 (a)(3)(A)(ii), and the nonquantitative treatment limitation may not be imposed by the plan (or health insurance coverage) with respect to mental health or substance use disorder benefits in the classification.

(i) *Requirements related to design and application of a nonquantitative treatment limitation—(A) In general.* A plan (or health insurance coverage) may not impose a nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in any classification unless, under the terms of the plan (or health insurance coverage), as written and in operation, any processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, the processes,

strategies, evidentiary standards, or other factors used in designing and applying the limitation with respect to medical/surgical benefits in the classification.

(B) *Prohibition on discriminatory factors and evidentiary standards.* For purposes of determining comparability and stringency under paragraph (c)(4)(i)(A) of this section, a plan (or health insurance coverage) may not rely upon discriminatory factors or evidentiary standards to design a nonquantitative treatment limitation to be imposed on mental health or substance use disorder benefits. A factor or evidentiary standard is discriminatory if the information, evidence, sources, or standards on which the factor or evidentiary standard are based are biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits.

(1) Information, evidence, sources, or standards are considered to be biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits if, based on all the relevant facts and circumstances, the information, evidence, sources, or standards systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits. For purposes of this paragraph (c)(4)(i)(B)(1), relevant facts and circumstances may include, but are not limited to, the reliability of the source of the information, evidence, sources, or standards, including any underlying data; the independence of the information, evidence, sources, and standards relied upon; the analyses and methodologies employed to select the information and the consistency of their application; and any known safeguards deployed to prevent reliance on skewed data or metrics. Information, evidence, sources, or standards are not considered biased or not objective for this purpose if the plan or issuer has taken the steps necessary to correct, cure, or supplement any information, evidence, sources, or standards that would have been biased or not objective in the absence of such steps.

(2) For purposes of this paragraph (c)(4)(i)(B), historical plan data or other historical information from a time when the plan or coverage was not subject to PHS Act section 2726 or was not in compliance with PHS Act section 2726 are considered to be biased or not objective in a manner that discriminates against mental health or substance use

disorder benefits as compared to medical/surgical benefits, if the historical plan data or other historical information systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits, and the plan or issuer has not taken the steps necessary to correct, cure, or supplement the data or information.

(3) For purposes of this paragraph (c)(4)(i)(B), generally recognized independent professional medical or clinical standards and carefully circumscribed measures reasonably and appropriately designed to detect or prevent and prove fraud and abuse that minimize the negative impact on access to appropriate mental health and substance use disorder benefits are not information, evidence, sources, or standards that are biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits. However, plans and issuers must comply with the other requirements in this paragraph (c)(4), as applicable, with respect to such standards or measures that are used as the basis for a factor or evidentiary standard used to design or apply a nonquantitative treatment limitation.

(ii) *Illustrative, non-exhaustive list of nonquantitative treatment limitations.* Nonquantitative treatment limitations include—

(A) Medical management standards (such as prior authorization) limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative;

(B) Formulary design for prescription drugs;

(C) For plans with multiple network tiers (such as preferred providers and participating providers), network tier design;

(D) Standards related to network composition, including but not limited to, standards for provider and facility admission to participate in a network or for continued network participation, including methods for determining reimbursement rates, credentialing standards, and procedures for ensuring the network includes an adequate number of each category of provider and facility to provide services under the plan or coverage;

(E) Plan or issuer methods for determining out-of-network rates, such as allowed amounts; usual, customary, and reasonable charges; or application of other external benchmarks for out-of-network rates;

(F) Refusal to pay for higher-cost therapies until it can be shown that a lower-cost therapy is not effective (also known as fail-first policies or step therapy protocols);

(G) Exclusions based on failure to complete a course of treatment; and

(H) Restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits for services provided under the plan or coverage.

(iii) *Required use of outcomes data—*
(A) *In general.* To ensure that a nonquantitative treatment limitation applicable to mental health or substance use disorder benefits in a classification, in operation, is no more restrictive than the predominant nonquantitative treatment limitation applied to substantially all medical/surgical benefits in the classification, a plan or issuer must collect and evaluate relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits and carefully consider the impact as part of the plan's or issuer's evaluation. As part of its evaluation, the plan or issuer may not disregard relevant outcomes data that it knows or reasonably should know suggest that a nonquantitative treatment limitation is associated with material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits. The Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, may specify in guidance the type, form, and manner of collection and evaluation for the data required under this paragraph (c)(4)(iii)(A).

(1) *Relevant data generally.* For purposes of this paragraph (c)(4)(iii)(A), relevant data could include, as appropriate, but are not limited to, the number and percentage of claims denials and any other data relevant to the nonquantitative treatment limitation required by State law or private accreditation standards.

(2) *Relevant data for nonquantitative treatment limitations related to network composition.* In addition to the relevant data set forth in paragraph (c)(4)(iii)(A)(1) of this section, relevant data for nonquantitative treatment limitations related to network composition could include, as appropriate, but are not limited to, in-network and out-of-network utilization rates (including data related to provider claim submissions), network adequacy metrics (including time and distance

data, and data on providers accepting new patients), and provider reimbursement rates (for comparable services and as benchmarked to a reference standard).

(3) *Unavailability of data.* (i) If a plan or issuer newly imposes a nonquantitative treatment limitation for which relevant data is initially temporarily unavailable and the plan or issuer therefore cannot comply with this paragraph (c)(4)(iii)(A), the plan or issuer must include in its comparative analysis, as required under § 146.137(c)(5)(i)(C), a detailed explanation of the lack of relevant data, the basis for the plan's or issuer's conclusion that there is a lack of relevant data, and when and how the data will become available and be collected and analyzed. Such a plan or issuer also must comply with this paragraph (c)(4)(iii)(A) as soon as practicable once relevant data becomes available.

(ii) If a plan or issuer imposes a nonquantitative treatment limitation for which no data exist that can reasonably assess any relevant impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits, the plan or issuer must include in its comparative analysis, as required under § 146.137(c)(5)(i)(D), a reasoned justification as to the basis for the conclusion that there are no data that can reasonably assess the nonquantitative treatment limitation's impact, why the nature of the nonquantitative treatment limitation prevents the plan or issuer from reasonably measuring its impact, an explanation of what data was considered and rejected, and documentation of any additional safeguards or protocols used to ensure the nonquantitative treatment limitation complies with this section. If a plan or issuer becomes aware of data that can reasonably assess any relevant impact of the nonquantitative treatment limitation, the plan or issuer must comply with this paragraph (c)(4)(iii)(A) as soon as practicable.

(iii) Consistent with paragraph (a)(1) of this section, paragraphs (c)(4)(iii)(A)(3)(i) and (ii) of this section shall only apply in very limited circumstances and, where applicable, shall be construed narrowly.

(B) *Material differences.* To the extent the relevant data evaluated under paragraph (c)(4)(iii)(A) of this section suggest that the nonquantitative treatment limitation contributes to material differences in access to mental health and substance use disorder

benefits as compared to medical/surgical benefits in a classification, such differences will be considered a strong indicator that the plan or issuer violates this paragraph (c)(4).

(1) Where the relevant data suggest that the nonquantitative treatment limitation contributes to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits in a classification, the plan or issuer must take reasonable action, as necessary, to address the material differences to ensure compliance, in operation, with this paragraph (c)(4) and must document the actions that have been or are being taken by the plan or issuer to address material differences in access to mental health or substance use disorder benefits, as compared to medical/surgical benefits, as required by § 146.137(c)(5)(iv).

