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FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Parts 303 and 345

RIN 3064-AG10

Establishment and Relocation of Branches and Offices

AGENCY: Federal Deposit Insurance Corporation.

ACTION: Final rule.

SUMMARY: The Federal Deposit Insurance Corporation (FDIC) is amending the processes by which an insured State nonmember bank may establish a branch or relocate a main office or branch by eliminating certain filing requirements, reducing processing timelines, and updating public notice procedures. The FDIC is also making corresponding changes to procedures applicable to the relocation of an insured branch of a foreign bank.

DATES: The final rule will be effective February 27, 2026.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Policy Objectives

The objectives of the final rule are to improve the speed and certainty of, and reduce the regulatory burden associated with, the filing process for insured State

nonmember banks seeking to establish a branch or relocate a main office or branch and for foreign banks seeking to relocate an insured branch (collectively, FDIC-supervised banks). The final rule also makes certain definitional clarifications to further improve regulatory efficiency and certainty.

As discussed further in sections III.A and III.C of this **SUPPLEMENTARY INFORMATION**, the FDIC's experience with branch filings has demonstrated that aspects of the filing process should be modified or eliminated. For example, through its supervisory programs, the FDIC has access to much of the information an applicant must provide under the existing regulation. In addition, branch filings are subject to a public comment process that is not mandated by statute, causes a meaningful delay in the amount of time to render a final decision, and typically does not yield information that materially aids the FDIC's evaluation of the statutory factors pursuant to which these filings are considered. The FDIC also has found that branch filings generally present minimal supervisory concerns, particularly where a branch changes its physical address but remains in approximately the same location.

Accordingly, the final rule accelerates expedited processing for institutions that satisfy certain criteria, removes select informational requirements, eliminates the public comment process, extends the expiration date for an approved filing, and excludes from the scope of filing requirements *de minimis* changes in address. The revisions in the final rule are expected to reduce the regulatory burden imposed on FDIC-supervised banks and the FDIC to complete the filing process.

II. Background

A. Statutory Requirements

Section 18(d)(1) of the Federal Deposit Insurance Act (FDI Act) requires the FDIC's prior written consent for an insured State nonmember bank to establish and operate a new domestic branch or to move its main office or any domestic branch from one location to another.¹ This section also prohibits a foreign bank from moving an insured branch from one location to another

without the FDIC's prior written consent.

When considering whether to grant or withhold such consent, the FDIC must consider the factors listed in section 6 of the FDI Act (statutory factors). The statutory factors are as follows: (1) the financial history and condition of the depository institution; (2) the adequacy of the depository institution's capital structure; (3) the future earnings prospects of the depository institution; (4) the general character and fitness of the management of the depository institution; (5) the risk presented by the depository institution to the Deposit Insurance Fund; (6) the convenience and needs of the community to be served by the depository institution; and (7) whether the depository institution's corporate powers are consistent with the purposes of the FDI Act. In addition, when evaluating an application to establish a branch, relocate a branch, or relocate a main office, the Community Reinvestment Act (CRA) requires the FDIC to take into consideration the bank's record of meeting the credit needs of its entire community, including low- and moderate-income neighborhoods, consistent with the safe and sound operation of the bank.² With respect to a bank establishing a *de novo* interstate branch that is not in the State nonmember bank's home State and in which the bank does not already have a branch, the Riegle-Neal Interstate Banking and Branching Efficiency Act of 1994 (IBBEA),³ as amended, imposes certain additional restrictions and requirements codified in sections 18(d) and 44 of the FDI Act. Section 38 of the FDI Act imposes additional requirements and restrictions on undercapitalized institutions seeking to establish a branch.

B. FDIC Rules and Regulations

Subpart C of 12 CFR part 303 of the FDIC Rules and Regulations (subpart C) implements section 18(d) of the FDI Act and sets forth the filing requirements and procedures for insured State nonmember banks to establish a branch,

² 12 U.S.C. 2903(a).

³ Public Law 103-328, 108 Stat. 2338 (1994). IBBEA also imposes restrictions on out-of-State banks opening a new interstate branch in a host State in which the appropriate Federal banking agency has determined that the bank is not reasonably helping to meet the credit needs of the communities served by the bank in the host State. See also 12 CFR part 369.

¹ 12 U.S.C. 1828(d)(1).

relocate a branch or main office, and retain an existing branch after the interstate relocation of a main office. Subpart C requires all insured State nonmember banks to submit an application to the appropriate FDIC office prior to establishing a new branch, relocating a branch or a main office, or retaining a branch after the interstate relocation of a main office.⁴ All applicants are required to submit the same information regardless of the type of proposed change and regardless of the bank's supervisory history, except that, consistent with section 38 of the FDI Act, undercapitalized institutions must submit relatively more information. Further, the FDIC retains the right to request additional information to complete application processing.⁵

The application processing timeline depends primarily upon whether the bank meets the definition of an "eligible depository institution."⁶ An application submitted by an eligible depository institution is generally subject to expedited processing, and applications submitted by all other insured State nonmember banks are subject to standard processing.⁷ The FDIC Rules and Regulations at 12 CFR part 303 (part 303) define an "eligible depository institution" as a depository institution that meets the following criteria: (1) received an FDIC-assigned composite rating of 1 or 2 under the Uniform Financial Institutions Rating System (UFIRS) as a result of its most recent Federal or State examination; (2) received a satisfactory or better CRA rating from its primary Federal regulator at its most recent examination, if the depository institution is subject to examination under 12 CFR part 345; (3) received a compliance rating of 1 or 2 from its primary Federal regulator at its most recent examination; (4) is well-capitalized, as defined in the appropriate capital regulation and guidance of the institution's primary Federal regulator; and (5) is not subject to a cease and desist order, consent order, prompt corrective action directive, written agreement, memorandum of understanding, or other administrative agreement with its primary Federal regulator or chartering authority.⁸

Under the current rule, the FDIC retains the right to move an application from expedited processing to standard

processing when appropriate.⁹ Absent such removal, an application processed under expedited processing is deemed approved the latest of (1) 21 days after the FDIC receives a substantially complete application, (2) 5 days after the public comment period expires, or (3) in the case of an interstate branch application that represents new entry into a State where the applicant does not maintain a branch, 5 days after the FDIC receives the requisite confirmation from the host State that its filing requirements have been satisfied. The FDIC must provide the applicant with written notification of the final action when the decision is rendered.¹⁰

Subpart J of part 303 (subpart J) sets forth the procedures for an insured branch of a foreign bank seeking the FDIC's consent to move from one location to another at 12 CFR 303.184. The requirements in subpart J largely mirror the requirements found in subpart C.

C. Branch Application Statistics

From 2015 to September 30, 2025, the FDIC received 7,043 branch applications: 5,366 applications to establish a branch, 489 to relocate a main office, 1,183 to relocate a branch, and 5 applications related to an insured branch of a foreign bank, for an average of 655 applications received per year. During this period, the FDIC approved an average of 624 branch applications annually (479 branch establishment applications, 102 branch relocation applications, and 43 main office relocation applications). On average, 531 applications per year were approved under expedited processing (85 percent) and 92 were approved under standard processing (15 percent). From 2015 to September 30, 2025, the average time between the FDIC's receipt of an application to establish a branch or relocate a branch or main office and the application being approved, denied, returned to the applicant, or withdrawn, was 25 days for applications subject to expedited processing and 70 days for applications subject to standard processing.

D. Public Comments

On July 18, 2025, the FDIC published in the **Federal Register** a notice of proposed rulemaking on the Establishment and Relocation of Branches and Offices (NPR).¹¹ The FDIC invited public comment on all aspects of the NPR. The comment period ended on September 16, 2025. The FDIC

received 8 total comments from 7 different individuals, financial institutions, industry groups, and consumer organizations.

Several comments were supportive of the NPR. More specifically, several commenters supported the FDIC's efforts to shorten filing processing timelines, simplify certain filing requirements, and eliminate unnecessary delays. Two of these commenters generally supported the elimination of public notice and comment requirements, and one of these commenters supported providing reasonable advance notice to customers for *de minimis* changes in address but requested clarification on what would constitute reasonable advance notice.

Two commenters supported the proposed changes to expedited processing, with one of these commenters noting that the NPR would shorten expedited processing timelines and another of these commenters noting that the NPR would expand the number of eligible institutions. One commenter requested clarification on what would constitute a "substantially complete" filing and guidance on how the FDIC would determine an institution's eligibility for expedited processing.

One commenter expressed support for the proposed definitions. In particular, the commenter noted that clarification of terms, including "branch," "remote service unit," and "*de minimis* change in address," will help to ensure consistent interpretation and application. One commenter requested clarification on several definitions, including examples of what features distinguish a remote service unit (RSU) from other service models and examples of what qualifies as an intrastate relocation. The commenter also requested that the FDIC clarify whether the same streamlined filing requirements apply to intrastate relocations of main offices.

One commenter requested that the FDIC make an additional change to 12 CFR 303.45(c) to extend the expiration date for an approved filing from 18 months to 36 months. The commenter reasoned that preparations for a relocation generally take longer than the 18 months provided by the current regulation, and a longer expiration period would enable institutions to seek regulatory approval earlier in the process.

Several commenters opposed aspects of the NPR. Four commenters asserted that some of the proposed changes may be inconsistent with the CRA. Specifically, three of these commenters expressed concerns regarding the proposed elimination of the provisions

⁴ 12 CFR 303.42(a).

⁵ See 12 CFR 303.42(b) through (d).

⁶ See 12 CFR 303.43.

⁷ 12 CFR 303.2(r).

⁸ 12 CFR 303.2(r).

⁹ 12 CFR 303.43(a).

¹⁰ 12 CFR 303.43(b).

¹¹ 90 FR 33898 (July 18, 2025).

concerning public comments and public hearings, two of these commenters opposed the elimination of public notice and filing requirements, and one of these commenters objected to the removal of local newspaper posting requirements. These commenters argued that, by eliminating public notice and comment processes, the FDIC would be unable to fulfill its obligations under the CRA with respect to branch filings.

One commenter opposed the creation of a new definition for *de minimis* changes in address. The commenter asserted that the proposed exclusion of *de minimis* changes in address could have negative community impacts.

Three commenters expressed concerns regarding the proposed changes to expedited processing. Two of these commenters expressed concerns regarding the proposed shortening of the filing approval period and the proposed elimination of the FDIC's discretion to remove a filing from expedited processing. One of these commenters expressed concerns about making UFIRS 3-rated institutions eligible for expedited processing. The commenter reasoned that UFIRS 3-rated institutions are underperforming institutions and should not be permitted to receive "fast-tracked" approval under the proposed rule. Another of these commenters objected to the proposed eligibility of intrastate branch and main office relocation filings for expedited processing.

III. Description of the Final Rule

A. Rules of General Applicability

1. Public Notice Requirements

Public notice requirements under subpart A of 12 CFR part 303 of the FDIC Rules and Regulations (subpart A) generally apply to applications submitted under subpart C.¹² The NPR proposed to eliminate the public notice and related public comment period from subpart C and to make conforming changes to subpart A. Specifically, the FDIC proposed to strike the provisions in 12 CFR 303.7(a) and (c) that reference the establishment of a branch or a branch or main office relocation as being subject to the public notice requirements in subpart A. In addition, the FDIC proposed to make technical conforming changes to the CRA regulations in 12 CFR part 345, which cross reference the public notice provisions of subpart A.

Three commenters generally supported the FDIC's efforts to streamline subpart C filings, with two of these commenters specifically

supporting the elimination of the public notice and comment period. Four commenters objected to the elimination of the public notice and related public comment period.

Some commenters argued that the elimination would violate the CRA. As explained in the NPR, elimination of the public notice and related public comment period does not change the FDIC's obligations under the CRA. The FDIC will continue to take into consideration a bank's CRA rating.¹³ An institution's ability to qualify for expediting processing as an eligible depository institution depends on a satisfactory or better CRA rating. The FDIC does not propose to alter this element of the definition of eligible depository institution. Accordingly, eliminating the public notice and comment period does not impact the FDIC's existing obligations under the CRA.

Furthermore, as noted in the NPR, the FDIC expects that a bank will provide reasonable advance notice to customers affected by a branch or main office relocation. One commenter asked the FDIC to clarify the scope of this expectation and to provide additional details regarding compliance. As discussed in section III.E of this **SUPPLEMENTARY INFORMATION**, the FDIC is adopting a regulatory customer notification obligation and includes additional details regarding compliance below.

The FDIC is adopting the changes to 12 CFR 303.7(a) and (c) as proposed. The FDIC will continue to comply with its obligations under the CRA, which does not require public notice or comment for branch establishments or branch and main office relocations.

2. Hearings and Other Meetings

Applications submitted under subpart C are generally subject to subpart A's provisions concerning hearings and other meetings.¹⁴ The NPR proposed to eliminate branch filings from the hearings and other meetings provisions in subpart A. Specifically, the FDIC proposed to strike the provisions in 12 CFR 303.10(a) that reference the establishment of a branch or a branch or main office relocation because these public hearing provisions are not statutorily required. The NPR also explained that public hearings do not materially aid the FDIC's consideration of the statutory factors when evaluating an application to establish a branch or to relocate a main office or branch.

Three commenters objected to the elimination of branch filings from the hearings and other meetings provisions in subpart A. Two of these commenters urged that the small number of requests for hearings received and granted by the FDIC is not a justification for eliminating the right of the public to request hearings. One of these commenters claimed that the elimination of branch filings from the hearings and other meetings provisions in subpart A, coupled with the proposed reduction of filing processing timelines, would provide limited opportunity for community feedback.

The FDIC is adopting the changes to 12 CFR 303.10(a) as proposed. The FDI Act does not require the FDIC to hold public hearings for applications submitted under subpart C, and they have not materially aided the FDIC's consideration of the statutory factors when evaluating an application to establish a branch or to relocate a main office or branch.

B. Definitions

1. Branch

The FDIC is revising the definition of "branch" at 12 CFR 303.41(a) to clarify that a branch does not include an RSU to reflect the FDI Act's statutory exclusion of RSUs from the definition of "domestic branch."¹⁵ One commenter supported the proposed definition for the term "branch" with this clarification. No commenters opposed the proposed definition of "branch." The FDIC is adopting the change as proposed.

2. Branch Relocation

The FDIC is establishing a rule of construction within the definition of "branch relocation" at 12 CFR 303.41(b) in the final rule to provide that a branch relocation does not include a *de minimis* change in address. The rule of construction defines a "*de minimis* change in address" as occurring when a branch exchanges one physical facility for another within the same approximate location, such as where (1) a direct line of sight exists between the two facilities, (2) the facilities share the same parking area, or (3) the facilities are located on contiguous properties or on the same block.

The FDIC has found that in some situations a change in facility may be in a bank's best interest for a business, operational, or other reason outside the control of a bank, such as the same landlord expanding a shopping center and offering more advantageous lease

¹³ See 12 U.S.C. 2902(3)(C) through (D).

¹⁴ See generally 12 CFR 303.10.

¹⁵ See 12 U.S.C. 1813(o).

¹² 12 CFR 303.44.

terms for the exchange of one suite in the shopping center for another. Such changes are often time-sensitive due to external circumstances. In the FDIC's experience, the exchange of one physical facility for another that results in such a *de minimis* change in address is not appropriately contemplated under the filing requirements of subpart C. The final rule recognizes the absence of a significant supervisory purpose to processing filings for such *de minimis* changes in address by removing the requirement to submit a filing for such changes.

Although a *de minimis* change in address is not subject to the requirements in 12 CFR 303.42 through 303.44, the final rule requires a bank undertaking a *de minimis* change in address to provide reasonable advance written notice to customers of the branch undergoing a *de minimis* change in address and the appropriate FDIC office.

Several commenters supported the exclusion of *de minimis* changes in address from filing requirements. One commenter noted that the clarification of key terms like "*de minimis* change in address" will help ensure consistent interpretation and application of filing requirements. Another commenter opposed the proposal to exclude *de minimis* changes in address from filing requirements. The commenter reasoned that, by "fast-tracking" these filings, the FDIC would be unable to gather enough information to assess potential community impacts resulting from *de minimis* changes in address. For example, the commenter hypothesized that a *de minimis* change in address could result in the closing of a street level branch in favor of a new branch in a high rise building that is less accessible to customers.

The FDIC is adopting 12 CFR 303.41(b) as proposed. The FDIC has retained the definition of *de minimis* change in address and the corresponding exception from filing requirements because the expected reductions in regulatory burden and cost for both banks and the FDIC outweigh the potential risks. The purpose of the exception is to allow a bank to move to a nearby facility when it is in its best interest for a business, operational, or other reason outside the control of a bank, and therefore the FDIC does not expect that FDIC-supervised banks would utilize the *de minimis* change in address exception to move to a branch that would be more difficult for its customers to access.

3. De Novo Interstate Branch

The FDIC is replacing the term "de novo branch" with "de novo interstate branch" in subpart C. The term "de novo branch" is defined in section 18(d)(4)(C) of the FDI Act within the more narrow context of interstate branching. However, the current definition of "de novo branch" in subpart C does not account for the interstate context of the statutory definition. The FDIC is revising 12 CFR 303.41(c) to change the defined term to "de novo interstate branch" and updating the definition to indicate that it is a branch of a bank that is established by the bank as a branch in a State other than the bank's home State or one in which the bank does not maintain a branch, and does not become a branch of such bank as a result of (1) the acquisition by the bank of an insured depository institution or a branch of an insured depository institution, or (2) the conversion, merger, or consolidation of any such institution or branch.

The final rule makes conforming changes to account for the new defined term by replacing "de novo branch" with "de novo interstate branch" where it is used in subpart C. Under the final rule, this defined term is only relevant to ensure that a filing for a de novo interstate branch will be deemed approved only after relevant host State filing requirements have been satisfied. The FDIC did not receive any comments regarding these conforming changes.

4. Remote Service Unit

The FDIC is defining the term "remote service unit" in subpart C at 12 CFR 303.41(g). Section 3(o) of the FDI Act excludes automated teller machines (ATMs) and RSUs from the definition of "domestic branch" but does not define either term.¹⁶ The final rule adopts a definition of RSU that aligns the FDIC Rules and Regulations with the regulations of the Office of the Comptroller of the Currency (OCC).¹⁷ The final rule defines "remote service unit" as an automated or unstaffed facility, operated by a customer of a bank with at most delimited assistance from bank personnel, that conducts banking functions such as receiving deposits, paying withdrawals, or lending money.

An RSU includes an ATM, automated loan machine, automated device for receiving deposits, personal computer, telephone, other similar electronic devices, and drop boxes. An RSU may be equipped with a telephone or tele-

video device that allows contact with bank personnel. The final rule excludes a drop box from the definition of "branch" by including a drop box in the definition of "remote service unit" to avoid the incongruous result where the definition of "branch" encompasses a drop box but not an ATM.¹⁸

The FDIC's definition of an RSU is intended to accommodate most facilities commonly referred to as "interactive teller machines" (ITMs). In 2024, the FDIC issued a Financial Institution Letter stating that an ITM would qualify for the RSU exclusion, and thus would not be a branch, under the following circumstances: (1) the ITM is an automated, unstaffed banking facility owned or operated by, or operated exclusively for, the bank, which is equipped to enable existing customers to initiate an interactive session with remotely located bank personnel; and, (2) to the extent that bank personnel have the ability to remotely assist the customer with the operation of the ITM to perform core banking functions, customers must also be able to perform such transactions without the involvement of bank personnel and must have the sole discretion to initiate and terminate interactive sessions with bank personnel.¹⁹ As part of the proposal, the FDIC sought comment on whether those criteria should be retained or modified.

One commenter supported the exclusion of RSUs from the definition of "branch," but suggested that the FDIC provide examples or frequently asked questions (FAQs) to help banks distinguish RSUs from other types of staffed service channels. The commenter noted that, as technology evolves, the line between RSUs and other staffed service channels may become less clear. The FDIC recognizes that technological advancements can make it difficult to assess what may distinguish an RSU from other staffed service channels. The FDIC intends to provide the industry with flexibility as innovations drive new methods of serving customers in a rapidly evolving technology landscape, and the agency may issue additional guidance based on future technological advancements at a later date.

¹⁸ See also OCC, "Activities and Operations of National Banks and Federal Savings Associations," 85 FR 83686, 83703 (Dec. 22, 2020).

¹⁹ See FDIC, FIL-53-2024, "Classification of Interactive Teller Machines as Domestic Branches or Remote Service Units" (Aug. 9, 2024), available at <https://www.fdic.gov/news/financial-institution-letters/2024/classification-interactive-teller-machines-domestic>.

¹⁶ 12 U.S.C. 1813(o).

¹⁷ See 12 CFR 7.1027.

C. Filing Procedures

1. General

The NPR proposed eliminating the timing requirement for the submission of a subpart C filing. Regulations at 12 CFR 303.42(a) currently require applicants to submit an application to the appropriate FDIC office on the date the bank's required newspaper notice is published or within 5 days after the date of the last required newspaper publication. The FDIC proposed eliminating the timing requirement because it is tied to the newspaper publication requirement, which the NPR also eliminated. The FDIC did not receive comments regarding this proposed change. The FDIC is adopting the revisions to 12 CFR 303.42(a) as proposed.

2. Content of Filing

The NPR proposed to streamline the information required to be included with a branch filing under 12 CFR 303.42(b). The FDIC explained that through its routine examination and supervisory processes, it maintains sufficient information to consider the statutory factors without requiring a bank to compile and submit all the information currently required by subpart C.

The FDIC asked commenters for feedback on whether the proposed filing content requirements are appropriate to garner sufficient information for the FDIC to evaluate the statutory factors in the context of a branch establishment or a branch or main office relocation. Two commenters supported the proposed streamlining of filing content, noting that the result would reduce cost and regulatory burden for applicants. One commenter, however, noted that the sixth statutory factor under section 18(d)(1) of the FDI Act requires the FDIC to consider "the convenience and needs of the community to be served,"²⁰ and argued that the elimination of public notice, comment, and hearing procedures would prevent the FDIC from appropriately considering that factor. One commenter requested clarification regarding whether the proposed streamlined filing content requirements apply to intrastate main office relocations.

The FDIC is adopting the revisions to 12 CFR 303.42(b) as proposed. The FDIC reiterates that it maintains sufficient information to consider the statutory factors without requiring a bank to compile and submit all of the

information currently required by 12 CFR 303.42(b). Moreover, the FDIC is satisfied that it can obtain additional information necessary to analyze a branch establishment or a branch or main office relocation in accordance with the statutory factors, notwithstanding the streamlined content filing requirements in the final rule. In addition, the FDIC notes that the filing content requirements under 12 CFR 303.42 apply to all subpart C filings, which include intrastate main office relocations.

D. Processing

1. Expedited Processing for Eligible Depository Institutions

The NPR proposed to shorten the approval period for expedited processing for eligible depository institutions and eliminate the FDIC's discretion to remove a filing from expedited processing in 12 CFR 303.43(a). An application processed under expedited processing is currently deemed approved on the latest of the following: (1) 21 days after receipt by the FDIC of a substantially complete application; (2) 5 days after expiration of the comment period described in 12 CFR 303.44; or (3) in the case of an application to establish a de novo branch in a State that is not the applicant's home State and in which the applicant does not maintain a branch, 5 days after the FDIC receives confirmation from the host State that the applicant has both complied with the filing requirements of the host State and submitted a copy of the application with the FDIC to the host State bank supervisor.²¹

The NPR proposed that a filing submitted by an eligible depository institution that is processed under expedited processing would be deemed approved on the later of the following: (1) the third business day after receipt by the FDIC of a substantially complete filing; or (2) in the case of a filing to establish and operate a de novo interstate branch in a State that is not the applicant's home State and in which the applicant does not maintain a branch, the fifth day after the FDIC receives confirmation from the host State that the applicant has both complied with the filing requirements of the host State and submitted a copy of the filing with the FDIC to the host State bank supervisor.²² The FDIC proposed

to retain the definition of "eligible depository institution."²³ The final rule reflects the statutory prohibition against interstate deposit production offices by clarifying that a filing will not receive expedited processing if the filer is subject to sanctions under 12 CFR 369.5.²⁴

Some commenters expressed concern that the abbreviated approval period would not provide the FDIC with sufficient time to conduct a meaningful review of a subpart C filing. As explained in the NPR, the FDIC determined that qualification as an eligible depository institution,²⁵ in tandem with the relative immateriality of a branch establishment or relocation, enables the FDIC to conclude that a proposed branch establishment or relocation satisfies the statutory factors. The FDIC continues to believe the proposed approval timelines are appropriate to enhance the speed and certainty of filings and is therefore adopting those timelines as proposed.

One commenter encouraged the FDIC to explain how eligibility for expedited processing would be determined in practice. The FDIC notes that this would entail confirming that the institution meets the definition of "eligible depository institution" based on existing supervisory information.

The FDIC currently retains discretion to remove a filing from expedited processing for any reason described in 12 CFR 303.11(c)(2). Under the NPR, a subpart C filing from an eligible depository institution that satisfies the criteria for expedited processing would be deemed approved in accordance with the statutory factors, and the FDIC would not have discretion to remove the filing from expedited processing. The FDIC rarely exercised discretion to remove a subpart C filing from expedited processing and the proposed change would provide more certainty to filers who satisfy the expedited processing criteria.

One commenter supported the proposal to eliminate the FDIC's

requirements, satisfy concentration limits, be adequately capitalized, and be well capitalized and well managed upon establishment of the branch. See 12 U.S.C. 1831u(b)(1), (3), and (4).

²³ 12 CFR 303.2(r).

²⁴ 12 CFR 369.5 implements 12 U.S.C. 1835a, which provides that an out-of-State bank may not open a new interstate branch in the host State unless the bank provides reasonable assurances to the satisfaction of the FDIC that the bank will reasonably help to meet the credit needs of the community that the new branch will serve. Accordingly, expedited processing would be inappropriate for filers subject to sanctions under 12 CFR 369.5.

²⁵ 12 CFR 303.43(a) (providing the criteria that an institution must satisfy to qualify as an "eligible depository institution").

²⁰ 12 U.S.C. 1828(d)(1) includes a cross-reference to 12 U.S.C. 1816, which outlines the relevant statutory factors that the FDIC must consider in connection with a branch application.

²¹ 12 CFR 303.43(a).

²² Filings involving a de novo interstate branch typically involve a lengthier approval timeline because they are subject to additional statutory requirements. See 12 U.S.C. 1828(d)(4)(B). Specifically, the bank must comply with State filing

discretion to remove a filing from expedited review, noting that the change would provide greater certainty to filers and reduce delays. However, this commenter requested clarification on what constitutes a “substantially complete” filing, such that the expedited timeline would begin. Given that branch filings will not be information-intensive or require iterative information requests, rather than define “substantially complete” for the purposes of branch filings, the final rule deems a filing eligible for expedited processing (other than a *de novo* interstate branch) to be approved on the third business day after the FDIC receives a letter filing that includes the information set forth in 12 CFR 303.42.

Two commenters expressed concern that the FDIC would be unable to appropriately exercise its supervisory authority if its discretion to remove a filing from expedited processing was eliminated. The FDIC believes that the goal of providing more certainty to filers who satisfy the criteria for expedited processing supports elimination of its rarely exercised discretion to remove a filing from expedited processing. Accordingly, the final rule is adopted as proposed, with modifications. These modifications include eliminating the reference to a “substantially complete” application and clarifying that a filing will be processed under expedited processing if the informational requirements of 12 CFR 303.42 are satisfied. Furthermore, a modification to 12 CFR 303.43 clarifies that filers subject to sanctions under 12 CFR 369.5 are ineligible for expedited processing.

2. Expedited Processing for Branch Relocations and Main Office Relocations

The NPR proposed to revise 12 CFR 303.43(b) to establish a new category of expedited processing for intrastate branch and main office relocation filings submitted by a bank that received an FDIC-assigned composite UFIRS rating of 3 or better as a result of its most recent Federal or State examination. Expedited processing would apply to intrastate branch and main office relocation filings by institutions rated 3 or better under 12 CFR 303.43(b) regardless of whether the institution satisfied the other criteria in 12 CFR 303.2(r) for an eligible depository institution.

Section 303.41(b) defines a “branch relocation” narrowly as a move within the same immediate neighborhood of the existing branch that does not substantially affect the nature of the business of the branch or the customers

of the branch.²⁶ This definition also specifies that moving a branch to a location outside its immediate neighborhood is considered the closing of an existing branch and the establishment of a new branch. A main office relocation, while not defined, would not be expansionary in nature regardless of the distance involved, because the bank may only have a single main office. For these reasons, a branch or main office relocation typically presents a limited set of facts and circumstances for review and consideration of the statutory factors.

One commenter recommended the FDIC provide examples of what qualifies as an intrastate main office relocation. To promote clarity, the final rule adopts a definition of an “intrastate main office relocation” to be the relocation of a main office of a bank within the same State such that there is no change in the bank’s home State.

One commenter objected to expanding expedited processing for intrastate branch and main office relocations so as to include banks that received an FDIC-assigned composite rating of 3 or better under the UFIRS. The commenter characterized these banks as “underperforming” and argued that offering expedited processing to these banks would disincentivize them from correcting deficiencies. The final rule retains expedited processing for intrastate branch and main office relocations because, as discussed above, these relocations are non-expansionary in nature. The FDIC notes that, under the final rule, expedited processing for branch establishments, as opposed to relocations, remains limited to eligible depository institutions.

Other commenters expressed concern that the FDIC would not have discretion to remove an intrastate branch or main office relocation filing submitted by a bank with a composite rating of 3 or better from expedited processing. As discussed above, expedited processing for these non-expansionary filings by banks with a composite rating of 3 or better would promote the FDIC’s goal of providing more certainty and clarity regarding processing. The final rule adopts the provisions of 12 CFR 303.43(b) as proposed.

3. FDIC Internal Processes

The NPR noted the FDIC was evaluating and updating its internal processes to further streamline and expedite the review and consideration of filings submitted under subpart C. One commenter recommended that the FDIC confirm that acknowledgement

letters will clearly state when the expedited timeline begins and asked the FDIC to clarify how eligibility for expedited processing will be determined in practice. The FDIC intends to take these recommendations into account as it continues to update its internal processes and related publicly available materials to reflect the provisions of the final rule and comments received on the NPR.

E. Public Notice Requirements

The NPR proposed to eliminate the newspaper publication requirement in 12 CFR 303.44(a) and related provisions. One commenter urged the FDIC to maintain the newspaper publication requirement. The commenter reasoned that newspaper media outlets continue to play a role in educating the public. However, the NPR also noted the FDIC’s expectation that banks seeking to relocate a branch or main office provide reasonable advance notice to customers and the appropriate FDIC office. The FDIC believes that this will accomplish the underlying goal of ensuring that customers are aware of proposed branch and main office relocations and able to conveniently access banking services.

One commenter requested that the FDIC provide clear guidance on what constitutes reasonable advanced notice to customers. The FDIC intends to provide the industry with flexibility in determining how to best provide reasonable advance notice to customers. An applicant can choose the best method or methods of communicating a proposed branch or main office relocation with its affected customer base. Although the requirements of section 42 of the FDI Act do not apply to relocations, the type of notice provided in such contexts, such as a notice in a regular account statement, would necessarily be considered reasonable advance notice.²⁷ The final rule eliminates this provision of 12 CFR 303.44(a) as proposed, and, like the NPR, would continue to require confirmation of advance customer notice as part of a branch or main office relocation, and would require such notice in connection with a *de minimis* change in address. Specifically, the final rule adopts the provision proposed in the NPR that would make confirmation of advance written notice to customers part of the information requirements for a branch or main office relocation filing. With respect to a *de minimis* changes in address, the final rule adopts the provision proposed in the NPR that

²⁷ See 12 U.S.C. 1831r–1 and Joint Policy Statement on Branch Closings, 84 FR 34844 (June 29, 1999).

²⁶ 12 CFR 303.41(b).

requires reasonable advance written notice to customers of a branch undergoing a *de minimis* change in address.

F. Expiration of Approval

One commenter requested that the FDIC extend the expiration date for an approved filing under 12 CFR 303.45(c) from 18 months to 36 months. The commenter reasoned that preparations for a relocation generally take longer than the 18 months provided by the current regulation, and a longer expiration period would enable banks to seek regulatory approval earlier in the process. In the final rule, the FDIC modifies 12 CFR 303.45(c) to extend the expiration date for an approved filing to 24 months. The final rule adopts this 24-month expiration period, as it is the FDIC's expectation that 24 months would provide a reasonable timeframe for banks to consummate a branch establishment or relocation.

G. Moving an Insured Branch of a Foreign Bank

The NPR proposed making changes to subpart J to correspond to those proposed for subpart C. The FDIC did not receive comments on its proposed revisions to subpart J. The final rule adopts the previously proposed changes to subpart J to correspond with the changes to subpart C discussed in this **SUPPLEMENTARY INFORMATION**.

IV. Expected Effects

As previously discussed, the objective of the final rule is to improve the speed and certainty of, and reduce the regulatory burden associated with, the filing process for insured State nonmember banks seeking to establish a branch or relocate a main office or branch and for foreign banks seeking to relocate an insured branch (collectively, FDIC-supervised banks).

This analysis utilizes all regulations and guidance applicable to FDIC-supervised banks, as well as information on their financial condition as of the quarter ending June 30, 2025, as the baseline to which the effects of the final rule are estimated.

The final rule applies to FDIC-supervised banks seeking to establish a branch, relocate a main office or branch, or relocate an insured branch of a foreign bank. As of the quarter ending June 30, 2025, the FDIC supervises 2,776 State nonmember banks or insured branches of foreign banks which collectively operate 25,250 branches and main offices.²⁸ In the period from

January 1, 2015 to September 30, 2025, the FDIC received 7,043 branch applications: 5,366 applications to establish a branch, 489 to relocate a main office, 1,183 to relocate a branch, and 5 applications relating to an insured branch of a foreign bank, for an average of 655 applications received per year.²⁹ Based on this historical average, the FDIC estimates that the final rule will affect approximately 700 branch filings per year on average.³⁰

The final rule reduces the regulatory requirements for branch filings. Specifically, it only requires FDIC-supervised banks that seek to make a *de minimis* change in the address of a branch to notify the FDIC and customers of the branch undergoing such a change,³¹ rather than submit a filing. For all other branch filings, the final rule reduces filing content requirements from six to four items. The final rule also greatly reduces public notice requirements for filings and extends the expiration date for an approved filing from 18 months to 24 months.

For FDIC-supervised banks that seek a *de minimis* change in address, the FDIC estimates that the final rule will eliminate the entire estimated five-hour burden of preparing and submitting a branch filing.³² At a conservative estimate of \$200 per hour per application,³³ the resulting savings will be \$1,000 per *de minimis* change in address. For the purpose of estimating the number of *de minimis* changes in address per year, the FDIC assumes that

²⁸ FDIC supervisory data. 7,043 applications/10.75 years = 655 applications per year (rounded to the nearest integer).

²⁹ Although the final rule will result in a decrease in the burden for a branch application, the FDIC does not believe the final rule will likely result in a material increase in the number of branch applications. To the extent that the final rule results in a greater number of branch applications, the historical average of 655 branch applications per year may be an undercount of the number of applications affected by the final rule. The FDIC believes that using 700 as the number of branch applications per year is a conservative estimate for purposes of estimating the effects of the final rule.

³⁰ Final 12 CFR 303.41(b).

³¹ Based on Paperwork Reduction Act hourly burden estimates for branch applications by State nonmember banks under Information Collection Request OMB No. 3064-0070 (See https://www.reginfo.gov/public/do/PRAICList?ref_nbr=202301-3064-006). Hourly burden estimates for branch applications by foreign banks under Information Collection Request OMB No. 3064-0114 are not used for this analysis because only 5 out of 7,043 historical branch applications were submitted by a foreign bank.

³² In recent information collection requests, the FDIC estimated that the fully loaded costs of preparing and submitting branch applications are approximately \$147 per hour for State nonmember banks and \$135 per hour for foreign banks. See https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202312-3064-001, respectively.

the distances of such relocations will be less than 0.1 miles.³⁴ Of the 7,043 branch applications used in this analysis, 325 involved a relocation distance of less than 0.1 miles. As such, the FDIC estimates that approximately 30 branch applications per year will involve a *de minimis* change in address, resulting in an estimated aggregate benefit of \$30,000 annually.³⁵

For the remaining 670 branch applications that do not involve *de minimis* changes in address, the final rule will reduce the regulatory requirements for preparing and submitting branch filings. Specifically, it reduces filing content requirements from six to four items. The final rule also eliminates public notice requirements for these filings. The FDIC estimates these changes will benefit filers by reducing the time spent preparing and submitting branch filings by approximately two hours, on average.³⁶ At a conservative hourly burden estimate of \$200 per hour,³⁷ the final rule will result in aggregate cost savings of approximately \$268,000 per year.³⁸

Summing up the quantified effects for the approximately 700 affected branch applications, the FDIC estimates that the final rule will result in approximately \$298,000 in savings per year from the reduction of labor costs associated with preparing and submitting branch filings. As previously discussed, the final rule will generally reduce the time it takes for the FDIC to process a filing. In particular, the final rule will establish a deadline of three days for approval after receipt of a letter filing that includes the information set forth in 12 CFR 303.42; a reduction of between 18 days and 28 days, respectively.³⁹ Further, the final

³⁴ *De minimis* changes in address will only involve relocations "within the same approximate location," as per final 12 CFR 303.41(b)(1)(i).

³⁵ \$30,000 savings annually = \$1,000 per relocation application × 30 applications per year; and 30 branch applications per year = 325 applications/10.75 years (rounded to the nearest integer).

³⁶ See section VI.A of this **SUPPLEMENTARY INFORMATION**.

³⁷ In recent information collection requests, the FDIC estimated that the fully loaded costs of preparing and submitting branch applications are approximately \$147 per hour for State nonmember banks and \$135 per hour for foreign banks. See https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202312-3064-001, respectively.

³⁸ \$268,000 cost savings per year = 670 branch applications per year * 2 hours saved per application * \$200 per hour saved.

³⁹ As noted above, intrastate branch filings are deemed approved under expedited processing on the latest of: the 21st day after receipt by the FDIC of a substantially complete filing, or the fifth day after expiration of the comment period described in

²⁸ FDIC Call Report and Structure Data, June 30, 2025.

rule will expand expedited processing for intrastate branch filings and main office relocations to a bank that received an FDIC-assigned composite rating of 3 or better under the UFIRS as a result of its most recent Federal or State examination. The final rule also extends the expiration date of an approved filing from 18 months to 24 months. Finally, the final rule will eliminate the FDIC's discretion to remove a filing from expedited processing. As noted above, a filing to establish a branch, or to relocate a branch or main office, subject to expedited processing takes an average of 25 days to process.⁴⁰

The final rule's reduction in processing times for certain branch filings will have benefits for eligible depository institutions. Faster processing times will reduce uncertainty and costs associated with downtime while waiting for a decision from the FDIC. FDIC-supervised banks will be able to more swiftly respond to changes in local conditions that affect their branch network, such as a change in landlord for a bank's current location or a time-sensitive opportunity to relocate to a more desirable location. The FDIC does not have the information necessary to further quantify the benefits associated with the reduction in the time it takes for the FDIC to process filings, but believes that processing time reductions will improve productivity and competitiveness for applicants.

As previously discussed, the final rule clarifies certain definitions. Specifically, the final rule clarifies that the term "branch" does not include RSUs or drop boxes. In practice, the FDIC has not considered such locations branches. Finally, the final rule clarifies the definition of "de novo interstate branch." The FDIC does not have the information necessary to quantify the benefits to prospective filers associated with these aspects of the final rule. However, the FDIC believes that these clarifications will benefit filers and the industry by reducing uncertainty.

As previously discussed, the FDIC does not believe that the final rule will pose any material direct costs to filers. The FDIC acknowledges that there may be ancillary costs to the public. For example, the elimination of the public

notice and comment requirements for branch establishments and branch and main office relocations may have impacts that are difficult to quantify.⁴¹ The final rule eliminates any potential customer confusion by requiring confirmation of advance written notice to customers of a relocating branch or office as part of the filing information requirements. The FDIC does not have the data necessary to quantify the effect of the elimination of the public notice and comment requirements. However, given the limited historical number of public comments received in response to subpart C applications, and the advance notice provision, the FDIC does not believe this effect to be material. Moreover, the final rule does not affect the responsibility of FDIC-supervised banks to help meet the credit needs of the communities in which they are headquartered or operate branches. Therefore, the FDIC believes that the final rule will pose no substantive indirect costs to customers.

Finally, the FDIC believes that the final rule can provide indirect benefits to customers. To the extent that the shorter processing periods, reduced filing content requirements, and clarifications within the final rule reduce the time it takes banks to establish new branches and begin providing banking products and services at applicable locations, customers may benefit. The FDIC does not have the necessary information to quantify such benefits.

V. Other Alternatives Considered

The FDIC considered implementing internal process changes related to the review of subpart C filings that would result in abbreviated review periods without implementing a regulatory change. However, the FDIC determined that improving the speed, certainty, and regulatory burden associated with the processes for subpart C filings would be better achieved through a formal notice and comment rulemaking that considered feedback from all stakeholders.⁴² As discussed above, the FDIC also expects to implement changes to its internal processes and related publicly available materials addressing subpart C filings consistent with the amendments set forth in this final rule to further support these objectives.

VI. Regulatory Analysis

A. Administrative Procedure Act

The Administrative Procedure Act requires an agency to publish a

substantive rule not less than 30 days before its effective date, except when an agency otherwise publishes in the final rule good cause for providing for an earlier effective date.⁴³ Accordingly, the final rule is effective as of the date set forth above in this document under the **DATES** heading.

B. The Paperwork Reduction Act

Certain provisions of the final rule contain "collections of information" within the meaning of the Paperwork Reduction Act (PRA) of 1995.⁴⁴ In accordance with the requirements of the PRA, the FDIC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Budget and Management (OMB) control number. The information collections contained in the final rule have been submitted to OMB for review and approval by the FDIC under section 3507(d) of the PRA⁴⁵ and 5 CFR 1320.11 of OMB's implementing regulations.⁴⁶ The FDIC proposes to extend for three years, with revision, the following information collections:

Title of Information Collection:
Application for a Bank to Establish a Branch or Move its Main Office or Branch.

OMB Control Number: 3064-0070.
Respondents: Insured State nonmember banks.

Current Actions: The final rule revises the currently-approved information collection as follows:

Section 303.42, *Application for a bank to establish a branch or move its main office or Branch*. Pursuant to sections 13(f), 13(k), 18(d) and 44 of the FDI Act, insured State nonmember banks must obtain FDIC approval before establishing a branch, relocating a branch or main office, or retaining existing branches after the interstate relocation of the main office. This information collection represents the occasional reporting requirement associated with those banks' applications for FDIC approval. The final rule will reduce reporting burden by eliminating the requirement that the applicant provide information regarding insider involvement in the proposed branch office, comments on changes in services offered or the effect the proposal may have on the applicant's compliance with the CRA, and a copy of and information related to the required newspaper publication. As such, the FDIC estimates average time

¹² 12 CFR 303.44, which at most could be 23 days (consisting of 8 days to meet the newspaper publication requirement plus a 15-day comment period), and 5 + 23 = 28. The final rule's deadline of three days (down from 21) for intrastate branch filings represents a decrease of 18 days from baseline, and the elimination of the public notice requirements and associated five-day processing period represents a decrease of 28 days from baseline.

⁴⁰ Based on branch applications received from 2015 to September 30, 2025.

⁴¹ See final 12 CFR 303.44.

⁴² See sections II and III of this **SUPPLEMENTARY INFORMATION** for the FDIC's responses to comments.

⁴³ 5 U.S.C. 553(d).

⁴⁴ 44 U.S.C. 3501.

⁴⁵ 44 U.S.C. 3507(d).

⁴⁶ 5 CFR 1320.

per response will be reduced from 5 hours to 3 hours. However, to account for additional applications that may result from changes in the final rule as well as historical data since the most recent PRA renewal, the FDIC also estimates an increase in respondents from 436 to 700. Thus, the total estimated annual burden for OMB No. 3064-0070 is 2,100 hours, a decrease of 80 hours from the most recent PRA renewal.⁴⁷

Title of Information Collection:
Foreign Banks.

OMB Control Number: 3064-0114.

Respondents: Insured branches of foreign banks.

Current Actions: The final rule revises the currently-approved information collection as follows:

The FDIC is removing the information collection “Section 303.184, Moving a Branch” from the ICR under the OMB Control No. 3064-0114 and including it in the ICR under OMB Control No. 3064-0070. Under 12 CFR 303.183, insured branches of foreign banks seeking approval from the FDIC to move locations complete a substantially similar application as domestic banks seeking FDIC approval to move locations. To ensure consistent burden estimates between similar respondents completing similar applications, the FDIC will include burden estimates from the information collection “Section 303.184, Moving a Branch” in the information collection “Application for a bank to establish a branch or move its main office or Branch.” Combining these two information collections does not affect the FDIC estimates of respondents for the information collection under OMB Control No. 3064-0070 because historically the FDIC rarely receives applications to move insured branches from foreign banks. In the most recent PRA renewal for OMB Control No. 3064-0114, the FDIC used a placeholder of a single respondent to maintain the information collection.