(2) For purposes of this paragraph (c)(4)(iii)(B), relevant data are considered to suggest that the nonquantitative treatment limitation contributes to material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits if, based on all relevant facts and circumstances, and taking into account the considerations outlined in this paragraph (c)(4)(iii)(B)(2), the difference in the data suggests that the nonquantitative treatment limitation is likely to have a negative impact on access to mental health or substance use disorder benefits as compared to medical/surgical benefits.

(i) Relevant facts and circumstances, for purposes of this paragraph (c)(4)(iii)(B)(2), may include, but are not limited to, the terms of the nonquantitative treatment limitation at issue, the quality or limitations of the data, causal explanations and analyses, evidence as to the recurring or non-recurring nature of the results, and the magnitude of any disparities.

(ii) Differences in access to mental health or substance use disorder benefits attributable to generally recognized independent professional medical or clinical standards or carefully circumscribed measures reasonably and appropriately designed to detect or prevent and prove fraud and abuse that minimize the negative impact on access to appropriate mental health and substance use disorder benefits, which are used as the basis for a factor or evidentiary standard used to design or apply a nonquantitative treatment limitation, are not considered to be material for purposes of this paragraph (c)(4)(iii)(B). To the extent a plan or issuer attributes any differences in

access to the application of such standards or measures, the plan or issuer must explain the bases for that conclusion in the documentation prepared under § 146.137(c)(5)(iv)(A).

(C) *Nonquantitative treatment limitations related to network composition.* For purposes of applying paragraph (c)(4)(iii)(A) of this section with respect to nonquantitative treatment limitations related to network composition, a plan or issuer must collect and evaluate relevant data in a manner reasonably designed to assess the aggregate impact of all such nonquantitative treatment limitations on access to mental health and substance use disorder benefits and medical/surgical benefits. Examples of possible actions that a plan or issuer could take to comply with the requirement under paragraph (c)(4)(iii)(B)(1) of this section to take reasonable action, as necessary, to address any material differences in access with respect to nonquantitative treatment limitations related to network composition, to ensure compliance with this paragraph (c)(4), include, but are not limited to:

(1) Strengthening efforts to recruit and encourage a broad range of available mental health and substance use disorder providers and facilities to join the plan's or issuer's network of providers, including taking actions to increase compensation or other inducements, streamline credentialing processes, or contact providers reimbursed for items and services provided on an out-of-network basis to offer participation in the network;

(2) Expanding the availability of telehealth arrangements to mitigate any overall mental health and substance use disorder provider shortages in a geographic area;

(3) Providing additional outreach and assistance to participants and beneficiaries enrolled in the plan or coverage to assist them in finding available in-network mental health and substance use disorder providers and facilities; and

(4) Ensuring that provider directories are accurate and reliable.

(iv) *Prohibition on separate nonquantitative treatment limitations applicable only to mental health or substance use disorder benefits.* Consistent with paragraph (c)(2)(i) of this section, a group health plan (or health insurance coverage offered by an issuer in connection with such a plan) may not apply any nonquantitative treatment limitation that is applicable only with respect to mental health or substance use disorder benefits and does not apply with respect to any

medical/surgical benefits in the same benefit classification.

(v) *Effect of final determination of noncompliance under § 146.137.* (A) If a group health plan (or health insurance issuer offering coverage in connection with a group health plan) receives a final determination from the Secretary or applicable State authority that the plan or issuer is not in compliance with the requirements of PHS Act section 2726(a)(8) or § 146.137 with respect to a nonquantitative treatment limitation, the nonquantitative treatment limitation violates this paragraph (c)(4) and the Secretary or applicable State authority may direct the plan or issuer not to impose the nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in the relevant classification, unless and until the plan or issuer demonstrates to the Secretary or applicable State authority compliance with the requirements of this section or takes appropriate action to remedy the violation.

(B) A determination by the Secretary of whether to require cessation of a nonquantitative treatment limitation under this paragraph (c)(4)(v) will be based on an evaluation of the relevant facts and circumstances involved in the specific final determination and the nature of the underlying nonquantitative treatment limitation and will take into account the interest of plan participants and beneficiaries and feedback from the plan or issuer.

(vi) *Examples.* The rules of this paragraph (c)(4) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

(A) *Example 1 (not comparable and more stringent factors for reimbursement rate methodology, in operation)*—(1) *Facts.* A plan's reimbursement rate methodology for outpatient, in-network providers is based on a variety of factors. As written, for mental health, substance use disorder, and medical/surgical benefits, all reimbursement rates for physicians and non-physician practitioners for the same Current Procedural Terminology (CPT) code are based on a combination of factors, such as the nature of the service, duration of the service, intensity and specialization of training, provider licensure and type, number of providers qualified to provide the service in a given geographic area, and market need (demand). In operation, the plan utilizes an additional strategy to further reduce reimbursement rates for mental health and substance use disorder non-physician providers from those paid to mental health and substance use disorder physicians by the same percentage for every CPT code, but does not apply the

same reductions for non-physician medical/surgical providers.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(A) (*Example 1*), the plan violates the rules of this paragraph (c)(4). Because the plan reimburses non-physician providers of mental health and substance use disorder services by reducing their reimbursement rate from the rate for physician providers of mental health and substance use disorder services by the same percentage for every CPT code but does not apply the same reductions to non-physician providers of medical/surgical services from the rate for physician providers of medical/surgical services, in operation, the factors used in designing and applying the nonquantitative treatment limitation to mental health and substance use disorder benefits in the outpatient, in-network classification are not comparable to, and are applied more stringently than, the factors used in designing and applying the limitation with respect to medical/surgical benefits in the same classification. As a result, the nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in the outpatient, in-network classification is more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification.

(B) *Example 2 (strategy for exclusion for experimental or investigative treatment more stringently applied to ABA therapy in operation)*—(1) *Facts.* A plan, as written, generally excludes coverage for all treatments that are experimental or investigative for both medical/surgical benefits and mental health and substance use disorder benefits in the outpatient, in-network classification. As a result, the plan generally excludes, as experimental, a treatment or procedure when no professionally recognized treatment guidelines include the treatment or procedure as a clinically appropriate standard of care for the condition or disorder and fewer than two randomized controlled trials are available to support the treatment's use with respect to the given condition or disorder. The plan provides benefits for the treatment of ASD, which is a mental health condition, but, in operation, the plan excludes coverage for ABA therapy to treat children with ASD, deeming it experimental. More than one professionally recognized treatment guideline defines clinically appropriate standards of care for ASD and more than two randomized controlled trials are available to support the use of ABA therapy as one intervention to treat certain children with ASD.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(B) (*Example 2*), the plan violates the rules of this paragraph (c)(4). As written, the plan excludes coverage of experimental treatment of medical conditions and surgical procedures, mental health conditions, and substance use disorders when no professionally recognized treatment guidelines define clinically appropriate standards of care for the condition or disorder as including the treatment or procedure at issue, and fewer than two randomized controlled trials are available to

support the treatment's use with respect to the given condition or procedure. However, in operation, the plan deviates from this strategy with respect to ABA therapy because more than one professionally recognized treatment guideline defines clinically appropriate standards of care for ASD as including ABA therapy to treat certain children with ASD and more than two randomized controlled trials are available to support the use of ABA therapy to treat certain children with ASD. Therefore, in operation, the strategy used to design the nonquantitative treatment limitation for benefits for the treatment of ASD, which is a mental health condition, in the outpatient, in-network classification is not comparable to, and is applied more stringently than, the strategy used to design the nonquantitative treatment limitation for medical/surgical benefits in the same classification. As a result, the nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in the outpatient, in-network classification is more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification.

(C) *Example 3 (step therapy protocol with exception for severe or irreversible consequences, discriminatory factor)*—(1) *Facts.* A plan's written terms include a step therapy protocol that requires participants and beneficiaries who are prescribed certain drugs to try and fail a generic or preferred brand name drug before the plan will cover the drug originally prescribed by a participant's or beneficiary's attending provider. The plan provides an exception to this protocol that was developed solely based on a methodology developed by an external third-party organization. The third-party organization's methodology, which is not based on a generally recognized independent professional medical or clinical standard, identifies instances in which a delay in treatment with a drug prescribed for a medical condition or surgical procedure could result in either severe or irreversible consequences. However, with respect to a drug prescribed for a mental health condition or a substance use disorder, the third-party organization's methodology only identifies instances in which a delay in treatment could result in both severe and irreversible consequences, and the plan does not take any steps to correct, cure, or supplement the methodology.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(C) (*Example 3*), the plan violates the rules of paragraph (c)(4)(i)(B) of this section. The source upon which the factor used to apply the step therapy protocol is based is biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits because it addresses instances in which a delay in treatment with a drug prescribed for a medical condition or surgical procedure could result in either severe or irreversible consequences, but only addresses instances in which a delay in treatment with a drug prescribed for a mental health condition or substance use disorder could result in both

severe and irreversible consequences, and the plan fails to take the steps necessary to correct, cure, or supplement the methodology so that it is not biased and is objective. Based on the relevant facts and circumstances, this source systematically disfavors access or is specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits. Therefore, the factor used to apply the step therapy protocol is discriminatory for purposes of determining comparability and stringency under paragraph (c)(4)(i)(A) of this section, and may not be relied upon by the plan.

(D) *Example 4 (use of historical plan data and plan steps to correct, cure, or supplement)*—(1) *Facts.* A plan's methodology for calculating provider reimbursement rates relies only on historical plan data on total plan spending for each specialty, divided between mental health and substance use disorder providers and medical/surgical providers, from a time when the plan was not subject to PHS Act section 2726. The plan has used these historical plan data for many years to establish base reimbursement rates in all provider specialties for which it provides medical/surgical, mental health, and substance use disorder benefits in the inpatient, in-network classification. In evaluating the use of these historical plan data in the design of the methodology for calculating provider reimbursement rates, the plan determined, based on all the relevant facts and circumstances, that the historical plan data systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits. To ensure this information about historical reimbursement rates is not biased and is objective, the plan supplements its methodology to develop the base reimbursement rates for mental health and substance use disorder providers in accordance with additional information, evidence, sources, and standards that reflect the increased demand for mental health and substance use disorder benefits in the inpatient, in-network classification and to attract sufficient mental health and substance use disorder providers to the network, so that the relevant facts and circumstances indicate the supplemented information, evidence, sources, or standards do not systematically disfavor access and are not specifically designed to disfavor access to mental health and substance use disorder benefits as compared to medical/surgical benefits.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(D) (*Example 4*), the plan does not violate the rules of paragraph (c)(4)(i)(B) of this section with respect to the plan's methodology for calculating provider reimbursement rates in the inpatient, in-network classification. The relevant facts and circumstances indicate that the plan's use of only historical plan data to design its methodology for calculating provider reimbursement rates in the inpatient, in-network classification would otherwise be considered to be biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as

compared to medical/surgical benefits under paragraph (c)(4)(i)(B)(2) of this section, since the historical data systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits. However, the plan took the steps necessary to supplement the information, evidence, sources, and standards to reasonably reflect the increased demand for mental health and substance use disorder benefits in the inpatient, in-network classification, and adjust the methodology to increase reimbursement rates for those benefits, thereby ensuring that the information, evidence, sources, and standards relied upon by the plan for this purpose are not biased and are objective. Therefore, the factors and evidentiary standards used to design the plan's methodology for calculating provider reimbursement rates in the inpatient, in-network classification are not discriminatory.

(E) *Example 5 (generally recognized independent professional medical or clinical standards and more stringent prior authorization requirement in operation)*—(1) *Facts.* The provisions of a plan state that it relies on, and does not deviate from, generally recognized independent professional medical or clinical standards to inform the factor used to design prior authorization requirements for both medical/surgical and mental health and substance use disorder benefits in the prescription drug classification. The generally recognized independent professional medical standard for treatment of opioid use disorder that the plan utilizes—in this case, the American Society of Addiction Medicine national practice guidelines—does not support prior authorization every 30 days for buprenorphine/naloxone. However, in operation, the plan requires prior authorization for buprenorphine/naloxone combination for treatment of opioid use disorder, every 30 days, which is inconsistent with the generally recognized independent professional medical standard on which the factor used to design the limitation is based. The plan's factor used to design prior authorization requirements for medical/surgical benefits in the prescription drug classification relies on, and does not deviate from, generally recognized independent professional medical or clinical standards.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(E) (*Example 5*), the plan violates the rules of this paragraph (c)(4). The American Society of Addiction Medicine national practice guidelines on which the factor used to design prior authorization requirements for substance use disorder benefits is based are generally recognized independent professional medical or clinical standards that are not considered to be biased or not objective in a manner that discriminates against mental health and substance use disorder benefits under paragraph (c)(4)(i)(B)(3) of this section. However, the plan must comply with other requirements in this paragraph (c)(4), as applicable, with respect to such standards or measures that are used as the basis for a factor or evidentiary standard used to design or apply

a nonquantitative treatment limitation. In operation, the plan's factor used to design and apply prior authorization requirements with respect to substance use disorder benefits is not comparable to, and is applied more stringently than, the same factor used to design and apply prior authorization requirements for medical/surgical benefits, because the factor relies on, and does not deviate from, generally recognized independent professional medical or clinical standards for medical/surgical benefits, but deviates from the relevant guidelines for substance use disorder benefits. As a result, the nonquantitative treatment limitation with respect to substance use disorder benefits in the prescription drug classification is more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification.

(F) *Example 6 (plan claims no data exist to reasonably assess impact of nonquantitative treatment limitation on access; medical necessity criteria)*—(1) *Facts.* A plan approves or denies claims for mental health and substance use disorder benefits and for medical/surgical benefits in the inpatient, in-network and outpatient, in-network classifications based on medical necessity criteria. The plan states in its comparative analysis that no data exist that can reasonably assess any relevant impact of the medical necessity criteria nonquantitative treatment limitation on relevant outcomes related to access to mental health or substance use disorder benefits as compared to the plan's medical necessity criteria nonquantitative treatment limitation's impact on relevant outcomes related to access to medical/surgical benefits in the relevant classifications, without further explanation.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(F) (*Example 6*), the plan violates this paragraph (c)(4). The plan does not comply with paragraph (c)(4)(iii)(A)(3)(ii) of this section because the plan did not include in its comparative analysis, as required under § 146.137(c)(5)(i)(D), a reasoned justification as to the basis for its conclusion that there are no data that can reasonably assess the nonquantitative treatment limitation's impact, an explanation of why the nature of the nonquantitative treatment limitation prevents the plan from reasonably measuring its impact, an explanation of what data was considered and rejected, and documentation of any additional safeguards or protocols used to ensure the nonquantitative treatment limitation complies with this paragraph (c)(4). Data that could reasonably assess the medical necessity criteria nonquantitative treatment limitation's impact might include, for example, the number and percentage of claims denials, or the number and percentage of claims that were approved for a lower level of care than the level requested on the initial claim. Therefore, because the plan has not collected and evaluated relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits in the relevant classifications, the plan violates the requirements of paragraph

(c)(4)(iii) of this section, and violates the requirements under § 146.137(c)(5)(i)(D) because it did not include sufficient information in its comparative analysis with respect to the lack of relevant data.