C. Congressional Review Act

Pursuant to the Congressional Review Act, the OMB makes a determination regarding whether a final rule constitutes a “major rule,” defined in the Congressional Review Act as any rule that the Administrator of the Office of Information and Regulatory Affairs of the OMB finds has resulted in or is likely to result in (A) an annual effect on the economy of \$100,000,000 or

more; (B) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies or geographic regions; or (C) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. If OMB determines a rule is “major,” the Congressional Review Act generally provides that the rule may not take effect until at least 60 days following its publication. If a rule is not a “major rule,” it may take effect after the Federal agency submits to Congress a report required under the Congressional Review Act.

OMB has determined the final rule is not a major rule under the Congressional Review Act. Accordingly, the FDIC will submit the report to Congress required by the Congressional Review Act and the final rule will become effective as set forth under the **DATES** heading of this document.

D. The Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency, in connection with a final rule, to prepare and make available for public comment a final regulatory flexibility analysis that describes the impact of the final rule on small entities.⁴⁸ However, a final regulatory flexibility analysis is not required if the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. The Small Business Administration (SBA) has defined “small entities” to include banking organizations with total assets of less than or equal to \$850 million.⁴⁹ Generally, the FDIC considers a significant economic impact to be a quantified effect in excess of 5 percent of total annual salaries and benefits or 2.5 percent of total noninterest expenses. The FDIC believes that effects in excess of one or more of these thresholds typically represent

significant economic impacts for FDIC-supervised banks.

The final rule applies to certain FDIC-supervised banks seeking to establish a branch, relocate a main office or branch, or relocate an insured branch of a foreign bank. As of the quarter ending June 30, 2025, the FDIC supervised 2,776 banks, of which 2,055 were considered “small” for the purposes of RFA.⁵⁰ These 2,055 small banks collectively operated 8,204 branches and main offices.⁵¹ In the period from January 1, 2015 to September 30, 2025,⁵² small banks submitted 2,145 applications to establish a branch, 368 applications to relocate a branch, and 308 applications to relocate a main office, for a total of 2,821 applications and an average of 262 applications per year.⁵³ Based on this historical average, the FDIC estimates the final rule will affect approximately 300 branch applications from small banks per year on average.⁵⁴

In general, the final rule will reduce the regulatory requirements for establishing or relocating a branch. Specifically, it will eliminate filing requirements for *de minimis* changes in address and reduce filing content requirements from six to four items for all other filings. The final rule will also eliminate or greatly reduce public notice requirements for all branch establishments and relocations, and extend the expiration date of an

⁵⁰ FDIC Call Report data, June 30, 2025.

⁵¹ FDIC Call Report and Structure Data, June 30, 2025.

⁵² To estimate whether a bank was “small” for purposes of the RFA during the quarter ending September 30, 2025, the FDIC relied on banks’ status as of June 30, 2025, because bank holding company regulatory reports for the quarter ending September 30, 2025, were not available at the time this analysis was conducted.

⁵³ FDIC supervisory and Call Report data. For the purpose of these application counts, an FDIC-supervised bank is considered “small” for purposes of the RFA if it is identified in the FDIC’s data as “small” as of the quarter-end in which it sent a relevant application to the FDIC, with the exception for the quarter ending September 30, 2025, described in the previous footnote. Note that no insured branches of foreign banks are considered “small” for purposes of the RFA. 2,821 applications/10.75 years = 262 applications per year (when rounded to the nearest integer).

⁵⁴ Although the final rule will result in a decrease in the burden imposed by a branch application, the FDIC does not believe the final rule will likely result in a material increase in the number of branch filings. To the extent that the final rule results in a greater number of branch filings from small banks, the historical average of 262 branch applications per year may be an undercount of the number of applications affected by the final rule. The FDIC believes that using 300 as the number of branch applications from small banks per year is a conservative estimate for purposes of the RFA.

⁴⁷ FDIC Application for a bank to establish a branch or move its main office or branch, OMB No. 3064-0070, available at https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202301-3064-006.

⁴⁸ 5 U.S.C. 601 *et seq.*

⁴⁹ The SBA defines a small banking organization as having \$850 million or less in assets, where an organization’s “assets are determined by averaging the assets reported on its four quarterly financial statements for the preceding year.” See 13 CFR 121.201 (as amended by 87 FR 69118, effective Dec. 19, 2022). In its determination, the “SBA counts the receipts, employees, or other measure of size of the concern whose size is at issue and all of its domestic and foreign affiliates.” See 13 CFR 121.103. Following these regulations, the FDIC uses an insured depository institution’s affiliated and acquired assets, averaged over the preceding four quarters, to determine whether the insured depository institution is “small” for the purposes of RFA.

approved filing from 18 months to 24 months.⁵⁵

As discussed in the Expected Effects section of this **SUPPLEMENTARY INFORMATION**, the FDIC estimates that there will be upwards of 30 *de minimis* changes in address per year. Based on supervisory and Call Report data, the FDIC estimates that upwards of 10 *de minimis* changes in address will involve small banks. The final rule will reduce the burden for these *de minimis* changes in address by five hours, or \$1,000, per relocation.⁵⁶ Based on Call Report data for the quarter ending June 30, 2025, a cost savings of \$1,000 is in excess of 5 percent of total annual salaries and benefits or 2.5 percent of total noninterest expenses for one small bank.

For the remaining 290 branch applications from small banks that do not involve *de minimis* changes in address, the FDIC estimates the final rule will benefit small filers by reducing the time spent preparing and submitting branch filings by approximately two hours, on average, or \$400 per application.⁵⁷ Based on Call Report data for the quarter ending June 30, 2025, a cost savings of \$400 is in excess of 5 percent of total annual salaries and benefits or 2.5 percent of total noninterest expenses for one small bank (the same small bank previously identified).

Based on the quantified effects of the final rule described above, the FDIC estimates that the rule will not significantly affect more than one small bank.

As discussed in the Expected Effects section of this Supplementary Information, the final rule will also reduce the time it takes for the FDIC to process a filing. In particular, the final rule will establish a deadline of three days for approval after receipt of a letter filing that includes the information set forth in 12 CFR 303.42; a reduction of between 18 days and 28 days,

respectively.⁵⁸ Further, the final rule will expand expedited processing for intrastate branch filings and main office relocations to a bank that received an FDIC-assigned composite rating of 3 or better under the UFIRS as a result of its most recent Federal or State examination. Finally, the final rule will eliminate the FDIC's discretion to remove a filing from expedited processing. As mentioned above, a filing to establish a branch, or to relocate a branch or main office, subject to expedited processing takes an average of 25 days to process.⁵⁹

The final rule's reduction in processing times for certain branch filings will have benefits for eligible small depository institutions. Faster processing times will reduce the period of uncertainty for filers and reduce costs associated with downtime while waiting for a decision from the FDIC. Banks will be able to more swiftly respond to changes in local conditions, such as a change in landlord for a bank's current location or a time-sensitive opportunity to relocate to a more desirable location. The FDIC does not have the information necessary to further quantify the benefit associated with the reduction in the time it takes for the FDIC to process filings, but believes that processing time reductions will improve productivity and competitiveness for filers.

As mentioned above, the final rule extends the expiration date of an approved filing from 18 months to 24 months, lengthening the period of time an affected bank has to complete a branch relocation or establish a branch. This aspect of the final rule will benefit small applicants by providing greater flexibility for the planning and execution of the establishment or relocation of a branch or office. The FDIC does not have the information necessary to identify which small, FDIC-supervised institutions will utilize the additional time in future periods.

As previously discussed, the final rule clarifies certain definitions. Specifically, the final rule clarifies that "branch" does not include RSUs, drop boxes, or

financial education programs that include the provision of bank products and services. In practice the FDIC has not considered such locations branches. Finally, the final rule clarifies the definition of "de novo interstate branch" for the purposes of the filings requirements for establishing a branch, relocating a main office or branch, or relocating an insured branch of a foreign bank. The FDIC does not have the information necessary to quantify the benefits to prospective filers associated with these aspects of the final rule. However, the FDIC believes that these clarifications will benefit filers and the industry by reducing uncertainty.

The unquantified benefits discussed above are in addition to the quantified benefits. Conservatively, if each branch filing affected by the final rule were submitted by a distinct small bank, then the final rule would affect 300 small banks. The FDIC does not believe that the unquantified benefits would likely result in a significant effect for the vast majority of the 300 affected banks.

Finally, the FDIC concludes that the final rule does not pose any material direct costs to filers.

In light of the foregoing, the FDIC certifies that the final rule does not have a significant economic impact on a substantial number of small entities. Accordingly, a final regulatory flexibility analysis is not required.

E. Plain Language

Section 722 of the Gramm-Leach-Bliley Act requires Federal banking agencies to use plain language in all proposed and final rules published after January 1, 2000. The FDIC invited comments regarding the use of plain language but did not receive any relevant comments. The FDIC sought to clearly state the provisions of the rule in a simple and straightforward manner.

F. Riegle Community Development and Regulatory Improvement Act of 1994

Section 302 of the Riegle Community Development and Regulatory Improvement Act of 1994 (RCRIA) requires that the Federal banking agencies, including the FDIC, in determining the effective date and administrative compliance requirements of new regulations that impose additional reporting, disclosure, or other requirements on insured depository institutions (IDIs), consider, consistent with principles of safety and soundness and the public interest, any administrative burdens that such regulations would place on depository institutions, including small depository institutions, and customers of depository institutions, as well as the

⁵⁵ A bank completing a *de minimis* change in address will still be required to provide reasonable advance notice to customers of the branch per final 12 CFR 303.41(b).

⁵⁶ Based on a conservative hourly burden estimate of \$200 per hour. In recent information collection requests, the FDIC estimated that the fully loaded costs of preparing and submitting branch applications are approximately \$147 per hour for State nonmember banks and \$135 per hour for foreign banks. See https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202301-3064-006 and https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202312-3064-001, respectively.

⁵⁷ Details of the time to prepare and submit branch applications are provided in section VI.A., Paperwork Reduction Act, of this **SUPPLEMENTARY INFORMATION**.

⁵⁸ As noted above, intrastate branch filings are deemed approved under expedited processing on the latest of: the 21st day after receipt by the FDIC of a substantially complete filing, or the fifth day after expiration of the comment period described in 12 CFR 303.44, which at most could be 23 days (consisting of 8 days to meet the newspaper publication requirement plus a 15-day comment period), and $5 + 23 = 28$. The final rule's deadline of three days (down from 21) for intrastate branch filings represents a decrease of 18 days from baseline, and the elimination of the public notice requirements and associated five-day processing period represents a decrease of 28 days from baseline.

⁵⁹ Based on applications received from January 1, 2015, to September 30, 2025.

benefit of such regulations. New regulations and amendments to regulations prescribed by a Federal banking agency that impose additional reporting, disclosure, or other new requirements on IDI shall take effect on the first day of a calendar quarter that begins on or after the date on which the regulations are published in final form, with certain exceptions, including for good cause.

The final rule does not impose additional reporting, disclosure, or other new requirements on IDIs. As such, the provisions of RCDRIA do not apply to the FDIC's determination of the final rule's effective date.

G. Executive Orders 12866 and 13563

Under Executive Order 12866, as affirmed and supplemented by Executive Order 13563, "significant regulatory actions" are subject to review by OMB. The FDIC has submitted this regulatory action to OMB for review. OMB has determined the rule is not a significant regulatory action as defined by section 3(f) of Executive Order 12866. For more information on the analysis conducted in connection with Executive Order 12866, refer to other sections of this **SUPPLEMENTARY INFORMATION**.

H. Executive Order 14192

Executive Order 14192 directs agencies, unless prohibited by law, to identify at least 10 existing regulations to be repealed when the agency publicly proposes for notice and comment or otherwise promulgates a new regulation with total costs greater than zero. Executive Order 14192 further requires that new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations. An Executive Order 14192 deregulatory action is an action that has been finalized and has total costs less than zero. This final rule is considered an Executive Order 14192 deregulatory action.

List of Subjects

12 CFR Part 303

Administrative practice and procedure, Bank deposit insurance, Banks, banking, Reporting and recordkeeping requirements, Savings associations.

12 CFR Part 345

Banks, banking, Community development, Credit, Investments, Reporting and recordkeeping requirements.

Authority and Issuance

For the reasons stated in the preamble, the Board of Directors of the Federal Deposit Insurance Corporation amends 12 CFR parts 303 and 345 as follows:

PART 303—FILING PROCEDURES

- 1. The authority citation for part 303 continues to read as follows:

Authority: 12 U.S.C. 378, 1464, 1813, 1815, 1817, 1818, 1819(a) (Seventh and Tenth), 1820, 1823, 1828, 1829, 1831a, 1831e, 1831o, 1831p–1, 1831w, 1835a, 1843(l), 3104, 3105, 3108, 3207, 5414, 5415, and 15 U.S.C. 1601–1607.

- 2. Amend § 303.7 by revising paragraphs (a) and (c)(1)(i) to read as follows:

§ 303.7 Public notice requirements.

(a) *General*. The public must be provided with prior notice of a filing to engage in a merger transaction, initiate a change of control transaction, or request deposit insurance. The public has the right to comment on, or to protest, these types of proposed transactions during the relevant comment period. In order to fully apprise the public of this right, an applicant shall publish a public notice of its filing in a newspaper of general circulation. For specific publication requirements, consult subparts B (Deposit Insurance), D (Merger Transactions), and E (Change in Bank Control) of this part.

* * * * *

(c) * * *

(1) * * *

(i) In the case of an application for deposit insurance for a *de novo* depository institution, include the names of all organizers or incorporators. In the case of a merger application, include the names of all parties to the transaction. In the case of a notice of acquisition of control, include the name(s) of the acquiring parties.

* * * * *

§ 303.10 [Amended]

- 3. Amend § 303.10 by removing paragraphs (a)(2) and (3) and redesignating paragraphs (a)(4) through (6) as paragraphs (a)(2) through (4), respectively.

§ 303.40 [Amended]

- 4. Amend § 303.40 by:
 - a. In paragraph (a), removing the word "application" and adding, in its place, the word "filing"; and
 - b. In paragraph (c), removing the word "Applications" and adding, in its place, the word "Filings".

- 5. Amend § 303.41 by revising paragraph (a) introductory text, revising and republishing paragraph (b), revising paragraph (c) introductory text, and adding paragraphs (f) and (g) to read as follows:

§ 303.41 Definitions.

* * * * *

(a) *Branch*, except as provided in this paragraph (a), includes any branch bank, branch office, additional office, or any branch place of business located in any State of the United States or in any territory of the United States, Puerto Rico, Guam, American Samoa, the Trust Territory of the Pacific Islands, the Virgin Islands, and the Northern Mariana Islands at which deposits are received or checks paid or money lent. A branch does not include a remote service unit or a facility described in § 303.45. The term branch also includes the following:

* * * * *

(b) *Branch relocation* means a move within the same immediate neighborhood of the existing branch that does not substantially affect the nature of the business of the branch or the customers of the branch. Moving a branch to a location outside its immediate neighborhood is considered the closing of an existing branch and the establishment of a new branch. Closing of a branch is covered in the FDIC Statement of Policy Concerning Branch Closing Notices and Policies. 1 FDIC Law, Regulations, Related Acts 5391; see § 309.4(a) and (b) of this chapter for availability.

(1) *Rule of construction*. For the purposes of this subpart, a *de minimis* change in address is neither a branch establishment nor a branch relocation.

(i) A *de minimis* change in address occurs when a branch exchanges one physical facility for another within the same approximate location, such as where:

(A) A direct line of sight exists between the two facilities;

(B) The facilities share the same parking area; or

(C) The facilities are located on contiguous properties or on the same block.

(ii) *Notice required*. Notwithstanding the inapplicability of §§ 303.42 through 303.44, an insured State nonmember bank is required to provide reasonable advance written notice to customers of the branch undergoing a *de minimis* address change and advance notice to the appropriate FDIC office.

(2) [Reserved]

(c) *De novo interstate branch* means a branch of a bank that is established by the bank as a branch in a State other

than the bank's home State or one in which the bank does not maintain a branch, and does not become a branch of such bank as a result of:

* * * * *

(f) *Intrastate main office relocation* means the relocation of a main office of a bank within the same State such that there is no change in the bank's home State.

(g) *Remote service unit (RSU)* is an automated or unstaffed facility, operated by a customer of a bank with at most delimited assistance from bank personnel, that conducts banking functions such as receiving deposits, paying withdrawals, or lending money. An RSU includes an automated teller machine, automated loan machine, automated device for receiving deposits, personal computer, telephone, other similar electronic devices, and drop boxes. An RSU may be equipped with a telephone or tele-video device that allows contact with bank personnel.

■ 6. Amend § 303.42 by revising paragraph (a), revising and republishing paragraph (b), and revising paragraph (c) to read as follows:

§ 303.42 Filing procedures.

(a) *General*. Filings shall be submitted to the appropriate FDIC office.

(b) *Content of filing*. A complete letter filing shall include the following information:

(1) A statement of intent to establish a branch, or to relocate the main office or a branch;

(2) The exact location of the proposed site including the street address. With regard to messenger services, specify the geographic area in which the services will be available. With regard to a mobile branch, specify the community or communities in which the vehicle will operate and the manner in which it will be used;

(3) When a filing is submitted to relocate the main office of the bank from one State to another, a statement of the bank's intent regarding retention of branches in the State where the main office exists prior to relocation; and

(4) With respect to a branch relocation or a main office relocation, confirmation that advance written notice was provided to customers of the branch or main office being relocated.

(c) *Undercapitalized institutions*. Filings to establish a branch by banks subject to section 38 of the FDI Act (12 U.S.C. 1831o) also should provide the information required by § 303.204. Filings pursuant to sections 38 and 18(d) of the FDI Act (12 U.S.C. 1831o and 1828(d)) may be filed concurrently or as a single filing.

* * * * *

■ 7. Revise § 303.43 to read as follows:

§ 303.43 Processing.

(a) *Expedited processing for branch establishments*. Filings to establish a branch by an eligible depository institution as defined in § 303.2(r) will be acknowledged in writing by the FDIC and will receive expedited processing if the depository institution is not currently subject to sanctions under § 369.5 of this chapter. A filing processed under expedited processing will be deemed approved on the later of the following:

(1) The third business day after receipt by the FDIC of a letter filing that includes the information set forth in § 303.42; or

(2) In the case of a filing to establish and operate a *de novo* interstate branch, the 5th day after the FDIC receives confirmation from the host State that the bank has both complied with the filing requirements of the host State and submitted a copy of its filing with the FDIC to the host State bank supervisor.

(b) *Expedited processing for branch relocations and main office relocations*. Filings for intrastate branch relocations or intrastate main office relocations will be acknowledged in writing by the FDIC and will receive expedited processing if the bank received an FDIC-assigned composite rating of 3 or better under the Uniform Financial Institutions Rating System as a result of its most recent Federal or State examination. A filing processed under expedited processing will be deemed approved on the third business day after receipt by the FDIC of a letter filing that includes the information set forth in § 303.42.

(c) *Standard processing*. For those filings that are not processed pursuant to the expedited procedures, the FDIC will provide the bank with written notification of the final action when the decision is rendered.

§ 303.44 [Removed]

■ 8. Remove § 303.44.

§ 303.45 as [Redesignated § 303.44]

■ 9. Redesignate § 303.45 as § 303.44.

■ 10. Revise newly redesignated § 303.44 to read as follows:

§ 303.44 Special provisions.

(a) *Emergency or disaster events*. (1) In the case of an emergency or disaster at a main office or a branch that requires that an office be immediately relocated to a temporary location, banks shall notify the appropriate FDIC office within 3 days of such temporary relocation.

(2) Within 10 days of the temporary relocation resulting from an emergency

or disaster, the bank shall submit a filing to the appropriate FDIC office, that identifies the nature of the emergency or disaster, specifies the location of the temporary branch, and provides an estimate of the duration the bank plans to operate the temporary branch.

(3) As part of the review process, the FDIC will determine on a case by case basis whether additional information is necessary.

(b) *Redesignation of main office and existing branch*. In cases where a bank desires to redesignate its main office as a branch and redesignate an existing branch as the main office, a single filing shall be submitted.

(c) *Expiration of approval*. Approval of a filing expires if within 24 months after the approval date a branch has not commenced business or a relocation has not been completed.

§ 303.46 [Redesignated as § 303.45]

■ 11. Redesignate § 303.46 as § 303.45.

■ 12. Amend newly redesignated § 303.45 by revising the introductory text to read as follows:

§ 303.45 Financial education programs that include the provision of bank products and services.

No filing or prior approval is required in order for a State nonmember bank to participate in one or more financial education programs that involve receiving deposits, paying withdrawals, or lending money if:

* * * * *

■ 13. Revise and republish § 303.184 to read as follows:

§ 303.184 Moving an insured branch of a foreign bank.

(a) *Filing procedures*—(1) *Where and when to file*. A filing by an insured branch of a foreign bank seeking the FDIC's consent to move from one location to another, as required by section 18(d)(1) of the FDI Act (12 U.S.C. 1828(d)(1)), shall be submitted in writing to the appropriate FDIC office.

(2) *Content of filing*. A complete letter filing shall include the exact location of the proposed site, including the street address.

(3) *Comptroller's application*. If the filer is submitting an application with the Comptroller that contains the information required by paragraph (a)(2) of this section, the filer may submit a copy to the FDIC in lieu of a separate filing.

(4) *Additional information*. The FDIC may request additional information to complete processing.

(b) *Processing*—(1) *Expedited processing for eligible insured branches*.

A filing submitted by an eligible insured branch as defined in § 303.181(c) will be acknowledged in writing by the FDIC and will receive expedited processing if the filer is proposing to move within the same State. A filing processed under expedited processing will be deemed approved on the third business day after the FDIC's receipt of a letter filing that includes the information set forth in § 303.42.

(2) *Standard processing.* For those filings that are not processed pursuant to the expedited procedures, the FDIC will provide the filer with written notification of the final action as soon as the decision is rendered.

(c) *Other approval criteria.* The FDIC may approve a filing under this section if the criteria in paragraphs (c)(1) through (6) of this section are satisfied.

(1) The factors set forth in section 6 of the FDI Act (12 U.S.C. 1816) have been considered and favorably resolved;

(2) The filer is at least adequately capitalized as defined in subpart H of part 324 of this chapter;

(3) Any financial arrangements that have been made in connection with the proposed relocation and that involve the filer's directors, officers, major shareholders, or their interests are fair and reasonable in comparison to similar arrangements that could have been made with independent third parties;

(4) Compliance with the CRA and any applicable related regulations, including part 345 of this chapter, has been considered and favorably resolved;

(5) No CRA protest as defined in § 303.2(l) has been filed that remains unresolved or, where such a protest has been filed and remains unresolved, the Director or designee concurs that approval is consistent with the purposes of the CRA and the filer agrees in writing to any conditions imposed regarding the CRA; and

(6) The filer agrees in writing to comply with any conditions imposed by the FDIC, other than the standard conditions defined in § 303.2(dd) that may be imposed without the filer's written consent.

(d) *Relocation of insured branch from one State to another.* If the foreign bank proposes to relocate an insured State branch to a State that is outside the State where the branch is presently located, in addition to meeting the approval criteria contained in paragraph (c) of this section, the foreign bank must:

(1) Comply with any applicable State laws or regulations of the States affected by the proposed relocation; and

(2) Obtain any required regulatory approvals from the appropriate State licensing authority of the State to which

the insured branch proposes to relocate before relocating the existing branch operations and surrendering its existing license to the appropriate State licensing authority of the State from which the branch is relocating.

PART 345—COMMUNITY REINVESTMENT

■ 14. The authority citation for part 345 continues to read as follows:

Authority: 12 U.S.C. 1814–1817, 1819–1820, 1828, 1831u, 2901–2908, 3103–3104, and 3108(a).

■ 15. In appendix G to part 345, revise § 345.29(c) to read as follows:

Appendix G to Part 345—Community Reinvestment Regulations

§ 345.29 Effect of CRA Performance on Applications

* * * * *

(c) *Interested parties.* The FDIC takes into account any views expressed by interested parties that are submitted in accordance with the FDIC's procedures set forth in part 303 of this chapter in considering CRA performance in an application listed in paragraphs (a)(3) and (4) and (b) of this section.

* * * * *

Federal Deposit Insurance Corporation.

By order of the Board of Directors.

Dated at Washington, DC, on December 16, 2025.

Debra A. Decker,

Executive Secretary.

[FR Doc. 2025–23837 Filed 12–23–25; 8:45 am]

BILLING CODE 6714–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2025–5392; Project Identifier MCAI–2025–01494–R; Amendment 39–23221; AD 2025–25–13]

RIN 2120–AA64

Airworthiness Directives; Leonardo S.p.A. Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Leonardo S.p.A. Model A119 and AW119 MKII helicopters. This AD was prompted by reports of trapped residue in the rear pneumatic line due to a non-optimal cleaning procedure. This AD requires accomplishing repetitive

engine acceleration checks and, depending on the results, replacing the rear pneumatic line and inspecting the fuel control unit (FCU), and accomplishing any necessary corrective actions. This AD also requires replacing certain parts if the engine acceleration check exceeds the maximum limit, which terminates the repetitive acceleration checks. If the limits do not exceed the maximum limit, this AD would allow this replacement as an optional terminating action. Additionally, this AD prohibits installing an affected engine or FCU on a helicopter unless certain requirements are met. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 13, 2026.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of January 13, 2026.

The FAA must receive comments on this AD by February 12, 2026.

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

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

- *Fax:* (202) 493–2251.

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

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

AD Docket: You may examine the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA–2025–5392; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

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

- You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood

Parkway, Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at *regulations.gov* under Docket No. FAA–2025–5392.

FOR FURTHER INFORMATION CONTACT:

Mahmood Shah, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (817) 222–5538; email: *mahmood.g.shah@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments using a method listed under **ADDRESSES**. Include “Docket No. FAA–2025–5392; Project Identifier MCAI–2025–01494–R” at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

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

Confidential Business Information

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

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2025–0199, dated September 16, 2025 (EASA AD 2025–0199) (also referred to as the MCAI), to correct an unsafe condition on Leonardo S.p.A. Model A119 and AW119MKII helicopters. The MCAI states that there have been reports of trapped residue in the rear pneumatic line caused by a non-optimal cleaning procedure during an engine shop visit.

This condition, if not corrected, could result in uncommanded fuel flow changes, which could lead to accelerations, power rollbacks, or instability, and consequent reduced control of the helicopter.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2025–5392.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed EASA AD 2025–0199, which specifies procedures for repetitively conducting engine acceleration checks for certain helicopters and, depending on the results, replacing the rear pneumatic line and inspecting the FCU pneumatic line input fitting. If there is contamination in the FCU pneumatic line input fitting, EASA AD 2025–0199 specifies procedures for replacing the FCU and cleaning the forward pneumatic line. If no contamination is found in the FCU pneumatic line input fitting, EASA AD 2025–0199 specifies procedures for adjusting the engine acceleration and accomplishing repetitive engine acceleration checks until the rear pneumatic line, engine, or FCU is replaced.

Additionally, EASA AD 2025–0199 specifies that for certain helicopters replacing the rear pneumatic line with a serviceable one is a requirement and terminates the repetitive acceleration checks. EASA AD 2025–0199 also specifies that several actions including replacing certain parts and accomplishing certain checks also terminate the repetitive acceleration checks. Finally, EASA AD 2025–0199 prohibits installing an affected engine or FCU on a helicopter unless certain requirements are met.

This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in **ADDRESSES**.

FAA’s Determination

These products have been approved by the civil aviation authority (CAA) of

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

AD Requirements

This AD requires accomplishing the actions specified in EASA AD 2025–0199, described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this AD. See “Differences Between this AD and the MCAI” for a discussion of the general differences included in this AD.

The owner/operator (pilot) holding at least a private pilot certificate may perform the initial acceleration checks and must enter compliance with the applicable paragraph(s) of the AD into the helicopter maintenance records in accordance with 14 CFR 43.9(a) and 91.417(a)(2)(v). The pilot may perform these checks as they involve only a ground check and monitoring of the engine gauges. These actions could be performed equally well by a pilot or a mechanic. This is an exception to the FAA’s standard maintenance regulations.

Differences Between This AD and the MCAI

The MCAI specifies to replace the affected pneumatic line with a serviceable pneumatic line immediately if acceleration exceeds the maximum value during the engine acceleration check and within 300 FH [flight hours] or 24 months, whichever occurs first, for all other helicopters. The 300–FH or 24-month compliance time would allow enough time to provide notice and opportunity for prior public comment so this AD allows the replacement as an optional terminating action for the repetitive acceleration checks but does not require the replacement in regards to paragraph (5) of EASA AD 2025–0199. The FAA is considering further rulemaking for this replacement that would allow the public the opportunity for prior public comment.

Explanation of Required Compliance Information

In the FAA’s ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some CAA ADs as the primary source of information for compliance with requirements for corresponding

FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, EASA AD 2025–0199 is incorporated by reference in this AD. This AD requires compliance with EASA AD 2025–0199 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this AD. Using common terms that are the same as the heading of a particular section in EASA AD 2025–0199 does not mean that operators need comply only with that section. For example, where the AD requirement refers to “all required actions and compliance times,” compliance with this AD requirement is not limited to the section titled “Required Action(s) and Compliance Time(s)” in EASA AD 2025–0199. Material required by EASA AD 2025–0199 for compliance will be available at *regulations.gov* under Docket No. FAA–2025–5392 after this AD is published.

Justification for Immediate Adoption and Determination of the Effective Date

Section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) authorizes agencies to dispense

with notice and comment procedures for rules when the agency, for “good cause,” finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under this section, an agency, upon finding good cause, may issue a final rule without providing notice and seeking comment prior to issuance. Further, section 553(d) of the APA authorizes agencies to make rules effective in less than thirty days, upon a finding of good cause.

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies forgoing notice and comment prior to adoption of this rule because residue in the rear pneumatic line if not detected and addressed could result in uncommanded fuel flow changes resulting in accelerations, power rollbacks, or instability. Since this condition could already exist and result in reduced control of the helicopter at any time without warning the initial engine acceleration check must be accomplished within 10 hours time-in-service after the effective date of this

AD. This compliance time is shorter than the time necessary for the public to comment and for publication of the final rule. Accordingly, notice and opportunity for prior public comment are impracticable and contrary to the public interest pursuant to 5 U.S.C. 553(b).

In addition, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days, for the same reasons the FAA found good cause to forgo notice and comment.

Regulatory Flexibility Act

The requirements of the Regulatory Flexibility Act (RFA) do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because the FAA has determined that it has good cause to adopt this rule without prior notice and comment, RFA analysis is not required.

Costs of Compliance

The FAA estimates that this AD affects 12 helicopters of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Engine acceleration check	2 work-hours × \$85 per hour = \$170 per check ..	\$0	\$170	\$2,040

ESTIMATED COSTS FOR OPTIONAL ACTIONS

Action	Labor cost	Parts cost	Cost per product
Replace engine	10 work-hours × \$85 per hour = \$850	\$1,301,315	\$1,302,165

The FAA estimates the following costs to do any repairs or replacements that would be required based on the

results of the check. The agency has no way of determining the number of

helicopters that might need these repairs or replacements:

ESTIMATED COSTS OF ON-CONDITION COSTS

Action	Labor Cost	Parts Cost	Cost per product
Replace FCU	4 work-hours × \$85 per hour = \$340	9,000	9,340
Clean pneumatic line and bulkhead coupling	1.5 work-hours × \$85 per hour = \$128	9,154	9,282
Replace rear pneumatic line	4 work-hours × \$85 per hour = \$340	1,000	1,340

Authority for This Rulemaking

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

detail the scope of the Agency’s authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil

aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or

develop on products identified in this rulemaking action.

Regulatory Findings

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

For the reasons discussed above, I certify that this AD:

(1) Is not a “significant regulatory action” under Executive Order 12866, and

(2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

2025–25–13 Leonardo S.p.A.: Amendment 39–23221; Docket No. FAA–2025–5392; Project Identifier MCAI–2025–01494–R.

(a) Effective Date

This airworthiness directive (AD) is effective January 13, 2026.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Leonardo S.p.A. Model A119 and AW119 MKII helicopters, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code 7100, Powerplant System.

(e) Unsafe Condition

This AD was prompted by reports of trapped residue in the rear pneumatic line due to non-optimal cleaning procedures. The

FAA is issuing this AD to detect and correct a contaminated rear pneumatic line. The unsafe condition, if not corrected, could result in uncommanded fuel flow changes, which could lead to accelerations, power rollbacks, or instability, and consequent reduced control of the helicopter.

(f) Compliance

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

(g) Required Actions

Except as specified in paragraphs (h) and (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency AD 2025–0199, dated September 16, 2025 (EASA AD 2025–0199).

(h) Exceptions to EASA AD 2025–0199

(1) Where EASA AD 2025–0199 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where EASA AD 2025–0199 requires compliance in terms of flight hours, this AD requires using hours time-in-service.

(3) Where the definition of affected engines, affected FCU [fuel control unit], affected pneumatic line, and serviceable pneumatic line in EASA AD 2025–0199 all refer to “the P&WC SB No. A39125R1”, for this AD replace that text with “the applicable original issue of the alert service bulletin listed in the Ref. Publications section (referencing P&WC SB No. A39125R1)”.

(4) Where paragraph (1) and paragraph (4.2) of EASA AD 2025–0199 specifies “accomplish acceleration checks of the engine in accordance with the instructions of the Part 1 of the ASB (referencing Part A of the P&WC SB No. A39125R1)”, for this AD replace that text with “accomplish acceleration checks of the engine”. The owner/operator (pilot) holding at least a private pilot certificate may perform the checks required by paragraph (g) of this AD and must enter compliance with these paragraphs into the helicopter 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.

(5) Where paragraph (5) of EASA AD 2025–0199 specifies to replace the affected pneumatic line with a serviceable pneumatic line within 300 FH or 24 months, whichever occurs first, for this AD that replacement is only required before further flight per paragraph (2) of EASA AD 2025–0199. For this AD if not required by paragraph (2) of EASA AD 2025–0199 this replacement is an optional terminating action for the repetitive acceleration checks required by paragraph (1) of EASA AD 2025–0199.

(6) This AD does not adopt the “Remarks” section of EASA AD 2025–0199.

(i) No Reporting Requirement

Although the material referenced in EASA AD 2025–0199 specifies to submit certain

information to the manufacturer, this AD does not require that action.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (k) of this AD and email to: AMOC@faa.gov.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(k) Additional Information

For more information about this AD, contact Mahmood Shah, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (817) 222–5538; email: mahmood.g.shah@faa.gov.

(l) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2025–0199, dated September 16, 2025.

(ii) [Reserved]

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

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

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

Issued on December 12, 2025.

Steven W. Thompson,

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

[FR Doc. 2025–23861 Filed 12–22–25; 11:15 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 39**

[Docket No. FAA–2025–5390; Project Identifier MCAI–2025–01470–T; Amendment 39–23220; AD 2025–25–12]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2025–13–12, which applied to all Airbus SAS Model A350–941 and –1041 airplanes. AD 2025–13–12 required replacement of any affected elevator flight control remote module (FCRM), prohibited the installation of aileron or spoiler FCRMs in place of elevator or rudder FCRMs, and limited the installation of FCRMs under certain conditions. Since the FAA issued AD 2025–13–12, the manufacturer developed a modification that eliminates the unsafe condition. This AD continues to require the actions of AD 2025–13–12. This AD also requires installation of the flight control and guidance system (FCGS) primary computer (PRIM) P14.1.3 and secondary computer (SEC) S14.1.2 software standards and prohibits installation of earlier software standards. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 13, 2026.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of January 13, 2026.

The FAA must receive comments on this AD by February 12, 2026.

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

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

- *Fax:* (202) 493–2251.

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

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

AD Docket: You may examine the AD docket at [regulations.gov](https://www.regulations.gov) under Docket

No. FAA–2025–5390; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

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

- 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–2025–5390.

FOR FURTHER INFORMATION CONTACT:

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

SUPPLEMENTARY INFORMATION:**Comments Invited**

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments using a method listed under the **ADDRESSES** section. Include “Docket No. FAA–2025–5390; Project Identifier MCAI–2025–01470–T” at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt

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

Background

The FAA issued AD 2025–13–12, Amendment 39–23078 (90 FR 30577, July 10, 2025) (AD 2025–13–12), for all Model A350–941 and –1041 airplanes. AD 2025–13–12 was prompted by an MCAI originated by EASA, which is the Technical Agent for the Member States of the European Union. EASA issued AD 2025–0129, dated June 5, 2025 (EASA AD 2025–0129), to correct an unsafe condition. EASA AD 2025–0129 states that an occurrence of loss of control of an outboard aileron surface was reported. Subsequent investigations determined that the electronic card of the FCRM of that aileron had been contaminated by hydraulic fluid. In addition, EASA determined that certain servocontrols were exposed to hydraulic contamination before delivery of the airplane to its first operator. Due to the similarity of design, elevator and rudder FCRMs could be subject to the same failure mode. EASA AD 2025–0129 also stated the AD was considered an interim action and that further AD action might follow.

AD 2025–13–12 required replacement of any affected elevator FCRM and prohibited the installation of aileron or spoiler FCRMs in place of elevator or rudder FCRMs. AD 2025–13–12 also limited the installation of aileron or spoiler FCRMs in place of elevator or rudder FCRMs. The FAA issued AD 2025–13–12 to address the unsafe condition on all Model A350–941 and –1041 airplanes.

Actions Since AD 2025–13–12 Was Issued

Since the FAA issued AD 2025–13–12, EASA superseded EASA AD 2025–0129 with EASA AD 2025–0197R1,

dated September 26, 2025 (EASA AD 2025–0197R1) (also referred to as the MCAI), to correct an unsafe condition for all Airbus SAS Model A350–941 and –1041 airplanes. After issuance of EASA AD 2025–0129, Airbus developed a modification, which includes installing FCGS PRIM P14.1.3 and SEC S14.1.2 software standards, to eliminate the unsafe condition.

The preamble to AD 2025–13–12 explained that the FAA considered that AD an interim action. The FAA has determined that further rulemaking is indeed necessary to mandate the terminating action developed by the airplane manufacturer.

The FAA is issuing this AD to address the unsafe condition on these products. You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2025–5390.

Explanation of Retained Requirements

Although this AD does not explicitly restate the requirements of AD 2025–13–12, this AD retains all of the requirements of AD 2025–13–12. Those requirements are referenced in EASA AD 2025–0197R1, which, in turn, is referenced in paragraph (g) of this AD.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed EASA AD 2025–0197R1. This material describes procedures for replacing affected FCRMs, which have been exposed to hydraulic fuel contamination, with serviceable FCRMs and repairing any related hydraulic leaks. EASA AD 2025–0197R1 prohibits “swapping” elevator or rudder FCRMs with spoiler or aileron FCRMs and installing an FCRM unless it is a serviceable FCRM. EASA AD 2025–0197R1 also describes procedures for modifying the FCGS by installing PRIM P14.1.3 and SEC S14.1.2 software standards and prohibits installation of earlier FCGS software standards after modification. EASA AD 2025–0197R1 specifies that the modification terminates the replacement of affected FCRMs, the prohibition for swapping elevator or rudder FCRMs with spoiler or aileron FCRMs, and the limitation for installing only a serviceable FCRM.

This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

FAA’s Determination

These products have been approved by the civil aviation authority of another

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

AD Requirements

This AD retains all requirements of AD 2025–13–12. This AD requires accomplishing the actions specified in EASA AD 2025–0197R1 described previously, except for any differences identified as exceptions in the regulatory text of this AD.

Explanation of Required Compliance Information

In the FAA’s ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, EASA AD 2025–0197R1 is incorporated by reference in this AD. This AD requires compliance with EASA AD 2025–0197R1 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this AD. Using common terms that are the same as the heading of a particular section in EASA AD 2025–0197R1 does not mean that operators need comply only with that section. For example, where the AD requirement refers to “all required actions and compliance times,” compliance with this AD requirement is not limited to the section titled “Required Action(s) and Compliance Time(s)” in EASA AD 2025–0197R1. Material required by EASA AD 2025–0197R1 for compliance will be available at *regulations.gov* under Docket No. FAA–2025–5390 after this AD is published.

Justification for Immediate Adoption and Determination of the Effective Date

Section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) authorizes agencies to dispense with notice and comment procedures for rules when the agency, for “good cause,” finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under this

section, an agency, upon finding good cause, may issue a final rule without providing notice and seeking comment prior to issuance. Further, section 553(d) of the APA authorizes agencies to make rules effective in less than thirty days, upon a finding of good cause.

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies forgoing notice and comment prior to adoption of this rule because an aileron FCRM electronic card exposed to hydraulic fluid has led to loss of control of an outboard aileron surface, and elevator and rudder FCRM electronic cards exposed to hydraulic fluid are also subject to failure due to their similarity of design. Control of the airplane is significantly degraded through the loss of control of an elevator or rudder surface, resulting in loss of control of the airplane. To mitigate this unsafe condition, the FAA issued interim AD 2025–13–12 to require replacement of affected FCRMs. However, those replacements are not repetitive, and the modification must be accomplished to eliminate the unsafe condition. Additionally, the compliance time in this AD is shorter than the time necessary for the public to comment and for publication of the final rule. Accordingly, notice and opportunity for prior public comment are impracticable and contrary to the public interest pursuant to 5 U.S.C. 553(b).

In addition, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days, for the same reasons the FAA found good cause to forgo notice and comment.

Regulatory Flexibility Act

The requirements of the Regulatory Flexibility Act (RFA) do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because the FAA has determined that it has good cause to adopt this rule without notice and comment, RFA analysis is not required.

Costs of Compliance

The FAA estimates that this AD affects 39 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Retained actions from AD 2025–13–12	12 work-hours × \$85 per hour = \$1,020 ..	* \$110,256	Up to \$111,276 ..	Up to \$4,339,764.
New actions	14 work-hours × \$85 per hour = \$1,190 ..	1,044	\$2,234	\$87,126.

* Parts cost if all four FCRMs are replaced.

The FAA estimates the following costs to do any necessary on-condition action that would be required based on

the results of any required actions. The FAA has no way of determining the

number of aircraft that might need this on-condition action:

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
3 work-hours × \$85 per hour = \$255	Up to \$27,564	Up to \$27,819.

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify that this AD:

- (1) Is not a "significant regulatory action" under Executive Order 12866, and
- (2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

- 2. The FAA amends § 39.13 by:
 - a. Removing Airworthiness Directive 2025–13–12, Amendment 39–23078 (90 FR 30577, July 10, 2025); and
 - b. Adding the following new airworthiness directive:

2025–25–12 Airbus SAS: Amendment 39–23220; Docket No. FAA–2025–5390; Project Identifier MCAI–2025–01470–T.

(a) Effective Date

This airworthiness directive (AD) is effective January 13, 2026.

(b) Affected ADs

This AD replaces AD 2025–13–12, Amendment 39–23078 (90 FR 30577, July 10, 2025) (AD 2025–13–12).

(c) Applicability

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

(d) Subject

Air Transport Association (ATA) of America Code 27, Flight Controls.

(e) Reason

This AD was prompted by a report of loss of control of an outboard aileron surface due to hydraulic fluid contaminating an electronic card of the flight control remote module (FCRM). The FAA is issuing this AD to address FCRM electronic cards exposed to hydraulic fluid contamination. This condition, if not detected and corrected,

could lead to runaway of rudder or elevator surface, resulting in loss of control of the airplane.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2025–0197R1, dated September 26, 2025 (EASA AD 2025–0197R1).

(h) Exceptions to EASA AD 2025–0197R1

(1) Where EASA AD 2025–0197R1 refers to "07 May 2025 [the effective date of EASA AD 2025–0099]," this AD requires using July 25, 2025 (the effective date of AD 2025–13–12).

(2) Where EASA AD 2025–0197R1 refers to "12 June 2025 [the effective date of EASA AD 2025–0129]," this AD requires using July 25, 2025 (the effective date of AD 2025–13–12).

(3) Where EASA AD 2025–0197R1 refers to its effective date, this AD requires using the effective date of this AD.

(4) Where paragraph (1) of EASA AD 2025–0197R1 states "do not swap", this AD requires replacing that text with "do not replace".

(5) Where paragraph (2) of EASA AD 2025–0197R1 states "is reported on an aeroplane", this AD requires replacing that text with "is documented in the aircraft maintenance records or has been reported to Airbus".

(6) Where table 1 of EASA AD 2025–0197R1 states "close to", this AD requires replacing that text with "adjacent to".

(7) Where paragraph (13) of EASA AD 2025–0197R1 specifies installing certain software standards on the airplane in accordance with Airbus approved instructions, for this AD, those instructions must be approved using a method specified in paragraph (j)(2) of this AD.

(8) This AD does not adopt the "Remarks" section of EASA AD 2025–0197R1.

(i) No Reporting Requirement

Although material referenced in EASA AD 2025–0197R1 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Additional AD Provisions

The following provisions also apply to this AD:

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

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

(ii) AMOCs approved previously for AD 2025–13–12 are approved as AMOCs for the corresponding provisions of EASA AD 2025–0197R1 that are required by paragraph (g) of this AD.