(G) *Example 7 (concurrent review data collection; no material difference in access)*—

(1) *Facts.* A plan follows a written process to apply a concurrent review nonquantitative treatment limitation to all medical/surgical benefits and mental health and substance use disorder benefits within the inpatient, in-network classification. Under this process, a first-level review is conducted in every instance in which concurrent review applies and an authorization request is approved by the first-level reviewer only if the clinical information submitted by the facility meets the plan's criteria for a continued stay. If the first-level reviewer is unable to approve the authorization request because the clinical information submitted by the facility does not meet the plan's criteria for a continued stay, it is sent to a second-level reviewer who will either approve or deny the request. The plan collects relevant data, including the number of referrals to second-level review, and the number of denials of claims for medical/surgical benefits and mental health and substance use disorder benefits subject to concurrent review as compared to the total number of claims subject to concurrent review, in the inpatient, in-network classification. The plan also collects and evaluates the number of denied claims for medical/surgical benefits and mental health and substance use disorder benefits that are overturned on appeal in the inpatient, in-network classification. The plan evaluates the relevant data and determines that, based on the relevant facts and circumstances, the data do not suggest that the concurrent review nonquantitative treatment limitation contributes to material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits in the classification. Upon requesting the plan's comparative analysis for the concurrent review nonquantitative treatment limitation and reviewing the relevant data, the Secretary does not request additional data and agrees that the data do not suggest material differences in access.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(G) (*Example 7*), the plan does not violate the rules of paragraph (c)(4)(iii) of this section. The plan collected and evaluated relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits and considered the impact as part of its evaluation. Because the relevant data evaluated do not suggest that the nonquantitative treatment limitation contributes to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits in the inpatient, in-network classification, under paragraph (c)(4)(iii)(B) of this section, there is no strong indicator that the plan violates this paragraph (c)(4).

(H) *Example 8 (material difference in access for prior authorization requirement with reasonable action)*—(1) *Facts.* A plan

requires prior authorization that a treatment is medically necessary for all inpatient, in-network medical/surgical benefits and for all inpatient, in-network mental health and substance use disorder benefits. The plan collects and evaluates relevant data in a manner reasonably designed to assess the impact of the prior authorization requirement on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits in the inpatient, in-network classification. The plan's written process for prior authorization states that the plan approves inpatient, in-network benefits for medical conditions and surgical procedures and mental health and substance use disorder benefits for periods of 1, 3, and 7 days, after which a treatment plan must be submitted by the patient's attending provider and approved by the plan. Approvals for mental health and substance use disorder benefits are most commonly given only for 1 day, after which a treatment plan must be submitted by the patient's attending provider and approved by the plan. The relevant data show that approvals for 7 days are most common for medical conditions and surgical procedures under this plan. Based on all the relevant facts and circumstances, the difference in the relevant data suggests that the nonquantitative treatment limitation is likely to have a negative impact on access to mental health and substance use disorder benefits as compared to medical/surgical benefits. Therefore, the data suggest that the nonquantitative treatment limitation contributes to material differences in access. To address these material differences in access, the plan consults more recent medical guidelines to update the factors that inform its medical necessity nonquantitative treatment limitations. Based on this review, the plan modifies the limitation so that inpatient, in-network prior authorization requests for mental health or substance use disorder benefits are approved for similar periods to what is approved for medical/surgical benefits. The plan includes documentation of this action as part of its comparative analysis.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(H) (*Example 8*), the plan does not violate the rules of paragraph (c)(4)(iii) of this section. While relevant data for the plan's prior authorization requirements suggested that the nonquantitative treatment limitation contributes to material differences in access to mental health and substance use disorder benefits as compared to inpatient, in-network medical/surgical benefits under paragraph (c)(4)(iii)(B) of this section, the plan has taken reasonable action, as necessary, to ensure compliance, in operation, with this paragraph (c)(4) by updating the factors that inform its prior authorization nonquantitative treatment limitation for inpatient, in-network mental health and substance use disorder benefits so that these benefits are approved for similar periods to what is approved for medical/surgical benefits. The plan also documents its action taken to address material differences in access to inpatient, in-network benefits as required by paragraph (c)(4)(iii)(B)(1) of this section.

(I) *Example 9 (differences attributable to generally recognized independent professional medical or clinical standards)*—

(1) *Facts.* A group health plan develops a medical management requirement for all inpatient, out-of-network benefits for both medical/surgical benefits and mental health and substance use disorder benefits to ensure treatment is medically necessary. The factors and evidentiary standards used to design and apply the medical management requirement rely on independent professional medical or clinical standards that are generally recognized by health care providers and facilities in relevant clinical specialties. The processes, strategies, evidentiary standards, and other factors used in designing and applying the medical management requirement to mental health and substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the requirement with respect to medical/surgical benefits. The plan collects and evaluates relevant data in a manner reasonably designed to assess the impact of the medical management nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits, and considers the impact as part of the plan's evaluation, as required by paragraph (c)(4)(iii)(A) of this section. Within the inpatient, out-of-network classification, the application of the medical management requirement results in a higher percentage of denials for mental health and substance use disorder claims than medical/surgical claims, because the benefits were found to be medically necessary for a lower percentage of mental health and substance use disorder claims. The plan correctly determines that these differences in access are attributable to the generally recognized independent professional medical or clinical standards used as the basis for the factors and evidentiary standards used to design or apply the limitation and adequately explains the bases for that conclusion as part of its comparative analysis.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(I) (*Example 9*), the plan does not violate the rules of this paragraph (c)(4). Generally recognized independent professional medical or clinical standards of care are not considered to be information, evidence, sources, or standards that are biased and not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits, and the plan otherwise complies with the requirements in paragraph (c)(4)(i) of this section. Additionally, the plan does not violate paragraph (c)(4)(iii) of this section because it has collected and evaluated relevant data, the differences in access are attributable to the generally recognized independent professional medical or clinical standards that are used as the basis for the factors and evidentiary standards used to design or apply the medical management nonquantitative treatment limitation, and the plan explains the bases for this conclusion in its comparative analysis. As a result, the

nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in the inpatient, out-of-network classification is no more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification.

(J) *Example 10 (material differences in access for standards for provider admission to a network with reasonable action)*—(1) *Facts.* A plan applies nonquantitative treatment limitations related to network composition in the inpatient, in-network and outpatient, in-network classifications. The plan's networks are constructed by separate service providers for medical/surgical benefits and mental health and substance use disorder benefits. The processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitations related to network composition for mental health or substance use disorder benefits in the outpatient, in-network and inpatient, in-network classifications are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitations with respect to medical/surgical benefits in the classifications, as required under paragraph (c)(4)(i) of this section. In order to ensure, in operation, that the nonquantitative treatment limitations are no more restrictive than the predominant nonquantitative treatment limitations applied to substantially all medical/surgical benefits in the classification, the plan collects and evaluates relevant data in a manner reasonably designed to assess the aggregate impact of all the nonquantitative treatment limitations related to network composition on relevant outcomes related to access to mental health and substance use disorder benefits as compared with access to medical/surgical benefits and considers the impact as part of the plan's evaluation. The plan considers relevant data that is known, or reasonably should be known, including metrics relating to the time and distance from plan participants and beneficiaries to network providers in rural and urban regions; the number of network providers accepting new patients; the proportions of mental health and substance use disorder and medical/surgical providers and facilities that provide services in rural and urban regions who are in the plan's network; provider reimbursement rates (for comparable services and benchmarked to a reference standard, as appropriate); and in-network and out-of-network utilization rates (including data related to the dollar value and number of provider claims submissions). The plan determines that the relevant data suggest that the nonquantitative treatment limitations in the aggregate contribute to material differences in access to mental health and substance use disorder benefits compared to medical/surgical benefits in the classifications because, based on all the relevant facts and circumstances, the differences in the data suggest that the nonquantitative treatment limitations related to network composition are likely to have a

negative impact on access to mental health or substance use disorder benefits as compared to medical/surgical benefits. The plan takes reasonable actions, as necessary, to address the material differences in access, to ensure compliance, in operation, with this paragraph (c)(4), by strengthening its efforts to recruit and encourage a broad range of available providers and facilities to join the plan's network of providers, including by taking actions to increase compensation and other inducements, streamline credentialing processes, contact providers reimbursed for items and services provided on an out-of-network basis to offer participation in the network, and develop a process to monitor the effects of such efforts; expanding the availability of telehealth arrangements to mitigate overall provider shortages in certain geographic areas; providing additional outreach and assistance to participants and beneficiaries enrolled in the plan to assist them in finding available in-network providers and facilities; and ensuring that the plan's provider directories are accurate and reliable. The plan documents the efforts that it has taken to address the material differences in access that the data revealed, and the plan includes the documentation as part of its comparative analysis submission.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(J) (*Example 10*), the plan does not violate the rules of this paragraph (c)(4). The plan's nonquantitative treatment limitations related to network composition comply with the rules of paragraph (c)(4)(i) of this section. Additionally, the plan collects and evaluates relevant data, as required under paragraph (c)(4)(iii)(A) of this section, in a manner reasonably designed to assess the aggregate impact of all such nonquantitative treatment limitations on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits, as required under paragraph (c)(4)(iii)(C) of this section. While the data suggest that the nonquantitative treatment limitations contribute to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, the plan has taken reasonable action, as necessary, to ensure compliance with this paragraph (c)(4). The plan also documents the actions that have been and are being taken by the plan to address material differences as required by § 146.137(c)(5)(iv). As a result, the network composition nonquantitative treatment limitations with respect to mental health or substance use disorder benefits in the inpatient, in-network and outpatient, in-network classifications are no more restrictive than the predominant nonquantitative treatment limitations that apply to substantially all medical/surgical benefits in the same classifications.

(K) *Example 11 (separate EAP exhaustion treatment limitation applicable only to mental health or substance use disorder benefits)*—(1) *Facts.* An employer maintains both a major medical plan and an employee assistance program (EAP). The EAP provides, among other benefits, a limited number of mental health or substance use disorder counseling sessions, which, together with other benefits provided by the EAP, are not

significant benefits in the nature of medical care. Participants are eligible for mental health or substance use disorder benefits under the major medical plan only after exhausting the counseling sessions provided by the EAP. No similar exhaustion requirement applies with respect to medical/surgical benefits provided under the major medical plan.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(K) (*Example 11*), the requirement that limits eligibility for mental health and substance use disorder benefits under the major medical plan until EAP benefits are exhausted is a nonquantitative treatment limitation subject to the parity requirements of this paragraph (c)(4). Because the limitation does not apply to medical/surgical benefits, it is a separate nonquantitative treatment limitation applicable only to mental health and substance use disorder benefits that violates paragraph (c)(4)(iv) of this section. Additionally, this EAP would not qualify as excepted benefits under § 146.145(b)(3)(vi)(B)(1) because participants in the major medical plan are required to use and exhaust benefits under the EAP (making the EAP a gatekeeper) before an individual is eligible for benefits under the plan.

(L) *Example 12 (separate exclusion for treatment in a residential facility applicable only to mental health and substance use disorder benefits)*—(1) *Facts.* A plan generally covers inpatient, in-network and outpatient, out-of-network treatment without any limitations on setting, including skilled nursing facilities and rehabilitation hospitals, provided other medical necessity standards are satisfied. The plan has an exclusion for treatment at residential facilities, which the plan defines as an inpatient benefit for mental health and substance use disorder benefits. This exclusion was not generated through any broader nonquantitative treatment limitation (such as medical necessity or other clinical guideline).

(2) *Conclusion.* In this paragraph (c)(4)(vi)(L) (*Example 12*), the plan violates the rules of paragraph (c)(4)(iv) of this section. The exclusion of treatment at residential facilities is a separate nonquantitative treatment limitation applicable only to mental health and substance use disorder benefits in the inpatient, in-network and outpatient, out-of-network classifications because the plan does not apply a comparable exclusion with respect to any medical/surgical benefits in the same benefit classification.

(M) *Example 13 (impermissible nonquantitative treatment limitation imposed following a final determination of noncompliance and direction by the Secretary)*—(1) *Facts.* Following an initial request by the Secretary for a plan's comparative analysis of the plan's exclusion of mental health and substance use disorder benefits for failure to complete a course of treatment in the inpatient, in-network classification under § 146.137(d), the plan submits a comparative analysis for the nonquantitative treatment limitation. After review of the comparative analysis, as well as additional information submitted by the plan after the Secretary determines that the plan has not submitted sufficient information

to be responsive to the request, the Secretary makes an initial determination that the comparative analysis fails to demonstrate that the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the inpatient, in-network classification are comparable to, and applied no more stringently than, those used in designing and applying the limitation to medical/surgical benefits in the classification. Under § 146.137(d)(3), the plan submits a corrective action plan and additional comparative analyses within 45 calendar days after the initial determination. However, the corrective action plan does not alter or eliminate the exclusion or alter the processes, strategies, evidentiary standards, and other factors used in designing and applying the exclusion. Moreover, the additional comparative analysis still does not include sufficient information. The Secretary then determines that the additional comparative analyses do not demonstrate compliance with the requirements of this paragraph (c)(4). Accordingly, the plan receives a final determination of noncompliance with PHS Act section 2726 (a)(8) and § 146.137 from the Secretary, which concludes that the plan did not demonstrate compliance through the comparative analysis process. After considering the relevant facts and circumstances, and considering the interests of plan participants and beneficiaries, as well as feedback from the plan, the Secretary directs the plan not to impose the nonquantitative treatment limitation by a certain date, unless and until the plan demonstrates compliance to the Secretary or takes appropriate action to remedy the violation. The plan makes no changes to its plan terms by that date and continues to impose the exclusion of benefits for failure to complete a course of treatment in the inpatient, in-network classification.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(M) (*Example 13*), by continuing to impose the exclusion of mental health and substance use disorder benefits for failure to complete a course of treatment in the inpatient, in-network classification after the Secretary directs the plan not to impose this nonquantitative treatment limitation, the plan violates the requirements of paragraph (c)(4)(v) of this section.

* * * * *

(d) * * *

(3) *Provisions of other law.*

Compliance with the disclosure requirements in paragraphs (d)(1) and (2) of this section is not determinative of compliance with any other provision of applicable Federal or State law. In particular, in addition to those disclosure requirements, provisions of other applicable law require disclosure of information relevant to medical/surgical, mental health, and substance use disorder benefits. For example, § 147.136 of this subchapter sets forth rules regarding claims and appeals, including the right of claimants (or their

authorized representative) who have received an adverse benefit determination (or a final internal adverse benefit determination) to be provided, upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant to the claimant's claim for benefits. This includes documents with information on medical necessity criteria for both medical/surgical benefits and mental health and substance use disorder benefits, as well as the processes, strategies, evidentiary standards, and other factors used to apply a nonquantitative treatment limitation with respect to medical/surgical benefits and mental health or substance use disorder benefits under the plan and the comparative analyses and other applicable information required by § 146.137.