(2) *Contacting the Manufacturer*: For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, AIR–520, Continued Operational Safety Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC)*: Except as required by paragraph (j)(2) of this AD, where the service bulletins referenced in EASA AD 2025–0197R1 contain procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; and where the alert operators transmission (AOT) referenced in EASA AD 2025–0197R1 contains paragraphs that are labeled as RC, the instructions in RC paragraphs, including subparagraphs under and RC paragraph, must be done to comply with this AD. Any procedures or tests, and instructions in paragraphs including subparagraphs under those paragraphs, as applicable, that are not identified as RC are recommended. Procedures and tests, and instructions in paragraphs including subparagraphs under those paragraphs, as applicable, that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures, tests, and instructions, as applicable, identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures, tests, or instructions, as applicable, identified as RC require approval of an AMOC.

(k) Additional Information

For more information about this AD, contact Frank Carreras, Aviation Safety

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

(l) Material Incorporated by Reference

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

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

(i) European Aviation Safety Agency (EASA) AD 2025–0197R1, dated September 26, 2025.

(ii) [Reserved]

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

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

Issued on December 19, 2025.

Peter A. White,

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

[FR Doc. 2025–23858 Filed 12–22–25; 11:15 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 97**

[Docket No. 31641; Amdt. No. 4198]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These

changes are designed to provide for the safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective December 29, 2025. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 29, 2025.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops–M30, 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590–0001;

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Information Services, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA).

For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov.

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center online at nfdc.faa.gov to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT:

Rune Duke, Manager (Acting), Standards Section, Flight Procedures and Airspace Group, Aviation Safety, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., STB Annex, Bldg. 26, Room 217, Oklahoma City, OK 73099. Telephone (405) 954–1139.

SUPPLEMENTARY INFORMATION: This rule amends 14 CFR part 97 by amending the referenced SIAPs. The complete regulatory description of each SIAP is listed on the appropriate FAA Form 8260, as modified by the National Flight Data Center (NFDC)/Permanent Notice to Airmen (P–NOTAM), and is

incorporated by reference under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR 97.20. The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, pilots do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained on FAA form documents is unnecessary. This amendment provides the affected CFR sections, and specifies the SIAPs and Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPs, Takeoff Minimums and ODPs as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP and Takeoff Minimums and ODP as amended in the transmittal. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained for each SIAP and Takeoff Minimums and ODP as modified by FDC permanent NOTAMs.

The SIAPs and Takeoff Minimums and ODPs, as modified by FDC permanent NOTAM, and contained in this amendment are based on criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these changes to SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied only to specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a FDC NOTAM as an emergency action of immediate flight safety relating directly to published aeronautical charts.

The circumstances that created the need for these SIAP and Takeoff Minimums and ODP amendments require making them effective in less than 30 days.

Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making these SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under DOT regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact

on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air traffic control, Airports, Incorporation by reference, Navigation (air).

Issued in Washington, DC, December 19, 2025.

Rune Duke,

Manager (Acting), Standards Section, Flight Procedures and Airspace Group, Flight Technologies & Procedures Division, Federal Aviation Administration.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, 14 CFR part 97 is amended by amending Standard Instrument Approach Procedures and Takeoff Minimums and ODPs, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

* * * Effective Upon Publication

AIRAC date	State	City	Airport	FDC No.	FDC date	Procedure name
22-Jan-26 ...	VA	Galax Hillsville	Twin County	5/3182	12/2/2025	RNAV (GPS) RWY 1, Amdt 1C.
22-Jan-26 ...	OK	Ardmore	Ardmore Downtown Exec	5/3630	12/4/2025	Takeoff Minimums and Obstacle DP, Amdt 3.
22-Jan-26 ...	PA	Lock Haven	William T. Piper Meml	5/3632	12/4/2025	Takeoff Minimums and Obstacle DP, Amdt 1.
22-Jan-26 ...	WV	Huntington	Tri-State/Milton J. Ferguson Fld.	5/3635	12/4/2025	Takeoff Minimums and Obstacle DP, Amdt 1.
22-Jan-26 ...	WA	Seattle	Boeing Fld/King County Intl	5/4076	12/5/2025	RNAV (RNP) Z RWY 32L, Orig.
22-Jan-26 ...	AK	Minchumina	Minchumina	5/4799	10/6/2025	RNAV (GPS) RWY 3, Amdt 1.
22-Jan-26 ...	CO	Fort Collins/ Loveland.	Northern Colorado Rgnl	5/6385	7/29/2025	VOR–A, Amdt 7C.
22-Jan-26 ...	WA	Seattle	Boeing Fld/King County Intl	5/6478	11/12/2025	RNAV (GPS) Y RWY 32L, Orig-A.
22-Jan-26 ...	WA	Seattle	Boeing Fld/King County Intl	5/6488	11/12/2025	RNAV (RNP) Z RWY 14R, Orig-A.
22-Jan-26 ...	TN	Lewisburg	Ellington	5/8095	8/15/2025	RNAV (GPS) RWY 20, Amdt 1B.
22-Jan-26 ...	TX	Greenville	Majors	5/8495	12/5/2025	ILS Z OR LOC Z RWY 17, Amdt 9.
22-Jan-26 ...	TX	Greenville	Majors	5/8496	12/5/2025	TACAN RWY 35, Orig-B.
22-Jan-26 ...	TX	Greenville	Majors	5/8497	12/5/2025	TACAN RWY 17, Orig-C.

AIRAC date	State	City	Airport	FDC No.	FDC date	Procedure name
22-Jan-26 ...	AZ	Mesa	Falcon Fld	5/8887	9/25/2025	RNAV (GPS)–B, Amdt 1.

[FR Doc. 2025–23850 Filed 12–23–25; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31640; Amdt. No. 4197]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.
ACTION: Final rule.

SUMMARY: This rule establishes, amends, suspends, or removes Standard Instrument Approach Procedures (SIAPS) and associated Takeoff Minimums and Obstacle Departure procedures (ODPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective December 29, 2025. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 29, 2025.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops-M30. 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590–0001.
2. The FAA Air Traffic Organization Service Area in which the affected airport is located;
3. The office of Aeronautical Information Services, 6500 South

MacArthur Blvd., Oklahoma City, OK 73169 or,

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

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center at nfdc.faa.gov to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT:

Rune Duke, Manager (Acting), Standards Section, Flight Procedures and Airspace Group, Aviation Safety, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., STB Annex, Bldg. 26, Room 217, Oklahoma City, OK 73099. Telephone (405) 954–1139.

SUPPLEMENTARY INFORMATION: This rule amends 14 CFR part 97 by establishing, amending, suspending, or removes SIAPS, Takeoff Minimums and/or ODPs. The complete regulatory description of each SIAP and its associated Takeoff Minimums or ODP for an identified airport is listed on FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR 97.20. The applicable FAA Forms are 8260–3, 8260–4, 8260–5, 8260–15A, 8260–15B, when required by an entry on 8260–15A, and 8260–15C.

The large number of SIAPs, Takeoff Minimums and ODPs, their complex nature, and the need for a special format make publication in the **Federal Register** expensive and impractical. Further, pilots do not use the regulatory text of the SIAPs, Takeoff Minimums or ODPs, but instead refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP, Takeoff Minimums and ODP listed on FAA form documents is unnecessary. This amendment provides

the affected CFR sections and specifies the types of SIAPS, Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure, and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPS, Takeoff Minimums and/or ODPs as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP, Takeoff Minimums and ODP as amended in the transmittal. Some SIAP and Takeoff Minimums and textual ODP amendments may have been issued previously by the FAA in a Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flights safety relating directly to published aeronautical charts.

The circumstances that created the need for some SIAP and Takeoff Minimums and ODP amendments may require making them effective in less than 30 days. For the remaining SIAPs and Takeoff Minimums and ODPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs and Takeoff Minimums and ODPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making some SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally

current. It, therefore—(1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Lists of Subjects in 14 CFR Part 97

Air traffic control, Airports, Incorporation by reference, Navigation (air).

Issued in Washington, DC, on December 19, 2025.

Rune Duke,

Manager (Acting), Standards Section, Flight Procedures and Airspace Group, Flight Technologies & Procedures Division, Federal Aviation Administration.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, 14 CFR part 97 is amended by establishing, amending, suspending, or removing Standard Instrument Approach Procedures and/or Takeoff Minimums and Obstacle Departure Procedures effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

Effective 22 January 2026

Juneau, AK, JNU/PAJN, JUNEAU SEVEN, Graphic DP
Juneau, AK, JNU/PAJN, RNAV (GPS) Z RWY 8, Amdt 2D
Juneau, AK, JNU/PAJN, Takeoff Minimums and Obstacle DP, Amdt 5
Mesa, AZ, FFZ, RNAV (GPS) RWY 4L, Amdt 1E
Mesa, AZ, FFZ, RNAV (GPS) RWY 4R, Amdt 1G
Clearwater, FL, KCLW, RNAV (GPS) A, Orig
Clearwater, FL, KCLW, Takeoff Minimums and Obstacle DP, Orig
Beverly, MA, BVY, RNAV (GPS) RWY 9, Amdt 1A
Beverly, MA, BVY, RNAV (GPS) RWY 16, Amdt 2A
Beverly, MA, BVY, RNAV (GPS) RWY 27, Amdt 1D
Beverly, MA, BVY, RNAV (GPS) RWY 34, Orig-F

Bozeman, MT, BZN, ILS Y OR LOC Y RWY 12, ILS Y RWY 12 (SA CAT II), Amdt 11
Bozeman, MT, BZN, ILS Z OR LOC Z RWY 12, ILS Z RWY 12 (SA CAT II), Orig
Bozeman, MT, BZN, RNAV (RNP) Z RWY 12, Amdt 2
Kinston, NC, ISO, ILS OR LOC RWY 5, Amdt 13
Kinston, NC, ISO, RNAV (GPS) RWY 5, Amdt 4
Kinston, NC, ISO, RNAV (GPS) RWY 23, Amdt 4
Newark, NJ, EWR, GLS RWY 22L, Amdt 1B
Newark, NJ, EWR, GLS RWY 22R, Amdt 2A
Newark, NJ, EWR, ILS OR LOC RWY 22L, ILS RWY 22L (SA CAT I), ILS RWY 22L (CAT II), ILS RWY 22L (CAT III), Amdt 14A
Newark, NJ, EWR, ILS OR LOC RWY 22R, Amdt 7A
Newark, NJ, EWR, RNAV (GPS) RWY 22R, Amdt 2A
Newark, NJ, EWR, RNAV (GPS) Z RWY 22L, Amdt 3A
Newark, NJ, EWR, RNAV (RNP) Y RWY 22L, Amdt 1B
Teterboro, NJ, TEB, ILS Z OR LOC Z RWY 6, Amdt 32
Teterboro, NJ, TEB, RNAV (GPS) RWY 1, Orig
Teterboro, NJ, TEB, RNAV (GPS) Y RWY 6, Amdt 5
Columbus, OH, CMH, RNAV (RNP) Z RWY 10L, Amdt 4
Columbus, OH, CMH, RNAV (RNP) Z RWY 10R, Amdt 4
Redmond, OR, RDM, ILS OR LOC RWY 23, Amdt 6
Redmond, OR, RDM, RNAV (GPS) RWY 11, Amdt 4
Redmond, OR, RDM, RNAV (GPS) Y RWY 23, Amdt 2
Redmond, OR, RDM, RNAV (RNP) Z RWY 5, Amdt 3
Redmond, OR, RDM, RNAV (RNP) Z RWY 23, Amdt 3
Redmond, OR, RDM, VOR–A, Amdt 7
North Kingstown, RI, OQU, ILS OR LOC RWY 16, Amdt 11, CANCELED
North Kingstown, RI, OQU, LOC RWY 16, Orig
North Kingstown, RI, OQU, RNAV (GPS) RWY 16, Amdt 2
North Kingstown, RI, OQU, RNAV (GPS) RWY 34, Amdt 2
North Kingstown, RI, KOQU, Takeoff Minimums and Obstacle DP, Amdt 2
North Kingstown, RI, OQU, VOR RWY 34, Amdt 4
North Kingstown, RI, OQU, VOR–A, Amdt 7
Clarksville, VA, W63, Takeoff Minimums and Obstacle DP, Amdt 2
Emporia, VA, EMV, LOC RWY 34, Amdt 3
Burlington, VT, BTV, ILS OR LOC RWY 15, Amdt 27
Burlington, VT, BTV, ILS OR LOC RWY 33, Amdt 3
Burlington, VT, BTV, RNAV (GPS) RWY 1, Amdt 2
Burlington, VT, BTV, RNAV (GPS) Y RWY 33, Amdt 1
Burlington, VT, BTV, RNAV (GPS) Z RWY 33, Amdt 2
Burlington, VT, BTV, VOR RWY 1, Amdt 1A
[FR Doc. 2025–23849 Filed 12–23–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 58 and 1005

[Docket No. FR–5593–N–06]

RIN 2577–AD25

Strengthening the Section 184 Indian Housing Loan Guarantee Program; Extension of Compliance Date

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Final rule; extension of compliance date.

SUMMARY: This document indefinitely delays the compliance date for HUD’s final rule entitled “Strengthening the Section 184 Indian Housing Loan Guarantee Program” published on March 20, 2024 until HUD completes necessary updates to the handbook, which will provide necessary guidance for implementing the final rule.

DATES: The compliance date announced on January 17, 2025, at 90 FR 5604, is indefinitely delayed. HUD will publish a document in the **Federal Register** announcing a new compliance date.

FOR FURTHER INFORMATION CONTACT: Chung-Yiu “Andrew” Lee, Senior Native American Policy Advisor, Office of Loan Guarantee, Office of Native American Programs, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street SW, Room 4108, Washington, DC 20410; email at

Section184comments@hud.gov or telephone number 202–402–6190 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit <https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs>.

SUPPLEMENTARY INFORMATION:

I. Background

On March 20, 2024, HUD published the final rule (89 FR 20032), which amended the regulations to the Section 184 Indian Housing Loan Guarantee Program (Section 184 Program). Since its inception, the Section 184 Program has experienced an increase in demand. As a result, the final rule updated program regulations to minimize potential risk and increase program participation by financial institutions, and added eligibility and participation requirements for Lender Applicants,

Direct Guarantee Lenders, Non-Direct Guarantee Lenders, Holders and Servicers and other Section 184 Program participants. The final rule also clarified the rules governing Tribal participation in the program, established underwriting requirements, specifies rules on the closing and endorsement process, established stronger and clearer servicing requirements, established program rules governing claims submitted by servicers and paid by HUD, and added standards governing monitoring, reporting, sanctions, and appeals. Lastly, the final rule added new definitions and makes statutory conforming amendments, including the categorical exclusion of the Section 184 Program in HUD's environmental review regulations.

On June 14, 2024, HUD published a document in the **Federal Register** (89 FR 50523) announcing that the final rule's effective date would be delayed from June 18, 2024, to December 31, 2024, with a compliance date of March 1, 2025. Subsequently, HUD published an additional document in **Federal Register** (90 FR 5604) extending the compliance date for the final rule from March 1, 2025, to December 31, 2025.

II. Delay of Compliance Date

HUD is currently drafting a handbook to implement the final rule. The handbook will provide comprehensive guidance and clarification for all stakeholders to fully understand and implement the final rule. Given the size of the handbook, its accompanying forms, level of additional consultation with stakeholders needed to complete the handbook, and intensive training on key components of the new handbook that must be given to stakeholders, HUD has determined that it needs additional time before enforcing the final rule. Further, HUD has heard from Tribes, lenders, servicers, and other participants that additional time is needed after the publication of the handbook for these stakeholders to conform their policies, procedures, and systems to comply with the handbook and the final rule.

As a result of these factors, HUD is therefore indefinitely delaying the compliance date of the final rule. When HUD completes updates to the handbook, HUD will publish an additional **Federal Register** notice announcing a new compliance date for the final rule. This future notice will provide a reasonable time for implementation before requiring

compliance, of at least 30 and up to 90 days after the publication of the notice.

Benjamin Hobbs,

Principal Deputy Assistant Secretary for Public and Indian Housing.

[FR Doc. 2025–23884 Filed 12–23–25; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF JUSTICE

Office of the Attorney General

28 CFR Part 0

[Docket No. JMD165; AG Order No. 6570–2025]

Consolidation of the Office of the Executive Secretariat Into the Justice Management Division

AGENCY: Department of Justice.

ACTION: Final rule.

SUMMARY: This rule amends the Department's organizational regulations by eliminating the Office of the Executive Secretariat as a separate office and consolidating its functions within the Justice Management Division.

DATES: Effective December 29, 2025.

FOR FURTHER INFORMATION CONTACT: John E. Thompson, Deputy General Counsel, Justice Management Division; email: John.E.Thompson@usdoj.gov.

SUPPLEMENTARY INFORMATION:

I. Summary

On January 17, 2025, the Department of Justice published a final rule amending its organizational regulations to establish the functions of the Office of the Executive Secretariat ("OES") which had been created as a separate component of the Department on August 17, 2023. Office of the Executive Secretariat, 90 FR 5608 (Jan. 17, 2025).

Upon further consideration of the best way to organize the Department and consistent with the Administration's deregulatory and streamlining initiatives, this rule rescinds the prior establishment of OES as a separate component. This rule restores its functions to a staff within the Justice Management Division, which had formerly performed those functions prior to the August 17, 2023, establishment of OES.

This rule also revises 28 CFR 0.1 to delete OES from the list of Department components.

II. Administrative Procedure Act

This rule is a rule of agency organization, procedure, and practice and is limited to matters of agency management and personnel. Therefore,

it is not a substantive rule, and, as such, it is exempt from the requirements of prior notice and comment and a 30-day delay in the effective date. See 5 U.S.C. 553(a)(2), (b)(A), (d).

III. Regulatory Analyses

In developing this final rule, the Department considered numerous statutes and executive orders applicable to the rulemaking process. The Department's analysis of the applicability of those statutes and executive orders to this rule is summarized below.

A. Executive Order 12866 (Regulatory Planning and Review), Executive Order 13563 (Improving Regulation and Regulatory Review), and Executive Order 14192 (Unleashing Prosperity Through Deregulation)

This final rule is not a significant regulatory action under section 3(f) of Executive Order 12866, and as supplemented by Executive Order 13563. This rule is limited to agency organization, management, and personnel as described by Executive Order 12866, section 3(d)(3), and therefore is not a "regulation" or "rule" as defined by that Executive Order. Accordingly, this action has not been reviewed by the Office of Management and Budget.

Further, as this rule relates to agency organization, management, or personnel, it is fully exempt from the numerical 10-for-1 and cost offset requirements of Executive Order 14192.

B. Executive Order 14294 (Overcriminalization of Federal Regulations)

Executive Order 14294 requires agencies promulgating regulations with criminal regulatory offenses potentially subject to criminal enforcement to explicitly describe the conduct subject to criminal enforcement, the authorizing statutes, and the mens rea standard applicable to each element of those offenses. This final rule does not impose a criminal regulatory penalty and is thus exempt from E.O. 14294 requirements.

C. Regulatory Flexibility Act

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. 5 U.S.C. 601.

A Regulatory Flexibility Analysis is not required for this final rule because the Department is not required to publish a general notice of proposed rulemaking for this matter.

D. Paperwork Reduction Act

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

E. Executive Order 13132 (Federalism)

A rule has federalism implications under Executive Order 13132 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. E.O. 13132, sec. 1(a). The Department has analyzed this final rule under that Order and determined that this rule does not have federalism implications.

F. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1531–1538, requires Federal agencies to determine whether a rule, if promulgated, will result in the expenditure by State, local, or Tribal governments, in the aggregate, or by the private sector, of \$100 million (adjusted annually for inflation) or more in any one year. 2 U.S.C. 1532(a). This final rule does not require or result in expenditures by any of the above-named entities.

G. Executive Order 12988 (Civil Justice Reform), Plain Language

This final rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988.

H. Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments)

This final rule does not have Tribal implications under Executive Order 13175 because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

I. Congressional Review Act

This rule relates to agency management, personnel, and organization, and does not substantially affect the rights or obligations of non-agency parties. 5 U.S.C. 804(3)(B), (C). This action is accordingly not a “rule” as that term is used in the Congressional Review Act, *see* 5 U.S.C. 804(3), and the

reporting requirement of 5 U.S.C. 801 does not apply.

List of Subjects in 28 CFR Part 0

Authority delegations (Government agencies), Government employees, Organization and functions (Government agencies).

Authority and Issuance

For the reasons stated above, the Department of Justice amends 28 CFR Part 0 as follows:

PART 0—ORGANIZATION OF THE DEPARTMENT OF JUSTICE

■ 1. The authority citation for part 0 continues to read as follows:

Authority: 5 U.S.C. 301; 28 U.S.C. 509, 510, 515–519.

§ 0.1 [Amended]

■ 2. In § 0.1, amend table 1 by removing the entry for “Office of the Executive Secretariat.”

■ 3. Amend § 0.77 by adding paragraph (p) to read as follows:

§ 0.77 Operational functions.

* * * * *

(p) Ensure that official documents requiring the review, approval, or signature by the Attorney General, Deputy Attorney General, or Associate Attorney General are assigned, tracked, and cleared within the Department of Justice, as appropriate; manage select interagency requests for official approval or concurrence by the Attorney General, Deputy Attorney General, or Associate Attorney General; Departmental clearances; and submissions from other agencies for review and clearance, including rulemakings and guidance documents circulated by the Office of Management and Budget pursuant to Executive Order 12866 or any successor order and documents circulated by the Department of State for clearance, within the Department of Justice.

Subpart O–1 [Removed]

■ 4. Remove subpart O–1, including § 0.81.

Dated: December 19, 2025.

Pamela Bondi,

Attorney General.

[FR Doc. 2025–23880 Filed 12–23–25; 8:45 am]

BILLING CODE 4410–PR–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 27

Transportation Security Administration

49 CFR Part 1503

RIN 1601–AB16

Civil Monetary Penalty Adjustments for Inflation

AGENCY: Department of Homeland Security (DHS).

ACTION: Final rule; technical amendment.

SUMMARY: On January 2, 2025, DHS adjusted for inflation its civil monetary penalties for 2025, in accordance with the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 and Executive Order of the President (EOP) Office of Management and Budget (OMB) guidance. The new penalty amounts were effective for penalties assessed after January 2, 2025, whose associated violations occurred after November 2, 2015. DHS is making a technical amendment to the Code of Federal Regulations to make several clerical revisions to the codified 2025 penalty amounts.

DATES: This technical amendment is effective on December 29, 2025.

FOR FURTHER INFORMATION CONTACT: Hillary Hunnings, Attorney-Advisor, 202–878–9252, hillary.hunnings@hq.dhs.gov.

SUPPLEMENTARY INFORMATION:

I. Statutory and Regulatory Background

On November 2, 2015, the President signed into law the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Pub. L. 114–74 section 701 (Nov. 2, 2015)) (2015 Act). The 2015 Act amended the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note) to further improve the effectiveness of civil monetary penalties and to maintain their deterrent effect. The 2015 Act required agencies to make annual adjustments for inflation. On January 2, 2025, DHS published a final rule making the 2025 annual inflation adjustments to its civil monetary penalties pursuant to the 2015 Act and pursuant to guidance OMB issued to agencies on December 17, 2024 (January 2025 rule). See 90 FR 1 (Jan. 2, 2025). The penalty amounts were effective for penalties assessed after January 2, 2025,

whose associated violations occurred after November 2, 2015.

II. Technical Revisions

DHS is making a technical amendment to the Code of Federal Regulations. This technical amendment will make several clerical revisions to the codified 2025 penalty amounts. Specifically, DHS is making clerical

revisions in the Coast Guard’s and the Transportation Security Administration’s codified 2025 penalty amounts.

The preamble of the January 2025 rule described inflation adjustments to all 152 Coast Guard penalties. However, for five of the 152 penalties, the Coast Guard inadvertently failed to make corresponding adjustments to the

codified penalty table in 33 CFR 27.3. This rule revises Table 1 in 33 CFR 27.3 to include the correct 2025 inflation-adjusted penalty amounts for the affected penalties, consistent with the amounts set out in the preamble of the January 2025 rule. The Coast Guard is revising only the five penalties in the table below. All other penalty amounts in the table remain unchanged.

CORRECTED COAST GUARD 2025 PENALTY AMOUNTS
[Five affected entries]

Citation	Civil monetary penalty description	New penalty amount as adjusted by this final rule
46 U.S.C. 8701(d)	Merchant Mariners Documents	\$1,562
46 U.S.C. 10104(a)(2)	Requirement to Report Sexual Assault and Harassment; Mandatory Reporting by Responsible Entity of a Vessel.	52,962
46 U.S.C. 10104(d)(2)	Requirement to Report Sexual Assault and Harassment; Company After Action Summary, violation of 10104(d)(1).	26,481
46 U.S.C. 10104(d)(2)	Requirement to Report Sexual Assault and Harassment; Company After Action Summary, Daily Noncompliance Penalty.	529
46 U.S.C. 10104(d)(2)	Requirement to Report Sexual Assault and Harassment; Company After Action Summary, Civil Penalty Maximum.	52,962

In addition, TSA determined that a statutory revision enacted in May 2024 required an update to the January 2025 rule. The FAA Reauthorization Act of 2024 (Pub. L. 118–63, 138 Stat. 1025, 1102 (May 16, 2024)) amended 49 U.S.C. 46301 to raise the statutory

maximum civil monetary penalty amounts that TSA may assess for security violations. This rule revises the relevant penalty provisions to incorporate the 2024 statutory amendment to 49 U.S.C. 46301 and the 2025 adjustment for inflation. This rule

ensures that the regulatory text accurately reflects TSA’s current statutory penalty authority and accordingly the civil monetary penalty amounts as adjusted for inflation.

CORRECTED TSA 2025 PENALTY AMOUNTS
[Two affected entries]

Citation	Civil monetary penalty description	New penalty amount as adjusted by this final rule
49 U.S.C. 46301(a)(1), (4), (5); 49 U.S.C. 46301(d)(8); 49 CFR 1503.401(c)(1)–(2).	Violation of 49 U.S.C. ch. 449 (except secs. 44902, 44903(d), 44907(a)–(d)(1)(A), 44907(d)(1)(C)–(f), 44908, and 44909), or 49 U.S.C. 46302 or 46303, a regulation prescribed, or order issued thereunder by an individual (except an airman serving as an airman), any person not operating an aircraft for the transportation of passengers or property for compensation, or a small business concern.	\$17,062 (up to a total of 100,000 for individuals or small businesses, \$1,200,000 for others).
49 U.S.C. 46301(a)(1), (4), (5), (6); 49 U.S.C. 46301(d)(2), (8); 49 CFR 1503.401(c)(3).	Violation of 49 U.S.C. ch. 449 (except secs. 44902, 44903(d), 44907(a)–(d)(1)(A), 44907(d)(1)(C)–(f), 44908, and 44909), or 49 U.S.C. 46302 or 46303, a regulation prescribed, or order issued thereunder by a person operating an aircraft for the transportation of passengers or property for compensation.	\$42,657 (up to a total of \$1,200,000 per civil penalty action).

III. Administrative Procedure Act (APA)

DHS is issuing this rule without prior notice and comment because the Department has determined that good cause exists under 5 U.S.C. 553(b)(B). The APA permits an agency to dispense with notice and comment when doing so would be “impracticable, unnecessary, or contrary to the public

interest.” 5 U.S.C. 553(b)(B). This amendment falls within the unnecessary prong because, for both the Coast Guard and TSA revisions, it makes only non-substantive, corrective revisions to the civil monetary penalty adjustments published in the January 2025 rule. See *North Carolina Growers’ Ass’n, Inc. v. United Farm Workers*, 702 F.3d 755, 766–67 (4th Cir. 2012) (describing the

unnecessary prong as “when amendments are minor or merely technical and of little public interest” (citation omitted)). As discussed above, the Coast Guard inadvertently excluded several properly inflation-adjusted penalty amounts from the codified table in 33 CFR 27.3 in the 2025 annual adjustment rule, even though the correct amounts appeared in

the preamble. This technical amendment corrects that clerical oversight. The revision is non-substantive, as it merely brings the regulatory text into alignment with the penalty levels listed in the preamble, which the Coast Guard intended to be operative for 2025.

Also as discussed above, TSA updated the January 2025 rule to account for a statutory amendment enacted in May 2024 that increased certain maximum penalty authorities under 49 U.S.C. 46301. Without this update, the CFR would continue to reflect the outdated maximum amounts rather than those currently authorized by Congress. Accordingly, this rule revises the regulatory text to reflect the updated statutory maximum amounts. This revision is also non-substantive and corrective, as it merely conforms the CFR to statutorily authorized penalty maximums already in effect that

the Department lacks discretion to modify.

DHS therefore finds notice and comment unnecessary under 5 U.S.C. 553(b)(B). For the same reasons, DHS also finds good cause under 5 U.S.C. 553(d)(3) to make this technical amendment effective upon publication.

List of Subjects

33 CFR Part 27

Administrative practice and procedure, Penalties.

49 CFR Part 1503

Administrative practice and procedure, Investigations, Law enforcement, Penalties.

Amendments to the Regulations

Accordingly, for the reasons stated in the preamble, DHS is amending 33 CFR part 27, and 49 CFR part 1503 as follows:

Title 33—Navigation and Navigable Waters

PART 27—ADJUSTMENT OF CIVIL MONETARY PENALTIES FOR INFLATION

■ 1. The authority citation for part 27 continues to read as follows:

Authority: Secs. 1–6, Pub. L. 101–410, 104 Stat. 890, as amended by Sec. 31001(s)(1), Pub. L. 104–134, 110 Stat. 1321 (28 U.S.C. 2461 note); Department of Homeland Security Delegation No. 0170.1, sec. 2 (106).

■ 2. In § 27.3, revise the third sentence of the introductory text and table 1 to read as follows:

§ 27.3 Penalty adjustment table.

* * * The adjusted civil penalty amounts listed in Table 1 to this section are applicable for penalty assessments issued after December 29, 2025, with respect to violations occurring after November 2, 2015. * * *

TABLE 1 TO § 27.3—CIVIL MONETARY PENALTY INFLATION ADJUSTMENTS

U.S. code citation	Civil monetary penalty description	2025 adjusted maximum penalty amount (\$)
14 U.S.C. 521(c)	Saving Life and Property	13,295.
14 U.S.C. 521(e)	Saving Life and Property; Intentional Interference with Broadcast	1,365.
14 U.S.C. 936(i)	Confidentiality of Medical Quality Assurance Records (first offense)	6,677.
14 U.S.C. 936(i)	Confidentiality of Medical Quality Assurance Records (subsequent offenses)	44,521.
19 U.S.C. 70	Obstruction of Revenue Officers by Masters of Vessels	9,956.
19 U.S.C. 70	Obstruction of Revenue Officers by Masters of Vessels—Minimum Penalty	2,323.
19 U.S.C. 1581(d)	Failure to Stop Vessel When Directed; Master, Owner, Operator or Person in Charge ¹	5,000.
19 U.S.C. 1581(d)	Failure to Stop Vessel When Directed; Master, Owner, Operator or Person in Charge—Minimum Penalty ¹	1,000.
33 U.S.C. 471	Anchorage Ground/Harbor Regulations General	14,435.
33 U.S.C. 474	Anchorage Ground/Harbor Regulations St. Mary's River	996.
33 U.S.C. 495(b)	Bridges/Failure to Comply with Regulations	36,439.
33 U.S.C. 499(c)	Bridges/Drawbridges	36,439.
33 U.S.C. 502(c)	Bridges/Failure to Alter Bridge Obstructing Navigation	36,439.
33 U.S.C. 533(b)	Bridges/Maintenance and Operation	36,439.
33 U.S.C. 1208(a)	Bridge to Bridge Communication; Master, Person in Charge or Pilot	2,654.
33 U.S.C. 1208(b)	Bridge to Bridge Communication; Vessel	2,654.
33 U.S.C. 1321(b)(6)(B)(i)	Oil/Hazardous Substances: Discharges (Class I per violation)	23,647.
33 U.S.C. 1321(b)(6)(B)(i)	Oil/Hazardous Substances: Discharges (Class I total under paragraph)	59,114.
33 U.S.C. 1321(b)(6)(B)(ii)	Oil/Hazardous Substances: Discharges (Class II per day of violation)	23,647.
33 U.S.C. 1321(b)(6)(B)(ii)	Oil/Hazardous Substances: Discharges (Class II total under paragraph)	295,564.
33 U.S.C. 1321(b)(7)(A)	Oil/Hazardous Substances: Discharges (per day of violation) Judicial Assessment	59,114.
33 U.S.C. 1321(b)(7)(A)	Oil/Hazardous Substances: Discharges (per barrel of oil or unit discharged) Judicial Assessment	2,365.
33 U.S.C. 1321(b)(7)(B)	Oil/Hazardous Substances: Failure to Carry Out Removal/Comply With Order (Judicial Assessment)	59,114.
33 U.S.C. 1321(b)(7)(C)	Oil/Hazardous Substances: Failure to Comply with Regulation Issued Under 1321(j) (Judicial Assessment)	59,114.
33 U.S.C. 1321(b)(7)(D)	Oil/Hazardous Substances: Discharges, Gross Negligence (per barrel of oil or unit discharged) Judicial Assessment	7,093.
33 U.S.C. 1321(b)(7)(D)	Oil/Hazardous Substances: Discharges, Gross Negligence—Minimum Penalty (Judicial Assessment)	236,451.
33 U.S.C. 1322(j)	Marine Sanitation Devices; Operating	9,956.
33 U.S.C. 1322(j)	Marine Sanitation Devices; Sale or Manufacture	26,543.
33 U.S.C. 1608(a)	International Navigation Rules; Operator	18,610.
33 U.S.C. 1608(b)	International Navigation Rules; Vessel	18,610.
33 U.S.C. 1908(b)(1)	Pollution from Ships; General	93,058.
33 U.S.C. 1908(b)(2)	Pollution from Ships; False Statement	18,610.
33 U.S.C. 2072(a)	Inland Navigation Rules; Operator	18,610.
33 U.S.C. 2072(b)	Inland Navigation Rules; Vessel	18,610.
33 U.S.C. 2609(a)	Shore Protection; General	65,653.
33 U.S.C. 2609(b)	Shore Protection; Operating Without Permit	26,262.

TABLE 1 TO § 27.3—CIVIL MONETARY PENALTY INFLATION ADJUSTMENTS—Continued

U.S. code citation	Civil monetary penalty description	2025 adjusted maximum penalty amount (\$)
33 U.S.C. 2716a(a)	Oil Pollution Liability and Compensation	59,114.
33 U.S.C. 3852(a)(1)(A)	Clean Hulls; Civil Enforcement	54,124.
33 U.S.C. 3852(a)(1)(A)	Clean Hulls; related to false statements	72,164.
33 U.S.C. 3852(c)	Clean Hulls; Recreational Vessels	7,217.
42 U.S.C. 9609(a)	Hazardous Substances, Releases, Liability, Compensation (Class I)	71,545.
42 U.S.C. 9609(b)	Hazardous Substances, Releases, Liability, Compensation (Class II)	71,545.
42 U.S.C. 9609(b)	Hazardous Substances, Releases, Liability, Compensation (Class II subsequent offense)	214,637.
42 U.S.C. 9609(c)	Hazardous Substances, Releases, Liability, Compensation (Judicial Assessment)	71,545.
42 U.S.C. 9609(c)	Hazardous Substances, Releases, Liability, Compensation (Judicial Assessment subsequent offense)	214,637.
46 U.S.C. 80509(a)	Safe Containers for International Cargo	7,820.
46 U.S.C. 70305(c)	Suspension of Passenger Service	78,210.
46 U.S.C. 2110(e)	Vessel Inspection or Examination Fees	11,823.
46 U.S.C. 2115	Alcohol and Dangerous Drug Testing	9,624.
46 U.S.C. 2302(a)	Negligent Operations: Recreational Vessels	8,705.
46 U.S.C. 2302(a)	Negligent Operations: Other Vessels	43,527.
46 U.S.C. 2302(c)(1)	Operating a Vessel While Under the Influence of Alcohol or a Dangerous Drug	9,624.
46 U.S.C. 2306(a)(4)	Vessel Reporting Requirements: Owner, Charterer, Managing Operator, or Agent	14,988.
46 U.S.C. 2306(b)(2)	Vessel Reporting Requirements: Master	2,998.
46 U.S.C. 3102(c)(1)	Immersion Suits	14,988.
46 U.S.C. 3106(d)	Master Key Control System	1,059.
46 U.S.C. 3302(i)(5)	Inspection Permit	3,126.
46 U.S.C. 3318(a)	Vessel Inspection; General	14,988.
46 U.S.C. 3318(g)	Vessel Inspection; Nautical School Vessel	14,988.
46 U.S.C. 3318(h)	Vessel Inspection; Failure to Give Notice in accordance with (IAW) 3304(b)	2,998.
46 U.S.C. 3318(i)	Vessel Inspection; Failure to Give Notice IAW 3309(c)	2,998.
46 U.S.C. 3318(j)(1)	Vessel Inspection; Vessel ≥1600 Gross Tons	29,980.
46 U.S.C. 3318(j)(1)	Vessel Inspection; Vessel <1600 Gross Tons (GT)	5,996.
46 U.S.C. 3318(k)	Vessel Inspection; Failure to Comply with 3311(b)	29,980.
46 U.S.C. 3318(l)	Vessel Inspection; Violation of 3318(b)–3318(f)	14,988.
46 U.S.C. 3502(e)	List/count of Passengers	312.
46 U.S.C. 3504(c)	Notification to Passengers	31,252.
46 U.S.C. 3504(c)	Notification to Passengers; Sale of Tickets	1,562.
46 U.S.C. 3506	Copies of Laws on Passenger Vessels; Master	625.
46 U.S.C. 3507(h)(1)(A)	Passenger Vessel Security and Safety; Daily Penalty & Maximum Penalty	26,481 Daily/52,962 Maximum.
46 U.S.C. 3508(d)	Passenger Vessel Security and Safety; Crewmembers Crime Scene Preservation Training; Maximum Penalty	52,962.
46 U.S.C. 3718(a)(1)	Liquid Bulk/Dangerous Cargo	78,134.
46 U.S.C. 4106	Uninspected Vessels	13,132.
46 U.S.C. 4311(b)(1)	Recreational Vessels (maximum for related series of violations)	413,388.
46 U.S.C. 4311(b)(1)	Recreational Vessels; Violation of 4307(a)	8,267.
46 U.S.C. 4311(c)	Engine Cut-Off Switches; Violation of 4312(b), First Offense	106.
46 U.S.C. 4311(c)	Engine Cut-Off Switches; Violation of 4312(b), Second Offense	265.
46 U.S.C. 4311(c)	Engine Cut-Off Switches; Violation of 4312(b), Subsequent to Second Offense	529.
46 U.S.C. 4311(d)	Recreational Vessels	3,126.
46 U.S.C. 4507	Uninspected Commercial Fishing Industry Vessels	13,132.
46 U.S.C. 4703	Abandonment of Barges	2,224.
46 U.S.C. 5116(a)	Load Lines	14,308.
46 U.S.C. 5116(b)	Load Lines; Violation of 5112(a)	28,619.
46 U.S.C. 5116(c)	Load Lines; Violation of 5112(b)	14,308.
46 U.S.C. 6103(a)	Reporting Marine Casualties	49,848.
46 U.S.C. 6103(b)	Reporting Marine Casualties; Violation of 6104	13,132.
46 U.S.C. 8101(e)	Manning of Inspected Vessels; Failure to Report Deficiency in Vessel Complement	2,365.
46 U.S.C. 8101(f)	Manning of Inspected Vessels	23,647.
46 U.S.C. 8101(g)	Manning of Inspected Vessels; Employing or Serving in Capacity not Licensed by U.S. Coast Guard (USCG)	23,647.
46 U.S.C. 8101(h)	Manning of Inspected Vessels; Freight Vessel <100 GT, Small Passenger Vessel, or Sailing School Vessel	3,126.
46 U.S.C. 8102(a)	Watchmen on Passenger Vessels	3,126.
46 U.S.C. 8103(f)	Citizenship Requirements	1,562.
46 U.S.C. 8104(i)	Watches on Vessels; Violation of 8104(a) or (b)	23,647.
46 U.S.C. 8104(j)	Watches on Vessels; Violation of 8104(c), (d), (e), or (h)	23,647.
46 U.S.C. 8106(f)	Employing Qualified Available U.S. Citizens or Residents	10,592 Daily/105,923 Maximum.
46 U.S.C. 8302(e)	Staff Department on Vessels	312.
46 U.S.C. 8304(d)	Officer's Competency Certificates	312.
46 U.S.C. 8502(e)	Coastwise Pilotage; Owner, Charterer, Managing Operator, Agent, Master or Individual in Charge	23,647.

TABLE 1 TO § 27.3—CIVIL MONETARY PENALTY INFLATION ADJUSTMENTS—Continued

U.S. code citation	Civil monetary penalty description	2025 adjusted maximum penalty amount (\$)
46 U.S.C. 8502(f)	Coastwise Pilotage; Individual	23,647.
46 U.S.C. 8503	Federal Pilots	74,943.
46 U.S.C. 8701(d)	Merchant Mariners Documents	1,562.
46 U.S.C. 8702(e)	Crew Requirements	23,647.
46 U.S.C. 8906	Small Vessel Manning	49,848.
46 U.S.C. 9308(a)	Pilotage: Great Lakes; Owner, Charterer, Managing Operator, Agent, Master or Individual in Charge.	23,647.
46 U.S.C. 9308(b)	Pilotage: Great Lakes; Individual	23,647.
46 U.S.C. 9308(c)	Pilotage: Great Lakes; Violation of 9303	23,647.
46 U.S.C. 10104(a)(2)	Requirement to Report Sexual Assault and Harassment; Mandatory Reporting by Responsible Entity of a Vessel.	52,962.
46 U.S.C. 10104(d)(2)	Requirement to Report Sexual Assault and Harassment; Company After Action Summary, violation of 10104(d)(1).	26,481.
46 U.S.C. 10104(d)(2)	Requirement to Report Sexual Assault and Harassment; Company After Action Summary, Daily Noncompliance Penalty.	529.
46 U.S.C. 10104(d)(2)	Requirement to Report Sexual Assault and Harassment; Company After Action Summary, Civil Penalty Maximum.	52,962.
46 U.S.C. 10314(a)(2)	Pay Advances to Seamen	1,562.
46 U.S.C. 10314(b)	Pay Advances to Seamen; Remuneration for Employment	1,562.
46 U.S.C. 10315(c)	Allotment to Seamen	1,562.
46 U.S.C. 10321	Seamen Protection; General	10,831.
46 U.S.C. 10505(a)(2)	Coastwise Voyages: Advances	10,831.
46 U.S.C. 10505(b)	Coastwise Voyages: Advances; Remuneration for Employment	10,831.
46 U.S.C. 10508(b)	Coastwise Voyages: Seamen Protection; General	10,831.
46 U.S.C. 10711	Effects of Deceased Seamen	625.
46 U.S.C. 10902(a)(2)	Complaints of Unfitness	1,562.
46 U.S.C. 10903(d)	Proceedings on Examination of Vessel	312.
46 U.S.C. 10907(b)	Permission to Make Complaint	1,562.
46 U.S.C. 11101(f)	Accommodations for Seamen	1,562.
46 U.S.C. 11102(b)	Medicine Chests on Vessels	1,562.
46 U.S.C. 11104(b)	Destitute Seamen	312.
46 U.S.C. 11105(c)	Wages on Discharge	1,562.
46 U.S.C. 11303(a)	Log Books; Master Failing to Maintain	625.
46 U.S.C. 11303(b)	Log Books; Master Failing to Make Entry	625.
46 U.S.C. 11303(c)	Log Books; Late Entry	469.
46 U.S.C. 11506	Carrying of Sheath Knives	157.
46 U.S.C. 12151(a)(1)	Vessel Documentation	20,468.
46 U.S.C. 12151(a)(2)	Documentation of Vessels—Related to activities involving mobile offshore drilling units	34,116.
46 U.S.C. 12151(c)	Vessel Documentation; Fishery Endorsement	156,422.
46 U.S.C. 12309(a)	Numbering of Undocumented Vessels—Willful violation	15,628.
46 U.S.C. 12309(b)	Numbering of Undocumented Vessels	3,126.
46 U.S.C. 12507(b)	Vessel Identification System	26,262.
46 U.S.C. 14701	Measurement of Vessels	57,238.
46 U.S.C. 14702	Measurement; False Statements	57,238.
46 U.S.C. 31309	Commercial Instruments and Maritime Liens	26,262.
46 U.S.C. 31330(a)(2)	Commercial Instruments and Maritime Liens; Mortgagor	26,262.
46 U.S.C. 31330(b)(2)	Commercial Instruments and Maritime Liens; Violation of 31329	65,653.
46 U.S.C. 55112(d)	Vessel Escort Operations and Towing Assistance	10,592.
46 U.S.C. 70036(a)	Ports and Waterways Safety Regulations	117,608.
46 U.S.C. 70041(d)(1)(B)	Vessel Navigation: Regattas or Marine Parades; Unlicensed Person in Charge	11,823.
46 U.S.C. 70041(d)(1)(C)	Vessel Navigation: Regattas or Marine Parades; Owner Onboard Vessel	11,823.
46 U.S.C. 70041(d)(1)(D)	Vessel Navigation: Regattas or Marine Parades; Other Persons	5,911.
46 U.S.C. 70052(c)	Regulation of Vessels in Territorial Waters of the United States	26,481.
46 U.S.C. 70119(a)	Port Security	43,527.
46 U.S.C. 70119(b)	Port Security—Continuing Violations	78,210.
46 U.S.C. 70506	Maritime Drug Law Enforcement; Penalties	7,217.
49 U.S.C. 5123(a)(1)	Hazardous Materials: Related to Vessels—Maximum Penalty	102,348.
49 U.S.C. 5123(a)(2)	Hazardous Materials: Related to Vessels—Penalty from Fatalities, Serious Injuries/Illness or Substantial Damage to Property.	238,809.
49 U.S.C. 5123(a)(3)	Hazardous Materials: Related to Vessels—Training	617.

¹ Enacted under the Tariff Act of 1930 exempt from inflation adjustments.

Title 49—Transportation**PART 1503—INVESTIGATIVE AND ENFORCEMENT PROCEDURES**

■ 3. The authority citation for part 1503 continues to read as follows:

Authority: 6 U.S.C. 1142; 18 U.S.C. 6002; 28 U.S.C. 2461 (note); 49 U.S.C. 114, 20109, 31105, 40113–40114, 40119, 44901–44907, 44939, 46101–46107, 46109–46110, 46301, 46305, 46311, 46313–46314; Pub. L. 110–53 (121 Stat. 266, Aug. 3, 2007) secs. 1408 (6 U.S.C. 1137), 1501 (6 U.S.C. 1151), 1517 (6 U.S.C. 1167), and 1534 (6 U.S.C. 1184).

■ 4. In § 1503.401, revise paragraph (c) to read as follows:

§ 1503.401 Maximum penalty amounts.

* * * * *

(c) *Certain aviation related violations.*

(1) For violations that occurred on or before November 2, 2015, \$10,000 per violation, up to a total of \$50,000 per civil penalty action, in the case of an individual or small business concern (“small business concern” as defined in section 3 of the Small Business Act (15 U.S.C. 632)). For violations that occurred between November 2, 2015, and May 16, 2024, \$17,062 per violation, up to a total of \$85,314 per civil penalty action, in the case of an individual (except an airman serving as an airman), or a small business concern. For violations that occurred on or before May 16, 2024, \$10,000 per violation, up to a total of \$50,000 per civil penalty action, in the case of an individual or small business concern (“small business concern” as defined in section 3 of the Small Business Act (15 U.S.C. 632)). For violations that occurred after May 16, 2024, \$17,062 per violation, up to a total of \$100,000 per civil penalty action, in the case of an individual (except an airman serving as an airman), or a small business concern.

(2) For violations that occurred on or before November 2, 2015, \$10,000 per violation, up to a total of \$400,000 per civil penalty action, in the case of any other person (except an airman serving as an airman) not operating an aircraft for the transportation of passengers or property for compensation. For violations that occurred between November 2, 2015, and May 16, 2024, \$17,062 per violation, up to a total of \$682,509 per civil penalty action, in the case of any other person (except an airman serving as an airman) not operating an aircraft for the transportation of passengers or property for compensation. For violations that occurred on or before May 16, 2024, \$10,000 per violation, up to a total of \$400,000 per civil penalty action, in the case of any other person (except an

airman serving as an airman) not operating an aircraft for the transportation of passengers or property for compensation. For violations that occurred after May 16, 2024, \$17,062 per violation, up to a total of \$1,200,000 per civil penalty action, in the case of any other person (except an airman serving as an airman) not operating an aircraft for the transportation of passengers or property for compensation.

(3) For violations that occurred on or before November 2, 2015, \$25,000 per violation, up to a total of \$400,000 per civil penalty action, in the case of a person operating an aircraft for the transportation of passengers or property for compensation (except an individual serving as an airman). For violations that occurred between November 2, 2015, and May 16, 2024, \$42,657 per violation, up to a total of \$682,509 per civil penalty action, in the case of a person (except an individual serving as an airman) operating an aircraft for the transportation of passengers or property for compensation. For violations that occurred on or before May 16, 2024, \$25,000 per violation, up to a total of \$400,000 per civil penalty action, in the case of a person operating an aircraft for the transportation of passengers or property for compensation (except an individual serving as an airman). For violations that occurred after May 16, 2024, \$42,657 per violation, up to a total of \$1,200,000 per civil penalty action, in the case of a person (except an individual serving as an airman) operating an aircraft for the transportation of passengers or property for compensation.

Joseph Mazzara,

Acting General Counsel, U.S. Department of Homeland Security.

[FR Doc. 2025–23808 Filed 12–23–25; 8:45 am]

BILLING CODE 9110–04–P; 9110–05–P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 165**

[Docket Number USCG–2025–0643]

RIN 1625–AA00

Safety Zone; Beltway 8 Bridge Construction, Houston Ship Channel, Houston, TX

AGENCY: Coast Guard, Department of Homeland Security.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for certain navigable waters of the Houston Ship Channel around the Beltway 8 Bridge (Sam Houston Tollway Ship Channel Bridge), during bridge construction and demolition activities. The temporary safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by constructing a new bridge. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port, Sector Houston-Galveston.

DATES: This rule is effective without actual notice from December 29, 2025 through March 1, 2030. For the purposes of enforcement, actual notice will be used from December 22, 2025, until December 29, 2025.

ADDRESSES: To view available documents go to <https://www.regulations.gov> and search for USCG–2025–0643.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, contact Marine Science Technician Chief Petty Officer Anthony W. Booth, Sector Houston-Galveston Waterway Management Division, Coast Guard; Telephone (713) 398–5823, Email houstonwww@uscg.mil.

SUPPLEMENTARY INFORMATION:**I. Table of Abbreviations**

BNM Broadcast Notice to Mariners
CFR Code of Federal Regulations
CG Coast Guard
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
LNM Local Notice to Mariners
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code
VTS Vessel Traffic Service

II. Background and Authority

On July 24, 2025, construction of the new Beltway 8 Bridge (Sam Houston Tollway Ship Channel Bridge) started over the navigable waters of the Houston Ship Channel. The Coast Guard previously published a short-term temporary safety zone to cover the initial phase of this construction, which covers only a small area along the north and south shorelines around the bridge (90 FR 35437, July 28, 2025). The Coast Guard also published a notice of proposed rulemaking (NPRM) to establish a long-term temporary safety zone for this project (90 FR 43950, September 11, 2025). In that NPRM, we stated why we issued the NPRM and invited comments on our proposed regulatory action.

Under the authority in 46 U.S.C. 70034, the COTP has determined that this rule is necessary to protect personnel, vessels, and the marine environment from potential hazards associated with this bridge demolition and construction project. Hazards associated with this project include falling construction equipment, materials, or other debris. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or their designated representative during periods of enforcement.

The Coast Guard finds that under 5 U.S.C. 553(d)(3), good cause exists for making this rule effective less than 30 days after publication in the **Federal Register** because it is impracticable and contrary to the public interest. Construction for this project has begun, impacts to the waterway are on-going, and the previously established short-term safety zone regulation has expired. Therefore, this zone must be established immediately to protect personnel, vessels, and the marine environment.

III. Discussion of Comments and the Rule

During the comment period that ended on October 14, 2025, we received one comment. The comment supported the safety zone and encouraged the Coast Guard to elaborate on timing for closure of the federal channel to improve coordination and to assist affected users with preparation for the closure. Due to the length of the project and complexity and uncertainty regarding the project schedule, the Coast Guard is unable to provide this detailed information at this time. However, the Coast Guard will work closely with the project managers to ensure the public and waterway users are notified well in advance of any closure that will prohibit vessel navigation on the waterway. The Coast Guard will provide advance notice to the public through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and the Vessel Traffic Service (VTS).

The Coast Guard is also making two clarifying changes to the regulatory text. In paragraph (c)(1), the phrase “while overhead bridge construction or demolition activities are occurring” has been deleted. Also in paragraph (d), the sentence “[t]hat date should include some margin for error in case of delays[,]” was also deleted. Although not requested or commented upon, the Coast Guard believes these changes in the regulatory text will prevent potential confusion regarding times when the safety zone is activated. As written now, the regulatory text clearly states that

Coast Guard will provide advance notice to the public of the specific enforcement times and areas within the zone, which will depend on construction or demolition activities. There are no other changes in the regulatory text of this rule from the proposed rule in the NPRM.

This rule establishes a safety zone from December 22, 2025 through March 1, 2030. That date should include some margin for error in case of delays. Specific enforcement times and areas within the zone will depend on construction or demolition activities. The safety zone covers all navigable waters within the area encompassed by a line connecting the following points on the north and south shore of the Houston Ship Channel around the Beltway 8 Bridge (Sam Houston Tollway Ship Channel Bridge): Point 1 is the southeast corner at 29°44.033' N 95°8.733' W; thence west to Point 2 at 29°44.100' N 95°8.833' W; thence north to Point 3 at 29°44.267' N 95°8.817' W; thence east to Point 4 at 29°44.267' N 95°8.717' W; thence south returning to Point 1. No vessel or person is permitted to enter the safety zone without obtaining permission from the COTP or their designated representative.

IV. 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.

A. Impact on Small Entities

The Coast Guard certifies that, although some small entities may intend to transit the safety zone above, this rule will not have a significant economic impact on a substantial number of small entities, as mandated by the Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612 for the following reasons. During the times of overhead construction outside of the federal channel, vessels will still be allowed to transit under the bridge only within the federal channel. The channel will be closed for a short period when the construction or demolition is actively occurring over the main federal channel, and these closures will be coordinated between stakeholders, the construction contractor and Sector Houston-Galveston. The Coast Guard will work closely with the project managers to ensure the public and waterway users are notified well in advance of any closure that will prohibit vessel navigation on the main federal channel. While this zone will be in effect for several years, the Coast Guard (CG)

anticipates that the main federal channel will remain open for the majority of the effective period.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), if this rule will affect your small business, organization, or governmental jurisdiction and you have questions, contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards by calling 1–888–REG–FAIR (1–888–734–3247).

B. Collection of Information

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

C. Federalism and Indian Tribal Governments

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

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

D. Unfunded Mandates Reform Act

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

E. Environment

We have analyzed this 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 is a safety zone. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket.

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; DHS Delegation No. 00170.1, Revision No. 01.4.

■ 2. Add § 165.T08–0643 to read as follows:

§ 165.T08–0643 Safety Zone; Beltway 8 Bridge Construction, Houston Ship Channel, Houston, TX.

(a) *Location.* The following area is a safety zone: All navigable waters within the area encompassed by a line connecting the following points on the north and south shore of the Houston Ship Channel around the Beltway 8 Bridge (Sam Houston Tollway Ship Channel Bridge): Point 1 is the southeast corner at 29°44.033' N 95°8.733' W; thence west to Point 2 at 29°44.100' N 95°8.833' W; thence north to Point 3 at 29°44.267' N 95°8.817' W; thence east to Point 4 at 29°44.267' N 95°8.717' W; thence south returning to Point 1.

(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 Houston-Galveston (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) Persons or vessels seeking to enter the safety zone must request permission from the COTP on VHF–FM channel 16 or by telephone at 866–539–8114. 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.* The zone will be effective until the project ends, estimated completion date of March 1, 2030. Specific enforcement times and areas within the zone will depend on construction or demolition activities, and the Coast Guard will provide advance notice to the public through BNMs, LNM's, and the VTS.

Nicole D. Rodriguez,

Captain, U.S. Coast Guard, Captain of the Port Sector Houston-Galveston, Texas.

[FR Doc. 2025–23860 Filed 12–23–25; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2025–0990]

RIN 1625–AA00

Safety Zone; Lake of the Ozarks Fireworks Display, MM 0.2, Lake of the Ozarks, MO

AGENCY: Coast Guard, Department of Homeland Security.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for all navigable waters within a 500-foot radius of 38°12'11.1" N, 92°37'59.4" W, at Mile Marker 0.2 on the Lake of the Ozarks. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by a fireworks display. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port, Sector Upper Mississippi River.

DATES: This rule is effective from 8:30 p.m. through 10 p.m. on December 31, 2025.

ADDRESSES: To view available documents, go to <https://www.regulations.gov> and search for USCG–2025–0990.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, contact MST2 Rilie Inmon, Sector Upper Mississippi River Waterways Management Division, U.S. Coast Guard; telephone 319–520–8556, email Rilie.M.Inmon@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
§ Section
U.S.C. United States Code

II. Background and Authority

The Coast Guard received notification that fireworks will be launched from a barge on the Lake of the Ozarks at mile marker 0.2. Hazards from fireworks displays include accidental discharge of fireworks, dangerous projectiles, and falling hot embers or other debris. The Captain of the Port (COTP) Sector Upper Mississippi River has determined that potential hazards associated with fireworks are a safety concern for anyone within 500 feet of the fireworks display. Therefore, the COTP is issuing this rule under the authority in 46 U.S.C. 70034, which is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone.

The Coast Guard is issuing this rule without prior notice and comment. As is authorized by 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable and contrary to the public interest. We must establish this safety zone by December 31, 2025, to protect personnel, vessels, and the marine environment. Therefore, we do not have enough time to solicit and respond to comments.

For the same reasons, the Coast Guard finds that under 5 U.S.C. 553(d)(3), good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

III. Discussion of the Rule

This rule establishes a safety zone that will be enforced from 8:30 p.m. until 10 p.m. on December 31, 2025. The safety zone will cover all navigable water within a 500-foot radius of the fireworks barge on Lake of the Ozarks, at 38°12'11.08" N, 92°37'59.35" W. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or their designated representative.

IV. 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.

A. Impact on Small Entities

The regulatory flexibility analysis provisions of the Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, do not apply to rules that are not subject to

notice and comment. Because the Coast Guard has, for good cause, waived the notice and comment requirement that would otherwise apply to this rulemaking, the Regulatory Flexibility Act's flexibility analysis provisions do not apply here.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), if this rule will affect your small business, organization, or governmental jurisdiction and you have questions, contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards by calling 1–888–REG–FAIR (1–888–734–3247). 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.

B. 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).

C. Federalism and Indian Tribal Governments

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

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

D. Unfunded Mandates Reform Act

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

E. Environment

We have analyzed this 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 is a safety zone. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket.

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. 01.4.

■ 2. Add § 165.T08–0990 to read as follows:

§ 165.T08–0990 Safety Zone; Lake of the Ozarks Fireworks Display, MM 0.2, Lake of the Ozarks, MO.

(a) *Location.* The following area is a safety zone: All navigable waters within a 500-foot radius of 38°12'11.1" N, 92°37'59.4" W, at Mile Marker 0.2 on the Lake of the Ozarks. These coordinates are based on the World Geodetic System (WGS 84)/North American Datum 83 (NAD 83).

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

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

(2) To seek permission to enter, contact the COTP or the COTP's representative on VHF–FM channel 16

or by telephone at 1–866–360–3386. 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 8:30 p.m. to 10 p.m. on December 31, 2025.

B.N. Parker,

Captain, U.S. Coast Guard, Captain of the Port, Sector Upper Mississippi River.

[FR Doc. 2025–23848 Filed 12–23–25; 8:45 am]

BILLING CODE 9110–04–P

FEDERAL MARITIME COMMISSION

46 CFR Part 541

[Docket No. FMC–2025–0107]

RIN 3072–AD08

Demurrage and Detention Billing Requirements Properly Issued Invoices Provision Set Aside by Court

AGENCY: Federal Maritime Commission.

ACTION: Final rule.

SUMMARY: This final rule removes from the Code of Federal Regulations a section of the final rule published on February 26, 2024, entitled “Demurrage and Detention Billing Requirements.” This action is responsive to a decision of the U.S. Court of Appeals for the District of Columbia Circuit that set aside the properly issued invoices provision of the rule.

DATES: This action is effective on December 29, 2025.

FOR FURTHER INFORMATION CONTACT: David Eng, Secretary; Phone: (202) 523–5725; Email: secretary@fmc.gov.

SUPPLEMENTARY INFORMATION: On February 26, 2024, the Federal Maritime Commission (Commission) published a final rule entitled “Demurrage and Detention Billing Requirements” under the authority of the Ocean Shipping Reform Act of 2022, Public Law 117–14 (June 16, 2022), 89 FR 14330. This rule established requirements for common carriers and marine terminal operators to include specific minimum information on demurrage and detention invoices, outlined certain detention and demurrage billing practices, such as determination of which parties may appropriately be billed for demurrage or detention charges, and set timeframes for issuing invoices, disputing charges with the billing party, and resolving such disputes.

In April 2024, the World Shipping Council, a trade association representing the largest vessel-operating common

carriers globally, filed a petition for review in the United States Court of Appeals for the District of Columbia Circuit, challenging the rule as arbitrary and capricious under the Administrative Procedure Act. On September 23, 2025, the Court held that one section of the rule, 46 CFR 541.4, “is arbitrary and capricious because the Commission failed to explain the seeming inconsistency between its contractual-privity-based rationale and its categorical bar against billing motor carriers even when in privity with the billing party.” *World Shipping Council v. Federal Maritime Commission*, 152 F.4th 215, 220 (D.C. Cir. 2025). Accordingly, the court severed and set aside 46 CFR 541.4. Consistent with that decision, this rule removes 46 CFR 541.4 from the Code of Federal Regulations. The other provisions of the rule remain in effect.

The Commission is not required to provide notice and comment or delay the effective date of this rule. This rule

is not subject to the requirement to provide public comment because it falls under the good cause exception at 5 U.S.C. 553(b)(B). The good cause exception is satisfied when notice and comment is “impracticable, unnecessary, or contrary to the public interest.” Notice and comment for this action would be unnecessary and contrary to the public interest. This rule is a necessary administrative step following the court’s order setting aside 46 CFR 541.4. Per the court’s decision, section 541.4 has no legal effect. Public comment would not have any impact on the action. For those same reasons, and because this rule implements a court order already in effect, the Commission has good cause to waive the 30-day effective date under 5 U.S.C. 553(d)(3). Delaying the ministerial act of removing the regulatory text in the **Federal Register** is contrary to the public interest because it could lead to confusion, particularly among the regulated public.

List of Subjects in 46 CFR Part 541

Common carriers, Demurrage and detention, Exports, Imports, Marine terminal operators.

For the reasons set forth in the preamble, the Commission amends 46 CFR part 541 as follows:

PART 541—DEMURRAGE AND DETENTION

- 1. The authority citation for part 541 continues to read as follows:

Authority: 5 U.S.C. 553; 46 U.S.C. 40101, 40102, 40307, 40501–40503, 41101–41106, 40901–40904, and 46105; and 46 CFR 515.23.

§ 541.4 [Removed and Reserved]

- 2. Remove and reserve § 541.4.

By the Commission.

David Eng,

Secretary.

[FR Doc. 2025–23920 Filed 12–23–25; 8:45 am]

BILLING CODE 6730–02–P

Proposed Rules

Federal Register

Vol. 90, No. 245

Monday, December 29, 2025

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 AGRICULTURE

Office of the Secretary

7 CFR Part 781

[Docket No. FSA–2024–0005]

RIN 0560–AI70

Agricultural Foreign Investment Disclosure Act: Revisions to Reporting Requirements

AGENCY: Office of the Secretary, U.S. Department of Agriculture.

ACTION: Advanced notice of proposed rulemaking.

SUMMARY: The Agricultural Foreign Investment Disclosure Act of 1978 (AFIDA) implementing regulations establish requirements under which foreign persons must report interests in U.S. agricultural lands to the U.S. Department of Agriculture (USDA). AFIDA regulations describe the type of interest in agricultural land a foreign person must have to trigger the reporting requirement, specific information that must be included in the report, and the mechanics of filing the report with USDA. AFIDA also requires some information about foreign persons who hold an interest in the agricultural land even though they may not own it directly, provided those foreign persons have “significant interest or substantial control” in the direct interest holder. USDA uses information from the filings to produce periodic reports to Congress on the effect that foreign ownership of U.S. agricultural land has on family farms and rural communities, and for other purposes. AFIDA regulations were last updated in 2006. Since that time, national security attention to foreign ownership or substantial control of agricultural land has increased. Committee on Foreign Investment in the United States (CFIUS) agencies, including the U.S. Department of Defense, use USDA information from AFIDA filings to identify and review transactions that may pose national

security risks, such as the location of agricultural land near sensitive military bases. Recent analyses, including a report by the Government Accountability Office (GAO), have identified flaws in USDA’s processes for collecting, tracking, and sharing AFIDA data. These deficiencies, combined with evolving national security concerns and a Consolidated Appropriations Act, 2023 requirement for USDA to develop a streamlined process for electronic submission and retention of AFIDA disclosures, lead USDA to examine AFIDA regulations and invite public input on changes that would improve information collection activities in a manner responsive to national security and the use of agricultural land.

DATES: Comments must be received by January 28, 2026.

ADDRESSES: USDA invites public comments on this Advance Notice of Proposed Rulemaking (ANPRM) and encourages stakeholders, including farmers, industry representatives, CFIUS and national security agencies and experts, and state and local governments, to provide input. Comments will be considered in the development of any future regulatory changes to ensure the regulations effectively address national security interests and the effects of foreign-owned agricultural land on rural communities.

You may submit comments, identified by Docket ID: FSA–2024–0005, in the Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the online instructions for submitting comments. All comments will be posted without change and will be publicly available on www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Mary Estep; telephone: (202) 720–3217; email: mary.estep@usda.gov. Individuals with disabilities who require alternative means for communication should contact the USDA Target Center at (202) 720–2600 (voice and text telephone (TTY mode)) or dial 711 for Telecommunications Relay Service (both voice and text telephone users can initiate this call from any telephone).

SUPPLEMENTARY INFORMATION:

Need for This Notice

AFIDA requires foreign persons who acquire, transfer, or hold interests in U.S. agricultural land to report such

transactions to the Secretary of Agriculture. The statute was enacted by Congress in 1978 and directed USDA to analyze information contained in the reports and determine the effects of reported transactions and holdings, particularly on family farms and rural communities, and for other purposes. Foreign holdings of U.S. agricultural land increased by an average of 0.6 million acres per year from 2013 to 2017 and by an average of 2.6 million acres per year from 2017 to 2023.¹ In 2023, Congress passed a Consolidated Appropriations Act that included a requirement for USDA to streamline its process for electronic submission and retention of AFIDA disclosures. This requirement accelerated USDA’s transition from paper AFIDA filings to the development of an online filing portal with document retention capability. And in 2024, GAO completed a report to Congressional Requesters, “Foreign Investments in U.S. Agricultural Land: Enhancing Efforts to Collect, Track, and Share Key Information Could Better Identify National Security Risks.” GAO found that USDA did not timely share data collected under AFIDA, and that at least one CFIUS member agency required AFIDA information more current and specific than USDA’s annual report to Congress. GAO provided six recommendations, including that USDA improve its verification and monitoring of collected AFIDA data and that USDA ensure its AFIDA reporting is complete, such as by incorporating country information from additional foreign persons beyond the primary investor when available. The increased interest in national security combined with multiple identified opportunities for improvement in AFIDA processes have led to this notice.

USDA seeks input on regulatory or other changes that may improve the efficiency and effectiveness of its AFIDA reporting and filing requirements. USDA is interested in comments on topics including the interests in agricultural land covered under AFIDA, identification of required filers, and the information included on

¹ USDA, Farm Service Agency, “Foreign Holdings of U.S. Agricultural Land Through December 31, 2023,” (2023), available at <https://www.fsa.usda.gov/resources/economic-policy-analysis/afida/annual-reports/foreign-holdings-us-agricultural-land-december-31-2023>.

the filed report. USDA is receptive to suggested changes that could be made within the current statutory authority as well as changes that may require new or revised statutory authority. USDA believes that public comment can inform the development of any rule that may ultimately be proposed.

References—the Following References May Be Useful To Help Inform Those Wishing To Provide Comments

- (1) 7 U.S.C. 3501–3508.
- (2) 7 CFR part 781.
- (3) AFIDA summary information at the USDA Farm Service Agency (FSA) website, including AFIDA annual reports and form FSA–153. Available at: <https://www.fsa.usda.gov/resources/economic-policy-analysis/afida>.
- (4) Government Accountability Office Report, “Foreign Investments in U.S. Agricultural Land: Enhancing Efforts to Collect, Track, and Share Key Information Could Better Identify National Security Risks,” GAO–24–106337, Published: January 18, 2024. Available at: <https://www.gao.gov/products/gao-24-106337>.
- (5) The Committee on Foreign Investment in the United States (CFIUS) informational page on the U.S. Department of the Treasury website. Available at: <https://home.treasury.gov/policy-issues/international/the-committee-on-foreign-investment-in-the-united-states-cfius>.

Overview of Key AFIDA Requirements

Three requirement categories define the content and scope of an AFIDA filing: (1) Identification of foreign persons required to file; (2) The totality of information the filer is required to provide about the agricultural land; and (3) Information the filer is required to provide about other foreign persons with indirect interest in the agricultural land. Current AFIDA requirements and limitations are summarized below.

Identification of Foreign Persons Required To File

According to AFIDA regulations in 7 CFR 781.3(b), “Any foreign person who held, holds, acquires, or transfers any interest in United States agricultural land is subject to the requirement of filing a report on form FSA–153” within 90 days of acquiring the interest or becoming a foreign person. Section 781.2 defines key terms.

Broadly, a foreign person is a foreign government, a person (usually a legal entity) created or organized under the laws of a foreign government or that has its principal place of business outside the United States, or an individual who is not a citizen or national of the United

States or its territories. The term also includes a person (usually a legal entity) created or organized under the laws of any state in which one of the previously listed categories of “foreign person” holds a significant interest or substantial control. “Any interest” generally means all interests acquired, transferred, or held in agricultural lands by a foreign person. However, the definition of “any interest” specifically excludes security interests, leases of less than ten years, contingent future interests, noncontingent future interests that do not become possessory upon the termination of the present possessory estate, surface or subsurface easements and rights-of-way used for a purpose unrelated to agricultural production, and an interest solely in mineral rights.

Agricultural land is defined in section 781.2(b) as “land in the United States used for forestry production and land in the United States currently used for, or, if currently idle, land last used within the past five years, for farming, ranching, or timber production, except land not exceeding ten acres in the aggregate, if the annual gross receipts from the sale of the farm, ranch, or timber products produced thereon do not exceed \$1,000. Farming, ranching, or timber production includes, but is not limited to, activities set forth in the Standard Industrial Classification Manual (1987), Division A, exclusive of industry numbers 0711–0783, 0851, and 0912–0919 which cover animal trapping, game management, hunting carried on as a business enterprise, trapping carried on as a business enterprise, and wildlife management. Land used for forestry production means, land exceeding 10 acres in which 10 percent is stocked by trees of any size, including land that formerly had such tree cover and that will be naturally or artificially regenerated.”

Information the Filer Is Required To Provide About the Agricultural Land

Section 781.3 describes the required content of an AFIDA report using the form FSA–153. While the current regulations require filings in the FSA county office local to the agricultural land, USDA is in the process of implementing an electronic filing process (“on-line filing portal”) as required by the Consolidated Appropriations Act of 2023. A foreign person required to submit a report must file a FSA–153 form report containing a list of items in section 781.3(e), including but not limited to legal name and address; citizenship, if an individual; type of interest in the land; the nature of the interest, name of the interest holder, country of creation or

organization, and principal place of business if the foreign person is not a government or individual; a legal description of the agricultural land; the intended agricultural purpose of the land; the name, address, and relationship of any representative completing the FSA–153 form for the filer; how the tract of land was acquired or transferred and the relationship of the foreign person to the previous owner; and the date the interest in the land was acquired or transferred.

Information the Filer Is Required To Provide About Other Foreign Persons With Indirect Interest in the Agricultural Land

Section 781.3(f)(1) requires reporting by the filer on foreign persons who have a “significant interest or substantial control” in the filer. Any required filer, other than an individual or government, must also submit a report containing the legal name and the address of each foreign individual or government holding significant interest or substantial control in the filer. If the person holding significant interest or substantial control is an individual, the filer must also provide that individual’s citizenship. And, if the person holding significant interest or substantial control is a foreign person who is not also an individual or government, the filer must provide that foreign person’s name and nature of the interest held, the country in which the holder is created or organized, and the holder’s principal place of business.

“Significant interest or substantial control” is defined in section 781.2(k) as (1) an interest of 10 percent or more held by foreign person, by a single foreign individual, by a single foreign business, or by a single foreign government; (2) an interest of 10 percent or more held by a domestic entity in which a foreign person holds significant interest or substantial control, by foreign individuals, foreign entities, or by foreign governments, whenever such persons, individuals, or governments are acting in concert with respect to such interest even though no single individual, person, or government holds an interest of 10 percent or more; or (3) an interest of 50 percent or more, in the aggregate, held by a domestic entity in which a foreign person holds significant interest or substantial control, by foreign individuals, foreign entities, or by foreign governments, even though such individuals, persons, or governments may not be acting in concert.

Any person named in a report filed under section 781.3(f) may then be required, upon request, to submit additional reporting on additional

interest holders. In short, the AFIDA regulation requires reporting by the foreign person who is the direct owner or lessee of the land and any foreign person who may be one or two tiers or levels above the direct owner or lessee in a chain of ownership or corporate relationship.

Discussion and Identification of Topics for Comment

USDA is aware of requirement gaps in the current AFIDA regulations and is considering how it may address those gaps in a manner that balances national security interests with other interests in U.S. agricultural land. Specifically, USDA notes multiple exclusions in the definitions of “agricultural land” and “any interest” that may remove particular interests (for example, leases less than 10 years) from reporting requirements. Filers are only required to identify their land interest through a legal description and identification of acreage. In some instances, legal descriptions may be narratives referencing landmarks or natural features of the land with limited utility to those not actually present on the land. USDA does not receive or have sufficiently detailed information to create a geospatial map with property boundaries.

While AFIDA does require a report on foreign persons who hold “significant interest or substantial interest” over direct interest holders, the definition of “significant interest or substantial interest” is challenging to understand and apply, sets a high threshold (10 and 50 percent), and treats countries with longstanding ties to the United States the same as countries designated as foreign adversaries by the Secretary of Commerce in 15 CFR 791.4(a). Furthermore, existing regulations only require filing by the foreign person who is the direct owner or lessee of the land and any foreign person who may be one or two tiers or levels above the direct owner or lessee in a chain of ownership or corporate relationship. USDA may affirmatively seek additional information from other interest holders named in reports, but it does not have the authority to request any additional detailed corporate structures or ownership information. Specifically, USDA lacks a mechanism to require additional detailed information about foreign interests throughout an ownership chain or in a complex corporate structure with multiple holding companies. USDA’s information deficit extends to the identity, country, and ownership interest of the ultimate foreign owner if that person is more

than two or possibly three steps removed from the direct interest holder.

USDA’s policy goal is to obtain valuable, comprehensive, and verifiable information about interests in U.S. agricultural land held by foreign persons. USDA is further interested in streamlining and strengthening AFIDA regulations to improve process efficiency, address national security interests, and provide timely, accurate, and detailed data for CFIUS agencies’ use.

The following topics represent particular areas in which USDA is interested in receiving comments. However, USDA also invites commenters to address additional issues involving AFIDA, particularly as they relate to national security interests. Commenters are encouraged to be as specific as possible. Please include the rationale underlying any suggested changes.

- **Topic 1:** Identification of foreign persons who are required to file reports using the FSA-153 form. Questions to consider when responding to this topic include the following:

- The definitions of “agricultural land,” “any interest,” and “foreign person” determine the universe of required filers. Are the definitions currently sufficient or are changes recommended?

- Should USDA continue to treat foreign persons from countries designated as foreign adversaries the same as all other foreign persons with respect to the interest in agricultural land that triggers the filing requirement, or should different standards apply to foreign persons from countries designated as foreign adversaries?

- **Topic 2:** Information the filer is required to provide about the agricultural land. Questions to consider when responding to this topic include the following:

- Should filers be required to provide any additional information or documentation than the list of items in section 781.3(e)? If so, what additional information should USDA require and why?

- How can USDA best obtain a correct, verifiable description or geospatial map of the agricultural land that is broadly usable by a range of audiences?

- **Topic 3:** Information the filer is required to provide about other foreign persons with indirect interest in the agricultural land. Questions to consider when responding to this topic include the following:

- What information should USDA require about interest holders who are multiple steps removed from the direct

interest holder or part of complex organizational structures?

- How can USDA best ensure that the information it receives is complete and verifiable?

Brooke Rollins,

Secretary of Agriculture.

[FR Doc. 2025-23830 Filed 12-23-25; 8:45 am]

BILLING CODE 3411-E2-P

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 701

RIN 3133-AF72

Limits on Loans to Other Credit Unions

AGENCY: National Credit Union Administration (NCUA).

ACTION: Proposed rule.

SUMMARY: The NCUA Board (Board) seeks comment on a proposed rule to remove the regulations related to approval and policies on making loans to other credit unions. While this provision will no longer be codified in regulation, Federal Credit Unions would remain subject to statutory requirements related to making loans to credit unions. Federally insured state-chartered credit unions would remain subject to any other applicable NCUA or state law or regulation.

DATES: Comments must be received by February 27, 2026.

ADDRESSES: Comments may be submitted in one of the following ways. (*Please send comments by one method only*):

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. The docket number for this proposed rule is NCUA-2025-1435. Follow the “Submit a comment” instructions. If you are reading this document on [federalregister.gov](https://www.federalregister.gov), you may use the green “SUBMIT A PUBLIC COMMENT” button beneath this rulemaking’s title to submit a comment to the [regulations.gov](https://www.regulations.gov) docket. A plain language summary of the proposed rule is also available on the docket website.

- **Mail:** Address to Melane Conyers-Ausbrooks, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314-3428.

- **Hand Delivery/Courier:** Same as mailing address.

Mailed and hand-delivered comments must be received by the close of the comment period.

Public inspection: Please follow the search instructions on <https://www.regulations.gov> to view the public

comments. Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are public records; they are publicly displayed exactly as received and will not be deleted, modified, or redacted. Comments may be submitted anonymously. If you are unable to access public comments on the internet, you may contact the NCUA for alternative access by calling (703) 518–6540 or emailing OGCMail@ncua.gov.

FOR FURTHER INFORMATION CONTACT: Ariel Pereira, Senior Attorney, Office of General Counsel, at (703) 518–6540 or at 1775 Duke Street, Alexandria, VA 22314.

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Background

On February 23, 2021, the Board published a final rule amending various parts of the NCUA's regulations to permit low-income designated credit unions, complex credit unions, and new credit unions to issue subordinated debt for purposes of regulatory capital treatment.¹ Among other changes, the final rule established a new § 701.25, governing loans by Federal Credit Unions (FCUs) to other credit unions. The regulation establishes an aggregate limit on such loans of 25 percent of the lending FCU's paid-in and unimpaired capital and surplus. It also sets limits for loans to a single credit union borrower. The regulation sets forth specific eligibility requirements and aggregate limits for FCUs that invest in the Subordinated Debt of other credit unions. The requirements of § 701.25 are made applicable to federally insured state-chartered credit unions (FISCUs) through § 741.227.²

In addition to the limits discussed above, § 701.25 imposes documentation requirements on FCU boards of directors, and through § 741.227 on FISCU boards as well. Specifically, paragraph (b) of § 701.25 requires the board of directors to approve all loans to other credit unions and to establish written policies for managing the associated credit risk. The policies must specify the limits on the aggregate principal amount of loans the FICU can make to all other credit unions and the aggregate principal amount of loans the FICU can make to any single credit union. Such limits specific to the FICU

may not exceed the generally applicable limits established in § 701.25.

B. Legal Authority

The Board is issuing this proposed rule pursuant to its authority under the Federal Credit Union Act (FCU Act).³ Under the FCU Act, the NCUA is the chartering and supervisory authority for FCUs and the federal supervisory authority for FICUs. The FCU Act grants the NCUA a broad mandate to issue regulations governing both FCUs and FICUs. Section 120 of the FCU Act is a general grant of regulatory authority and authorizes the Board to prescribe regulations for the administration of the FCU Act.⁴ Section 209 of the FCU Act is a plenary grant of regulatory authority to the NCUA to issue regulations necessary or appropriate to carry out its role as share insurer for all FICUs.⁵ The FCU Act also includes an express grant of authority for the Board to subject federally chartered central, or corporate, credit unions to such rules, regulations, and orders as the Board deems appropriate.⁶

II. Proposed Rule

The Board proposes to remove § 701.25(b). Upon reconsideration, the Board believes that the regulation is unnecessary and overly prescriptive. The FCU Act already requires a FCU's board of directors to approve all loans to other credit unions.⁷ Accordingly, for FCUs, § 701.25(b) is largely redundant of an existing statutory requirement. Moreover, FICU boards are in the best position to determine whether formal approval policies are necessary for such loans, consistent with the number, size, and risks associated with the FICU's lending practices. Removing this regulation will provide FICUs with greater flexibility. The Board emphasizes that while the proposed rule would no longer require FICU boards to adopt written policies regarding aggregate limits on loans to other credit unions, FICUs remain subject to the limits and other requirements regarding such loans set forth in the other provisions of § 701.25. If the proposed rule is adopted, FISCUs would refer to state law to determine whether their boards must approve loans to other credit unions.

³ 12 U.S.C. 1751 *et seq.*

⁴ 12 U.S.C. 1766(a).

⁵ 12 U.S.C. 1789.

⁶ 12 U.S.C. 1766(a).

⁷ 12 U.S.C. 1757(5)(C).

III. Regulatory Procedures

A. Providing Accountability Through Transparency Act of 2023

The Providing Accountability Through Transparency Act of 2023 (5 U.S.C. 553(b)(4)) requires that a notice of proposed rulemaking include the internet address of a summary of not more than 100 words in length of a proposed rule, in plain language, that shall be posted on the internet website under section 206(d) of the E-Government Act of 2002 (44 U.S.C. 3501 note) (commonly known as *regulations.gov*). The Act, under its terms, applies to notices of proposed rulemaking and does not expressly include other types of documents that the Board publishes voluntarily for public comment, such as notices and interim-final rules that request comment despite invoking “good cause” to forgo such notice and public procedure. The Board, however, has elected to address the Act's requirement in these types of documents in the interests of administrative consistency and transparency. The Board seeks comment on a proposed rule to remove the regulations related to approval and policies on making loans to other credit unions. While this provision will no longer be codified in regulation, Federal Credit Unions would remain subject to statutory requirements related to making loans to credit unions. Federally insured state-chartered credit unions would remain subject to any other applicable NCUA or state law or regulation.

The proposal and the required summary can be found at <https://www.regulations.gov>.

B. Executive Orders 12866, 13563, and 14192

Pursuant to Executive Order 12866 (“Regulatory Planning and Review”), as amended by Executive Order 14215, a determination must be made whether a regulatory action is significant and therefore subject to review by the Office of Management and Budget (OMB) in accordance with the requirements of the Executive Order.⁸ Executive Order 13563 (“Improving Regulation and Regulatory Review”) supplements and reaffirms the principles, structures, and definitions governing contemporary regulatory review established in Executive Order 12866.⁹ This proposed rule was drafted and reviewed in accordance with Executive Order 12866 and Executive Order 13563. OMB has determined that this proposed rule is not a “significant regulatory action” as

⁸ 58 FR 51735 (Oct. 4, 1993).

⁹ 76 FR 3821 (Jan. 21, 2011).

¹ 86 FR 11060 (Feb. 23, 2021).

² FCUs and FISCUs are collectively referred to as federally insured credit unions, or FICUs.

defined in section 3(f)(1) of Executive Order 12866. Further, this proposed rule to remove the regulations requiring that a FICU board of directors adopt minimum approval and written policy standards regarding loans to other credit unions is consistent with Executive Order 13563.

Executive Order 14192 (“Unleashing Prosperity Through Deregulation”) requires that any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.¹⁰ This proposed rule is expected to be a deregulatory action under Executive Order 14192.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act¹¹ generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. If the agency makes such a certification, it shall publish the certification at the time of publication of either the proposed rule or the final rule, along with a statement providing the factual basis for such certification.¹² For purposes of this analysis, the NCUA considers small credit unions to be those having under \$100 million in assets.¹³ The Board fully considered the potential economic impacts of the regulatory amendments on small credit unions.

To the extent that the proposed rule would have any economic impacts, they will be deregulatory in nature. The proposed rule would remove the requirement that FICU boards adopt minimum approval and written policy standards regarding loans to other credit unions. While these documentation requirements might impose some economic costs on FICUs, they are unlikely to be significant. Accordingly, any impacts associated with their rescission are also unlikely to impose a significant economic burden.

Accordingly, the NCUA certifies the proposed rule would not have a significant economic impact on a substantial number of small credit unions.

D. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) generally provides that an agency may not conduct or sponsor, and not withstanding any other provision of law, a person is not required to respond to, a collection of information, unless it displays a currently valid Office of Management and Budget control number. The PRA applies to rulemakings in which an agency creates a new or amends existing information collection requirements. For purposes of the PRA, an information-collection requirement may take the form of a reporting, recordkeeping, or a third-party disclosure requirement. The information collection requirements contained in Part 701.25(b) are approved by OMB under OMB Control Number 3133–0207 with a current expiration date of October 31, 2025.

The proposed rule would revise the following information collection requirement(s): Removal of the Policies for loans to credit unions—12 CFR 701.25(b).

Upon the publication of the final rule in the **Federal Register**, as applicable, the NCUA will submit a request to OMB to revise OMB Control Number 3133–0207. The proposed rescission of these regulations, along with the information collection requirement(s) contained therein and the revision of OMB Control Number 3133–0207, would reduce public information collection burden by an estimated 1,650 annual burden hours.

If you want to comment on the proposed rescission of the information-collection requirements that would result from this proposed rule, please send your comments and suggestions on this proposed action as previously described in the **DATES** and **ADDRESSES** sections.

E. Executive Order 13132 on Federalism

Executive Order 13132 encourages certain regulatory agencies to consider the impact of their actions on state and local interests. The NCUA, an agency as defined in 44 U.S.C. 3502(5), complies with the executive order to adhere to fundamental federalism principles. This proposed rule applies to FCUs and to FISCUs. The rulemaking may, therefore, have some direct effect on the states, the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. However, to the extent the rule has any such effects, it will be to relieve FISCUs of regulatory burden. The proposed rule would

remove the requirement that FICU boards adopt minimum approval and written policy standards regarding loans to other credit unions. The NCUA welcomes comments on ways to eliminate, or at least minimize, any potential impact in this area.

F. Assessment of Federal Regulations and Policies on Families

The NCUA has determined that this proposed rule would not affect family well-being within the meaning of section 654 of the Treasury and General Government Appropriations Act, 1999.¹⁴ The proposed regulatory requirements are exclusively concerned with the adoption of written policies by FICUs regarding loans to other credit unions. The potential positive effect on family well-being, including financial well-being, is, at most, indirect.

List of Subjects in 12 CFR Part 701

Advertising, Aged, Civil rights, Credit, Credit unions, Fair housing, Individuals with disabilities, Insurance, Marital status discrimination, Mortgages, Religious discrimination, Reporting and recordkeeping requirements, Sex discrimination, Signs and symbols, Surety bonds.

By the National Credit Union Administration Board, this 19th day of December, 2025.

Melane Conyers-Ausbrooks,
Secretary of the Board.

For the reasons stated in the preamble, the NCUA Board proposes to amend 12 CFR part 701, as follows:

PART 701—ORGANIZATION AND OPERATION OF FEDERAL CREDIT UNIONS.

■ 1. The authority citation for part 701 continues to read as follows:

Authority: 12 U.S.C. 1752(5), 1755, 1756, 1757, 1758, 1759, 1761a, 1761b, 1766, 1767, 1782, 1784, 1785, 1786, 1787, 1788, 1789. Section 701.6 is also authorized by 15 U.S.C. 3717. Section 701.31 is also authorized by 15 U.S.C. 1601 *et seq.*; 42 U.S.C. 1981 and 3601–3610. Section 701.35 is also authorized by 42 U.S.C. 4311–4312.

§ 701.25 [Amended]

■ 2. In § 701.25 remove paragraph (b) and redesignate paragraph (c) as paragraph (b).

[FR Doc. 2025–23855 Filed 12–23–25; 8:45 am]

BILLING CODE 7535–01–P

¹⁴ Public Law 105–277, 112 Stat. 2681 (1998).

¹⁰ 90 FR 9065 (Feb. 6, 2025).

¹¹ 5 U.S.C. 601 *et seq.*

¹² 5 U.S.C. 605(b).

¹³ 80 FR 57512 (Sept. 24, 2015).

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 701

RIN 3133–AF80

Suretyship and Guaranty; Segregated Deposit and Collateral

AGENCY: National Credit Union
Administration (NCUA).

ACTION: Proposed rule.

SUMMARY: The NCUA Board (Board) seeks comment on a proposed rule to remove the segregated deposit and collateral requirements when a federally insured credit union (FICU) acts as a surety and guarantor. Removing this regulation will provide FICUs with greater flexibility to design products that meet member needs. FICUs would remain subject to the other requirements regarding surety and guaranty agreements.

DATES: Comments must be received by February 27, 2026.

ADDRESSES: Comments may be submitted in one of the following ways. (*Please send comments by one method only*):

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. The docket number for this proposed rule is NCUA–2025–1434. Follow the “Submit a comment” instructions. If you are reading this document on [federalregister.gov](https://www.federalregister.gov), you may use the green “SUBMIT A PUBLIC COMMENT” button beneath this rulemaking’s title to submit a comment to the [regulations.gov](https://www.regulations.gov) docket. A plain language summary of the proposed rule is also available on the docket website.

- *Mail:* Address to Melane Conyers-Ausbrooks, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.

- *Hand Delivery/Courier:* Same as mailing address.