(e) * * *

(4) *Coordination with EHB requirements.* Nothing in paragraph (f) or (g) of this section or § 146.137(g) changes the requirements of §§ 147.150 and 156.115 of this subchapter, providing that a health insurance issuer offering non-grandfathered health insurance coverage in the individual or small group market that is required to provide mental health and substance use disorder services, including behavioral health treatment services, as part of essential health benefits required under §§ 156.110(a)(5) and 156.115(a) of this subchapter, must comply with the requirements under section 2726 of the PHS Act and its implementing regulations in this section and § 146.137 to satisfy the requirement to provide coverage for mental health and substance use disorder services, including behavioral health treatment, as part of essential health benefits.

* * * * *

(i) * * *

(1) *In general.* Except as provided in paragraph (i)(2) of this section—

(i) This section applies to group health plans and health insurance issuers offering group health insurance coverage on the first day of the first plan year beginning on or after January 1, 2025, except that the requirements of paragraphs (c)(2)(ii)(A), (c)(4)(i)(B), and (c)(4)(iii) of this section apply on the first day of the first plan year beginning on or after January 1, 2026.

(ii) Until the applicability date in paragraph (i)(1)(i) of this section, plans and issuers are required to continue to comply with 45 CFR 146.136, revised as of October 1, 2023.

* * * * *

(j) *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 or the application of the provision to persons not similarly situated or to dissimilar circumstances.

■ 9. Add § 146.137 to read as follows:

§ 146.137 Nonquantitative treatment limitation comparative analysis requirements.

(a) *Meaning of terms.* Unless otherwise stated in this section, the terms of this section have the meanings indicated in § 146.136(a)(2).

(b) *In general.* In the case of a group health plan (or health insurance issuer offering coverage in connection with a group health plan) that provides both medical/surgical benefits and mental health or substance use disorder benefits and that imposes any nonquantitative treatment limitation on mental health or substance use disorder benefits, the plan or issuer must perform and document a comparative analysis of the design and application of each nonquantitative treatment limitation applicable to mental health or substance use disorder benefits. Each comparative analysis must comply with the content requirements of paragraph (c) of this section and be made available to the Secretary, upon request, in the manner required by paragraphs (d) and (e) of this section.

(c) *Comparative analysis content requirements.* With respect to each nonquantitative treatment limitation applicable to mental health or substance use disorder benefits under a group health plan (or health insurance coverage offered in connection with a group health plan), the comparative analysis performed by the plan or issuer must include, at minimum, the elements specified in this paragraph (c). In addition to the comparative analysis for each nonquantitative treatment limitation, each plan or issuer must prepare and make available to the Secretary, upon request, a written list of all nonquantitative treatment limitations imposed under the plan or coverage.

(1) *Description of the nonquantitative treatment limitation.* The comparative analysis must include, with respect to the nonquantitative treatment limitation that is the subject of the comparative analysis:

(i) Identification of the nonquantitative treatment limitation,

including the specific terms of the plan or coverage or other relevant terms regarding the nonquantitative treatment limitation, the policies or guidelines (internal or external) in which the nonquantitative treatment limitation appears or is described, and the applicable sections of any other relevant documents, such as provider contracts, that describe the nonquantitative treatment limitation;

(ii) Identification of all mental health or substance use disorder benefits and medical/surgical benefits to which the nonquantitative treatment limitation applies, including a list of which benefits are considered mental health or substance use disorder benefits and which benefits are considered medical/surgical benefits; and

(iii) A description of which benefits are included in each classification set forth in § 146.136(c)(2)(ii)(A).

(2) *Identification and definition of the factors and evidentiary standards used to design or apply the nonquantitative treatment limitation.* The comparative analysis must include, with respect to every factor considered or relied upon to design the nonquantitative treatment limitation or apply the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits:

(i) Identification of every factor considered or relied upon, as well as the evidentiary standards considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived, in determining which mental health or substance use disorder benefits and which medical/surgical benefits are subject to the nonquantitative treatment limitation; and

(ii) A definition of each factor, including:

(A) A detailed description of the factor;

(B) A description of each evidentiary standard used to design or apply each factor (and the source of each evidentiary standard) identified under paragraph (c)(2)(i) of this section; and

(C) A description of any steps the plan or issuer has taken to correct, cure, or supplement any information, evidence, sources, or standards that would otherwise have been considered biased or not objective under § 146.136(c)(4)(i)(B)(1) in the absence of such steps.

(3) *Description of how factors are used in the design and application of the nonquantitative treatment limitation.* The comparative analysis must include a description of how each factor identified and defined under paragraph (c)(2) of this section is used

in the design or application of the nonquantitative treatment limitation to mental health and substance use disorder benefits and medical/surgical benefits in a classification, including:

(i) A detailed explanation of how each factor identified and defined in paragraph (c)(2) of this section is used to determine which mental health or substance use disorder benefits and which medical/surgical benefits are subject to the nonquantitative treatment limitation;

(ii) An explanation of the evidentiary standards or other information or sources (if any) considered or relied upon in designing or applying the factors or relied upon in designing and applying the nonquantitative treatment limitation, including in the determination of whether and how mental health or substance use disorder benefits or medical/surgical benefits are subject to the nonquantitative treatment limitation;

(iii) If the application of the factor depends on specific decisions made in the administration of benefits, the nature of the decisions, the timing of the decisions, and the professional designations and qualifications of each decision maker;

(iv) If more than one factor is identified and defined in paragraph (c)(2) of this section, an explanation of:

(A) How all of the factors relate to each other;

(B) The order in which all the factors are applied, including when they are applied;

(C) Whether and how any factors are given more weight than others; and

(D) The reasons for the ordering or weighting of the factors; and

(v) Any deviations or variations from a factor, its applicability, or its definition (including the evidentiary standards used to define the factor and the information or sources from which each evidentiary standard was derived), such as how the factor is used differently to apply the nonquantitative treatment limitation to mental health or substance use disorder benefits as compared to medical/surgical benefits, and a description of how the plan or issuer establishes such deviations or variations.

(4) *Demonstration of comparability and stringency as written.* The comparative analysis must evaluate whether, in any classification, under the terms of the plan (or health insurance coverage) as written, any processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits are comparable to,

and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation with respect to medical/surgical benefits. The comparative analysis must include, with respect to the nonquantitative treatment limitation and the factors used in designing and applying the nonquantitative treatment limitation:

(i) Documentation of each factor identified and defined in paragraph (c)(2) of this section that was applied to determine whether the nonquantitative treatment limitation applies to mental health or substance use disorder benefits and medical/surgical benefits in a classification, including, as relevant:

(A) Quantitative data, calculations, or other analyses showing whether, in each classification in which the nonquantitative treatment limitation applies, mental health or substance use disorder benefits and medical/surgical benefits met or did not meet any applicable threshold identified in the relevant evidentiary standard to determine that the nonquantitative treatment limitation would or would not apply; and

(B) Records maintained by the plan or issuer documenting the consideration and application of all factors and evidentiary standards, as well as the results of their application;

(ii) In each classification in which the nonquantitative treatment limitation applies to mental health or substance use disorder benefits, a comparison of how the nonquantitative treatment limitation, as written, is designed and applied to mental health or substance use disorder benefits and to medical/surgical benefits, including the specific provisions of any forms, checklists, procedure manuals, or other documentation used in designing and applying the nonquantitative treatment limitation or that address the application of the nonquantitative treatment limitation;

(iii) Documentation demonstrating how the factors are comparably applied, as written, to mental health or substance use disorder benefits and medical/surgical benefits in each classification, to determine which benefits are subject to the nonquantitative treatment limitation; and

(iv) An explanation of the reasons for any deviations or variations in the application of a factor used to apply the nonquantitative treatment limitation, or the application of the nonquantitative treatment limitation, to mental health or substance use disorder benefits as compared to medical/surgical benefits,

and how the plan or issuer establishes such deviations or variations, including:

(A) In the definition of the factors, the evidentiary standards used to define the factors, and the sources from which the evidentiary standards were derived;

(B) In the design of the factors or evidentiary standards; or

(C) In the application or design of the nonquantitative treatment limitation.