Mailed and hand-delivered comments must be received by the close of the comment period.

Public inspection: Please follow the search instructions on <https://www.regulations.gov> to view the public comments. Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are public records; they are publicly displayed exactly as received and will not be deleted, modified, or redacted. Comments may be submitted anonymously. If you are unable to

access public comments on the internet, you may contact the NCUA for alternative access by calling (703) 518–6540 or emailing OGCMail@ncua.gov.

FOR FURTHER INFORMATION CONTACT:

Keisha Brooks, Attorney-Advisor, Office of General Counsel, at (703) 518–6540 or at 1775 Duke Street, Alexandria, VA 22314.

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Background

Federal Credit Unions (FCUs) may only engage in activities that are expressly authorized either by statute or within the FCU’s incidental powers. The Federal Credit Union Act (FCU Act) explicitly grants FCUs the power to, among other activities, make loans to members and to provide letters of credit on behalf of members.¹ The accompanying incidental powers provision states that each FCU may “exercise such incidental powers as shall be necessary or requisite to enable it to carry on effectively the business for which it is incorporated.”² The FCU Act defines the business for which each FCU is incorporated: “promoting thrift among its members and creating a source of credit for provident or productive purposes.”³ Section 701.20, established in 2004, recognizes the ability of FCUs to enter into suretyship and guaranty agreements for their members as an incidental power, providing additional flexibility to meet member needs.⁴ For example, the regulation allows FCUs to become one party in a three-way lending relationship, where the FCU agrees to take responsibility for repayment if the member is unable to meet the lending obligation.

Section 701.20 defines these arrangements and, to promote safety and soundness, requires that the FCU’s obligation be for a fixed amount and duration, that the FCU’s performance of the agreement creates an authorized loan that complies with the applicable lending regulations, and that it obtains a segregated deposit from the member sufficient to cover the potential liability.

As provided in § 741.221 of the NCUA regulations, these requirements also apply to federally insured state credit unions (FISCUs) that are authorized under state law to enter into suretyship and guaranty agreements.⁵ The rule was amended in 2019 as part of a regulatory

reform initiative to reduce burden and improve clarity by updating internal cross-references.⁶

B. Legal Authority

The Board has the legal authority to issue this proposed rule pursuant to its plenary rulemaking authority under the FCU Act and its specific rulemaking authority under the various acts the Board administers.⁷ Under the FCU Act, the NCUA is the chartering and supervisory authority for FCUs and the federal supervisory authority for FICUs.⁸ The FCU Act grants the NCUA a broad mandate to issue regulations governing both FCUs and all FICUs. Section 120 of the FCU Act is a general grant of regulatory authority and authorizes the Board to prescribe rules and regulations for the administration of the FCU Act.⁹ Section 207 of the FCU Act is a specific grant of authority over share insurance coverage, conservatorships, and liquidations.¹⁰ Section 209 of the FCU Act is a plenary grant of regulatory authority to the Board to issue rules and regulations necessary or appropriate to carry out its role as share insurer for all FICUs.¹¹ Accordingly, the FCU Act grants the Board broad rulemaking authority to ensure that the credit union industry and the National Credit Union Share Insurance Fund remain safe and sound.

II. Proposed Rule

As part of its deregulatory initiative, the Board proposes to remove paragraphs (c)(3) and (d) of § 701.20, which impose segregated deposit and collateral requirements when FICUs act as a surety and guarantor. Under these provisions, depending on the nature of the collateral, an FCU must have a perfected security interest in collateral equal to 100 or 110 percent of the obligation. The 100 percent collateral category includes cash; obligations of the United States or its agencies; obligations fully guaranteed by the United States or its agencies as to principal and interest; and notes, drafts, bills of exchange, and bankers’ acceptances that are eligible for rediscount or purchase by a Federal Reserve Bank.¹² The 110 percent collateral category includes real estate and marketable securities.¹³ Section 741.221 of the NCUA regulations applies these requirements to FISCUs

⁶ 84 FR 10975 (Mar. 25, 2019).

⁷ 12 U.S.C. 1766, 1789.

⁸ 12 U.S.C. 1752–1775.

⁹ 12 U.S.C. 1766(a).

¹⁰ 12 U.S.C. 1787(b)(1).

¹¹ 12 U.S.C. 1789(a)(11).

¹² 12 CFR 701.20(d)(2).

¹³ 12 CFR 701.20(d)(3).

¹ 12 U.S.C. 1757(5), 1757a.

² 12 U.S.C. 1757(17).

³ 12 U.S.C. 1752(1).

⁴ 69 FR 8547, Feb. 25, 2004.

⁵ 12 CFR 741.221.

that are authorized under state law to act as a surety or guarantor.

The Board is now of the view that removing these segregated deposit and collateral requirements will provide FICUs the flexibility to design products that meet member needs. These proposed changes are intended to simplify the regulatory framework and reduce unnecessary compliance burdens.

It is not always necessary to have a segregated deposit that fully covers the liability. For example, current regulations require a FICU acting as a surety or guarantor to create an authorized loan that complies with the applicable NCUA lending regulations.¹⁴ The NCUA's commercial lending regulations adopted in 2016 include collateral requirements that reflect a broad principles-based regulatory approach for FICUs engaged in member business lending activities.¹⁵ These principles are predicated on the Board's expectation that credit unions will maintain prudent risk management practices and sufficient capital to mitigate the risks associated with their commercial lending activities.¹⁶ Maintaining this additional requirement for a segregated deposit associated with suretyship or guaranty agreements adds complexity to these transactions. FICUs are best positioned to determine the amount and types of collateral they are willing to accept to cover the risk.

The Board invites comment on all aspects of this proposed rule.

III. Regulatory Procedures

A. Providing Accountability Through Transparency Act of 2023

The Providing Accountability Through Transparency Act of 2023 (5 U.S.C. 553(b)(4)) (Act) requires that a notice of proposed rulemaking include the internet address of a summary of not more than 100 words in length of a proposed rule, in plain language, that shall be posted on the internet website under section 206(d) of the E-Government Act of 2002 (44 U.S.C. 3501 note) (commonly known as *regulations.gov*). The Act, under its terms, applies to notices of proposed rulemaking and does not expressly

include other types of documents that the Board publishes voluntarily for public comment, such as notices and interim-final rules that request comment despite invoking "good cause" to forgo such notice and public procedure. The Board, however, has elected to address the Act's requirement in these types of documents in the interests of administrative consistency and transparency. In summary, the Board seeks comment on a proposed rule to remove the segregated deposit and collateral requirements when a FICU acts as a surety and guarantor. Removing this regulation will give FICUs the flexibility to design products that meet member needs. FICUs would remain subject to the other requirements regarding surety and guaranty agreements.

The proposal and the required summary can be found at <https://www.regulations.gov>.

B. Executive Orders 12866, 13563, and 14192

Pursuant to Executive Order 12866 ("Regulatory Planning and Review"), as amended by Executive Order 14215, a determination must be made whether a regulatory action is significant and therefore subject to review by the Office of Management and Budget (OMB) in accordance with the requirements of the Executive Order.¹⁷ Executive Order 13563 ("Improving Regulation and Regulatory Review") supplements and reaffirms the principles, structures, and definitions governing contemporary regulatory review established in Executive Order 12866.¹⁸ This proposed rule was drafted and reviewed in accordance with Executive Order 12866 and Executive Order 13563. This proposed rule will reduce a burden by removing the segregated deposit and collateral requirements for FICU suretyship and guaranty arrangements and is consistent with Executive Order 13563. OMB has determined that this proposed rule is not a "significant regulatory action" as defined in section 3(f) of Executive Order 12866.

Executive Order 14192 ("Unleashing Prosperity Through Deregulation") requires that any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.¹⁹ This proposed rule is expected to be a deregulatory action for purposes of Executive Order 14192.

C. The Regulatory Flexibility Act

The Regulatory Flexibility Act²⁰ generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. If the agency makes such a certification, it shall publish the certification at the time of publication of either the proposed rule or the final rule, along with a statement providing the factual basis for such certification.²¹ For purposes of this analysis, the NCUA considers small credit unions to be those having under \$100 million in assets.²² The Board fully considered the potential economic impacts of the regulatory amendments on small credit unions.

To the extent that the proposed rule would have any economic impacts, they will be deregulatory in nature. The current rule authorizes FCUs to enter into suretyship and guaranty agreements. The proposed rule would remove the segregated deposit and collateral requirements for FCUs to enter into such agreements. To the extent FISCUs are authorized to enter into surety and guaranty agreements under state law, FISCUs would similarly benefit from the removal. It is unlikely that small credit unions will participate in either of these activities. While these requirements might impose some economic costs or create an economic benefit for FICUs, they are unlikely to be significant.

Accordingly, the NCUA certifies the proposed rule would not have a significant economic impact on a substantial number of small credit unions.

D. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) generally provides that an agency may not conduct or sponsor, and not withstanding any other provision of law, a person is not required to respond to, a collection of information, unless it displays a currently valid Office of Management and Budget control number. The PRA applies to rulemakings in which an agency creates a new or amends existing information collection requirements. For purposes of the PRA, an information-collection requirement may take the form of a reporting, recordkeeping, or a third-party disclosure requirement. The NCUA has determined that the changes

¹⁴ See 12 CFR 701.20(c)(2), 741.203, 741.221.

¹⁵ See Final Rule, Member Business Loans; Commercial Lending, 81 FR 13530, 13533 (Mar. 14, 2016); 12 CFR part 723. For FISCUs, a state regulator may adopt state-specific rules if the state rule covers at least all provisions in part 723 and is no less restrictive as determined by the NCUA. FISCUs in states with an NCUA-approved state rule may comply with the state rule and need not comply with part 723. See 12 CFR 723.10, 741.203.

¹⁶ See Final Rule, Member Business Loans; Commercial Lending, 81 FR 13530, 13533 (Mar. 14, 2016).

¹⁷ 58 FR 51735 (Oct. 4, 1993).

¹⁸ 76 FR 3821 (Jan. 21, 2011).

¹⁹ 90 FR 9065 (Feb. 6, 2025).

²⁰ 5 U.S.C. 601 *et seq.*

²¹ 5 U.S.C. 605(b).

²² 80 FR 57512 (Sept. 24, 2015).

addressed in this notice do not create a new information collection or revise an existing information collection as defined by the PRA.

E. Executive Order 13132 on Federalism

Executive Order 13132 encourages certain agencies to consider the impact of their actions on state and local interests. The NCUA, an agency as defined in 44 U.S.C. 3502(5), voluntarily complies with the executive order to adhere to fundamental federalism principles. This proposed rule would apply to all FICUs, including FISCUs.

The NCUA expects that any effect on states or on the distribution of power and responsibilities among the various levels of government will be minor. These proposed changes are not intended to affect the division of responsibilities between the NCUA and state regulatory authorities with oversight of FISCUs. The proposed rule would remove the segregated deposit and collateral requirements imposed by § 701.20 when FCUs or FISCUs act as a surety and guarantor. FISCUs would remain subject to the other requirements, including compliance with applicable NCUA and state lending regulations.

The proposed rulemaking may, therefore, have some direct effect on the states, the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. However, to the extent the rule has any such effects, it will be to relieve FISCUs of a regulatory burden.

F. Assessment of Federal Regulations and Policies on Families

The NCUA has determined that this proposed rule would not affect family well-being within the meaning of section 654 of the Treasury and General Government Appropriations Act, 1999. The proposed rule relates to the collateral requirements for FICUs to enter into surety and guaranty agreements, and any effect on family well-being is expected to be indirect. The proposed regulatory changes are exclusively concerned with removing the unnecessary segregated deposit and collateral requirements specific to such agreements. Any potential positive effect on family well-being, including financial well-being is, at most, indirect.

List of Subjects in 12 CFR Part 701

Advertising, Aged, Civil rights, Credit, Credit unions, Fair housing, Individuals with disabilities, Insurance, Marital status discrimination, Mortgages, Religious discrimination, Reporting and

recordkeeping requirements, Sex discrimination, Signs and symbols, Surety bonds.

By the National Credit Union Administration Board, this 19th day of December, 2025.

Melane Conyers-Ausbrooks,
Secretary of the Board.

For the reasons stated in the preamble, the NCUA Board proposes to amend 12 CFR part 701, as follows:

PART 701—ORGANIZATION AND OPERATION OF FEDERAL CREDIT UNIONS

- 1. The authority citation for part 701 continues to read as follows:

Authority: 12 U.S.C. 1752(5), 1755, 1756, 1757, 1758, 1759, 1761a, 1761b, 1766, 1767, 1782, 1784, 1785, 1786, 1787, 1788, 1789. Section 701.6 is also authorized by 15 U.S.C. 3717. Section 701.31 is also authorized by 15 U.S.C. 1601 *et seq.*; 42 U.S.C. 1981 and 3601–3610. Section 701.35 is also authorized by 42 U.S.C. 4311–4312.

§ 701.20 [Amended]

- 2. Amend § 701.20 by:
 - a. Removing paragraphs (c)(3) and (d) and
 - b. Revising paragraph (c) to read as follows:

§ 701.20 Suretyship and guaranty.

* * * * *

(c) * * *

(1) The federal credit union limits its obligations under the agreement to a fixed dollar amount and a specified duration and

(2) The federal credit union's performance under the agreement creates an authorized loan that complies with the applicable lending regulations, including the limitations on loans to one member or associated members or officials for purposes of §§ 701.21(c)(5), (d); 723.4(c).

[FR Doc. 2025–23857 Filed 12–23–25; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 740

RIN 3133–AF75

Accuracy of Advertising and Notice of Insured Status

AGENCY: National Credit Union Administration (NCUA).

ACTION: Proposed rule.

SUMMARY: The NCUA Board (Board) is issuing this proposed rule to streamline its regulations governing advertising

and the notice of insured status. This proposed rule would eliminate provisions concerning the official advertising statement. This action is undertaken to reduce regulatory complexity, and the intended effect is to reduce the administrative burden and costs for federally insured credit unions (FICUs) and provide them with greater flexibility in their advertising activities. The proposed rule would not amend requirements related to displaying the official sign.

DATES: Comments must be received by February 27, 2026.

ADDRESSES: Comments may be submitted in one of the following ways. (Please send comments by one method only):

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. The docket number for this proposed rule is NCUA–2025–1436. Follow the “Submit a comment” instructions. If you are reading this document on [federalregister.gov](https://www.federalregister.gov), you may use the green “SUBMIT A PUBLIC COMMENT” button beneath this rulemaking’s title to submit a comment to the [regulations.gov](https://www.regulations.gov) docket. A plain language summary of the proposed rule is also available on the docket website.

- **Mail:** Address to Melane Conyers-Ausbrooks, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.

- **Hand Delivery/Courier:** Same as mailing address.

Mailed and hand-delivered comments must be received by the close of the comment period.

Public inspection: Please follow the search instructions on <https://www.regulations.gov> to view the public comments. Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are public records; they are publicly displayed exactly as received, and will not be deleted, modified, or redacted. Comments may be submitted anonymously. If you are unable to access public comments on the internet, you may contact the NCUA for alternative access by calling (703) 518–6540 or emailing OGCMail@ncua.gov.

FOR FURTHER INFORMATION CONTACT: Rachel Ackmann, Senior Attorney, Office of General Counsel, at (703) 518–6540 or at 1775 Duke Street, Alexandria, VA 22314.

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Background

The Board comprehensively revised and streamlined part 740 in a 2003 final rule.¹ The primary purpose of the 2003 revision was to modernize the regulation for clarity, address the growing use of the internet for member transactions, and clarify the use of trade names in advertising. The NCUA's goal was to ensure members were adequately informed of their federal share insurance coverage while imposing a minimal regulatory burden.

Over the subsequent years, the NCUA amended these regulations several times. In the 2006 final rule, the NCUA revised the official sign to reflect statutory changes from the Federal Deposit Insurance Reform Act of 2005, which included adding a statement that insured accounts are backed by the full faith and credit of the United States Government.

A subsequent 2008 final rule provided credit unions with additional flexibility by permitting the use of a shortened advertising statement, "Federally insured by NCUA," or the official sign itself in advertisements.² In a 2011 final rule, the Board made the advertising rules more stringent.³ This amendment, among other changes, reduced the time exemption for radio and television advertisements from 30 seconds to 15 seconds. It also introduced the requirement to include the official advertising statement in annual reports and statements of condition, clarified that the statement's font size in print must be no smaller than the smallest font used for other consumer information, and defined the term "advertisement" for the first time.

However, in a 2018 final rule, the NCUA reversed the 2011 change to the broadcast advertisement exemption to provide regulatory relief and restore parity with regulations for banks insured by the Federal Deposit Insurance Corporation.⁴ The 2018 rule expanded the radio and television exemption back to 30 seconds and introduced a shorter advertising statement option: "Insured by NCUA." Most recently, a 2020 final rule made technical corrections to improve clarity.⁵

B. Legal Authority

Section 205(a) of the Federal Credit Union Act (FCU Act) (12 U.S.C. 1785(a))

requires each FICU to display a sign relating to the insurance of its share accounts.⁶ The NCUA implements this requirement in part 740 of its rules (part 740).⁷ Part 740 also requires that each FICU include an official advertising statement related to share insurance in all advertisements.⁸ This requirement originated from a historic statutory provision in section 1785(a). Before 2005, section 1785(a) required every FICU to include a statement in all advertisements reiterating that its member accounts are insured by the Board. Section 1785(a) also provided that the Board may exempt advertisements from this requirement if the advertisements do not relate to member accounts or when it is impractical to include such a statement.

The 2005 statutory amendment retained the requirement for FICUs to post official signs but removed the requirement to include official advertising statements. The NCUA issued a final rule implementing changes associated with the 2005 statutory amendments in 2006 (2006 final rule) but did not remove the portions of part 740 that implemented the historical requirement to include an official advertising statement.⁹ Part 740 currently includes both the requirements for an official sign and advertising statement.¹⁰

II. Proposed Rule

This proposed rule would amend two sections within part 740 and is intended to promote regulatory efficiency and reduce unnecessary burdens on FICUs. This proposed rule would remove § 740.5 related to the official advertising statement and revise § 740.0 to remove references to the official advertising statement. This action is intended to provide FICUs with greater flexibility in

their advertising activities while ensuring that members continue to receive clear and accurate information about their share insurance coverage through other required disclosures.

Section 740.5 establishes the specific requirements for the official advertising statement. It mandates that FICUs include one of three prescribed official statements or an alternative, namely—"This credit union is federally insured by the National Credit Union Administration," "Federally insured by NCUA," "Insured by NCUA," or a reproduction of the official sign—in all advertisements, unless specifically exempted. The regulation requires the statement to be clearly legible and with a font that is no smaller than the smallest font used for other consumer information in the advertisement. Section 740.5 also details numerous exemptions, specifying that the official statement is not required for certain items such as stationery, checks, signs within a credit union's office, directory listings, radio and television advertisements of 30 seconds or less, promotional items where inclusion is impractical, and advertisements that do not relate to member accounts, such as those for loans or safe deposit box services.

The Board is proposing to eliminate § 740.5 because the section imposes an unnecessary and undue compliance burden on FICUs that is disproportionate to its limited public benefit. The highly prescriptive nature of the rule, with its specific textual requirements and complex list of exceptions for items ranging from radio spots to promotional pens, forces FICUs to dedicate administrative resources to compliance. This approach is inflexible and poorly suited to the modern, fast-paced advertising landscape, particularly in the context of digital and social media, where space is often limited and communication must be concise.

Furthermore, the Board believes the rule is largely unnecessary because its core objective—ensuring members are aware of their federal insurance coverage—is effectively achieved through other, more direct means. The NCUA has long held it is important for consumers of advertisements to know that the share accounts in the advertising FICU are federally insured by the NCUA.¹¹ The Board has also stated that it believes the benefits to consumers and FICUs—namely, enhanced consumer confidence and agency name recognition—outweigh the relatively minor burden associated with

⁶ 12 U.S.C. 1785(a).

⁷ 12 CFR pt. 740.

⁸ 12 CFR 740.5.

⁹ 71 FR 36719 (2006). The Board notes that the FCU Act grants the NCUA a broad mandate to issue regulations governing both federal and state-chartered credit unions. Section 120 of the FCU Act is a general grant of regulatory authority, and it authorizes the Board to prescribe rules and regulations for the administration of the FCU Act. 12 U.S.C. 1766(a). Section 209 of the FCU Act is a plenary grant of regulatory authority to the NCUA to issue rules and regulations necessary or appropriate to carry out its role as share insurer for all FICUs. 12 U.S.C. 1789. Additionally, Section 204 of the FCU Act authorizes the Board, through its examiners, "to examine any [FICU] . . . to determine the condition of any such credit union for insurance purposes." 12 U.S.C. 1784.

¹⁰ The NCUA has updated part 740 several times since 2006 but has not discussed the change in statutory authority, and it does not appear commenters have raised concerns either. *See*, 73 FR 56935 (Oct. 1, 2008); 76 FR 30521 (May 26, 2011), and 83 FR 17910 (Apr. 25, 2018).

¹¹ 76 FR 30521 (May 26, 2011).

¹ 68 FR 23382 (May 2, 2003).

² 73 FR 56936 (Oct. 1, 2008).

³ 76 FR 30523 (May 26, 2011).

⁴ 83 FR 17913 (Apr. 25, 2018).

⁵ 85 FR 62213 (Oct. 2, 2020).

requiring the inclusion of the official advertising statement.

However, the Board now believes these objectives are best met through other provisions of part 740, and the advertising statement is unnecessary. First, the requirements in § 740.4, which are not being amended by this rule, mandate the display of the official NCUA sign in a FICU's offices and on its website where members can open share accounts and deposit funds.¹² This ensures that members receive prominent notice of their insured status at the key points of transaction and interaction. Second, the requirements in § 740.2 mandate that FICU advertising be accurate and truthful. This provision ensures that, if a FICU references its federal share insurance in advertisements, it does so accurately. For example, if a FICU states it is NCUA insured in an advertisement that includes noninsured products, the advertisement should be clear that the product is not insured. The additional requirement to include a specific statement in all advertisements on share insurance is therefore redundant and does not materially enhance member protection in a way that justifies the associated compliance costs.

This policy to remove the requirement for an official advertising statement is also supported by the fact that the requirement in § 740.5 is not statutorily mandated. As discussed above, the FCU Act explicitly directs the Board to issue regulations regarding the display of the official sign. No provision in the FCU Act compels the Board to create or enforce a separate, distinct official advertising statement to be included in all advertisements. As the rule is not required by law and imposes an unnecessary burden, its removal is a logical step to streamline the regulatory framework. FICUs may continue to include an advertising statement, provided the inclusion is not inaccurate or deceptive, but will not be required to include an advertising statement.

Finally, the proposed rule would also amend § 740.0, which outlines the scope of part 740. Part 740 currently references the official advertising statement. With the removal of the substantive requirements in § 740.5, retaining a scope section that references these rules would be inaccurate and

create confusion. Therefore, the proposed rule would remove references in § 740.0 to the advertising statement.

The Board solicits comments on all aspects of the proposed rule.

III. Regulatory Procedures

A. Providing Accountability Through Transparency Act of 2023

The Providing Accountability Through Transparency Act of 2023 (5 U.S.C. 553(b)(4)) (Act) requires that a notice of proposed rulemaking include the internet address of a summary of not more than 100 words in length of a proposed rule, in plain language, that shall be posted on the internet website under section 206(d) of the E-Government Act of 2002 (44 U.S.C. 3501 note) (commonly known as *regulations.gov*). The Act, under its terms, applies to notices of proposed rulemaking and does not expressly include other types of documents that the Board publishes voluntarily for public comment, such as notices and interim-final rules that request comment despite invoking "good cause" to forgo such notice and public procedure. The Board, however, has elected to address the Act's requirement in these types of documents in the interests of administrative consistency and transparency.

The Board is issuing this proposed rule to streamline its regulations governing advertising and the notice of insured status. This proposed rule would eliminate provisions concerning the official advertising statement. This action is undertaken to reduce regulatory complexity and the intended effect is to reduce the administrative burden and costs for FICUs and provide them with greater flexibility in their advertising activities.

The proposal and the required summary can be found at <https://www.regulations.gov>.

B. Executive Orders 12866, 13563, and 14192

Pursuant to Executive Order 12866 ("Regulatory Planning and Review"), as amended by Executive Order 14215, a determination must be made whether a regulatory action is significant and therefore subject to review by the Office of Management and Budget (OMB) in accordance with the requirements of the Executive Order.¹³ Executive Order 13563 ("Improving Regulation and Regulatory Review") supplements and reaffirms the principles, structures, and definitions governing contemporary regulatory review established in

Executive Order 12866.¹⁴ This proposed rule was drafted and reviewed in accordance with Executive Order 12866 and Executive Order 13563. OMB has determined that this proposed rule is not a "significant regulatory action" as defined in section 3(f)(1) of Executive Order 12866. This proposed rule will reduce the burden of including an official advertising statement on all advertisements unless otherwise exempt and is consistent with Executive Order 13563.

Executive Order 14192 ("Unleashing Prosperity Through Deregulation") requires that any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.¹⁵ This proposed rule is expected to be a deregulatory action for purposes of Executive Order 14192.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act¹⁶ generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. If the agency makes such a certification, it shall publish the certification at the time of publication of either the proposed rule or the final rule, along with a statement providing the factual basis for such certification.¹⁷ For purposes of this analysis, the NCUA considers small credit unions to be those having under \$100 million in assets.¹⁸ The Board fully considered the potential economic impacts of the regulatory amendments on small credit unions.

This rule is narrow in scope and purely deregulatory. Further, FICUs may voluntarily continue to include the official advertising statement in their advertisements and may choose not to change their current practices. Accordingly, the NCUA certifies the proposed rule would not have a significant economic impact on a substantial number of small credit unions.

D. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) generally provides that an agency may not conduct or sponsor, and not withstanding any other provision of

¹² The Board notes that it treats mobile banking applications similar to internet pages and the official sign is required on the main page and the log-on screen where members identify themselves to conduct transactions online. The official sign is also required on a membership application page. Displaying the official sign there will provide adequate notice of federal share insurance to the member.

¹³ 58 FR 51735 (Oct. 4, 1993).

¹⁴ 76 FR 3821 (Jan. 21, 2011).

¹⁵ 90 FR 9065 (Feb. 6, 2025).

¹⁶ 5 U.S.C. 601 *et seq.*

¹⁷ 5 U.S.C. 605(b).

¹⁸ 80 FR 57512 (Sept. 24, 2015).

law, a person is not required to respond to, a collection of information, unless it displays a currently valid Office of Management and Budget (OMB) control number. The PRA applies to rulemakings in which an agency creates a new or amends existing information collection requirements. For purposes of the PRA, an information-collection requirement may take the form of a reporting, recordkeeping, or a third-party disclosure requirement. The NCUA has determined that the changes described in this notice do not create a new information collection or revise an existing information collection as defined by the PRA.

E. Executive Order 13132 on Federalism

Executive Order 13132 encourages certain agencies to consider the impact of their actions on state and local interests. The NCUA, a regulatory agency as defined in 44 U.S.C. 3502(5), voluntarily complies with the executive order to adhere to fundamental federalism principles. This proposed rule would apply to all FICUs, including state-chartered credit unions. The NCUA expects that any effect on states or on the distribution of power and responsibilities among the various levels of government will be minor. The proposed changes would remove an existing requirement on state-chartered credit unions and would not affect the division of responsibilities between the NCUA and state regulatory authorities with oversight of federally insured, state-chartered credit unions. These changes relate to the NCUA's insurance of member accounts, which is a distinct federal function. The proposed changes are deregulatory and would relieve burdens on state-chartered credit unions. The rulemaking would therefore not have a direct effect on the states, the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Assessment of Federal Regulations and Policies on Families

The NCUA has determined that this proposed rule would not affect family well-being within the meaning of section 654 of the Treasury and General Government Appropriations Act, 1999.¹⁹ The proposed rule relates to FICUs' advertisements, but the Board does not believe it will cause member confusion regarding share insurance coverage. Therefore, any effect on family well-being is expected to be indirect.

List of Subjects in 12 CFR Part 740

Bank deposit insurance, Credit unions, Reporting and recordkeeping requirements, Signs and symbols.

By the National Credit Union Administration Board, this 19th day of December, 2025.

Melane Conyers-Ausbrooks,
Secretary of the Board.

For the reasons set forth in the preamble, the Board proposes to amend 12 CFR part 740 to read as follows:

PART 740—ACCURACY OF ADVERTISING AND NOTICE OF INSURED STATUS

■ 1. The authority citation for part 740 continues to read as follows:

Authority: 12 U.S.C. 1766, 1781, 1785, and 1789.

■ 2. Revise § 740.0 to read as follows:

§ 740.0 Scope.

This part applies to all federally insured credit unions. It prescribes the requirements for the official sign insured credit unions must display. It requires that all other kinds of advertisements be accurate. It also establishes requirements for advertisements of excess insurance.

§ 740.5 [Removed]

■ 3. Remove § 740.5.

[FR Doc. 2025–23854 Filed 12–23–25; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 748

RIN 3133–AF77

Catastrophic Act Reporting

AGENCY: National Credit Union Administration (NCUA).

ACTION: Proposed rule.

SUMMARY: The NCUA Board (Board) is publishing this proposed rule to amend the requirements for federally insured credit unions (FICUs) to report catastrophic acts to the agency. By providing more time for FICUs to notify the agency of the occurrence of a catastrophic act and by eliminating the specific list of items to be documented, the Board expects the proposed rule to reduce the compliance burden and allow FICUs to focus their resources on recovery and core functions without compromising safety and soundness.

DATES: Comments must be received on or before February 27, 2026.

ADDRESSES: Comments may be submitted in one of the following ways. (Please send comments by one method only):

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. The docket number for this proposed rule is NCUA–2025–1437. Follow the “Submit a comment” instructions. If you are reading this document on [federalregister.gov](https://www.federalregister.gov), you may use the green “SUBMIT A PUBLIC COMMENT” button beneath this rulemaking’s title to submit a comment to the [regulations.gov](https://www.regulations.gov) docket. A plain language summary of the proposed rule is also available on the docket website.

- **Mail:** Address to Melane Conyers-Ausbrooks, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.

- **Hand Delivery/Courier:** Same as mailing address.

Mailed and hand-delivered comments must be received by the close of the comment period.

Public inspection: Please follow the search instructions on <https://www.regulations.gov> to view the public comments. Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are public records; they are publicly displayed exactly as received, and will not be deleted, modified, or redacted. Comments may be submitted anonymously. If you are unable to access public comments on the internet, you may contact the NCUA for alternative access by calling (703) 518–6540 or emailing OGCMail@ncua.gov.

FOR FURTHER INFORMATION CONTACT: Gira Bose, Senior Staff Attorney, at (703) 518–6540 or at 1775 Duke Street, Alexandria, VA 22314.

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Background

Part 748 requires a FICU to notify the appropriate NCUA Regional Director within five business days of any catastrophic act that occurs at its office(s). NCUA regulations define a catastrophic act as “any disaster, natural or otherwise, resulting in physical destruction or damage to the credit union or causing an interruption in vital member services, as defined in § 749.1 of this chapter, projected to last more than two consecutive business days.”¹

¹ 12 CFR 748.1(b). See also 12 CFR 749, App. B, Catastrophic Act Preparedness Guidelines. The

¹⁹ Public Law 105–277, 112 Stat. 2681 (1998).

The agency adopted this requirement under 12 U.S.C. 1785(e), which requires the agency to promulgate rules establishing minimum safety standards relating to security.

In 2007, NCUA amended the definition of catastrophic act “to address concerns that relatively minor events could be construed to trigger the need to file a report and, also, clarifying the causal link between a disaster and an interruption in vital member services.”² The Board believed these changes to be “consistent with the usual and customary meaning of the word catastrophe.”³ The Board stated, “[t]hese changes also reinforce the Board’s view that the reporting requirement applies only to a disaster as opposed to a circumstance where physical damage or a business closing occurs but is not disaster-related.”⁴ While natural disasters were the leading concern in the aftermath of hurricanes Katrina and Rita, the use of the phrasing “any disaster, natural or otherwise” in the definition of catastrophic act was meant to illustrate other events, such as a power grid failure or physical attack, for example, could have a similar impact on access to member services and vital records.

B. Legal Authority

The Board is issuing this proposed rule pursuant to its authority under the Federal Credit Union Act (FCU Act).⁵ Under the FCU Act, the NCUA is the chartering and supervisory authority for federal credit unions (FCUs) and the federal supervisory authority for federally insured credit unions (FICUs). The FCU Act grants the NCUA a broad mandate to issue regulations governing both FCUs and FICUs. Section 120 of the FCU Act is a general grant of regulatory authority and authorizes the Board to prescribe regulations for the administration of the FCU Act.⁶ Section 209 of the FCU Act is a plenary grant

of regulatory authority to the NCUA to issue regulations necessary or appropriate to carry out its role as share insurer for all FICUs.⁷ The FCU Act also includes an express grant of authority for the Board to subject federally chartered central, or corporate, credit unions to such rules, regulations, and orders as the Board deems appropriate.⁸

II. Proposed Rule

The Board is proposing to further ease the reporting burden with the following amendments. First, the proposal would amend the regulation to require that credit unions notify “NCUA” rather than the specific “regional director.” This change is intended to modernize the reporting process and provide greater operational flexibility for both FICUs and the agency. By designating “NCUA” as the recipient, the agency can centralize and streamline the intake of these critical reports, ensuring they are routed efficiently to the appropriate personnel for response and monitoring. This change would remove the burden on a credit union, which may be operating under emergency conditions, to identify and direct its report to a specific regional office.

Second, the proposal would extend the timeframe for submitting a catastrophic act report from “5 business days” to “15 calendar days.” The Board believes the current five-day deadline may be impractical for an institution recovering from a significant operational disruption. Extending the deadline to 15 calendar days provides credit union management with a more reasonable amount of time to stabilize operations, assess the full scope of the damage, and provide a more accurate report to the agency. This change acknowledges the significant operational challenges that follow a catastrophic act and would allow a credit union to prioritize recovery efforts over immediate administrative reporting.

Finally, the Board proposes to remove the prescriptive list of items that a credit union should include in its internal record of a catastrophic act and replace it with a requirement that a credit union record the basic facts of the event. The current rule suggests documenting details such as the location, timing, loss amount, and potential operational deficiencies. While maintaining a record containing the basic facts of an event is a prudent business practice, the Board believes that specifying the exact contents of this internal record to the degree currently required is an unnecessary and overly prescriptive

regulatory burden. FICUs already maintain records of such events as part of their own business continuity and disaster recovery planning. Removing the list of items in this sentence would reduce administrative overhead and allow FICUs the flexibility to document these incidents in a manner that best suits their operational and recordkeeping policies, while still ensuring a record is created and maintained. This change would also make the regulation clearer by removing a provision that is phrased as a suggestion and not a requirement with the use of the word “should.”

Commenters are invited to provide feedback on these proposed changes to the catastrophic act reporting requirements. Specifically, the Board seeks feedback on whether the proposed amendments appropriately balance the agency’s need for timely information with the operational burdens faced by FICUs during a crisis. The Board is also seeking comment on whether credit unions should be permitted to use existing notification tools, such as the form currently used to report cybersecurity incidents under section 748.1(c), to report catastrophic acts. Commenters are also invited to address whether the proposed 15-calendar-day reporting timeframe is appropriate and whether the removal of the recordkeeping elements would provide meaningful burden reduction.

III. Regulatory Procedures

A. Providing Accountability Through Transparency Act of 2023

The Providing Accountability Through Transparency Act of 2023 (5 U.S.C. 553(b)(4)) (Act) requires that a notice of proposed rulemaking include the internet address of a summary of not more than 100 words in length of a proposed rule, in plain language, that shall be posted on the internet website under section 206(d) of the E-Government Act of 2002 (44 U.S.C. 3501 note) (commonly known as *regulations.gov*). The Act, under its terms, applies to notices of proposed rulemaking and does not expressly include other types of documents that the Board publishes voluntarily for public comment, such as notices and interim-final rules that request comment despite invoking “good cause” to forgo such notice and public procedure. The Board, however, has elected to address the Act’s requirement in these types of documents in the interests of administrative consistency and transparency.

In summary, NCUA is publishing this proposed rule to amend the

NCUA has long required catastrophic act reporting. In 1970, Congress amended the Federal Credit Union Act (FCU Act) to require that the NCUA promulgate rules establishing minimum standards for the installation, maintenance, and operation of security devices and procedures to discourage robberies, burglaries, and larcenies. The 1970 amendment to the FCU Act also required the agency to adopt time limits for compliance and mandated the submission of periodic reports. See 12 U.S.C. 1785(e) (Pub. L. 91–468) (84 Stat. 1002). Thus, since 1971, the NCUA has promulgated regulations requiring the submission of reports within five working days of an occurrence, or attempted occurrence, of a crime or catastrophic act. See 36 FR 10940 (June 1, 1971). See also 47 FR 17981 (Apr. 27, 1982); 50 FR 53295 (Dec. 31, 1985).

² 72 FR 42271 (Aug. 2, 2007).

³ *Id.*

⁴ *Id.*

⁵ 12 U.S.C. 1751 *et seq.*

⁶ 12 U.S.C. 1766(a).

⁷ 12 U.S.C. 1789.

⁸ 12 U.S.C. 1766(a).

requirements for FICUs to report catastrophic acts to the agency. By providing more time for FICUs to notify the agency of the occurrence of a catastrophic act and by eliminating the specific list of items to be documented, the Board expects the proposed rule to reduce their compliance burden and allow FICUs to focus their resources on recovery and core functions without compromising safety and soundness.

The proposal and the required summary can be found at <https://www.regulations.gov>.

B. Executive Orders 12866, 13563, and 14192

Pursuant to Executive Order 12866 (“Regulatory Planning and Review”), as amended by Executive Order 14215, a determination must be made whether a regulatory action is significant and therefore subject to review by the Office of Management and Budget (OMB) in accordance with the requirements of the Executive Order.⁹ Executive Order 13563 (“Improving Regulation and Regulatory Review”) supplements and reaffirms the principles, structures, and definitions governing contemporary regulatory review established in Executive Order 12866.¹⁰ This proposed rule was drafted and reviewed in accordance with Executive Order 12866 and Executive Order 13563. OMB has determined that this proposed rule is not a “significant regulatory action” as defined in section 3(f)(1) of Executive Order 12866. Further, this proposed rule is consistent with Executive Order 13563. The proposed rule will reduce the burden of catastrophic act reporting by increasing the time FICUs have to report to the agency and giving them the flexibility to determine what to incorporate into their record of an incident.

Executive Order 14192 (“Unleashing Prosperity Through Deregulation”) requires that any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.¹¹ This proposed rule is expected to be a deregulatory action for purposes of Executive Order 14192.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act¹² generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the

agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. If the agency makes such a certification, it shall publish the certification at the time of publication of either the proposed rule or the final rule, along with a statement providing the factual basis for such certification.¹³ For purposes of this analysis, the NCUA considers small credit unions to be those having under \$100 million in assets.¹⁴ The Board fully considered the potential economic impacts of the regulatory amendments on small credit unions.

The proposed rule reduces and simplifies aspects of part 748 related to catastrophic act reporting. Even if the magnitude of the change is significant, the NCUA certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities.

Accordingly, the NCUA certifies the proposed rule would not have a significant economic impact on a substantial number of small credit unions.

D. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) generally provides that an agency may not conduct or sponsor, and not withstanding any other provision of law, a person is not required to respond to, a collection of information, unless it displays a currently valid Office of Management and Budget (OMB) control number. The PRA applies to rulemakings in which an agency creates a new or amends existing information collection requirements. For purposes of the PRA, an information-collection requirement may take the form of a reporting, recordkeeping, or a third-party disclosure requirement. The NCUA has determined that the changes described in this notice do not create a new information collection or revise an existing information collection as defined by the PRA.

E. Executive Order 13132 on Federalism

Executive Order 13132 encourages certain agencies to consider the impact of their actions on state and local interests. The NCUA, an agency as defined in 44 U.S.C. 3502(5), complies with the executive order to adhere to fundamental federalism principles. This proposed rule is intended to reduce the burden on FICUs by simplifying catastrophic act reporting. The rulemaking would therefore not have direct effect on the states, the

relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Assessment of Federal Regulations and Policies on Families

The NCUA has determined that this proposed rule would not affect family well-being within the meaning of section 654 of the Treasury and General Government Appropriations Act, 1999.¹⁵ The proposed rule relates to FICU operations in the aftermath of a catastrophic act, and any effect on family well-being is expected to be indirect.

List of Subjects in 12 CFR Part 748

Credit unions; reporting and recordkeeping requirements; computer technology; internet; security measures; privacy; personally identifiable information; confidential business information; crime; currency.

By the National Credit Union Administration Board, this 19th day of December, 2025.

Melane Conyers-Ausbrooks,
Secretary of the Board.

For the reasons stated in the preamble, the NCUA Board proposes to amend 12 CFR part 748, as follows:

PART 748—SECURITY PROGRAM, SUSPICIOUS TRANSACTIONS, CATASTROPHIC ACTS, CYBER INCIDENTS, AND BANK SECRECY ACT COMPLIANCE

■ 1. The authority citation for part 748 continues to read as follows:

Authority: 12 U.S.C. 1766(a), 1786(b)(1), 1786(q), 1789(a)(11); 15 U.S.C. 6801–6809; 31 U.S.C. 5311 and 5318.

■ 2. Revise § 748.1(b) to read as follows:

§ 748.1 Filing of reports.

* * * * *

(b) *Catastrophic act report.* Each federally insured credit union will notify NCUA within 15 calendar days of any catastrophic act that occurs at its office(s). A catastrophic act is any disaster, natural or otherwise, resulting in physical destruction or damage to the credit union or causing an interruption in vital member services, as defined in § 749.1 of this chapter, projected to last more than two consecutive business days. Within a reasonable time after a catastrophic act occurs, the credit union shall ensure that a record of the incident

⁹ 58 FR 51735 (Oct. 4, 1993).

¹⁰ 76 FR 3821 (Jan. 21, 2011).

¹¹ 90 FR 9065 (Feb. 6, 2025).

¹² 5 U.S.C. 601 *et seq.*

¹³ 5 U.S.C. 605(b).

¹⁴ 80 FR 57512 (Sept. 24, 2015).

¹⁵ Public Law 105–277, 112 Stat. 2681 (1998).

is prepared that contains the basic facts of the event.

* * * * *

[FR Doc. 2025–23856 Filed 12–23–25; 8:45 am]

BILLING CODE 7535–01–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

37 CFR Part 1

[Docket No. PTO–P–2025–0008]

RIN 0651–AD85

Required Use by Foreign Applicants and Patent Owners of a Patent Practitioner

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice of proposed rulemaking.

SUMMARY: The United States Patent and Trademark Office (USPTO or Office) is proposing to amend the Rules of Practice in Patent Cases to require patent applicants and patent owners whose domicile is not located within the United States (U.S.) or its territories (hereinafter foreign applicants/inventors and patent owners) to be represented by a registered patent practitioner. A requirement that foreign applicants/inventors and patent owners be represented by a registered patent practitioner would bring the United States in line with most other countries that require that such parties be represented by a licensed or registered person of that country. Additionally, this requirement would increase efficiency and enable the USPTO to more effectively use available mechanisms to enforce compliance by all foreign applicants/inventors and patent owners with U.S. statutory and regulatory requirements in patent matters, and enhance the USPTO's ability to respond to false certifications, misrepresentations, and fraud.

DATES: Comments must be received by January 28, 2026 to ensure consideration.

ADDRESSES: For reasons of government efficiency, comments must be submitted through the Federal eRulemaking Portal at www.regulations.gov. To submit comments via the portal, one should enter docket number PTO–P–2025–0008 on the homepage and select “Search.” The site will provide search results listing all documents associated with this docket. Commenters can find a reference to this proposed rule and select the “Comment” icon, complete

the required fields, and enter or attach their comments. Attachments to electronic comments will be accepted in Adobe® portable document format (PDF) or Microsoft Word® format. Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included in the comments.

Visit the Federal eRulemaking Portal for additional instructions on providing comments via the portal. If electronic submission of or access to comments is not feasible due to a lack of access to a computer and/or the internet, please contact the USPTO using the contact information below for special instructions.

FOR FURTHER INFORMATION CONTACT:

Mark Polutta, Senior Legal Advisor, at (571) 272–7709, or Andrew St. Clair, Legal Advisor, at (571) 270–0238, of the Office of Patent Legal Administration or via email addressed to patentpractice@uspto.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Pursuant to its authority under 35 U.S.C. 2(b)(2), the USPTO is proposing to revise the rules in part 1 of title 37 of the Code of Federal Regulations to require foreign applicants/inventors and patent owners to be represented by a registered patent practitioner, as defined in 37 CFR 1.32(a)(1) (*i.e.*, a registered patent attorney or registered patent agent under 37 CFR 11.6 or an individual given limited recognition under § 11.9(a) or (b) or § 11.16) (hereinafter, registered patent practitioner). Requiring all foreign applicants/inventors and patent owners to be represented by a registered patent practitioner (1) treats foreign applicants/inventors and patent owners similarly to how U.S. applicants/inventors and patent owners are treated in other countries and harmonizes U.S. practice with the rest of the world; (2) increases efficiency as the USPTO spends extra resources to handle *pro se* applicants (*i.e.*, an applicant who is prosecuting the application without a registered patent practitioner); (3) enables the USPTO to more effectively use available mechanisms to enforce compliance with statutory and regulatory requirements in patent matters; and (4) enhances the USPTO's ability to respond to false certifications, misrepresentations, and fraud.

A. Harmonization of U.S. Practice With Other Intellectual Property (IP) Offices With Respect to Representation

Almost all IP Offices require foreign applicants/inventors and patent owners to be represented by a person licensed or registered in that country. The USPTO is proposing to implement a similar requirement. Requiring foreign applicants/inventors and patent owners to be represented by a registered patent practitioner would help to harmonize patent filing practice across IP Offices.

B. Increase Efficiency

The USPTO utilizes extra resources to assist *pro se* inventors. Requiring foreign applicants/inventors and patent owners to use registered patent practitioners will increase efficiency, as the applications will be in better form for examination. Applications from *pro se* inventors generally require additional processing by the Office of Patent Application Processing because the application papers are often not in condition for publication, examination, or both. Additionally, *pro se* applications usually require patent examiners to spend examination time on procedural matters, thereby increasing overall patent application pendency. Implementing this proposed rule would help allocate USPTO resources to the merits of examination and, accordingly, decrease patent application processing times.

C. Enforce Compliance With U.S. Statutory and Regulatory Requirements

The requirement for representation by a registered patent practitioner is also necessary to enforce compliance by all foreign patent applicants/inventors and patent owners with U.S. statutory and regulatory requirements in patent matters. Registered patent practitioners are subject to the USPTO Rules of Professional Conduct and disciplinary sanctions for violations of those rules. See 37 CFR 11.15, 11.20, and 11.100–11.901. Accordingly, registered patent practitioners have various obligations to the USPTO, including a duty to cooperate with inquiries and investigations. See, *e.g.*, 37 CFR 11.303 and 11.801.

The USPTO has noticed an increase in the number of false micro entity certifications to claim a reduction in fees and other false certification documents being filed. False certifications unjustly diminish the monetary resources of the USPTO, and false certifications on petitions or requests to expedite examination result in applications being unjustly advanced out of turn. Requiring submissions to be

made by registered patent practitioners subject to the USPTO Rules of Professional Conduct and concomitant disciplinary sanctions imposed by the USPTO Director will make it less likely that the submissions will be signed by an unauthorized party or contain inaccurate or fraudulent statements, particularly with regard to any certification of micro entity status to claim a reduction in fees and any certification relevant to expediting the application.

D. Fraud Mitigation and the Integrity of the U.S. Patent System

Requiring foreign patent applicants/inventors and patent owners to use registered patent practitioners will also facilitate fraud mitigation and protect the integrity of the U.S. patent system. As discussed, registered patent practitioners have a duty to cooperate with investigations and respond to lawful requests for information. *See* 37 CFR 11.801(b). Further, it is professional misconduct for a registered patent practitioner to engage in conduct involving dishonesty, fraud, deceit, or misrepresentation. *See* 37 CFR 11.804(c). It is also professional misconduct for a registered patent practitioner to engage in conduct that is prejudicial to the administration of justice. *See* 37 CFR 11.804(d). Because registered patent practitioners are subject to disciplinary sanctions pursuant to 37 CFR 11.15 and 11.20, they have an interest in responding to inquiries and investigations that extends beyond the outcome of a particular application.

For example, the USPTO currently sends fee deficiency notices in applications which appear to have false micro entity certifications, and can also send requests for information or show cause orders in applications in which an apparent misrepresentation has been made. In patent applications with *pro se* inventor-applicants, abandonment of the application effectively terminates the USPTO's ability to gather information. If a subsequent application is filed on the same subject matter, it may be difficult or impossible for the USPTO to establish that the applications are commonly owned or otherwise attributable to the same parties. However, when a registered patent practitioner is of record in the application or files papers in the application, the ability of the USPTO to gather information about the certifications or representations that were made extends beyond abandonment of the application. Therefore, requiring foreign patent applicants/inventors and patent owners

to use registered patent practitioners would facilitate fraud mitigation and protect the integrity of the U.S. patent system.

II. Enforcement

Unsigned or improperly signed papers are not entered into the record of the application or patent. *See, e.g.*, MPEP 714.01. As such, when representation by a registered patent practitioner is required, papers such as amendments and other replies, application data sheets, information disclosure statements, or petitions, would not be entered unless they are signed by a registered patent practitioner. This would not apply to papers which are required to be signed by a specific party, such as the inventor's oath or declaration under 37 CFR 1.63.

The definition of the term "domicile" is provided in proposed 37 CFR 1.9(p). The domicile of an inventor-applicant will normally be determined by the residence information provided in the application data sheet (ADS) under 37 CFR 1.76, or the inventor's oath or declaration under 37 CFR 1.63 (including a substitute statement under 37 CFR 1.64). The domicile of an applicant who is not an inventor will normally be determined based on the mailing address provided in the Applicant Information section of the ADS. If an ADS is inconsistent with the information provided in another document that was submitted at the same time or prior to the ADS submission, the ADS will control. *See* 37 CFR 1.76(d). This is because the ADS is intended to be the means by which an applicant provides complete bibliographic information. In some instances, the USPTO may refer to sources other than those listed above for purposes of assessing compliance with the domicile requirement. For example, in order to determine whether the domicile is accurate, the USPTO may refer to the notarized Patent Electronic System Verification form or other identity verification information.

A paper filed on behalf of the patent owner may indicate the domicile of the patent owner if such information is not present in the application file. When it is necessary for the USPTO to act on a paper submitted in the file of an issued patent and the paper is not signed by a registered patent practitioner, the paper may not be treated on its merits. For example, if a petition to accept unintentionally delayed payment of a maintenance fee in an expired patent under 37 CFR 1.378(b) is filed that is not signed by a registered patent practitioner, the petition may be dismissed before consideration on the

merits if it cannot be determined whether the paper complies with 37 CFR 1.31 and 1.33(b).

Regarding the assessment of compliance referred to above, applicants, patent owners, and practitioners are reminded that the presentation to the Office of any paper by a party, whether a practitioner or non-practitioner, constitutes a certification under 37 CFR 11.18(b). A misrepresentation of the domicile of an applicant or patent owner would not be "to the best of the party's knowledge, information and belief, formed after an inquiry reasonable under the circumstances" as required under 37 CFR 11.18(b)(2). Violations of 37 CFR 11.18(b)(2) by a party, whether a practitioner or non-practitioner, may result in the imposition of sanctions under 37 CFR 11.18(c), which may include termination of the proceedings. *See* 37 CFR 1.4(d)(5)(i).

III. Discussion of Specific Rules

The following is a discussion of proposed amendments to 37 CFR part 1:

A. Section 1.9

Section 1.9 is proposed to be amended to add new paragraph (p) defining domicile as the permanent legal place of residence of a natural person or the principal place of business of a juristic entity. The domicile of an inventor-applicant will normally be determined by the residence information provided in the ADS under 37 CFR 1.76, or the inventor's oath or declaration under 37 CFR 1.63 (including a substitute statement under 37 CFR 1.64). The domicile of an applicant who is not an inventor will normally be determined based on the mailing address provided in the Applicant Information section of the ADS. *See* section II. above for further discussion.

B. Section 1.31

Section 1.31 is proposed to be amended to add the title and rule to include "patent owner," and reformatting the rule language into paragraphs (a) and (b). The section is further proposed to be amended to indicate that an applicant as defined in § 1.42 or patent owner whose domicile is not located within the U.S. or its territories must be represented by a registered patent practitioner. The section is also proposed to be amended to require that a patent owner who is a juristic entity must be represented by a registered patent practitioner. The section previously required a juristic entity who was the applicant to be represented by a registered patent

practitioner, but has now been expanded to make a similar requirement for patent owners in post-grant proceedings.

The phrase “an applicant as defined in § 1.42” in paragraph (a) encompasses any inventor, joint inventor, legal representative, person to whom the inventor has assigned, person to whom the inventor is under an obligation to assign, or person who otherwise shows sufficient proprietary interest in the matter who is named as an applicant. Thus, an applicant as defined in § 1.42 must be represented by a registered patent practitioner if at least one of the parties identified as the applicant has a domicile that is not located within the U.S. or its territories. *See* § 1.31(a)(2). As a reminder, powers of attorney must be signed by all parties identified as the applicant in order to be effective.

C. Section 1.32

Section 1.32 is proposed to be amended to add the definition of patent practitioner to partially parallel § 11.10(a).

D. Section 1.33

Section 1.33 is proposed to be amended to add paragraph (b)(3) to indicate that for amendments and other papers filed in an application or patent unless otherwise specified submitted on behalf of a juristic entity, an applicant as defined in § 1.42 whose domicile is not located within the United States or its territories, or a patent owner whose domicile is not located within the United States or its territories must be signed by a patent practitioner. These revisions to paragraph (b)(3) are consistent with the changes to § 1.31, discussed above.

A foreign domiciled inventor who is the applicant may initially file a U.S. patent application with the USPTO and pay the filing fee at the time of filing. However, any application data sheet that accompanies the application papers or is submitted later, as well as all follow-on correspondence, must be signed by a patent practitioner. A patent practitioner must also sign any petition that is filed in such an application, including but not limited to a request for prioritized examination and a petition to make special. To pay the issue fee, PTOL-85 Part B would also have to be signed by a patent practitioner.

IV. Rulemaking Considerations

A. Administrative Procedure Act

This rulemaking would revise the procedures governing the representation of patent applicants and patent owners

at the USPTO. The proposed changes do not change the substantive criteria of patentability. Therefore, the changes in this rulemaking involve rules of agency practice and procedure and/or interpretive rules and do not require notice-and-comment rulemaking, pursuant to 5 U.S.C. 553(b)(A)). *See Perez v. Mortg. Bankers Ass’n*, 575 U.S. 92, 97, 101 (2015) (explaining that interpretive rules “advise the public of the agency’s construction of the statutes and rules which it administers” and do not require notice-and-comment when issued or amended); *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1336–37 (Fed. Cir. 2008) (5 U.S.C. 553, and thus 35 U.S.C. 2(b)(2)(B), do not require notice-and-comment rulemaking for “interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice”); *In re Chestek PLLC*, 92 F.4th 1105, 1110 (Fed. Cir. 2024) (noting that rule changes that “do[] not alter the substantive standards by which the USPTO evaluates trademark applications” are procedural in nature and thus “exempted from notice-and-comment rulemaking.”); and *JEM Broadcasting Co. v. F.C.C.*, 22 F.3d 320, 328 (D.C. Cir. 1994) (“[T]he ‘critical feature’ of the procedural exception [in 5 U.S.C. 553(b)(A)] ‘is that it covers agency actions that do not themselves alter the rights or interests of parties, although [they] may alter the manner in which the parties present themselves or their viewpoints to the agency.’” (quoting *Batterton v. Marshall*, 648 F.2d 694, 707 (D.C. Cir. 1980))). However, the USPTO has chosen to seek public comment before implementing the rule to benefit from the public’s input.

B. Regulatory Flexibility Act

As prior notice and an opportunity for public comment are not required pursuant to 5 U.S.C. 553 or any other law, neither a Regulatory Flexibility Act analysis nor a certification under the Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*) is required. *See* 5 U.S.C. 603. Nevertheless, the USPTO publishes this IRFA to examine the impact on small entities of the Office’s proposed requirement that patent applicants and patent owners whose domicile is not located within the United States (U.S.) or its territories (hereinafter “foreign applicants/inventors and patent owners”) be represented by a registered patent practitioner, as defined in 37 CFR 1.32(a)(1), and to seek the public’s views. The USPTO developed this IRFA to promote transparency and to inform the public of the impacts of this rule. The term domicile is defined as the permanent legal place of residence of a

natural person or the principal place of business of a juristic entity, as provided in new paragraph (p) under 37 CFR 1.9 of this proposed rule. Items 1–5 below discuss the five items specified in 5 U.S.C. 603(b)(1)–(5) to be addressed in an IRFA. Item 6 below discusses any alternatives to this proposal that the Office considered under 5 U.S.C. 603(c).

1. Description of the Reasons That Action by the USPTO Is Being Considered

The USPTO proposes to require that foreign applicants/inventors and patent owners be represented by a registered patent practitioner, as defined in proposed 37 CFR 1.32(a)(1). An “applicant” is the person applying for a patent, and can be any inventor, joint inventor, legal representative, person to whom the inventor has assigned, person to whom the inventor is under an obligation to assign, or person who otherwise shows sufficient proprietary interest in the matter who is named as an applicant. Under this proposed rule, foreign applicants/inventors and patent owners must be represented by a registered patent practitioner if at least one of the parties identified as an applicant or a patent owner has a domicile that is not located within the U.S. or its territories. A patent practitioner as defined in proposed 37 CFR 1.32(a)(1) means a registered patent attorney or registered patent agent under 37 CFR 11.6 or an individual given limited recognition under § 11.9(a) or (b) or § 11.16. When representation by a registered patent practitioner is required, papers such as amendments and other replies, application data sheets, information disclosure statements, or petitions, will not be entered unless they are signed by a registered patent practitioner; papers which are required to be signed by a specific party, such as the inventor’s oath or declaration under 37 CFR 1.63, are excluded. The requirement for a registered patent practitioner is applicable to all applications types (*i.e.*, utility, plant, design, *etc.*). This proposed rule would bring the United States in line with most other countries that require that such parties be represented by a licensed or registered person of that country. Additionally, this proposed rule would increase efficiency and enable the USPTO to more effectively use available mechanisms to enforce compliance by all foreign applicants/inventors and patent owners with U.S. statutory and regulatory requirements in patent matters, and enhance the USPTO’s ability to respond to false certifications, misrepresentations, and fraud. The rule

is also amended to require that a patent owner who is a juristic entity must be represented by a registered patent practitioner. The rule previously required a juristic entity who was the applicant to be represented by a registered patent practitioner, and has now been expanded to make explicit a similar requirement for patent owners in post-grant proceedings.

2. Succinct Statement of the Objectives of, and Legal Basis for, the Proposed Rule

The USPTO undertakes this proposed rule pursuant to its authority under 35 U.S.C. 2(b)(2), which authorizes the USPTO Director to establish regulations, not inconsistent with law, governing the conduct of proceedings in the Office. The policy objectives of the proposed rule are to: (1) treat foreign applicants/inventors and patent owners similarly to how U.S. applicants/inventors and patent owners are treated in other countries and harmonize U.S. practice with the rest of the world; (2) increase efficiency by reducing the extra resources the USPTO spends to handle *pro se* applicants (*i.e.*, an applicant who is prosecuting the application without a registered patent practitioner); (3) enable the USPTO to more effectively use available mechanisms to enforce compliance with statutory and regulatory requirements in patent matters; and (4) enhance the USPTO's ability to respond to false certifications, misrepresentations, and fraud.

3. Description of and, Where Feasible, an Estimate of the Number of Small Entities to Which the Proposed Rule Will Apply

The Small Business Administration (SBA) small business size standards that are applicable to most analyses conducted to comply with the RFA are set forth in 13 CFR 121.201. These regulations generally define small businesses as those with fewer than a specified maximum number of employees or less than a specified level of annual receipts for the entity's industrial sector or North American Industry Classification System (NAICS) code. As provided by the RFA, and after consulting with the SBA, the USPTO formally adopted an alternate size standard for the purpose of conducting an analysis or making a certification under the RFA for patent-related regulations. *See Business Size Standard for Purposes of United States Patent and Trademark Office Regulatory Flexibility Analysis for Patent-Related Regulations*, 71 FR 67109 (Nov. 20, 2006), 1313 Off. Gaz. Pat. Office 60 (Dec. 12, 2006). The USPTO's alternate small business size

standard is SBA's previously established size standard that identifies the criteria entities must meet to be entitled to pay reduced patent fees. *See* 13 CFR 121.802.

If patent applicants assert or certify entitlement for reduced patent fees, the USPTO captures this data in its patent application data repository (formerly the Patent Application Locating and Monitoring (PALM) system and now called the One Patent Service Gateway (OPSG) system), which tracks information on each patent application submitted to the Office.

Unlike the SBA small business size standards set forth in 13 CFR 121.201, the size standard for the USPTO is not industry specific. The Office's definition of a small business concern for RFA purposes is a business or other concern that: (1) meets the SBA's definition of a "business concern or concern" set forth in 13 CFR 121.105; and (2) meets the size standards set forth in 13 CFR 121.802 for the purpose of paying reduced patent fees, namely, an entity: (a) whose number of employees, including affiliates, does not exceed 500 persons; and (b) which has not assigned, granted, conveyed, or licensed (and is under no obligation to do so) any rights in the invention to any person who made it and could not be classified as an independent inventor, or to any concern that would not qualify as a nonprofit organization or a small business concern under this definition. *See Business Size Standard for Purposes of United States Patent and Trademark Office Regulatory Flexibility Analysis for Patent-Related Regulations*, 71 FR at 67112 (Nov. 20, 2006), 1313 Off. Gaz. Pat. Office at 63 (Dec. 12, 2006). Thus, for the purpose of this analysis, the USPTO defines small entities to include applicants/inventors and patent owners who pay "small" or "micro" entity fees at the USPTO.

In fiscal year (FY) 2022, the USPTO received 512,038 patent applications.¹ As discussed above, this proposed rule would impact those applications from foreign applicants/inventors or patent owners who are not represented by counsel. An applicant is considered to be a foreign applicant/inventor or patent owner if at least one party who was identified as an applicant or a patent

owner had a domicile that was not located within the U.S. or its territories.

As seen in Table 1 below, of the total 512,038 patent applications filed in FY 2022, 215,459 (42.1%) were filed by U.S. applicants/inventors and patent owners, and 296,579 (57.9%) were filed by foreign applicants/inventors and patent owners.

TABLE 1—FILINGS FROM FOREIGN OR U.S. APPLICANTS AS A PERCENTAGE OF TOTAL FILINGS

Applicant	FY 2022	Percentage (%)
US	215,459	42.1
Foreign	296,579	57.9
Total	512,038	100.0

Table 2 below shows the number of applications that were filed without a registered patent practitioner (*i.e.*, *pro se*) and those that were filed with a registered patent practitioner, in addition to the entity status of the applicant(s). Of the total 296,579 filings made by a foreign applicant/inventor or patent owner, 295,362 were represented by a registered patent practitioner (foreign represented) and 1,217 were not represented by a registered patent practitioner (foreign *pro se*).² The 1,217 foreign *pro se* applications would be impacted by the requirement to retain representation by a registered patent practitioner under this proposed rule.

The USPTO anticipates that this proposed rule would not have a substantial impact on foreign small entities. Of the total 295,362 foreign represented applications, 75,111 are considered to be small entities for the purposes of this analysis because they paid the "small" or "micro" entity fee (foreign represented small entities), and of the 1,217 foreign *pro se* applications, 1,102 are considered to be small entities because they paid the "small" or "micro" entity fee (foreign *pro se* small entities). The USPTO acknowledges that representation status in an application is dynamic, and some number of applicants change their status of representation after filing by either retaining a registered patent practitioner or separating from a registered patent practitioner and proceeding *pro se*. For the purposes of this analysis, the USPTO will assume that the 1,102 applications filed by foreign *pro se* small entities did not change their

¹ Fiscal year (FY) 2022 data is being used for this analysis to correspond with the most current available estimates of legal costs as published by American Intellectual Property Law Association in its 2023 Report on the Economic Survey. Patent application data show that filing trends in FY 2023 and FY 2024 have been consistent with FY 2022, with filings in FY 2023 totaling 516,915 and filings in FY 2024 totaling 527,538.

² An application is determined to be *pro se* if there are no current attorney(s) associated with the application or if no attorney(s) has been directly associated with the application over the application's prosecution history.

representation status and thus would be subject to the requirement to be represented by a registered patent practitioner. This proposed rule is not

expected to significantly impact foreign small entities, as the vast majority are represented by a registered patent practitioner. Only 1,102 foreign *pro se*

small entities, or 1.4% of the 76,213 total foreign small entities filing patent applications, would be affected.

TABLE 2

Application type	Total number of applications filed in FY 2022 (per OPPDA data obtained in June 2025)					
	Undisc.	Small	Micro	Total	Percentage (%)	
US <i>Pro Se</i>	1,664	1,747	2,180	5,591	1.09	215,459
US Represented	129,805	67,318	12,745	209,868	40.99	
Foreign <i>Pro Se</i>	115	490	612	1,217	.24	296,579
Foreign Represented	220,251	60,720	14,391	295,362	57.86	
Totals	351,835	130,275	29,928	512,038	100.0	

4. Description of the reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record:

The proposed rule imposes no new reporting or recordkeeping requirements. Compliance with the rule will be enforced by requiring an appropriate signature on papers submitted in patent matters. Any registered patent practitioner retained by the foreign applicants/inventors and patent owners as a result of this proposed rule would be required to be a registered patent attorney or registered patent agent under 37 CFR 11.6 or an individual given limited recognition under § 11.9(a) or (b) or § 11.16.

5. Identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap or conflict with the proposed rule:

This proposed rule does not duplicate, overlap, or conflict with other Federal rules.

6. Description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the rule on small entities:

The USPTO considered one alternative before proposing the requirement that foreign applicants/inventors and patent owners be represented by a registered patent practitioner, as defined in proposed 37 CFR 1.32(a)(1). A description of the proposed rule and the one alternative follows.

Proposed Rule: Under the proposed rule, the USPTO proposes to require that foreign applicants/inventors and patent owners be represented by a registered patent practitioner, as defined in proposed 37 CFR 1.32(a)(1). An applicant must be represented by a registered patent practitioner if at least one of the parties identified as the applicant or patent owner has a domicile that is not located within the U.S. or its territories. When representation by a registered patent practitioner is required, papers such as amendments and other replies, application data sheets, information disclosure statements, or petitions, will not be entered unless they are signed by a registered patent practitioner; papers which are required to be signed by a specific party, such as the inventor's oath or declaration under 37 CFR 1.63, are excluded. The requirement for a registered patent practitioner is applicable to all applications types (*i.e.*, utility, plant, design, *etc.*).

Due to the difficulty in quantifying the intangible benefits associated with the proposed rule, the Office provides a discussion of the qualitative benefits to patent applicants/inventors and patent owners. The primary benefits of the proposed rule are ensuring compliance by all foreign patent applicants/inventors and patent owners with U.S. statutory and regulatory requirements in patent matters, and facilitating fraud mitigation and protecting the integrity of the U.S. patent system. The USPTO has noticed an increase in the number of false micro entity certifications to claim a reduction in fees and other false certification documents being filed. False certifications unjustly diminish the monetary resources of the USPTO, and false certifications on petitions or requests to expedite examination result

in applications being unjustly advanced out of turn. Requiring submissions to be made by registered patent practitioners subject to the USPTO Rules of Professional Conduct and concomitant disciplinary sanctions imposed by the USPTO Director will make it less likely that the submissions will be signed by an unauthorized party or contain inaccurate or fraudulent statements, particularly with regard to any certification of micro entity status to claim a reduction in fees and any certification relevant to expediting the application.

The proposed rule also addresses the increasing problem of patent application pendency. *Pro se* applications generally require additional processing by the Office of Patent Application Processing because the application papers are often not in condition for publication, examination, or both. Additionally, *pro se* applications usually require patent examiners to spend examination time on procedural matters, thereby increasing overall patent application pendency. This proposed rule would help allocate USPTO resources to the merits of examination and, accordingly, decrease patent application processing times. Requiring foreign applicants/inventors and patent owners to use registered patent practitioners will increase efficiency, as the applications will be in better form for examination. Thus, the proposed rule would provide qualitative value to all applicants/inventors and patent owners because this rule would help allocate USPTO resources to the merits of examination and, accordingly, generally decrease processing times for all patent applications.

The RFA requires agencies to consider the economic impact of their regulatory proposals on small entities, specifically

U.S. small businesses, small governmental jurisdictions and small organizations. This proposed rule would require all applicants/inventors and patent owners, in which at least one party identified as the applicant or patent owner has a foreign domicile, to be represented by a registered patent practitioner. Although there will be some number of U.S.-domiciled applicants/inventors and patent owners that will be affected because at least one party identified as the applicant or patent owner has a foreign domicile, the USPTO estimates that the number of foreign *pro se* small entities impacted by this rule (1,102) is small when compared to the 76,213 total foreign small entities that file patent applications. The costs incurred by the 1,102 foreign *pro se* small entities would vary depending on the nature of

legal services provided and complexity of the application.

Tables 3, 4, and 5 below provide the estimated costs for a U.S. patent practitioner to prosecute an application based on professional rates as reported by the American Intellectual Property Law Association in the 2023 Report on the Economic Survey.³ The professional rates⁴ shown below are the median charges in FY 2022 for legal services rendered for a utility application.⁵ The tables do not include services for which legal counsel is not required (e.g., payment of maintenance fees) or services that are not part of prosecution (such as *ex parte* reexamination, novelty search, validity and infringement opinions, and reference management). The figures in Tables 3 and 4 show the estimated legal cost for prosecuting applications that are of minimal complexity as well as applications that are relatively complex.

Table 3 below provides the estimated cost to impacted entities if a U.S. patent practitioner is retained prior to filing of a non-provisional application. These cases include applications of foreign origin where no substantive direction is provided by the foreign attorney, and thus the patent practitioner would be required to provide substantive legal advice to prosecute the application, including legal services connected with preparing, filing, and prosecuting an application. Based on the total estimated number of applications filed by foreign applicants/inventors and patent owners that are also considered to be small entities, the total legal cost for non-provisional applications to comply with this proposed rule would range from \$13,124,820 to \$13,334,200 for minimal complexity applications, to \$16,430,820 to \$19,395,200 for relatively complex applications.

TABLE 3—COST FOR LEGAL SERVICES BY PERFORMED U.S. PATENT PRACTITIONERS (FY 22) PATENTS OF U.S. ORIGIN

Service	Cost for minimal complexity applications	Cost for relatively complex applications (biotech/chemical; electrical/computer; mechanical)
Original (not divisional, continuation, or CIP) non-provisional application on invention	\$8,000	\$10,000 to \$12,000
Application amendment/argument	\$2,000	\$3,000 to \$3,500
Issuing an allowed application	\$750	\$750
Preparing and filing Information Disclosure Statement (IDS), less than 50 references and more than 50 references	\$360 to \$550	\$360 to \$550
Patent Term Adjustment calculation	\$400	\$400
Formalities, including preparing and filing formal declarations, assignment, and powers of attorney, responding to pre-examination notices and preparing papers to make corrections	\$400	\$400
Cost	\$11,910 to \$12,100	\$14,910 to \$17,600
Pro Se Foreign Applicants/Inventors and Patent Owners (Small Entities) Non-Provisional ...	1,102	1,102
Total Cost	\$13,124,820 to \$13,334,200	\$16,430,820 to \$19,395,200

Table 4 below provides the estimated cost to impacted entities if a U.S. patent practitioner is retained to file a non-provisional application of foreign origin that is in condition for filing and in which the foreign attorney provides substantive direction. In these cases, the U.S. patent practitioner would provide

only minimal legal services connected with the initial filing an application and the subsequent filing of other documents. Based on the total estimated number of applications filed by foreign applicants/inventors and patent owners that are also considered to be small entities, the total legal cost for a non-

provisional application to comply with this proposed rule would range from \$4,336,370 to \$4,545,750 for minimal complexity applications, to \$5,190,420 to \$5,399,800 for relatively complex applications.

TABLE 4—COST FOR LEGAL SERVICES PERFORMED BY U.S. PATENT PRACTITIONERS (FY 22) PATENTS OF FOREIGN ORIGIN

Service	Cost for minimal complexity applications	Cost for relatively complex applications (biotech/chemical; electrical/computer; mechanical)
Filing in USPTO, received ready for filing	\$1,200	\$1,200

³ See Am. Intellectual Prop. Law Ass'n, Report of the Economic Survey 43 (2023).

⁴ Copy, drawing, and government fees are not included in the rates.

⁵ The Report on the Economic Survey provides professional rates for legal services rendered only in utility applications. Because the professional rates in utility applications typically represent the

upper range of legal costs, these rates will be used as a proxy to calculate the costs for legal services rendered for all applications, including plant and design applications.

TABLE 4—COST FOR LEGAL SERVICES PERFORMED BY U.S. PATENT PRACTITIONERS (FY 22) PATENTS OF FOREIGN ORIGIN—Continued

Service	Cost for minimal complexity applications	Cost for relatively complex applications (biotech/chemical; electrical/computer; mechanical)
Application amendment/argument, where foreign counsel or client provides detailed response instructions	\$1,225	\$2,000
Issuing an allowed application	\$750	\$750
Preparing and filing Information Disclosure Statement (IDS), less than 50 references and more than 50 references	\$360 to \$550	\$360 to \$550
Formalities, including preparing and filing formal declarations, assignment, and powers of attorney, responding to pre-examination notices and preparing papers to make corrections	\$400	\$400
Total Cost	\$3,935 to \$4,125	\$4,710 to \$4,900
Pro Se Foreign Applicants/Inventors and Patent Owners (Small Entities) Non-Provisional ...	1,102	1,102
Total Cost	\$4,336,370 to \$4,545,750	\$5,190,420 to \$5,399,800

Table 5 below provides a list of services that may be provided to impacted entities before or during prosecution, but are dependent on the nature of the application. The

prosecution of a patent application is highly variable and a particular application may or may not require any of these services. If these services are provided, then the costs below would be

added to the total legal costs in Tables 3 or 4, as applicable. The table below provides the percentage of all applications that have utilized these services.

TABLE 5

Service	Cost	Applications utilizing service	Percentage (%)
Appeal to Board with/without oral argument	\$5,000 to \$8,000	8,205	2
Preparing and filing formal drawings	600	30,822	6
Preparing for and conducting examination interview	1,000	176,908	35
Providing a continuation recommendation (including proposed claim strategy)	1,000	151,130	30
Filing previously prepared US applications as PCT application in US	1,090	57,112	11
Entering National Stage in US Receiving Office from foreign Origin PCT application ...	1,200	108,855	21
Provisional application	3,900 to 5,000	147,275	29

As seen above, the USPTO estimates that only 1,102 (or 1.4%) foreign *pro se* small entities would be impacted by this proposed rule. This is a very small number when compared to the 76,213 total foreign small entities that file patent applications. Although the number of impacted small entities is not expected to be substantial, the economic impact varies depending on the nature of legal services provided and complexity of the application. Because prosecution of patent applications is highly variable, the legal costs incurred by the 1,102 foreign *pro se* small entities would depend on whether the application is of U.S. origin or foreign origin, with applications of U.S. origin incurring more cost than those of foreign origin, and the level of complexity of the application, with relatively complex applications incurring more cost than minimally complex applications. Legal costs would increase if any of the additional available services are utilized before or during prosecution.

Alternative 1: The USPTO also considered the alternative to take no action and maintain the status quo (“Alternative 1”). Alternative 1 was rejected because the USPTO has determined that the requirement that foreign applicant/inventors and patent owners to be represented by a registered patent practitioner is needed to accomplish the stated objectives to increase efficiency and enable the USPTO to more effectively use available mechanisms to enforce compliance with U.S. statutory and regulatory requirements in patent matters, and to enhance the USPTO’s ability to respond to false certifications, misrepresentations, and fraud.

C. Executive Order 12866 (Regulatory Planning and Review)

This rulemaking has been determined to be not significant for purposes of Executive Order 12866 (September 30, 1993).

D. Executive Order 13563 (Improving Regulation and Regulatory Review)

The USPTO has complied with Executive Order 13563 (January 18, 2011). Specifically, and as discussed above, the USPTO has, to the extent feasible and applicable: (1) reasonably determined that the benefits of the rule justify its costs; (2) tailored the rule to impose the least burden on society consistent with obtaining the agency’s regulatory objectives; (3) selected a regulatory approach that maximizes net benefits; (4) specified performance objectives; (5) identified and assessed available alternatives; (6) involved the public in an open exchange of information and perspectives among experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole, and provided online access to the rulemaking docket; (7) attempted to promote coordination, simplification, and harmonization across government agencies and identified goals designed to promote innovation; (8) considered approaches

that reduce burdens while maintaining flexibility and freedom of choice for the public; and (9) ensured the objectivity of scientific and technological information and processes.

E. Executive Order 14192 (Deregulation)

This regulation is not an Executive Order 14192 regulatory action because it is not significant under Executive Order 12866.

F. Executive Order 13132 (Federalism)

This rulemaking pertains strictly to federal agency procedures and does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (August 4, 1999).

G. Executive Order 13175 (Tribal Consultation)

This rulemaking will not: (1) have substantial direct effects on one or more Indian tribes; (2) impose substantial direct compliance costs on Indian tribal governments; or (3) preempt tribal law. Therefore, a tribal summary impact statement is not required under Executive Order 13175 (November 6, 2000).

H. Executive Order 13211 (Energy Effects)

This rulemaking is not a significant energy action under Executive Order 13211 because this rulemaking is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required under Executive Order 13211 (May 18, 2001).

I. Executive Order 12988 (Civil Justice Reform)

This rulemaking meets applicable standards to minimize litigation, eliminate ambiguity, and reduce burden as set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 (February 5, 1996).

J. Executive Order 13045 (Protection of Children)

This rulemaking does not concern an environmental risk to health or safety that may disproportionately affect children under Executive Order 13045 (April 21, 1997).

K. Executive Order 12630 (Taking of Private Property)

This rulemaking will not effect a taking of private property or otherwise have taking implications under Executive Order 12630 (March 15, 1988).

L. Congressional Review Act

Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801, *et seq.*), the USPTO will submit a report containing the final rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the Government Accountability Office. The changes in this rulemaking are not expected to result in an annual effect on the economy of \$100 million or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. Therefore, this rulemaking is not expected to result in a "major rule" as defined in 5 U.S.C. 804(2).

M. Unfunded Mandates Reform Act of 1995

The changes set forth in this rulemaking do not involve a Federal intergovernmental mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, of \$100 million (as adjusted) or more in any one year, or a Federal private sector mandate that will result in the expenditure by the private sector of \$100 million (as adjusted) or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995. *See* 2 U.S.C. 1501 *et seq.*

N. National Environmental Policy Act of 1969

This rulemaking will not have any effect on the quality of the environment and is thus categorically excluded from review under the National Environmental Policy Act of 1969. *See* 42 U.S.C. 4321 *et seq.*

O. National Technology Transfer and Advancement Act of 1995

The requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) are not applicable because this rulemaking does not contain provisions that involve the use of technical standards.

P. Paperwork Reduction Act of 1995

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*) requires that the USPTO consider the impact of paperwork and other information collection burdens imposed on the

public. The collection of information involved in this proposed rule has been reviewed and previously approved by OMB under control number 0651–0035. The USPTO will submit an update to the 0651–0035 information collection in the form of a nonsubstantive change request.

Notwithstanding any other provision of law, no person is required to respond to, nor shall any 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.

Q. E-Government Act Compliance

The USPTO is committed to compliance with the E-Government Act to promote the use of the internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes.

List of Subjects in 37 CFR Part 1

Administrative practice and procedure, Biologics, Courts, Freedom of information, Inventions and patents, Reporting and recordkeeping requirements, Small businesses.

For the reasons stated in the preamble, the USPTO proposes to amend 37 CFR part 1 as follows:

PART 1—RULES OF PRACTICE IN PATENT CASES

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

Authority: 35 U.S.C. 2(b)(2), unless otherwise noted.

■ 2. Amend § 1.9 by adding paragraph (p) to read as follows:

§ 1.9 Definitions.

* * * * *

(p) The term domicile as used in this chapter means the permanent legal place of residence of a natural person or the principal place of business of a juristic entity.

■ 3. Revise § 1.31 to read as follows:

§ 1.31 Applicant and patent owner may be represented by one or more patent practitioners or joint inventors.

(a) An applicant for patent or patent owner may file and prosecute the applicant's or patent owner's own case, or the applicant or patent owner may give power of attorney so as to be represented by one or more patent practitioners or joint inventors, except that the following persons or entities must be represented by a patent practitioner:

(1) a juristic entity (e.g., organizational assignee);

(2) an applicant as defined in § 1.42, in which the domicile of at least one of the parties identified as the applicant in the application is not located within the United States or its territories; and

(3) a patent owner, in which the domicile of at least one of the parties identified as the patent owner is not located within the United States or its territories.

(b) The Office cannot aid in the selection of a patent practitioner.

■ 4. Amend § 1.32 by revising paragraph (a)(1) to read as follows:

§ 1.32 Power of attorney.

(a) * * *

(1) *Patent practitioner* means a practitioner registered under § 11.6 or an individual given limited recognition under § 11.9(a) or (b) or § 11.16. Only these persons are permitted to represent others before the Office in patent matters. An attorney or agent registered under § 11.6(d) may only act as a practitioner in design patent applications or other design patent matters or design patent proceedings.

* * * * *

■ 5. Amend § 1.33 by revising paragraph (b)(3) to read as follows:

§ 1.33 Correspondence respecting patent applications, reexamination proceedings, and other proceedings.

* * * * *

(b) * * *

(3) The applicant (§ 1.42) or patent owner. Unless otherwise specified, all papers submitted on behalf of a juristic entity, an applicant as defined in § 1.42 in which the domicile of at least one of the parties identified as the applicant is not located within the United States or its territories, or a patent owner in which the domicile of at least one of the parties identified as the patent owner is not located within the United States or its territories must be signed by a patent practitioner.

* * * * *

John A. Squires,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2025-23917 Filed 12-23-25; 8:45 am]

BILLING CODE 3510-16-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Parts 170, 171, and 172

RIN 0955-AA08

Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability; Withdrawal

AGENCY: Assistant Secretary for Technology Policy (ASTP)/Office of the National Coordinator for Health Information Technology (ONC) (collectively, ASTP/ONC), Department of Health and Human Services (HHS).

ACTION: Proposed rule; withdrawal of non-finalized provisions.

SUMMARY: ASTP/ONC published in the **Federal Register** on August 5, 2024, a proposed rule, titled “Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability” (HTI-2), in which it proposed updating and adding regulations regarding health information technology, information blocking, and the Trusted Exchange Framework and the Common Agreement. The comment period closed on October 4, 2024.

ASTP/ONC is withdrawing the remaining proposals that have not been finalized from the HTI-2 Proposed Rule.

DATES: The non-finalized provisions of the proposed rule published at 89 FR 63498 on August 5, 2024, are withdrawn effective December 29, 2025.

ADDRESSES: Comments on the proposed rule published at 89 FR 63498 on August 5, 2024, can be found at <https://www.regulations.gov/document/HHS-ONC-2024-0010-0001>.

FOR FURTHER INFORMATION CONTACT: Michael Lipinski, Office of Policy, Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology, 202-690-7151.

SUPPLEMENTARY INFORMATION: On August 5, 2024, ASTP/ONC issued the HTI-2 Proposed Rule proposing to update 45 CFR parts 170 and 171 and add part 172. The comment period closed on October 4, 2024.

ASTP/ONC finalized certain proposals from the HTI-2 Proposed Rule in December 2024 through the Health Data, Technology, and Interoperability: Trusted Exchange Framework and Common Agreement (TEFCA) (HTI-2) Final Rule (89 FR 101772) and the Health Data, Technology, and Interoperability:

Protecting Care Access (HTI-3) Final Rule (89 FR 102512).

On January 31, 2025, President Donald J. Trump signed Executive Order (E.O.) 14192, “Unleashing Prosperity Through Deregulation.”¹ Section 1 of E.O. 14192 states that it is the policy of the Administration to significantly reduce the private expenditures required to comply with Federal regulations to secure America’s economic prosperity and national security and the highest possible quality of life for each citizen. Consistent with E.O. 14192 and our planned deregulatory proposed rule (Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions to Unleash Prosperity (HTI-5) Proposed Rule),² ASTP/ONC reexamined the HTI-2 Proposed Rule. ASTP/ONC reviewed comments received in response to the HTI-2 Proposed Rule and reevaluated proposals not yet finalized. We determined that certain proposals should be finalized, while other proposals should not be finalized or needed further consideration, revision, or both. Recently, the Office of Management and Budget, the Department of Health and Human Services, and Centers for Medicare & Medicaid Services (CMS), in collaboration with ASTP/ONC, issued separate requests for information (RFIs) related to deregulation. We reviewed comments received on these RFIs related to ASTP/ONC activities. In response to the Request for Information; Health Technology Ecosystem (90 FR 21034) (CMS-ASTP/ONC RFI), commenters expressed a strong desire to modernize the ONC Health IT Certification Program (Certification Program) by making it more modular, application programming interface (API)-focused, and less centered on specific electronic health record (EHR) functionalities. After reviewing these additional comments and the comments submitted in response to the HTI-2 Proposed Rule, we are withdrawing the remaining non-finalized proposals from the HTI-2 Proposed Rule.

We determined that certain proposals would improve interoperability and reduce costs and burden within the U.S. health care system. Therefore, we finalized proposals for six new and one revised certification criteria in the Health Data, Technology, and Interoperability: Electronic Prescribing, Real-Time Prescription Benefit and

¹ <https://www.federalregister.gov/documents/2025/02/06/2025-02345/unleashing-prosperity-through-deregulation>.

² <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202504&RIN=0955-AA09>.

Prior Authorization (HTI-4) Final Rule (90 FR 37130). This final rule was published as a part of the Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals (IPPS) and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year (FY) 2026 Rates; Changes to the FY 2025 IPPS Rates Due to Court Decision; Requirements for Quality Programs; and Other Policy Changes; Health Data, Technology, and Interoperability: Electronic Prescribing, Real-Time Prescription Benefit and Electronic Prior Authorization Final Rule, which appeared in the **Federal Register** on August 4, 2025 (90 FR 36536).

ASTP/ONC is, however, withdrawing the remaining non-finalized proposals from the HTI-2 Proposed Rule for the following reasons: comments received on the HTI-2 Proposed Rule and the above-referenced RFIs; a focus on deregulation; and changes in applicable technologies, such as newer standards, updated application programming interfaces, and emerging artificial intelligence technologies. As to comments received on the HTI-2 Proposed Rule, a number of commenters expressed concerns regarding the non-finalized proposals, such as a lack of clarity in some proposals, the availability of newer and/or more appropriate standards for certain proposed certification criteria, and excessive costs and burden for meeting certain proposals, if finalized. ASTP/ONC will consider these and other stakeholder comments in conjunction with Administration and ASTP/ONC policies and priorities when crafting any future regulatory proposals related to the non-finalized provisions of the HTI-2 Proposed Rule. For now, we have concluded finalization of proposals from the HTI-2 Proposed Rule. We withdraw the remaining proposals of the HTI-2 Proposed Rule, generally identified as proposals to:

- **USCDI.** Adopt the United States Core Data for Interoperability (USCDI) standard v4 (45 CFR 170.213(c)); establish an expiration date for USCDI v3; and update certification criteria that cross-reference USCDI:

- “Care coordination—Transitions of care—Create” (§ 170.315(b)(1)(iii)(A)(1) and (2));
- “Care coordination—Clinical information reconciliation and incorporation—Reconciliation” (§ 170.315(b)(2)(iii)(D)(1) through (3));
- “Decision support interventions—Decision support configuration” (§ 170.315(b)(11)(ii)(A) and (B), and “Source attributes” (§ 170.315(b)(11)(iv)(A)(5) through (13));

- “Patient engagement—View, download, and transmit to 3rd party—View” (§ 170.315(e)(1)(i)(A)(1) and (2)), and “Multi-factor authentication” (§ 170.315(e)(1)(iii));

- “Transmission to public health agencies—electronic case reporting” (§ 170.315(f)(5)(i)(C)(2)(i));

- “Design and performance—Consolidated CDA creation performance” (§ 170.315(g)(6)(i)(A) and (B));

- “Design and performance—Application access—all data request—Functional requirements” (§ 170.315(g)(9)(i)(A)(1) and (2)); and

- “Design and performance—Standardized API for patient and population services—Data response” (§ 170.315(g)(10)(i)(A) and (B)).

- **Imaging.** Revise the certification criteria adopted in § 170.315(b)(1), (e)(1), and (g)(9) and (10) to include new certification requirements to support the access, exchange, and use of diagnostic images via imaging links.

- **Clinical Information Reconciliation and Incorporation.** Require Health IT Modules to be capable of reconciling and incorporating all USCDI v4 data classes. As an alternative proposal, require reconciliation and incorporation of a smaller subset of data.

- **Standards for Encryption and Decryption of Electronic Health Information.** Adopt the updated version of Annex A of the Federal Information Processing Standards (FIPS) 140-2 (Draft, October 12, 2021) in § 170.210(a)(3) and incorporate it by reference in § 170.299; add an expiration date of January 1, 2026, to the FIPS 140-2 (October 8, 2014) version of the standard adopted in § 170.210(a)(2); remove the standard found in § 170.210(f); and revise impacted certification criteria:

- § 170.315(d)(7) “health IT encryption;”

- § 170.315 (d)(9) “trusted connection;” and

- § 170.315 (d)(12) “protect stored authentication credentials.”

- **Minimum Standards Code Sets.** Adopt newer versions of the following minimum standards code sets:

- § 170.207(a)—Problems;
- § 170.207(c)—Laboratory tests;
- § 170.207(e)—Immunizations;
- § 170.207(f)—Race and Ethnicity;
- § 170.207(n)—Sex;
- § 170.207(o)—Sexual orientation and gender information; and
- § 170.207(p)—Social, psychological, and behavioral data.