(5) *Demonstration of comparability and stringency in operation.* The comparative analysis must evaluate whether, in any classification, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the limitation with respect to medical/surgical benefits. The comparative analysis must include, with respect to the nonquantitative treatment limitation and the factors used in designing and applying the nonquantitative treatment limitation:

(i) A comprehensive explanation of how the plan or issuer evaluates whether, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation with respect to medical/surgical benefits, including:

(A) An explanation of any methodology and underlying data used to demonstrate the application of the nonquantitative treatment limitation, in operation;

(B) The sample period, inputs used in any calculations, definitions of terms used, and any criteria used to select the mental health or substance use disorder benefits and medical/surgical benefits to which the nonquantitative treatment limitation is applicable;

(C) With respect to a nonquantitative treatment limitation for which relevant data is temporarily unavailable as described in § 146.136(c)(4)(iii)(A)(3)(i), a detailed explanation of the lack of relevant data, the basis for the plan's or issuer's conclusion that there is a lack of relevant data, and when and how the data will become available and be collected and analyzed; and

(D) With respect to a nonquantitative treatment limitation for which no data exist that can reasonably assess any relevant impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits as described in § 146.136(c)(4)(iii)(A)(3)(ii), a reasoned justification as to the basis for the conclusion that there are no data that can reasonably assess the nonquantitative treatment limitation's impact, an explanation of why the nature of the nonquantitative treatment limitation prevents the plan or issuer from reasonably measuring its impact, an explanation of what data was considered and rejected, and documentation of any additional safeguards or protocols used to ensure that the nonquantitative treatment limitation complies with § 146.136(c)(4);

(ii) Identification of the relevant data collected and evaluated, as required under § 146.136(c)(4)(iii)(A);

(iii) Documentation of the outcomes that resulted from the application of the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits, including:

(A) The evaluation of relevant data as required under § 146.136(c)(4)(iii)(A); and

(B) A reasoned justification and analysis that explains why the plan or issuer concluded that any differences in the relevant data do or do not suggest the nonquantitative treatment limitation contributes to material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits, in accordance with § 146.136(c)(4)(iii)(B)(2);

(iv) A detailed explanation of any material differences in access demonstrated by the outcomes evaluated under paragraph (c)(5)(iii) of this section, including:

(A) A reasoned explanation of any material differences in access that are not attributable to differences in the comparability or relative stringency of the nonquantitative treatment limitation as applied to mental health or substance use disorder benefits and medical/surgical benefits (including any considerations beyond a plan's or issuer's control that contribute to the existence of material differences) and a detailed explanation of the bases for concluding that material differences are not attributable to differences in the comparability or relative stringency of the nonquantitative treatment limitation; and

(B) To the extent differences in access to mental health or substance use

disorder benefits are attributable to generally recognized independent professional medical or clinical standards or carefully circumscribed measures reasonably and appropriately designed to detect or prevent and prove fraud and abuse that minimize the negative impact on access to appropriate mental health and substance use disorder benefits, and such standards or measures are used as the basis for a factor or evidentiary standard used to design or apply a nonquantitative treatment limitation, documentation explaining how any such differences are attributable to those standards or measures, as required in § 146.136(c)(4)(iii)(B)(2)(ii); and

(v) A discussion of the actions that have been or are being taken by the plan or issuer to address any material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits, including the actions the plan or issuer has taken or is taking under § 146.136(c)(4)(iii)(B)(1) to address material differences to comply, in operation, with § 146.136(c)(4), including, as applicable:

(A) A reasoned explanation of any material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits that persist despite reasonable actions that have been or are being taken; and

(B) For a plan or issuer designing and applying one or more nonquantitative treatment limitations related to network composition, a discussion of the actions that have been or are being taken to address material differences in access to in-network mental health and substance use disorder benefits as compared to in-network medical/surgical benefits, including those listed in § 146.136(c)(4)(iii)(C).

(6) *Findings and conclusions.* The comparative analysis must address the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits within each classification, and the relative stringency of their application, both as written and in operation, and include:

(i) Any findings or conclusions indicating that the plan or coverage is or is not (or might or might not be) in compliance with the requirements of § 146.136(c)(4), including any additional actions the plan or issuer has taken or intends to take to address any potential areas of concern or noncompliance;

(ii) A reasoned and detailed discussion of the findings and conclusions described in paragraph (c)(6)(i) of this section;

(iii) Citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions described in paragraph (c)(6)(i) of this section not otherwise discussed in the comparative analysis;

(iv) The date the analysis is completed and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis; and

(v) If the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan or issuer to be an expert, an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of the nonquantitative treatment limitation applicable to both mental health or substance use disorder benefits and medical/surgical benefits.

(d) *Requirements related to submission of comparative analyses to the Secretary upon request*—(1) *Initial request by the Secretary for comparative analysis.* A group health plan (or health insurance issuer offering coverage in connection with a group health plan) must make the comparative analysis required by paragraph (b) of this section available and submit it to the Secretary within 10 business days of receipt of a request from the Secretary (or an additional period of time specified by the Secretary).

(2) *Additional information required after a comparative analysis is deemed to be insufficient.* In instances in which the Secretary determines that the plan or issuer has not submitted sufficient information under paragraph (d)(1) of this section for the Secretary to determine whether the comparative analysis required in paragraph (b) of this section complies with paragraph (c) of this section or whether the plan or issuer complies with § 146.136(c)(4), the Secretary will specify to the plan or issuer the additional information the plan or issuer must submit to the Secretary to be responsive to the request under paragraph (d)(1). Any such information must be provided to the Secretary by the plan or issuer within 10 business days after the Secretary specifies the additional information to be submitted (or an additional period of time specified by the Secretary).

(3) *Initial determination of noncompliance, required action, and*

corrective action plan. In instances in which the Secretary reviewed the comparative analysis submitted under paragraph (d)(1) of this section and any additional information submitted under paragraph (d)(2) of this section, and made an initial determination that the plan or issuer is not in compliance with the requirements of § 146.136(c)(4) or this section, the plan or issuer must respond to the initial determination by the Secretary and specify the actions the plan or issuer will take to bring the plan or coverage into compliance, and provide to the Secretary additional comparative analyses meeting the requirements of paragraph (c) of this section that demonstrate compliance with § 146.136(c)(4), not later than 45 calendar days after the Secretary's initial determination that the plan or issuer is not in compliance.

(4) *Requirement to notify participants and beneficiaries of final determination of noncompliance*—(i) *In general.* If the Secretary makes a final determination of noncompliance, the plan or issuer must notify all participants and beneficiaries enrolled in the plan or coverage that the plan or issuer has been determined to not be in compliance with the requirements of § 146.136(c)(4) or this section with respect to such plan or coverage. Such notice must be provided within 7 business days of receipt of the final determination of noncompliance, and the plan or issuer must provide a copy of the notice to the Secretary, any service provider involved in the claims process, and any fiduciary responsible for deciding benefit claims within the same timeframe.