- **Computerized Provider Order Entry—Laboratory Criterion.** Update the “computerized provider order entry—laboratory” certification criterion

(§ 170.315(a)(2)) to require a Health IT Module to enable a user to create and transmit laboratory orders electronically according to the standard proposed in § 170.205(g)(2) (HL7® Laboratory Order Interface (LOI) Implementation Guide (IG)); and require technology to receive and validate laboratory results according to the standard proposed in § 170.205(g)(3) (HL7® Laboratory Results Interface (LRI) IG).

- **Encrypt Authentication Credentials.** Revise § 170.315(d)(12) by replacing the “yes” or “no” attestation requirement with a new requirement that Health IT Modules be able to demonstrate that they are able to store authentication credentials and protect the confidentiality and integrity of stored authentication credentials according to the Federal Information Processing Standards (FIPS) 140-2³ (October 12, 2021) standard; and by changing the name of the certification criterion to “protect stored authentication credentials”.

- **Public Health Data Exchange.** Revise the certification criteria related to public health in § 170.315(f) by: adding several new functional requirements and adopting newer versions of standards within the current (f) certification criteria; adding two new certification criteria in the current (f) certification criteria for birth reporting and bi-directional exchange with a prescription drug monitoring program (PDMP); and adopting new certification criteria for health IT for public health in § 170.315(f)(21) through (29). In addition, adopt a new certification criterion for a standardized FHIR-based API for public health data exchange in § 170.315(g)(20), which we also proposed to adopt as part of the Base EHR definition.

- **Dynamic Client Registration Protocol.** Add requirements to support dynamic client registration and subsequent authentication and authorization for dynamically registered apps for patient-facing, user-facing, and system confidential applications. Specifically, add these requirements to:

- § 170.315(g)(10) certification criterion;
- § 170.315(g)(20), (30), and (32) through (35) proposed certification criteria;
- § 170.315(j)(2), (5), (8), and (11) proposed certification criteria; and
- API Conditions and Maintenance of Certification requirements in § 170.404.

- **Modular API Capabilities.** Add a new paragraph (j) to § 170.315 titled “modular API capabilities.”

³ <https://csrc.nist.gov/files/pubs/fips/140-2/upd2/final/docs/fips1402annexa.pdf>.

Note: We finalized two new criteria: “workflow triggers for decision support interventions—clients” (45 CFR 170.315(j)(20)) and “subscriptions—client” (45 CFR 170.315(j)(21)) in the HTI-4 Final Rule.

- *Patient, Provider, and Payer APIs.* Adopt a set of certification criteria in 45 CFR 170.315(g)(30) through (36) to support data exchange between healthcare payers, providers, and patients.

Note: We adopted electronic prior authorization criteria in 45 CFR 170.315(g)(31), (32), and (33) in the HTI-4 Final Rule based on the capabilities originally proposed in the HTI-2 Proposed Rule for the “prior authorization API—provider” certification criterion (45 CFR 170.315(g)(34)).

- *Conditions and Maintenance of Certification.* Revise the Insights and Attestations Conditions and Maintenance of Certification requirements.

- *Definitions in 45 CFR 171.102.* Revise the definition of “health care provider” and add definitions for “business day or business days” and “health information technology.”

- *Interference.* Add a new section (45 CFR 171.104) to codify certain practices that constitute “interference” and “interfere with” (as defined in § 171.102) for purposes of the information blocking definition in § 171.103.

- *Requestor Preferences Exception.* Adopt a new exception in § 171.304 for actors limiting, when asked to by a requestor, how much EHI is made available to that requestor, including when and/or under what conditions the EHI is made available.

- *Infeasibility Exception—Responding to Requests Condition.* Modify the *responding to requests* condition (§ 171.204(b)) to clarify timeframes for telling requestors why requested access, exchange, or use of EHI is not feasible.

Robert F. Kennedy Jr.,
Secretary, Department of Health and Human Services.

[FR Doc. 2025-23890 Filed 12-22-25; 4:15 pm]

BILLING CODE 4150-45-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[RTID 0648-XF387]

Fisheries of the Northeastern United States; Amendment 21 to the Atlantic Surfclam and Ocean Quahog Fishery Management Plan

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

ACTION: Notice of availability of proposed fishery management plan amendment; request for comments.

SUMMARY: NMFS announces that the Mid-Atlantic Fishery Management Council has submitted Amendment 21 to the Atlantic Surfclam and Ocean Quahog Fishery Management Plan for review and approval by the Secretary of Commerce. We are requesting comments from the public on the amendment. Amendment 21, also known as the Species Separation Requirements Amendment, would allow both surfclams and ocean quahogs to be landed on the same fishing trip. To ensure accurate accounting for the catch, the amendment would also implement additional monitoring and reporting requirements, both at sea and at the dealer where the mixed catch would be sorted.

DATES: Comments must be received on or before February 27, 2026.

ADDRESSES: You may submit comments on this document, identified by NOAA-NMFS-2025-1197, by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to <https://www.regulations.gov> and enter NOAA-NMFS-2025-1197 in the Search box. Click the “Comment” icon, complete the required fields, and enter or attach your comments.

- *Mail:* Submit written comments to Michael Pentony, Regional Administrator, NMFS, Greater Atlantic Regional Fisheries Office, 55 Great Republic Drive, Gloucester, MA 01930. Mark the outside of the envelope: “Comments on Surfclam/Ocean Quahog Amendment 21.”

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record

and will generally be posted for public viewing on www.regulations.gov without change. All personal identifying information (e.g., name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter “N/A” in the required fields if you wish to remain anonymous).

Copies of Amendment 21, including the draft Environmental Assessment (EA), are available on request from the Mid-Atlantic Fishery Management Council, 800 North State Street, Suite 201, Dover, DE 19901. These documents are also accessible via the internet at <https://www.mafmc.org>.

FOR FURTHER INFORMATION CONTACT: Douglas Potts, Fishery Policy Analyst, 978-281-9341.

SUPPLEMENTARY INFORMATION: We are soliciting public comments on Amendment 21, also known as the Species Separation Requirements Amendment, and its incorporated documents through the end of the comment period stated in this notice of availability. All comments received by February 27, 2026, will be considered in the approval/disapproval decision on the amendment. To be considered, comments must be received by close of business on the last day of the comment period. Comments received after that date will not be considered in the decision to approve or disapprove Amendment 21, including those postmarked or otherwise transmitted by the last day of the comment period. If the amendment is approved, a proposed rule would be published in the **Federal Register** at a later date with an opportunity for public comment on the specific regulatory changes being proposed.

The Mid-Atlantic Fishery Management Council developed this amendment at the request of members of the commercial surfclam fishing industry who were increasingly encountering a mix of surfclams and ocean quahogs on the same fishing trip. When the Council adopted an Individual Transferable Quota (ITQ) management system for the surfclam and ocean quahog fisheries in 1990, regulations were adopted that prohibited landing both species on the same trip. This provision simplified enforcement of the new ITQ system and had minimal impact on the fishery as the two species were geographically separated. Surfclams were predominantly found in shallower water and ocean quahogs occupied deeper waters farther offshore. As ocean bottom

temperatures have risen, the surfclam population has progressively shifted offshore and into deeper water. Juvenile surfclams have increasingly settled on, and grown to maturity on top of, existing beds of the much longer-lived ocean quahogs. Because of the high volume and industrial nature of this fishery, it is impractical to thoroughly sort the catch on board the vessel. As a result, the industry asserts that it has been effectively unable to fish in a sizable and growing area.

The measures approved by the Council in Amendment 21 would allow vessels to land both surfclams and ocean quahogs on the same fishing trip. The landed catch would be sorted after it arrives at the dealer's processing

facility. To ensure accurate accounting for catch, including landings and discards of both species under the ITQ system, Amendment 21 calls for the creation of a new monitoring program within dealer processing facilities. It also calls for additional at-sea observer coverage up to an initial target coverage of 5 percent of all clam dredge fishing trips. The additional monitoring would be funded by the industry through cost recovery. The Magnuson-Stevens Fishery Conservation and Management Act authorizes the government to collect a fee to recover the actual costs directly related to management, data collection, and enforcement of any limited access privilege program, such as the surfclam and ocean quahog ITQ program. This fee

cannot exceed three percent of the ex-vessel value of the fish harvested under the program.

Additional details of the proposed measures are available in the amendment document. Specific regulatory changes to implement this amendment, if approved, would be detailed in a future proposed rule that would include an additional opportunity for public comment.

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

Dated: December 22, 2025.

Michael P. Ruccio,

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

[FR Doc. 2025-23875 Filed 12-23-25; 8:45 am]

BILLING CODE 3510-22-P

Notices

Federal Register

Vol. 90, No. 245

Monday, December 29, 2025

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2025–0277]

Notice of Request To Renew an Approved Information Collection: New Swine Inspection System

AGENCY: Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture (USDA).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 and Office of Management and Budget (OMB) regulations, FSIS is announcing its intention to renew an approved information collection regarding swine slaughter inspection. The approval for this information collection will expire on February 28, 2026. FSIS is making no changes to the information collection.

DATES: Submit comments on or before February 27, 2026.

ADDRESSES: FSIS invites interested persons to submit comments on this **Federal Register** notice. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This website provides commenters the ability to type short comments directly into the comment field on the web page or to attach a file for lengthier comments. Go to <https://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

- *Mail:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Washington, DC 20250–3700.

- *Hand- or courier-delivered submittals:* Deliver to 1400 Independence Avenue SW, Jamie L. Whitten Building, Room 350–E, Washington, DC 20250–3700.

Instructions: All items submitted by mail or electronic mail must include the

Agency name and docket number FSIS–2025–0277. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <https://www.regulations.gov>.

Docket: For access to background documents or comments received, call (202) 286–2255 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Washington, DC 20250–3700.

FOR FURTHER INFORMATION CONTACT: Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW, Mailstop 3758, South Building, Washington, DC 20250–3700; 202–720–5046.

SUPPLEMENTARY INFORMATION:

Title: New Swine Inspection System.

OMB Number: 0583–0171.

Type of request: Renewal of an approved information collection.

Abstract: FSIS has been delegated the authority to exercise the functions of the Secretary (7 CFR 2.18, 2.53) as specified in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, *et seq.*). This statute mandates that FSIS protect the public by verifying that meat and meat products are safe, wholesome, and properly labeled.

FSIS is requesting a renewal of the approved information collection regarding swine slaughter inspection. The approval for this information collection will expire on February 28, 2026. FSIS is making no changes to the information collection.

FSIS requires that all swine slaughter establishments operating under the New Swine Slaughter Inspection System (NSIS) monitor their systems through microbial testing and recordkeeping. Swine slaughter establishments operating under NSIS must also maintain records to document the total number of animals and carcasses sorted and removed per day and the reasons for their removal. Swine slaughter establishments may record their disposition data on FSIS Form 6200–3, Establishment Sorting Record, or provide the same information as requested on the form electronically if it is submitted in a format approved by FSIS.

FSIS has made the following estimates based upon an information collection assessment:

Estimate of burden: The public reporting burden for this collection of information is estimated to average .048 hours per response.

Estimated total number of respondents: 84.

Estimated annual number of responses: 91,078.

Estimated total annual burden on respondents: 4,348 hours.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record. Copies of this information collection assessment can be obtained from Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW, Mailstop 3758, South Building, Washington, DC 20250–3700; 202–720–5046.

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of FSIS' functions, including whether the information will have practical utility; (b) the accuracy of FSIS' estimate of the burden of the proposed collection of information, including the validity of the method and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology. Comments may be sent to both FSIS, at the addresses provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington, DC 20253.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS web page located at: <https://www.fsis.usda.gov/federal-register>.

FSIS will also announce and provide a link to this **Federal Register** publication through the FSIS *Constituent Update*, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information

that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS can provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service that provides automatic and customized access to selected food safety news and information. This service is available at: <https://www.fsis.usda.gov/subscribe>. The available information ranges from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

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Justin Ransom,
Administrator.

[FR Doc. 2025-23832 Filed 12-23-25; 8:45 am]

BILLING CODE 3410-DM-P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B-53-2025]

Foreign-Trade Zone (FTZ) 30, Notification of Proposed Production Activity; Boart Longyear Company; (Diamond Drill Bits); West Valley City, Utah

Boart Longyear Company submitted a notification of proposed production activity to the FTZ Board (the Board) for its facility in West Valley City, Utah, within FTZ 30. The notification conforming to the requirements of the Board's regulations (15 CFR 400.22) was received on December 2, 2025.

Pursuant to 15 CFR 400.14(b), FTZ production activity would be limited to the specific foreign-status material(s)/component(s) and specific finished product(s) described in the submitted notification (summarized below) and subsequently authorized by the Board. The benefits that may stem from conducting production activity under FTZ procedures are explained in the background section of the Board's website—accessible via www.trade.gov/ftz.

The proposed finished product is diamond drill bits (duty rate 5.0%).

The proposed foreign-status materials/components include graphite rods for machining into molds, graphite molds, synthetic industrial diamonds used for drill bits, diamond powder, and tungsten powder (duty rate ranges from duty-free to 7.0%). The request indicates that certain materials/components are subject to duties under section 1702(a)(1)(B) of the International Emergency Economic Powers Act (section 1702), or section 301 of the Trade Act of 1974 (section 301), depending on the country of origin. The applicable section 1702 and section 301 decisions require subject merchandise to be admitted to FTZs in privileged foreign (PF) status (19 CFR 146.41). The request also indicates that graphite rods are subject to an antidumping/countervailing duty (AD/CVD) order/investigation if imported from the People's Republic of China. The Board's regulations (15 CFR 400.13(c)(2)) require that merchandise subject to AD/CVD orders, or items which would be

otherwise subject to suspension of liquidation under AD/CVD procedures if they entered U.S. customs territory, be admitted to the zone in PF status.

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 February 9, 2026.

A copy of the notification will be available for public inspection in the "Online FTZ Information System" section of the Board's website.

For further information, contact Juanita Chen at juanita.chen@trade.gov.

Dated: December 15, 2025.

Elizabeth Whiteman,
Executive Secretary.

[FR Doc. 2025-23881 Filed 12-23-25; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[C-351-865]

Hard Empty Capsules From Brazil: Final Affirmative Countervailing Duty Determination

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

SUMMARY: The U.S. Department of Commerce (Commerce) determines that countervailable subsidies are being provided to producers and exporters of hard empty capsules (capsules) from Brazil. The period of investigation (POI) is January 1, 2023, through December 31, 2023.

DATES: Applicable December 29, 2025.

FOR FURTHER INFORMATION CONTACT: Samuel Evans, AD/CVD Operations, Office IX, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-2420.

SUPPLEMENTARY INFORMATION:

Background

On March 31, 2025, Commerce published the *Preliminary Determination* in the **Federal Register** and invited interested parties to comment.¹ In the *Preliminary Determination*, and in accordance with section 705(a)(1) of the Tariff Act of

¹ See *Hard Empty Capsules from Brazil: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Determination with Final Antidumping Duty Determination*, 90 FR 14235 (March 31, 2025) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum (PDM).

1930, as amended (the Act), and 19 CFR 351.210(b)(4), Commerce aligned the final CVD determination with the final determination in the less-than-fair-value investigation of capsules from Brazil.²

Due to the lapse in appropriations and Federal Government shutdown, on November 14, 2025, Commerce tolled all deadlines in administrative proceedings by 47 days.³ Additionally, due to a backlog of documents that were electronically filed via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS) during the Federal Government shutdown, on November 24, 2025, Commerce tolled all deadlines in administrative proceedings by an additional 21 days.⁴ Accordingly, the deadline for this final determination is now December 18, 2025.

For a complete discussion of the events that followed the *Preliminary Determination*, see the Issues and Decision Memorandum.⁵ The Issues and Decision Memorandum is a public document and is made available to the public via ACCESS. ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Scope of the Investigation

The products covered by this investigation are hard empty capsules from Brazil. For a complete description of the scope of this investigation, see Appendix I.

Scope Comments

In the Preliminary Scope Memorandum, we set aside a period of time for parties to raise issues regarding product coverage (*i.e.*, scope) in scope-specific case briefs or other written comments.⁶ We received scope case and

rebuttal briefs from multiple interested parties. For a summary of the product coverage comments and rebuttal responses submitted to the record for this final determination, and accompanying discussion and analysis of all comments timely received, see the Final Scope Memorandum.⁷ In the Final Scope Memorandum, Commerce determined that it is modifying the scope language as it appeared in the *Initiation Notice*.⁸ See Appendix I.

Verification

As provided in section 782(i) of the Act, in May 2025, Commerce verified the information reported by ACG do Brasil S.A. (ACG Brazil) for use in our final determination. We used standard verification procedures, including an examination of relevant accounting records and original source documents provided at verification.⁹

Analysis of Subsidy Programs and Comments Received

The subsidy programs under investigation and the issues raised in the case and rebuttal briefs that were submitted by interested parties in this investigation are discussed in the Issues and Decision Memorandum. For a list of the issues raised by interested parties and addressed in the Issues and Decision Memorandum, see Appendix II.

Methodology

Commerce conducted this investigation in accordance with section 701 of the Act. For each of the subsidy programs found to be countervailable, Commerce determines that there is a subsidy, *i.e.*, a financial contribution by an "authority" that gives rise to a benefit to the recipient, and that the subsidy is specific. For a full description of the methodology underlying our final determination, see the Issues and Decision Memorandum.

In making this final determination, Commerce relied, in part, on facts

otherwise available, including with an adverse inference, pursuant to sections 776(a) and (b) of the Act. For a further discussion of our application of adverse facts available (AFA), see the Issues and Decision Memorandum.

Changes Since the Preliminary Determination

Based on our findings at verification, we made changes to our subsidy rate calculations for ACG Brazil for the provision of electricity for less-thanadequate-remuneration program, as well as the Ex-Tarifário program. For a discussion of these changes, see the Issues and Decision Memorandum.

All-Others Rate

Section 705(c)(5)(A)(i) of the Act states that, for companies not individually investigated, Commerce will determine an all-others rate equal to the weighted-average countervailable subsidy rates established for exporters and/or producers individually investigated, excluding any zero and *de minimis* countervailable subsidy rates, and any rates determined entirely under section 776 of the Act.

Commerce calculated an individual estimated countervailable subsidy rate for ACG Brazil, the only individually examined exporter/producer in this investigation. Because the only individually calculated rate is not zero, *de minimis*, or based entirely on facts otherwise available, the estimated countervailable subsidy rate calculated for ACG Brazil is the rate assigned to all other producers and exporters, pursuant to section 705(c)(5)(A)(i) of the Act.

Final Determination

Commerce determines that the following estimated countervailable subsidy rates exist for the period January 1, 2023, through December 31, 2023:

Company	Subsidy rate (percent <i>ad valorem</i>)
ACG do Brasil S.A	10.67
All Others	10.67

Disclosure

Commerce intends to disclose its calculations performed to interested parties in this final determination within five days of its public announcement or, if there is no public announcement, within five days of the date of the publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

² *Id.*, 90 FR at 14236.
³ See Memorandum, "Deadlines Affected by the Shutdown of the Federal Government," dated November 14, 2025.
⁴ See Memorandum, "Tolling of all Case Deadlines," dated November 24, 2025.
⁵ See Memorandum, "Issues and Decision Memorandum for the Final Affirmative Determination of the Countervailing Duty Investigation of Hard Empty Capsules from the People's Republic of China," dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).
⁶ See Memorandum, "Less-Than-Fair-Value Investigations of Hard Empty Capsules from Brazil, the People's Republic of China, India, and the Socialist Republic of Vietnam and Countervailing Duty Investigations from Brazil, the People's Republic of China, India, and the Socialist Republic of Vietnam: Preliminary Scope Decision Memorandum," dated March 24, 2025 (Preliminary Scope Memorandum).

⁷ See Memorandum, "Less-Than-Fair-Value and Countervailing Duty Investigations of Hard Empty Capsules from Brazil, the People's Republic of China, India, and the Socialist Republic of Vietnam: Final Scope Decision Memorandum," dated concurrently with this notice (Final Scope Memorandum).
⁸ See *Hard Empty Capsules from Brazil, the People's Republic of China, India, and the Socialist Republic of Vietnam: Initiation of Countervailing Duty Investigations*, 89 FR 91680 (November 20, 2024) (*Initiation Notice*).
⁹ See Memorandum, "Verification of the Questionnaire Responses of ACG do Brasil S.A.," dated June 3, 2025.
¹⁰ See sections 771(5)(B) and (D) of the Act regarding financial contribution; see also section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

Suspension of Liquidation

As a result of our *Preliminary Determination*, and pursuant to sections 703(d)(1)(B) and (d)(2) of the Act, we instructed U.S. Customs and Border Protection (CBP) to collect cash deposits and suspend liquidation of entries of subject merchandise from Brazil that were entered, or withdrawn from warehouse, for consumption, on or after March 31, 2025, the date of the publication of the *Preliminary Determination* in the **Federal Register**.¹¹ In accordance with section 703(d) of the Act, we instructed CBP to discontinue the suspension of liquidation of all entries of subject merchandise entered or withdrawn from warehouse, on or after July 29, 2025, but to continue the suspension of liquidation of all entries of subject merchandise on or before July 28, 2025.

If the U.S. International Trade Commission (ITC) issues a final affirmative injury determination, we will issue a countervailing duty (CVD) order, reinstate the suspension of liquidation under section 706(a) of the Act, and require a cash deposit of estimated countervailing duties for entries of subject merchandise in the amounts indicated above. Pursuant to section 705(c)(2) of the Act, if the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated, and all estimated duties deposited or securities posted as a result of the suspension of liquidation will be refunded or cancelled.

ITC Notification

In accordance with section 705(d) of the Act, Commerce will notify the ITC of its final affirmative determination that countervailable subsidies are being provided to producers and exporters of capsules from Brazil. As Commerce's final determination is affirmative, in accordance with section 705(b) of the Act, the ITC will determine, within 45 days, whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of import of capsules from Brazil. In addition, we are making available to the ITC all non-privileged and non-proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under administrative protective order (APO), without the written consent of the Assistant Secretary for Enforcement and Compliance.

If the ITC determines that material injury or threat of material injury does not exist, this proceeding will be terminated, and all cash deposits will be refunded. If the ITC determines that such injury does exist, Commerce will issue a CVD order directing CBP to assess, upon further instruction by Commerce, countervailing duties on all imports of the subject merchandise that are entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation, as discussed above in the "Suspension of Liquidation" section.

Administrative Protective Order

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

Notification to Interested Parties

This determination is issued and published in accordance with sections 705(d) and 777(i) of the Act, and 19 CFR 351.210(c).

Dated: December 18, 2025.

Christopher Abbott,

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

Appendix I

Scope of the Investigation

The merchandise subject to the scope of this investigation is hard empty capsules, which are comprised of two prefabricated, hollowed cylindrical sections (cap and body). The cap and body pieces each have one closed and rounded end and one open end, and are constructed with different or equal diameters at their open ends.

Hard empty capsules are unfilled cylindrical shells composed of at least 80 percent by weight of a water soluble polymer that is considered non-toxic and appropriate for human or animal consumption by the United States Pharmacopeia—National Formulary (USP–NF), Food Chemical Codex (FCC), or equivalent standards. The most common polymer materials in hard empty capsules are gelatin derived from animal collagen (including, but not limited to, pig, cow, or fish collagen), hydroxypropyl methylcellulose (HPMC), and pullulan.

Hard empty capsules may also contain water and additives, such as opacifiers, colorants, processing aids, controlled release

agents, plasticizers, and preservatives. Hard empty capsules may also be imprinted or otherwise decorated with markings.

Hard empty capsules are covered by the scope of this investigation regardless of polymer material, additives, transparency, opacity, color, imprinting, or other markings.

Hard empty capsules are also covered by the scope of this investigation regardless of their size, weight, length, diameter, thickness, and filling capacity.

Cap and body pieces of hard empty capsules are covered by the scope of this investigation regardless of whether they are imported together or separately, and regardless of whether they are imported in attached or detached form.

Hard empty capsules covered by the scope of this investigation are those that disintegrate in water, simulated intestinal fluid, simulated gastric fluid, or other similar water-based (*i.e.*, aqueous) fluids within 2 hours under tests specified in Chapter 701 of the USP–NF, or equivalent disintegration tests.

Hard empty capsules are classifiable under subheadings 9602.00.1040 and 9602.00.5010 of the Harmonized Tariff Schedule of the United States (HTSUS). In addition, hard empty capsules may be imported under HTSUS subheading 1905.90.9090; gelatin hard empty capsules may be imported under HTSUS subheading 3503.00.5510; HPMC hard empty capsules may be imported under HTSUS subheading 3923.90.0080; and pullulan hard empty capsules may be imported under HTSUS subheading 2106.90.9998. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise covered by this investigation is dispositive.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Use of Facts Available and Adverse Inferences
- IV. Subsidies Valuation
- V. Analysis of Programs
- VI. Discussion of the Issues
 - Comment 1: Whether to Apply Adverse Facts Available to Countervail the Access Road Funding—Pouso Alegre Municipality Program
 - Comment 2: Whether the Government of Brazil Provided Electricity for Less Than Adequate Remuneration (LTAR) to ACG Brazil
 - Comment 3: Whether to Modify the Benchmark for the Provision of Electricity for LTAR Program
- VII. Recommendation

[FR Doc. 2025–23823 Filed 12–23–25; 8:45 am]

BILLING CODE 3510–DS–P

¹¹ See *Preliminary Determination*, 90 FR at 14236.

DEPARTMENT OF COMMERCE

International Trade Administration

[A-351-864]

Hard Empty Capsules From Brazil: Final Affirmative Determination of Sales at Less Than Fair Value

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

SUMMARY: The U.S. Department of Commerce (Commerce) determines that hard empty capsules (capsules) from Brazil are being, or are likely to be, sold in the United States at less than fair value (LTFV), as provided in section 735 of the Tariff Act of 1930, as amended (the Act), for the period of investigation October 1, 2023, through September 30, 2024.

DATES: Applicable December 29, 2025.

FOR FURTHER INFORMATION CONTACT: Gemma Larsen, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-8125.

SUPPLEMENTARY INFORMATION:**Background**

On May 29, 2025, Commerce published in the *Federal Register* its preliminary affirmative determination in the LTFV investigation of capsules from Brazil, in which it also postponed the final determination until October 14, 2025.¹ On August 7, 2025, Commerce issued a post-preliminary analysis memorandum in which it made certain changes to its differential pricing analysis.² We invited interested parties to comment on the *Preliminary Determination* and changes to the differential pricing analysis.³

Due to the lapse in appropriations and Federal Government shutdown, on November 14, 2025, Commerce tolled all deadlines in administrative proceedings by 47 days.⁴ Additionally, due to a backlog of documents that were

electronically filed via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS) during the Federal Government shutdown, on November 24, 2025, Commerce tolled all deadlines in administrative proceedings by an additional 21 days.⁵ Accordingly, the deadline for this final determination is now December 18, 2025.

A summary of the events that occurred since the *Preliminary Determination*, as well as a full discussion of the issues raised by parties for this final determination, may be found in the Issues and Decision Memorandum.⁶ The Issues and Decision Memorandum is a public document and is on file electronically via ACCESS. ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Scope of the Investigation

The products covered by this investigation are capsules from Brazil. For a complete description of the scope of this investigation, see Appendix I.

Scope Comments

In the Preliminary Scope Memorandum, we set aside a period of time for parties to raise issues regarding product coverage (*i.e.*, scope) in scope-specific case briefs or other written comments.⁷ We received scope case and rebuttal briefs from multiple interested parties. For a summary of the product coverage comments and rebuttal responses submitted to the record for this final determination, and accompanying discussion and analysis of all comments timely received, see the Final Scope Memorandum.⁸ In the Final Scope Memorandum, Commerce

⁵ See Memorandum, "Tolling of All Case Deadlines," dated November 24, 2025.

⁶ See Memorandum, "Issues and Decision Memorandum for the Final Affirmative Determination of Sales at Less Than Fair Value in the Investigation of Hard Empty Capsules from Brazil," dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

⁷ See Memorandum, "Less-Than-Fair-Value and Countervailing Duty Investigations of Hard Empty Capsules from Brazil, the People's Republic of China, India, and the Socialist Republic of Vietnam: Scope Comments Decision Memorandum for the Preliminary Determination," dated March 24, 2025 (Preliminary Scope Memorandum).

⁸ See Memorandum, "Less-Than-Fair-Value and Countervailing Duty Investigations of Hard Empty Capsules from Brazil, the People's Republic of China, India, and the Socialist Republic of Vietnam: Final Scope Decision Memorandum," dated concurrently with this memorandum (Final Scope Memorandum).

determined that it is modifying the scope language as it appeared in the *Initiation Notice*.⁹ See Appendix I.

Verification

Commerce conducted verification of the information relied upon in making its final determination in this investigation, in accordance with section 782(i) of the Act. Specifically, we conducted on-site verifications of the sales and cost information submitted by ACG do Brasil S.A. (ACG Brazil), for use in our final determination. We used standard verification procedures, including an examination of relevant sales and accounting records, and original source documents provided by ACG Brazil.

Analysis of Comments Received

All issues raised in the case brief submitted by ACG Brazil in this investigation are addressed in the Issues and Decision Memorandum. A list of the issues addressed in the Issues and Decision Memorandum is attached to this notice as Appendix II.

Changes Since the Preliminary Determination

We made certain changes to the dumping margin calculation for ACG Brazil since the *Preliminary Determination* and Post-Preliminary Analysis. For a discussion of these changes, see the Issues and Decision Memorandum.

All-Others Rate

Section 735(c)(5)(A) of the Act provides that Commerce shall determine an estimated all-others rate for all exporters and producers not individually examined. This rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for producers and exporters individually investigated, excluding any zero and *de minimis* margins, and any margins determined entirely under section 776 of the Act.

Commerce calculated an individual estimated weighted-average dumping margin for ACG Brazil, the only individually examined producer/exporter in this investigation, that is not zero, *de minimis*, or based entirely on facts otherwise available. Therefore, we assigned the estimated weighted-average dumping margin that we calculated for ACG Brazil to all other producers and

⁹ See *Hard Empty Capsules From Brazil, the People's Republic of China, India, and the Socialist Republic of Vietnam: Initiation of Less-Than-Fair-Value Investigations*, 89 FR 91684 (November 20, 2024) (*Initiation Notice*).

¹ See *Hard Empty Capsules from Brazil: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Extension of Provisional Measures*, 90 FR 22688 (May 29, 2025) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum.

² See Memorandum, "Post-Preliminary Analysis for the Affirmative Preliminary Determination in the Less-Than-Fair-Value Investigation of Hard Empty Capsules from Brazil," dated August 7, 2025.

³ See Memorandum, "Notification of Deadlines for submission of Case and Rebuttal Briefs," dated August 12, 2025.

⁴ See Memorandum, "Deadlines Affected by the Shutdown of the Federal Government," dated November 14, 2025.

exporters, pursuant to section 735(c)(5)(A) of the Act.

Final Determination

Commerce determines that the following estimated weighted-average dumping margins exist:

Producer/exporter	Weighted-average dumping margin (percent)	Cash deposit rate (percent) ¹⁰
ACG do Brasil S.A	77.63	77.63
All Others	77.63	77.63

Disclosure

Commerce intends to disclose the calculations and analysis performed in connection with this final determination to interested parties within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Suspension of Liquidation

In accordance with section 733(d)(1)(B) of the Act, we instructed U.S. Customs and Border Protection (CBP) to suspend liquidation of all entries of subject merchandise, as described in Appendix I of this notice, which were entered, or withdrawn from warehouse, for consumption on or after May 29, 2025, the date of publication of the *Preliminary Determination* in the **Federal Register**. In accordance with section 733(d) of the Act, we instructed CBP to discontinue the suspension of liquidation of all entries of subject merchandise entered or withdrawn from warehouse, on or after November 25, 2025, but to continue the suspension of liquidation of all entries of subject merchandise on or before November 24, 2025.

If the U.S. International Trade Commission (ITC) issues a final affirmative injury determination, we will issue an antidumping duty order, reinstate the suspension of liquidation under section 736(a) of the Act, and require a cash deposit of estimated antidumping duties for such entries of subject merchandise in the amounts indicated above, in accordance with section 736(a) of the Act. If the ITC determines that material injury, or threat of material injury, does not exist, then this proceeding will be terminated, the suspension of liquidation will be lifted, and all cash deposits for

estimated antidumping duties will be refunded.

ITC Notification

In accordance with section 735(d) of the Act, Commerce will notify the ITC of its final affirmative determination of sales at LTFV. Because Commerce's final determination is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports, or sales (or the likelihood of sales) for importation, of capsules no later than 45 days after this final determination. If the ITC determines that material injury or threat of material injury does not exist, this proceeding will be terminated, all cash deposits will be refunded or canceled, and suspension of liquidation will be lifted. If the ITC determines that such injury does exist, Commerce will issue an antidumping duty order directing CBP to assess, upon further instructions by Commerce, antidumping duties on all imports of the subject merchandise that are entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation, as discussed above in the "Suspension of Liquidation" section.

Administrative Protective Order (APO)

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

Notification To Interested Parties

This final determination is issued and published in accordance with sections 735(d) and 777(i) of the Act, and 19 CFR 351.210(c).

Dated: December 18, 2025.

Christopher Abbott,

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

Appendix I

Scope of the Investigation

The merchandise subject to the scope of the investigation is hard empty capsules, which are comprised of two prefabricated, hollowed cylindrical sections (cap and body). The cap and body pieces each have one closed and rounded end and one open end, and are constructed with different or equal diameters at their open ends.

Hard empty capsules are unfilled cylindrical shells composed of at least 80 percent by weight of a water soluble polymer that is considered non-toxic and appropriate for human or animal consumption by the United States Pharmacopeia—National Formulary (USP–NF), Food Chemical Codex (FCC), or equivalent standards. The most common polymer materials in hard empty capsules are gelatin derived from animal collagen (including, but not limited to, pig, cow, or fish collagen), hydroxypropyl methylcellulose (HPMC), and pullulan.

Hard empty capsules may also contain water and additives, such as opacifiers, colorants, processing aids, controlled release agents, plasticizers, and preservatives. Hard empty capsules may also be imprinted or otherwise decorated with markings.

Hard empty capsules are covered by the scope of the investigation regardless of polymer material, additives, transparency, opacity, color, imprinting, or other markings.

Hard empty capsules are also covered by the scope of the investigation regardless of their size, weight, length, diameter, thickness, and filling capacity.

¹⁰ To determine the cash deposit rate, Commerce normally adjusts the estimated weighted-average dumping margin by the amount of export subsidies countervailed in a companion countervailing duty (CVD) proceeding, when CVD provisional measures are in effect. Accordingly, where Commerce has made a final affirmative determination for

countervailable export subsidies, Commerce offsets the estimated weighted-average dumping margin by the appropriate CVD rate. However, in the final determination of the companion CVD investigation of capsules from Brazil, we found no export subsidies. See unpublished **Federal Register** notice entitled, "Hard Empty Capsules from Brazil: Final

Affirmative Countervailing Duty Determination," signed and dated concurrently with this **Federal Register** notice. Therefore, Commerce has not adjusted the antidumping duty cash deposit rate for export subsidies in the companion CVD investigation.

Cap and body pieces of hard empty capsules are covered by the scope of the investigation regardless of whether they are imported together or separately, and regardless of whether they are imported in attached or detached form.

Hard empty capsules covered by the scope of the investigation are those that disintegrate in water, simulated intestinal fluid, simulated gastric fluid, or other similar water-based (*i.e.*, aqueous) fluids within 2 hours under tests specified in Chapter 701 of the USP–NF, or equivalent disintegration tests.

Hard empty capsules are classifiable under subheadings 9602.00.1040 and 9602.00.5010 of the Harmonized Tariff Schedule of the United States (HTSUS). In addition, hard empty capsules may be imported under HTSUS subheading 1905.90.9090; gelatin hard empty capsules may be imported under HTSUS subheading 3503.00.5510; HPMC hard empty capsules may be imported under HTSUS subheading 3923.90.0080; and pullulan hard empty capsules may be imported under HTSUS subheading 2106.90.9998. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise covered by the investigation is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Changes since the *Preliminary Determination*
- IV. Discussion of the Issues
 - Comment 1: Revising the Finance Expense Ratio
 - Comment 2: Revising the General and Administrative (G&A) Expense Ratio
- V. Recommendation

[FR Doc. 2025–23822 Filed 12–23–25; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–555–005]

Paper File Folders From Cambodia: Final Negative Determination of Sales at Less Than Fair Value

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

SUMMARY: The U.S. Department of Commerce (Commerce) determines that paper file folders from Cambodia are not being, or are not likely to be, sold in the

United States at less than fair value (LTFV). The period of investigation is October 1, 2023, through September 30, 2024.

DATES: Applicable December 29, 2025.

FOR FURTHER INFORMATION CONTACT: Kelsie Hohenberger, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2517.

SUPPLEMENTARY INFORMATION:

Background

On May 29, 2025, Commerce published its *Preliminary Determination* in the **Federal Register** and invited interested parties to comment.¹ However, no parties submitted comments. Because no interested party submitted comments, the only modification we have made from the *Preliminary Determination* is to incorporate a finding from the cost verification and rely on a revised cost database obtained following issuance of the *Preliminary Determination*.² Accordingly, an analysis memorandum accompanies this **Federal Register** notice.³

Due to the lapse in appropriations and Federal Government shutdown, on November 14, 2025, Commerce tolled all deadlines in administrative proceedings by 47 days.⁴ Additionally, due to a backlog of documents that were electronically filed via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS) during the Federal Government shutdown, on November 24, 2025, Commerce tolled all deadlines in administrative proceedings by an additional 21 days.⁵ Accordingly, the

¹ See *Paper File Folders from Cambodia: Preliminary Negative Determination of Sales at Less Than Fair Value and Postponement of Final Determination*, 90 FR 22694 (May 29, 2025) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum.

² See Memorandum, “Final Determination Analysis Memorandum for Three-Color Stone Stationery (Cambodia) Co., Ltd.,” dated concurrently with this notice (TCS Final Analysis Memorandum).

³ *Id.*

⁴ See Memorandum, “Deadlines Affected by the Shutdown of the Federal Government,” dated November 14, 2025.

⁵ See Memorandum, “Tolling of all Case Deadlines,” dated November 24, 2025.

deadline for this final determination is now December 18, 2025.

Scope of the Investigation

The products covered by this investigation are paper file folders from Cambodia. For a complete description of the scope of this investigation, *see* the appendix to this notice.

Scope Comments

No interested party commented on the scope of the investigation as it appeared in the *Preliminary Determination*. Therefore, no changes were made to the scope of the investigation.

Verification

As provided in section 782(i) of the Tariff Act of 1930, as amended (the Act), in June 2025, we conducted verification of information submitted by Three-Color Stone Stationery (Cambodia) Co., Ltd. (TCS) for use in our final determination. We used standard verification procedures, including an examination of relevant accounting records and original source documents provided by TCS.⁶

Changes Since the Preliminary Determination

As noted above, we have incorporated certain changes in our final margin calculations for TCS. Specifically, we are: (1) relying on a revised cost database submitted by TCS following the *Preliminary Determination*, and (2) revising TCS's general and administrative expense ratio to include certain expenses related to other non-operating expenses as a result of a finding made during our cost verification. We are making no other changes from the *Preliminary Determination*. For a discussion of these changes, *see* the TCS Final Analysis Memorandum.

Final Determination

Commerce determines that the following estimated weighted-average dumping margin exists:

⁶ See Memoranda, “Verification of the Sales Responses of Three-Color Stone Stationery (Cambodia) Co., Limited in the Less-Than-Fair-Value Investigation of Paper File Folders from Cambodia,” dated August 4, 2025; and “Verification of the Cost Response of Three-Color Stone Stationery (Cambodia) Co., Limited in the Less-Than-Fair-Value Investigation of Paper File Folders from Cambodia,” dated August 14, 2025.

Producer/exporter	Weighted-average dumping margin (percent)	Cash deposit rate (percent)
Three-Color Stone Stationery (Cambodia) Co., Ltd./Three-Color Stone Manufacture Limited ⁷	0.00	Not Applicable.

Commerce has not calculated an estimated weighted-average dumping margin for all other producers and exporters pursuant to sections 735(c)(1)(B) and (c)(5) of the Act, because it has not made an affirmative final determination of sales at LTFV.

Disclosure

Commerce intends to disclose the calculations performed in connection with this final determination to interested parties within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Suspension of Liquidation

In the *Preliminary Determination*, we calculated an estimated weighted-average dumping margin for TCS that was zero percent and, therefore, we did not suspend liquidation of entries of paper file folders from Cambodia.⁸ Because Commerce has made a negative final determination of sales at LTFV, we will not direct U.S. Customs and Border Protection to suspend liquidation or to require cash deposits of estimated antidumping duties for entries of paper file folders from Cambodia.

U.S. International Trade Commission (ITC) Notification

In accordance with section 735(d) of the Act, Commerce will notify the ITC of its negative final determination of sales at LTFV. Because the final determination is negative, this proceeding is terminated in accordance with section 735(c)(2) of the Act.

Administrative Protective Order (APO)

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

APO is a violation which is subject to sanction.

Notification to Interested Parties

This determination is issued and published pursuant to sections 735(d) and 777(i) of the Act, and 19 CFR 351.210(c).

Dated: December 18, 2025.

Christopher Abbott,

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

Appendix

Scope of the Investigation

The products within the scope of this investigation are file folders consisting primarily of paper, paperboard, pressboard, or other cellulose material, whether coated or uncoated, that has been folded (or creased in preparation to be folded), glued, taped, bound, or otherwise assembled to be suitable for holding documents. The scope includes all such folders, regardless of color, whether or not expanding, whether or not laminated, and with or without tabs, fasteners, closures, hooks, rods, hangers, pockets, gussets, or internal dividers. The term “primarily” as used in the first sentence of this scope means 50 percent or more of the total product weight, exclusive of the weight of fasteners, closures, hooks, rods, hangers, removable tabs, and similar accessories, and exclusive of the weight of the packaging.

Subject folders have the following dimensions in their folded and closed position: lengths and widths of at least 8 inches and no greater than 17 inches, regardless of depth.

The scope covers all varieties of folders, including but not limited to manila folders, hanging folders, fastener folders, classification folders, expanding folders, pockets, jackets, and wallets.

Excluded from the scope are:

- mailing envelopes with a flap bearing one or more adhesive strips that can be used permanently to seal the entire length of a side such that, when sealed, the folder is closed on all four sides;
- binders, with two or more rings to hold documents in place, made of paperboard or pressboard encased entirely in plastic;
- binders consisting of a front cover, back cover, and spine, with or without a flap; to be excluded, a mechanism with two or more metal rings that must be included on or adjacent to the interior spine;
- non-expanding folders with a depth exceeding 2.5 inches and that are closed or closeable on the top, bottom, and all four sides (e.g., boxes or cartons);
- expanding folders that have: (1) 13 or more pockets; (2) a flap covering the top; (3)

a latching mechanism made of plastic and/or metal to close the flap; and (4) an affixed plastic or metal carry handle;

- folders that have an outer surface (other than the gusset, handles, and/or closing mechanisms, if any) that is covered entirely with fabric, leather, and/or faux leather;
- fashion folders, which are defined as folders with all of the following characteristics: (1) plastic lamination covering the entire exterior of the folder; (2) printing, foil stamping, embossing (*i.e.*, raised relief patterns that are recessed on the opposite side), and/or debossing (*i.e.*, recessed relief patterns that are raised on the opposite side), covering the entire exterior surface area of the folder; (3) at least two visible and printed or foil stamped colors (other than the color of the base paper), each of which separately covers no less than 10 percent of the entire exterior surface area; and (4) patterns, pictures, designs, or artwork covering no less than thirty percent of the exterior surface area of the folder;
- portfolios, which are folders having: (1) a width of at least 16 inches when open flat; (2) no tabs or dividers; and (3) one or more pockets that are suitable for holding letter size documents and that cover at least 15 percent of the surface area of the relevant interior side or sides; and
- report covers, which are folders having: (1) no tabs, dividers, or pockets; and (2) one or more fasteners or clips, each of which is permanently affixed to the center fold, to hold papers securely in place.

Imports of the subject merchandise are provided for under Harmonized Tariff Schedule of the United States (HTSUS) subheading 4820.30.0040. Subject imports may also enter under other HTSUS subheadings. While the HTSUS subheading is provided for convenience and customs purposes, the written description of the scope of the investigation is dispositive.

[FR Doc. 2025–23781 Filed 12–23–25; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–934]

Hard Empty Capsules From India: Final Affirmative Determination of Sales at Less Than Fair Value

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

SUMMARY: The U.S. Department of Commerce (Commerce) determines that imports of hard empty capsules (capsules) from India are being, or are likely to be, sold in the United States at

⁷ See Memorandum, “Single-Entity Analysis for Three-Color Stone Stationery (Cambodia) Co., Ltd. and Affiliated Companies,” dated May 21, 2025 (Single Entity Analysis Memo). As discussed in the Single Entity Analysis Memo, Commerce determined that TCS and Three-Color Stone Manufacture Limited constitute a single entity.

less than fair value (LTFV), as provided in section 735 of the Tariff Act of 1930, as amended (the Act), for the period of investigation (POI) October 1, 2023, to September 30, 2024.

DATES: Applicable December 29, 2025.

FOR FURTHER INFORMATION CONTACT:

Joseph Molokwu or Luke Caruso, 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) 482–8043 or (202) 482–2081, respectively.