(ii) *Content of notice.* The notice to participants and beneficiaries required in paragraph (d)(4)(i) of this section shall be written in a manner calculated to be understood by the average plan participant and must include, in plain language, the following information in a standalone notice:

(A) The following statement prominently displayed on the first page, in no less than 14-point font:

“Attention! The Department of Health and Human Services has determined that [insert the name of group health plan or health insurance issuer] is not in compliance with the Mental Health Parity and Addiction Equity Act.”;

(B) A summary of changes the plan or issuer has made as part of its corrective action plan specified to the Secretary following the initial determination of noncompliance, including an explanation of any opportunity for a participant or beneficiary to have a claim for benefits submitted or reprocessed;

(C) A summary of the Secretary's final determination that the plan or issuer is not in compliance with § 146.136(c)(4) or this section, including any provisions or practices identified as being in violation of § 146.136(c)(4) or this section, additional corrective actions identified by the Secretary in the final determination notice, and information on how participants and beneficiaries can obtain from the plan or issuer a copy of the final determination of noncompliance;

(D) Any additional actions the plan or issuer is taking to come into compliance with § 146.136(c)(4) or this section, when the plan or issuer will take such actions, and a clear and accurate statement explaining whether the Secretary has concurred with those actions; and

(E) Contact information for questions and complaints, and a statement explaining how participants and beneficiaries can obtain more information about the notice, including:

(1) The plan's or issuer's phone number and an email or web portal address; and

(2) The Centers for Medicare & Medicaid Services' phone number and email or web portal address.

(iii) *Manner of notice.* The plan or issuer must make the notice required under paragraph (d)(4)(i) of this section available in paper form, or electronically (such as by email or an internet posting) if:

(A) The format is readily accessible;

(B) The notice is provided in paper form free of charge upon request; and

(C) In a case in which the electronic form is an internet posting, the plan or issuer timely notifies the participant or beneficiary in paper form (such as a postcard) or email, that the documents are available on the internet, provides the internet address, includes the statement required in paragraph (d)(4)(ii)(A) of this section, and notifies the participant or beneficiary that the documents are available in paper form upon request.

(e) *Requests for a copy of a comparative analysis.* In addition to making a comparative analysis available upon request to the Secretary, a plan or issuer must make available a copy of the comparative analysis required by paragraph (b) of this section when requested by:

(1) Any applicable State authority; and

(2) A participant or beneficiary (including a provider or other person acting as a participant's or beneficiary's authorized representative) who has received an adverse benefit

determination related to mental health or substance use disorder benefits.

(f) *Rule of construction.* Nothing in this section or § 146.136 shall be construed to prevent the Secretary from acting within the scope of existing authorities to address violations of § 146.136 or this section.

(g) *Applicability.* The provisions of this section apply to group health plans and health insurance issuers offering group health insurance coverage described in § 146.136(e), to the extent the plan or issuer is not exempt under § 146.136(f) or (g), on the first day of the first plan year beginning on or after January 1, 2025, except the requirements of paragraphs (c)(2)(ii)(C), (c)(5)(i)(C) and (D), and (c)(5)(ii) through (v) of this section apply on the first day of the first plan year beginning on or after January 1, 2026.

(h) *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 or the application of the provision to persons not similarly situated or to dissimilar circumstances.

■ 10. Amend § 146.180 by:

■ a. Revising paragraph (a)(2);

■ b. Redesignating paragraphs (a)(3) through (7) as paragraphs (a)(4) through (8);

■ c. Adding new paragraph (a)(3);

■ d. Revising newly redesignated paragraphs (a)(5) and (a)(7)(i) and paragraph (f)(1); and

■ e. Adding paragraph (f)(4)(iii).

The revisions and additions read as follows:

§ 146.180 Treatment of non-Federal governmental plans.

(a) * * *

(2) *General rule.* For plans years beginning on or after September 23, 2010, a sponsor of a non-Federal governmental plan may elect to exempt its plan, to the extent the plan is not provided through health insurance coverage (that is self-funded), from one or more of the requirements described in paragraphs (a)(1)(iv) through (vii) of this section, except as provided in paragraphs (a)(3) and (f)(1) of this section with respect to the requirements

described in paragraph (a)(1)(v) of this section.

(3) *Sunset of election option related to parity in mental health and substance use disorder benefits.* A sponsor of a non-Federal governmental plan may not newly elect to exempt its plans from the requirements described in paragraph (a)(1)(v) of this section on or after December 29, 2022.

* * * * *

(5) *Examples—(i) Example 1.* A non-Federal governmental employer has elected to exempt its self-funded group health plan from all of the requirements described in paragraph (a)(1) of this section. The plan year commences September 1st of each year. The plan is not subject to the provisions of paragraph (a)(2) of this section until the plan year that commences on September 1, 2011. Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from the requirements described in paragraphs (a)(1)(iv) through (vii) of this section, subject to paragraphs (a)(3) and (f)(1) of this section with respect to the requirements described in paragraph (a)(1)(v) of this section.

(ii) *Example 2.* A non-Federal governmental employer has elected to exempt its collectively bargained self-funded plan from all of the requirements described in paragraph (a)(1) of this section. The collective bargaining agreement applies to 5 plan years, October 1, 2009, through September 30, 2014. For the plan year that begins on October 1, 2014, the plan sponsor is no longer permitted to elect to exempt its plan from the requirements described in paragraphs (a)(1)(i) through (iii) of this section. Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from the requirements described in paragraphs (a)(1)(iv) through (vii) of this section, subject to paragraphs (a)(3) and (f)(1) of this section with respect to the requirements described in paragraph (a)(1)(v) of this section.

* * * * *

(7) * * *

(i) Subject to paragraph (a)(7)(ii) of this section, the purchase of stop-loss or excess risk coverage by a self-funded non-Federal governmental plan does not prevent an election under this section.

* * * * *

(f) * * *

(1) *Election renewal.* A plan sponsor may renew an election under this section through subsequent elections.

Notwithstanding the previous sentence and except as provided in paragraph (f)(4)(iii) of this section, an election with respect to the requirements described in paragraph (a)(1)(v) of this section expiring on or after June 27, 2023, may not be renewed. The timeliness standards described in paragraph (c) of this section apply to election renewals under paragraph (f) of this section.

* * * * *

(4) * * *

(iii) In the case of a plan that is subject to multiple collective bargaining agreements of varying lengths and that has an election with respect to the requirements described in paragraph (a)(1)(v) of this section in effect as of December 29, 2022, that expires on or after June 27, 2023, the plan may extend such election until the date on which the term of the last such agreement expires.

* * * * *

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 11. The authority citation for part 147 continues to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, 300gg–92, and 300gg–111 through 300gg–139, as amended, and section 3203, Pub. L. 116–136, 134 Stat. 281.

■ 12. Revise § 147.160 to read as follows:

§ 147.160 Parity in mental health and substance use disorder benefits.

(a) *In general.* The provisions of §§ 146.136 and 146.137 of this subchapter apply to individual health insurance coverage offered by a health insurance issuer in the same manner and to the same extent as such provisions apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the large group market.

(b) *Applicability date.* The provisions of this section apply for policy years beginning on or after January 1, 2026. Until the applicability date in the preceding sentence, issuers are required to continue to comply with 45 CFR 147.160, incorporating 45 CFR 146.136, each revised as of October 1, 2023. This section applies to non-grandfathered and grandfathered health plans as defined in § 147.140.

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