SUPPLEMENTARY INFORMATION:

Background

On May 29, 2025, Commerce published in the **Federal Register** its preliminary affirmative determination in the LTFV investigation of capsules from India, in which it also postponed the final determination until October 14, 2025.¹ On September 5, 2025, Commerce issued a post-preliminary analysis memorandum in which it made certain changes to its differential pricing analysis.² We invited interested parties to comment on the *Preliminary Determination* and changes to the differential pricing analysis.³

Due to the lapse in appropriations and Federal Government shutdown, on November 14, 2025, Commerce tolled all deadlines in administrative proceedings by 47 days.⁴ Additionally, due to a backlog of documents that were electronically filed via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS) during the Federal Government shutdown, on November 24, 2025, Commerce tolled all deadlines in administrative proceedings by an additional 21 days.⁵ Accordingly, the deadline for this final results determination is now December 18, 2025.

¹ See *Hard Empty Capsules from India: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination and Extension of Provisional Measures*, 90 FR 22699 (May 29, 2025) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum (PDM).

² See Memorandum, "Post-Preliminary Analysis for the Affirmative Determination in the Less-Than-Fair-Value Investigation of Hard Empty Capsules from India," dated September 5, 2025 (Post-Preliminary Analysis).

³ See Memorandum, "Notification of Deadlines for the Submission of Case and Rebuttal Briefs," dated September 15, 2025.

⁴ See Memorandum, "Deadlines Affected by the Shutdown of the Federal Government," dated November 14, 2025.

⁵ See Memorandum, "Tolling of all Case Deadlines," dated November 24, 2025.

A summary of the events that occurred since Commerce published the *Preliminary Determination*, as well as a full discussion of the issues raised by parties for this final determination, may be found in the Issues and Decision Memorandum.⁶ The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Scope of the Investigation

The products covered by this investigation are capsules from India. For a complete description of the scope of this investigation, see Appendix I.

Scope Comments

In the Preliminary Scope Memorandum, we set aside a period of time for parties to raise issues regarding product coverage (*i.e.*, scope) in scope-specific case briefs or other written comments.⁷ We received scope case and rebuttal briefs from multiple interested parties. For a summary of the product coverage comments and rebuttal responses submitted to the record for this final determination, and accompanying discussion and analysis of all comments timely received, see the Final Scope Memorandum.⁸ In the Final Scope Memorandum, Commerce determined that it is modifying the scope language as it appeared in the *Initiation Notice*.⁹ See Appendix I.

Verification

Commerce conducted verification of the information relied upon in making

⁶ See Memorandum, "Issues and Decision Memorandum for the Final Affirmative Determination in the Less-Than-Fair-Value Investigation of Hard Empty Capsules from India," dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

⁷ See Memorandum, "Less-Than-Fair-Value and Countervailing Duty Investigations of Hard Empty Capsules from Brazil, the People's Republic of China, India, and the Socialist Republic of Vietnam: Scope Comments Decision Memorandum for the Preliminary Determination," dated March 24, 2025 (Preliminary Scope Memorandum).

⁸ See Memorandum, "Less-Than-Fair-Value and Countervailing Duty Investigations of Hard Empty Capsules from Brazil, the People's Republic of China, India, and the Socialist Republic of Vietnam: Final Scope Decision Memorandum," dated concurrently with this notice (Final Scope Memorandum).

⁹ See *Hard Empty Capsules From Brazil, the People's Republic of China, India, and the Socialist Republic of Vietnam: Initiation of Less-Than-Fair-Value Investigations*, 89 FR 91684 (November 20, 2024) (*Initiation Notice*).

its final determination in this investigation, in accordance with section 782(i) of the Act. Specifically, we conducted on-site verifications of the sales and cost information submitted by ACG Associated Capsules Private Limited (ACG India) and HealthCaps India Limited (HIL).¹⁰ We used standard verification procedures, including an examination of relevant sales and accounting records, and original source documents provided by ACG India and HIL.

Analysis of Comments Received

All issues raised in the case briefs submitted by interested parties in this investigation are addressed in the Issues and Decision Memorandum. A list of the issues addressed in the Issues and Decision Memorandum is attached to this notice as Appendix II.

Changes Since the Preliminary Determination

We made certain changes to the dumping margin calculations for ACG India and HIL since the *Preliminary Determination* and Post-Preliminary Analysis. In addition, Commerce has relied on adverse facts available under sections 776(a) of the Act for ACG India. For a discussion of these changes, see the Issues and Decision Memorandum.

All-Others Rate

Section 735(c)(5)(A) of the Act provides that Commerce shall determine an estimated all-others rate for all exporters and producers not individually examined. This rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero and *de minimis* dumping margins, and any margins determined entirely under section 776 of the Act.

Commerce calculated individual estimated weighted-average dumping margins for ACG India and HIL that are not zero, *de minimis*, or based entirely on facts otherwise available. Publicly-ranged total U.S. sales values are not available for each of the companies examined in this investigation.

¹⁰ See Memoranda, "Verification of the Sales and Cost Responses of ACG Associated Capsules Private Limited in the Less Than Fair Value Investigation of Hard Empty Capsules from India," dated September 15, 2025, and "Verification of the Sales and Cost Responses of HealthCaps India Limited in the Less Than Fair Value Investigation of Hard Empty Capsules from India," dated September 15, 2025, and "Verification of the Sales and Cost Responses of HealthCaps India Limited in the Less Than Fair Value Investigation of Hard Empty Capsules from India," dated September 15, 2025.

Therefore, Commerce calculated the estimated weighted-average dumping margin for all-other producers and exporters using a simple average of the

estimated weighted-average dumping margins calculated for the examined respondents.¹¹

Final Determination

Commerce determines that the following estimated weighted-average dumping margins exist:

Exporter or producer	Estimated weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offset(s)) (percent)
ACG Associated Capsules Private Limited; ACG Universal Capsules Private Limited; and Custom Capsules Private Limited ¹²	26.69	19.71
HealthCaps India Limited	10.66	3.68
All Others	18.68	11.70

Disclosure

Commerce intends to disclose the calculations and analysis performed in connection with this final determination to interested parties within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Suspension of Liquidation and Cash Deposit Requirements

In accordance with section 735(c)(1)(B) of the Act, we instructed U.S. Customs and Border Protection (CBP) to suspend liquidation of all entries of subject merchandise, as described in Appendix I of this notice, which were entered, or withdrawn from warehouse, for consumption on or after May 29, 2025, the date of publication of the *Preliminary Determination* in the **Federal Register**. In accordance with section 733(d) of the Act, we instructed CBP to discontinue the suspension of liquidation of all entries of subject merchandise entered or withdrawn from warehouse, on or after November 25, 2025, but to continue the suspension of liquidation of all entries of subject merchandise on or before November 24, 2025.

If the U.S. International Trade Commission (ITC) publishes an affirmative final injury determination, then Commerce will publish an antidumping duty order, reinstate the suspension of liquidation under section

736(a) of the Act, and require a cash deposit of estimated antidumping duties for entries of subject merchandise in the amounts indicated above, in accordance with section 736(a) of the Act. If the ITC determines that material injury, or threat of material injury, does not exist, then this proceeding will be terminated, the suspension of liquidation will be lifted, and all cash deposits for estimated antidumping duties will be refunded.

To determine the cash deposit rate, Commerce normally adjusts the estimated weighted-average dumping margin by the amount of export subsidies countervailed in a companion countervailing duty (CVD) investigation, when CVD provisional measures are in effect. Accordingly, where Commerce made an affirmative determination for countervailable export subsidies, Commerce would offset the estimated weighted-average dumping margins by the appropriate export subsidy rate.¹³ Any such adjusted cash deposit rates may be found in the “Final Determination” section above. If the U.S. International Trade Commission (ITC) makes a final affirmative determination of injury due to both dumping and subsidies, then the cash deposit rate will include the offsets for the export subsidies collected as part of the CVD final determination.

ITC Notification

In accordance with section 735(d) of the Act, Commerce will notify ITC of its final affirmative determination of sales

at LTFV. Because Commerce’s final determination is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports or sales (or the likelihood of sales) of capsules for importation from India no later than 45 days after this final determination. If the ITC determines that such injury does not exist, then this proceeding will be terminated, all cash deposits posted will be refunded, and suspension of liquidation will be lifted. If the ITC determines that such injury does exist, then Commerce will issue an antidumping duty order directing CBP to assess, upon further instruction by Commerce, antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation, as discussed in the “Suspension of Liquidation and Cash Deposit Requirements” section above.

Administrative Protective Order (APO)

This notice serves as the only reminder to parties subject to an APO of their responsibility concerning the disposition of proprietary information disclosed under the APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is

¹¹ With two respondents under examination, Commerce normally calculates: (A) a weighted-average of the estimated weighted-average dumping margins calculated for the examined respondents; (B) a simple average of the estimated weighted-average dumping margins calculated for the examined respondents; and (C) a weighted-average of the estimated weighted-average dumping margins calculated for the examined respondents using each company’s publicly-ranged U.S. sales values for the merchandise under consideration. Commerce then compares (B) and (C) to (A) and selects the rate closest to (A) as the most appropriate rate for all other producers and exporters. *See, e.g., Ball Bearings and Parts Thereof from France, Germany,*

Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews, Final Results of Changed-Circumstances Review, and Revocation of an Order in Part, 75 FR 53661, 53662 (September 1, 2010), and accompanying Issues and Decision Memorandum at Comment 1. Publicly-ranged total U.S. sales values are not available for each of the companies examined in this investigation. Accordingly, we cannot calculate an estimated weighted-average dumping margin based on a weighted-average to consider applying to the non-examined respondents in this investigation. Instead, we have determined to calculate the simple average of the estimated weighted-average dumping margins calculated for the examined companies to

the companies not selected for individual examination in this investigation. For a complete analysis of the data, see Memorandum, “Final Determination All-Others Rate Calculation,” dated concurrently with this notice.

¹² In the *Preliminary Determination*, Commerce preliminarily determined that these companies are a single entity. *See Preliminary Determination PDM* at 4–5; *see also* Memorandum, “Preliminary Affiliation and Collapsing Analysis Memorandum,” dated April 21, 2025. No parties commented on this determination; thus, we continue to treat these companies as a single entity for purposes of this final determination.

¹³ *See Preliminary Determination PDM* at 18.

hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

This final determination and notice are issued and published in accordance with sections 735(d) and 777(i) of the Act, and 19 CFR 351.210(c).

Dated: December 18, 2025.

Christopher Abbott,

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

Appendix I

Scope of the Investigation

The merchandise subject to the scope of this investigation is hard empty capsules, which are comprised of two prefabricated, hollowed cylindrical sections (cap and body). The cap and body pieces each have one closed and rounded end and one open end, and are constructed with different or equal diameters at their open ends.

Hard empty capsules are unfilled cylindrical shells composed of at least 80 percent by weight of a water soluble polymer that is considered non-toxic and appropriate for human or animal consumption by the United States Pharmacopeia—National Formulary (USP–NF), Food Chemical Codex (FCC), or equivalent standards. The most common polymer materials in hard empty capsules are gelatin derived from animal collagen (including, but not limited to, pig, cow, or fish collagen), hydroxypropyl methylcellulose (HPMC), and pullulan.

Hard empty capsules may also contain water and additives, such as opacifiers, colorants, processing aids, controlled release agents, plasticizers, and preservatives. Hard empty capsules may also be imprinted or otherwise decorated with markings.

Hard empty capsules are covered by the scope of these investigations regardless of polymer material, additives, transparency, opacity, color, imprinting, or other markings.

Hard empty capsules are also covered by the scope of these investigations regardless of their size, weight, length, diameter, thickness, and filling capacity.

Cap and body pieces of hard empty capsules are covered by the scope of these investigations regardless of whether they are imported together or separately, and regardless of whether they are imported in attached or detached form.

Hard empty capsules covered by the scope of these investigations are those that disintegrate in water, simulated intestinal fluid, simulated gastric fluid, or other similar water-based (*i.e.*, aqueous) fluids within 2 hours under tests specified in Chapter 701 of the USP–NF, or equivalent disintegration tests.

Hard empty capsules are classifiable under subheadings 9602.00.1040 and 9602.00.5010 of the Harmonized Tariff Schedule of the United States (HTSUS). In addition, hard empty capsules may be imported under HTSUS subheading 1905.90.9090; gelatin hard empty capsules may be imported under

HTSUS subheading 3503.00.5510; HPMC hard empty capsules may be imported under HTSUS subheading 3923.90.0080; and pullulan hard empty capsules may be imported under HTSUS subheading 2106.90.9998. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise covered by these investigations is dispositive.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary

II. Background

III. Changes Since the Preliminary Determination

IV. Discussion of the Issues

Comment 1: Whether Commerce Should Correct Certain Errors in Its Calculation of ACG's Estimated Weighted-Average Dumping Margin

Comment 2: Whether Commerce Should Apply Adverse Facts Available (AFA) in Calculating ACG's Final Estimated Weighted-Average Dumping Margin

Comment 3: Whether Commerce Improperly Rejected ACG North America LLC (ACG NA)'s Minor Correction of the Reported U.S. Duty Expenses

Comment 4: Whether Commerce Should Apply AFA in Calculating HIL's Inland Freight from Warehouse to Customer Expenses

Comment 5: Whether Commerce Has a Statutory Basis to Depart from the Average-to-Average (A-to-A) Comparison Method

V. Recommendation

[FR Doc. 2025–23826 Filed 12–23–25; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–954, C–570–955]

Certain Magnesia Carbon Bricks From the People's Republic of China: Notice of Court Decision Not in Harmony With the Final Determination in Covered Merchandise Inquiry; and Notice of Amended Final Covered Merchandise Inquiry Determination

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

SUMMARY: On October 9, 2025, the U.S. Court of International Trade (CIT) issued its final judgment in *Fedmet Resources Corporation v. United States*, Court No. 23–00117, sustaining the U.S. Department of Commerce (Commerce)'s remand redetermination pertaining to the covered merchandise inquiry (CMI) related to refractory bricks with added alumina. Commerce is notifying the public that the CIT's final judgment is not in harmony with Commerce's final

determination in that CMI, and that Commerce is amending the final CMI determination to find that refractory bricks with added alumina are excluded from the orders.

DATES: Applicable October 19, 2025.

FOR FURTHER INFORMATION CONTACT:

Brittany Bauer, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3860.

SUPPLEMENTARY INFORMATION:

Background

On May 4, 2023, Commerce published its *Final CMI Determination*, which found that refractory bricks with less than five percent added alumina were magnesia carbon bricks (MCBs) and were, thus, covered by the scope of the *Orders*.¹

Fedmet Resources Corporation appealed Commerce's *Final CMI Determination*. On December 12, 2024, the CIT remanded the *Final CMI Determination* to Commerce, holding that precedent from the U.S. Court of Appeals for the Federal Circuit (Federal Circuit) interpreted the scope to not specify a cut-off percentage for low alumina versus high alumina refractory bricks, such that the addition of any alumina to an MCB renders the brick outside the scope of the *Orders*.²

In its final remand redetermination, issued in March 2025, Commerce found, under protest, that MCBs with any added alumina were excluded from the scope of the *Orders*.³ The CIT sustained Commerce's final redetermination.⁴

¹ See *Certain Magnesia Carbon Bricks from the People's Republic of China: Final Determination in Covered Merchandise Inquiry*, 88 FR 28495 (May 4, 2023), and accompanying Issues and Decision Memorandum (*Final CMI Determination*); see also *Certain Magnesia Carbon Bricks from Mexico and the People's Republic of China: Antidumping Duty Orders*, 75 FR 57257 (September 20, 2010); and *Certain Magnesia Carbon Bricks from the People's Republic of China: Countervailing Duty Order*, 75 FR 57442 (September 21, 2010) (collectively, *Orders*).

² See *Fedmet Resources Corporation v. United States*, Slip Op. 24–136 (CIT December 12, 2024); see also *Fedmet Resources Corp. v. United States*, 755 F. 3d 912 (Fed. Cir. 2014).

³ See *Final Results of Redetermination Pursuant to Court Remand, Fedmet Resources Corporation v. United States*, Court No. 23–00117, Slip Op. 24–136 (CIT December 12, 2024), dated March 12, 2025, available at <https://access.trade.gov/public/FinalRemandRedetermination.aspx>.

⁴ See *Fedmet Resources Corporation v. United States*, Court No. 23–00117, Slip Op. 25–136 (CIT October 9, 2025).

Timken Notice

In its decision in *Timken*,⁵ as clarified by *Diamond Sawblades*,⁶ the Federal Circuit held that, pursuant to sections 516A(c) and (e) of the Tariff Act of 1930, as amended (the Act), Commerce must publish a notice of court decision that is not “in harmony” with a Commerce determination and must suspend liquidation of entries pending a “conclusive” court decision. The CIT’s October 9, 2025, judgment constitutes a final decision of the CIT that is not in harmony with Commerce’s *Final CMI Determination*. Thus, this notice is published in fulfillment of the publication requirements of *Timken*.

Amended Final Determination

Commerce will instruct U.S. Customs and Border Protection (CBP) that, pending any appeals, the cash deposit rate will be zero percent for refractory bricks with any added alumina. In the event that the CIT’s final judgment is upheld on appeal, Commerce will instruct CBP to liquidate entries of refractory bricks with added alumina without regard to antidumping and countervailing duties and to lift suspension of liquidation of such entries.

Notification to Interested Parties

This notice is issued and published in accordance with sections 516A(c) and (e) and 777(i)(1) of the Act.

Dated: December 19, 2025.

Christopher Abbott,

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

[FR Doc. 2025–23772 Filed 12–23–25; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE**International Trade Administration**

[A–428–850]

Thermal Paper From Germany: Notice of Court Decision Not in Harmony With the Final Determination of Antidumping Investigation; Notice of Amended Final Determination; Notice of Amended Order, In Part

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

⁵ See *Timken Co. v. United States*, 893 F.2d 337 (Fed. Cir. 1990) (*Timken*).

⁶ See *Diamond Sawblades Manufacturers Coalition v. United States*, 626 F.3d 1374 (Fed. Cir. 2010) (*Diamond Sawblades*).

SUMMARY: On November 20, 2025, the U.S. Court of International Trade (CIT) issued its final judgment in *Matra Americas, LLC et al. v. United States*, Slip Op. 25–145, Consol. Court No. 21–00632, sustaining the U.S. Department of Commerce (Commerce)’s final remand redetermination pertaining to the antidumping duty (AD) investigation of thermal paper from Germany covering the period of investigation October 1, 2019, through September 30, 2020. Commerce is notifying the public that the CIT’s final judgment is not in harmony with Commerce’s final determination in that investigation, and that Commerce is amending the final determination and the resulting AD order with respect to the dumping margin assigned to Koehler Paper SE (Koehler) and all other producers and/or exporters.

DATES: Applicable December 1, 2025.

FOR FURTHER INFORMATION CONTACT: Anne Entz, AD/CVD Operations, Office IX, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3845.

SUPPLEMENTARY INFORMATION:**Background**

On September 30, 2021, Commerce published its *Final Determination* in the AD investigation of thermal paper from Germany. Commerce: (1) applied the Cohen’s *d* test as part of its differential pricing analysis;¹ (2) accepted Koehler’s reporting of the static sensitivity product characteristic in its sales and cost databases for all but one product in the final determination;² and (3) recalculated Koehler’s reported financial expense ratio to include the interest expenses accrued on Koehler’s unpaid antidumping duties from the revoked *LWTP Order*.³ Commerce subsequently published the AD order on thermal paper from Germany.⁴

Certain parties appealed Commerce’s *Final Determination*. On February 8, 2024, the CIT remanded the *Final Determination* to Commerce to

¹ See *Thermal Paper from Germany: Final Affirmative Determination of Sales at Less Than Fair Value and Final Affirmative Determination of Critical Circumstances*, in Part, 86 FR 54152 (September 30, 2021) (*Final Determination*), and accompanying Issues and Decision Memorandum at Comment 1.

² *Id.* at Comments 3 and 4.

³ *Id.* at Comment 5; see also *Antidumping Duty Orders: Lightweight Thermal Paper from Germany and the People’s Republic of China*, 73 FR 70959 (November 24, 2008) (*LWTP Order*).

⁴ See *Thermal Paper from Germany, Japan, the Republic of Korea, and Spain: Antidumping Duty Orders*, 86 FR 66284 (November 22, 2021) (*Order*).

reconsider or explain: (1) its application of the Cohen’s *d* test to Koehler’s U.S. sales; (2) the coding of the static sensitivity product characteristic; and (3) the decision not to treat Koehler’s accrued interest expenses related to unpaid antidumping duties as part of indirect selling expenses.⁵

In its final remand redetermination, issued in August 2025, Commerce: (1) reconsidered its application of the Cohen’s *d* test as part of its differential pricing analysis; (2) reopened the record to provide Koehler with an opportunity to remedy its reporting of the static sensitivity product characteristic; and (3) provided further explanation of the inclusion of Koehler’s accrued interest expenses related to unpaid antidumping duties as part of the financial expense ratio in the calculation of the cost of production, instead of as U.S. indirect selling expenses.⁶ The CIT sustained Commerce’s final redetermination.⁷

Timken Notice

In its decision in *Timken*,⁸ as clarified by *Diamond Sawblades*,⁹ the U.S. Court of Appeals for the Federal Circuit held that, pursuant to section 516A(c) and (e) of the Tariff Act of 1930, as amended (the Act), Commerce must publish a notice of court decision that is not “in harmony” with a Commerce determination and must suspend liquidation of entries pending a “conclusive” court decision. The CIT’s November 20, 2025, judgment constitutes a final decision of the CIT that is not in harmony with Commerce’s *Final Determination*. Thus, this notice is published in fulfillment of the publication requirements of *Timken*.

Amended Final Determination

Because there is now a final court judgment, Commerce is amending its *Final Determination* as follows:

⁵ See *Matra Americas, LLC et al. v. United States*, 681 F. Supp. 3d 1339, 1382 (CIT 2024) (*Remand Order*).

⁶ See *Final Results of Redetermination Pursuant to Court Remand, Matra Americas, LLC v. United States*, 681 F. Supp. 3d 1339 (CIT 2024), dated August 28, 2025 (*Final Remand*), available at <https://access.trade.gov/public/FinalRemandRedetermination.aspx>.

⁷ See *Matra Americas, LLC et al. v. United States*, Slip Op. 25–145, Consol. Court No. 21–00632 (CIT 2025).

⁸ See *Timken Co. v. United States*, 893 F. 2d 337 (Fed. Cir. 1990) (*Timken*).

⁹ See *Diamond Sawblades Manufacturers Coalition v. United States*, 626 F.3d 1374 (Fed. Cir. 2010) (*Diamond Sawblades*).

Exporter/producer	Weighted-average dumping margin (percent)
Koehler Paper SE; Koehler Kehl GmbH	6.27
All Others	6.27

Amended AD Order

Pursuant to section 735(c)(2) of the Act, Commerce shall “issue an antidumping duty order under section 736” of the Act when the final determination is affirmative. As a result of this amended final determination, Commerce is hereby amending the Order to revise the weighted-average dumping margin assigned to Koehler and all other producers and/or exporters of subject merchandise, as noted above.

Cash Deposit Requirements

Because Koehler has a superseding cash deposit rate, *i.e.*, there have been final results published in a subsequent administrative review, this notice will not affect the current cash deposit rate for Koehler. For the rate applicable to all other exporters and/or producers, Commerce will issue revised cash deposit instructions to U.S. Customs and Border Protection.

Notification to Interested Parties

This notice is issued and published in accordance with sections 516A(c) and (e) and 777(i)(1) of the Act.

Dated: December 15, 2025.

Christopher Abbott,
Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.
[FR Doc. 2025–23883 Filed 12–23–25; 8:45 am]
BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration
[C–533–935]

Hard Empty Capsules From India: Final Affirmative Countervailing Duty Determination

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

SUMMARY: The U.S. Department of Commerce (Commerce) determines that countervailable subsidies are being provided to producers and exporters of hard empty capsules (capsules) from India. The period of investigation (POI) is April 1, 2023, through March 31, 2024.

DATES: Applicable December 29, 2025.
FOR FURTHER INFORMATION CONTACT: Katherine Smith or Gorden Struck, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0557 or (202) 482–8151, respectively.

SUPPLEMENTARY INFORMATION:

Background

On March 31, 2025, Commerce published *Preliminary Determination* in the **Federal Register** and invited interested parties to comment.¹ In the *Preliminary Determination*, and in accordance with section 705(a)(1) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.210(b)(4), Commerce aligned the final countervailing duty (CVD) determination with the final determination in the less-than-fair-value investigation of capsules from India.²

Due to the lapse in appropriations and Federal Government shutdown, on November 14, 2025, Commerce tolled all deadlines in administrative proceedings by 47 days.³ Additionally, due to a backlog of documents that were electronically filed via Enforcement and Compliance’s Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS) during the Federal Government shutdown, on November 24, 2025, Commerce tolled all deadlines in administrative proceedings by an additional 21 days.⁴ Accordingly, the deadline for this final determination is now December 18, 2025.

For a complete description of the events that followed the *Preliminary Determination*, see the Issues and Decision Memorandum.⁵ The Issues and Decision Memorandum is a public document and is made available to the public via ACCESS. ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete

version of the Issues and Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Scope of the Investigation

The products covered by this investigation are hard empty capsules from India. For a complete description of the scope of the investigation, see Appendix I.

Scope Comments

In the Preliminary Scope Memorandum, we set aside a period of time for parties to raise issues regarding product coverage (*i.e.*, scope) in scope-specific case briefs or other written comments.⁶ We received scope case and rebuttal briefs from multiple interested parties. For a summary of the product coverage comments and rebuttal responses submitted to the record for this final determination, and accompanying discussion and analysis of all comments timely received, see the Final Scope Memorandum.⁷ In the Final Scope Memorandum, Commerce determined that it is modifying the scope language as it appeared in the *Initiation Notice*.⁸ See Appendix I.

Verification

As provided in section 782(i) of the Act, in July and August 2025, Commerce conducted verification of the subsidy information reported by ACG Associated Capsules Private Limited (ACPL) and its affiliates, ACG Pam Pharma Technologies Private Limited (ACG PAM) and ACG Universal Capsules Private Limited (AUCPL) (collectively, ACG).⁹

Analysis of Subsidy Programs and Comments Received

The subsidy programs under investigation, and the issues raised in

¹ See *Hard Empty Capsules from India: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Determination With Final Antidumping Duty Determination*, 90 FR 14237 (March 31, 2025) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum (PDM).
² See *Preliminary Determination*, 90 FR 14238.
³ See Memorandum, “Deadlines Affected by the Shutdown of the Federal Government,” dated November 14, 2025.
⁴ See Memorandum, “Tolling of all Case Deadlines,” dated November 24, 2025.
⁵ See Memorandum, “Issues and Decision Memorandum for the Final Affirmative Determination of the Countervailing Duty Investigation of Hard Empty Capsules from India,” dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).
⁶ See Memorandum, “Less-Than-Fair-Value Investigations of Hard Empty Capsules from Brazil, the People’s Republic of China, India, and the Socialist Republic of Vietnam and Countervailing Duty Investigations from Brazil, the People’s Republic of China, India, and the Socialist Republic of Vietnam: Preliminary Scope Decision Memorandum,” dated March 24, 2025 (Preliminary Scope Memorandum).
⁷ See Memorandum, “Less-Than-Fair-Value and Countervailing Duty Investigations of Hard Empty Capsules from Brazil, the People’s Republic of China, India, and the Socialist Republic of Vietnam: Final Scope Decision Memorandum,” dated concurrently with this notice (Final Scope Memorandum).
⁸ See *Hard Empty Capsules from Brazil, the People’s Republic of China, India, and the Socialist Republic of Vietnam: Initiation of Countervailing Duty Investigations*, 89 FR 91680 (November 20, 2024) (*Initiation Notice*).
⁹ See Memorandum, “Verification of the Questionnaire Responses of ACG Associated Capsules Private Limited,” dated August 21, 2025 (ACG Verification Report).

the case and rebuttal briefs by parties in this investigation, are discussed in the Issues and Decision Memorandum. For a list of the issues raised by parties, and to which we responded in the Issues and Decision Memorandum, *see* Appendix II.

Methodology

Commerce conducted this investigation in accordance with section 701 of the Act. For each of the subsidy programs found to be countervailable, Commerce determines that there is a subsidy, *i.e.*, a financial contribution by an “authority” that gives rise to a benefit to the recipient, and that the subsidy is specific.¹⁰ For a full description of the methodology underlying our final determination, *see* the Issues and Decision Memorandum.

Changes Since the Preliminary Determination

Based on our review and analysis of the information received during verification and comments received from parties, for this final determination, we made certain changes

to the countervailable subsidy rate calculations for ACG, and for all other producers/exporters. For a discussion of these changes, *see* the Issues and Decision Memorandum.

All-Others Rate

Section 705(c)(5)(A) of the Act provides that in a final determination, Commerce shall determine an estimated all-others rate for companies not individually examined equal to the weighted average of the estimated countervailable subsidy rates established for exporters and producers individually examined, excluding any zero or *de minimis* countervailable subsidy rates and any rates based entirely under section 776 of the Act (facts available). If the individual estimated countervailable subsidy rates established for all exporters and producers individually examined are zero, *de minimis*, or determined entirely under section 776 of the Act, section 705(c)(5)(A)(ii) of the Act provides that Commerce may use any reasonable method to establish an estimated all-

others countervailable subsidy rate for exporters and producers not individually investigated, including averaging the weighted average countervailable subsidy rates determined for the exporters and producers individually investigated.

In this investigation, we continue to calculate an individual total net countervailable subsidy rate for ACG, the only individually examined producer/exporter in this investigation, that is not zero, *de minimis*, or based entirely on facts otherwise available and there are no other countervailable subsidy rates on the record. Given these facts, Commerce has determined that a reasonable method for establishing the estimated all-others’ countervailable subsidy rate is to assign ACG’s estimated countervailable subsidy rate to all other producers and exporters.

Final Determination

Commerce determines that the following estimated net countervailable subsidy rates exist for the period April 1, 2023, through March 31, 2024:

Company	Subsidy rate (percent <i>ad valorem</i>)
ACG Associated Capsules Private Limited; ACG Pam Pharma Technologies Private Limited; ACG Universal Capsules Private Limited	7.06
All Others	7.06

Disclosure

Commerce intends to disclose its calculations performed to interested parties in this final determination within five days of its public announcement or, if there is no public announcement, within five days of the date of the publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Suspension of Liquidation

As a result of our *Preliminary Determination*, and pursuant to sections 703(d)(1)(B) and (d)(2) of the Act, we instructed U.S. Customs and Border Protection (CBP) to collect cash deposits and suspend liquidation of entries of subject merchandise from India that were entered, or withdrawn from warehouse, for consumption on or after March 31, 2025, the date of publication of the *Preliminary Determination* in the **Federal Register**. In accordance with section 703(d) of the Act, we instructed CBP to discontinue the suspension of liquidation of all entries of subject merchandise entered or withdrawn from

warehouse, on or after July 29, 2025, but to continue the suspension of liquidation of all entries of subject merchandise on or before July 28, 2025.

If the U.S. International Trade Commission (ITC) issues a final affirmative injury determination, we will issue a CVD order, reinstate the suspension of liquidation under section 706(a) of the Act, and require a cash deposit of estimated countervailing duties for such entries of subject merchandise in the amounts indicated above. Pursuant to section 705(c)(2) of the Act, if the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated, and all estimated duties deposited or securities posted as a result of the suspension of liquidation will be refunded or cancelled.

ITC Notification

In accordance with section 705(d) of the Act, Commerce will notify the ITC of its final affirmative determination that countervailable subsidies are being provided to producers and exporters of capsules from India. As Commerce’s

final determination is affirmative, in accordance with section 705(b) of the Act, the ITC will determine, within 45 days, whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of import of capsules from India. In addition, we are making available to the ITC all non-privileged and non-proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under administrative protective order (APO), without the written consent of the Assistant Secretary for Enforcement and Compliance.

If the ITC determines that material injury or threat of material injury does not exist, this proceeding will be terminated and all cash deposits will be refunded. If the ITC determines that such injury does exist, Commerce will issue a CVD order directing CBP to assess, upon further instruction by Commerce, countervailing duties on all imports of the subject merchandise that are entered, or withdrawn, for

¹⁰ See sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E)

of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

consumption on or after the effective date of the suspension of liquidation, as discussed above in the “Suspension of Liquidation” section.

Administrative Protective Order

This notice will serve as the only reminder to parties subject to the APO of their responsibility concerning the destruction of proprietary information disclosed under APO, in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/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 violation which is subject to sanction.

Notification to Interested Parties

This determination is issued and published pursuant to sections 705(d) and 777(i) of the Act, and 19 CFR 351.210(c).

Dated: December 18, 2025.

Christopher Abbott,

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

Appendix I

Scope of the Investigation

The merchandise subject to the scope of this investigation is hard empty capsules, which are comprised of two prefabricated, hollowed cylindrical sections (cap and body). The cap and body pieces each have one closed and rounded end and one open end, and are constructed with different or equal diameters at their open ends.

Hard empty capsules are unfilled cylindrical shells composed of at least 80 percent by weight of a water soluble polymer that is considered non-toxic and appropriate for human or animal consumption by the United States Pharmacopeia—National Formulary (USP–NF), Food Chemical Codex (FCC), or equivalent standards. The most common polymer materials in hard empty capsules are gelatin derived from animal collagen (including, but not limited to, pig, cow, or fish collagen), hydroxypropyl methylcellulose (HPMC), and pullulan.

Hard empty capsules may also contain water and additives, such as opacifiers, colorants, processing aids, controlled release agents, plasticizers, and preservatives. Hard empty capsules may also be imprinted or otherwise decorated with markings.

Hard empty capsules are covered by the scope of this investigation regardless of polymer material, additives, transparency, opacity, color, imprinting, or other markings.

Hard empty capsules are also covered by the scope of this investigation regardless of their size, weight, length, diameter, thickness, and filling capacity.

Cap and body pieces of hard empty capsules are covered by the scope of this investigation regardless of whether they are

imported together or separately, and regardless of whether they are imported in attached or detached form.

Hard empty capsules covered by the scope of this investigation are those that disintegrate in water, simulated intestinal fluid, simulated gastric fluid, or other similar water-based (*i.e.*, aqueous) fluids within 2 hours under tests specified in Chapter 701 of the USP–NF, or equivalent disintegration tests.

Hard empty capsules are classifiable under subheadings 9602.00.1040 and 9602.00.5010 of the Harmonized Tariff Schedule of the United States (HTSUS). In addition, hard empty capsules may be imported under HTSUS subheading 1905.90.9090; gelatin hard empty capsules may be imported under HTSUS subheading 3503.00.5510; HPMC hard empty capsules may be imported under HTSUS subheading 3923.90.0080; and pullulan hard empty capsules may be imported under HTSUS subheading 2106.90.9998. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise covered by this investigation is dispositive.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Use of Facts Otherwise Available and Application of Adverse Inferences
- IV. Subsidies Valuation
- V. Changes Since the *Preliminary Determination*
- VI. Analysis of Programs
- VII. Discussion of the Issues
 - Comment 1: Whether Commerce Erred in Selecting ACPL as the Sole Mandatory Respondent in This Proceeding
 - Comment 2: Whether Commerce Should Apply Adverse Facts Available (AFA) Due to AGC PAM’s Misreported Export Sales
 - Comment 3: Whether Commerce Should Apply AFA to ACG Regarding Its Relationship With Custom Capsules Private Limited (Custom Capsules)
 - Comment 4: Whether Commerce Should Find that the State Government of Maharashtra (SGOM) Provided Land for LTAR to ACG
 - Comment 5: Whether Commerce Should Correct its Benefit Calculation for the SGOM Waiver of Stamp Duty and Find this Program Provided a Countervailable Benefit During the POI
 - Comment 6: Whether Commerce Used the Correct AUL Period Export Sales Figures for ACG India Throughout its Calculations
 - Comment 7: Whether Commerce Should Complete its Benefit Calculation for EPCGS Loans Outstanding
 - Comment 8: Whether Commerce Should Correct Its Calculation for the Advance Authorization Program (AAP)
 - Comment 9: Whether Commerce Should Correct the Methodology for Calculating Benefits for Duty Free Import Authorizations (DFIA) Under the Special Economic Zone Program

Comment 10: Whether Commerce Incorrectly Allocated Benefits Under the Duty Drawback Program (DDP)

Comment 11: Whether Commerce Should Revise the Methodology to Calculate Benefits Related to the Remission of Duties and Taxes on Export Products (RODTEP) Scheme

VIII. Recommendation

[FR Doc. 2025–23827 Filed 12–23–25; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–552–848]

Hard Empty Capsules From the Socialist Republic of Vietnam: Final Affirmative Countervailing Duty Determination

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

SUMMARY: The U.S. Department of Commerce (Commerce) determines that countervailable subsidies are being provided to producers and exporters of hard empty capsules (capsules) from the Socialist Republic of Vietnam (Vietnam). The period of investigation (POI) is January 1, 2023, through December 31, 2023.

DATES: Applicable December 29, 2025.

FOR FURTHER INFORMATION CONTACT: Jonathan Schueler or Joshua Nixon, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–9175 or (202) 482–8361, respectively.

SUPPLEMENTARY INFORMATION:

Background

On March 31, 2025, Commerce published the *Preliminary Determination* in the **Federal Register**, invited interested parties to comment on the *Preliminary Determination*, and aligned this countervailing duty (CVD) investigation with the final determination with the final investigation of capsules from Vietnam, in accordance with section 705(a)(1) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.210(b)(4).¹

Due to the lapse in appropriations and Federal Government shutdown, on

¹ See *Hard Empty Capsules from the Socialist Republic of Vietnam: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Determination with Final Antidumping Duty Determination*, 90 FR 14240 (March 31, 2025) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum (PDM).

November 14, 2025, Commerce tolled all deadlines in administrative proceedings by 47 days.² Additionally, due to a backlog of documents that were electronically filed via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS) during the Federal Government shutdown, on November 24, 2025, Commerce tolled all deadlines in administrative proceedings by an additional 21 days.³ Accordingly, the deadline for this final determination is now December 18, 2025.

For a complete description of the events that followed the *Preliminary Determination*, see the Issues and Decision Memorandum.⁴ The Issues and Decision Memorandum is a public document and is on file electronically via ACCESS. ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Scope of the Investigation

The products covered by this investigation are capsules. For a complete description of the scope of this investigation, see Appendix I.

Scope Comments

In the Preliminary Scope Memorandum, we set aside a period of time for parties to raise issues regarding product coverage (*i.e.*, scope) in scope-specific case briefs or other written comments.⁵ We received scope case and rebuttal briefs from multiple interested parties. For a summary of the product coverage comments and rebuttal responses submitted to the record for this final determination, and accompanying discussion and analysis of all comments timely received, see the Final Scope Memorandum.⁶ In the Final

Scope Memorandum, Commerce made certain changes to the scope language as it appeared in the *Initiation Notice*.⁷ See Appendix I.

Verification

As provided in section 782(i) of the Act, in May 2025, Commerce conducted on-site verifications of the subsidy information reported by the Government of Vietnam, the Government of Korea, Suheung Vietnam Co., Ltd. (Suheung Vietnam), and Cuu Long Joint Stock Company. We used standard verification procedures, including an examination of relevant sales and accounting records, and original source documents provided by the respondents.⁸

Analysis of Subsidy Programs and Comments Received

The subsidy programs under investigation, and the issues raised in the case and rebuttal briefs by parties in this investigation, are discussed in the Issues and Decision Memorandum. For a list of the issues raised by parties, and addressed in the Issues and Decision Memorandum, see Appendix II.

Methodology

Commerce conducted this investigation in accordance with section 701 of the Act. For each of the subsidy programs found to be countervailable, Commerce determines that there is a subsidy, *i.e.*, a financial contribution by an "authority" that gives rise to a benefit to the recipient, and that the subsidy is specific.⁹ For a full description of the methodology underlying our final determination, see the Issues and Decision Memorandum.

In making this final determination, Commerce relied, in part, on facts available, pursuant to section 776(a) of the Act.¹⁰ For a full discussion of our

Socialist Republic of Vietnam, and Countervailing Duty Investigations from Brazil the People's Republic of China, India, and the Socialist Republic of Vietnam: Final Scope Decision Memorandum," dated concurrently with this notice (Final Scope Memorandum).

⁷ See *Hard Empty Capsules from Brazil, the People's Republic of China, India, and the Socialist Republic of Vietnam: Initiation of Countervailing Duty Investigations*, 89 FR 91680 (November 20, 2024) (*Initiation Notice*).

⁸ See Memoranda, "Verification of the Questionnaire Responses of Suheung Vietnam Co., Ltd.," dated August 12, 2025; "Verification of the Questionnaire Responses of the Government of Vietnam," dated August 21, 2025; "Verification of the Questionnaire Responses of the Government of Korea," dated August 20, 2025; and "Verification of the Questionnaire Responses of Cuu Long Joint Stock Company," dated August 12, 2025.

⁹ See sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

¹⁰ See section 776(a) of the Act.

application of facts available, see the "Use of Facts Otherwise Available" section in the Issues and Decision Memorandum.

Changes Since the Preliminary Determination

Based on our findings at verification and our review and analysis of the comments received from parties, for this final determination, we made certain changes to the countervailable subsidy rate calculations for Suheung Vietnam and for all other producers/exporters from the *Preliminary Determination*. For a discussion of these changes, see the Issues and Decision Memorandum.

All-Others Rate

In accordance with section 705(c)(1)(B)(i) of the Act, we calculated an individual estimated countervailable subsidy rate for the mandatory respondent, Suheung Vietnam. Section 705(c)(5)(A)(i) of the Act states that, for companies not individually investigated, Commerce will determine an all-others rate equal to the weighted-average countervailable subsidy rates established for exporters and/or producers individually investigated, excluding any zero and *de minimis* countervailable subsidy rates, and any rates determined entirely under section 776 of the Act. For this final determination, Suheung Vietnam's subsidy rate is not zero, *de minimis*, or determined entirely under section 776 of the Act. Consequently, we have assigned the subsidy rate calculated for Suheung Vietnam as the rate for all other producers and/or exporters.

Final Determination

Commerce determines that the following estimated countervailable subsidy rates exist for the period January 1, 2023, through December 31, 2023:

Company	Subsidy rate (percent <i>ad valorem</i>)
Suheung Vietnam Co., Ltd ...	2.45
All Others	2.45

Disclosure

Commerce intends to disclose its calculations and analysis performed to interested parties in this final determination within five days of any public announcement, or if there is no public announcement, within five days of the date of the publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

² See Memorandum, "Deadlines Affected by the Shutdown of the Federal Government," dated November 14, 2025.

³ See Memorandum, "Tolling of all Case Deadlines," dated November 24, 2025.

⁴ See Memorandum, "Issues and Decision Memorandum for the Final Affirmative Determination of the Countervailing Duty Investigation of Hard Empty Capsules from the Socialist Republic of Vietnam," dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

⁵ See Memorandum, "Less-Than-Fair-Value and Countervailing Duty Investigations of Hard Empty Capsules from Brazil, the People's Republic of China, India, and the Socialist Republic of Vietnam: Scope Comments Decision Memorandum for the Preliminary Determination," dated March 24, 2025 (Preliminary Scope Memorandum).

⁶ See Memorandum, "Less-Than-Fair-Value Investigations of Hard Empty Capsules from Brazil, the People's Republic of China, India, and the

Continuation of Suspension of Liquidation

As a result of our *Preliminary Determination*, and pursuant to sections 703(d)(1)(B) and (d)(2) of the Act, we instructed U.S. Customs and Border Protection (CBP) to collect cash deposits and suspend liquidation of entries of subject merchandise from Vietnam that were entered, or withdrawn from warehouse, for consumption on or after March 31, 2025, the date of publication of the *Preliminary Determination* in the **Federal Register**. In accordance with section 703(d) of the Act, on July 30, 2025, we instructed CBP to discontinue the suspension of liquidation of all entries of subject merchandise entered or withdrawn from warehouse on or after July 29, 2025, but to continue the suspension of liquidation of all entries of subject merchandise on or before July 28, 2025.

If the U.S. International Trade Commission (ITC) issues a final affirmative injury determination, we will issue a CVD order, reinstate the suspension of liquidation under section 706(a) of the Act, and require a cash deposit of estimated countervailing duties for such entries of subject merchandise in the amounts indicated above. Pursuant to section 705(c)(2) of the Act, if the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated, and all estimated duties deposited or securities posted as a result of the suspension of liquidation will be refunded or canceled.

ITC Notification

In accordance with section 705(d) of the Act, Commerce will notify the ITC of its final affirmative determination that countervailable subsidies are being provided to producers and exporters of capsules from Vietnam. As Commerce's final determination is affirmative, in accordance with section 705(b) of the Act, the ITC will determine, within 45 days, whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of capsules from Vietnam. In addition, we are making available to the ITC all non-privileged and non-proprietary information related to this investigation. We will allow the ITC access to all privileged and business proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under an administrative protective order (APO), without the written consent of the Assistant Secretary for Enforcement and Compliance.

If the ITC determines that material injury does not exist, this proceeding will be terminated and all cash deposits will be refunded. If the ITC determines that such injury does exist, Commerce will issue a CVD order directing CBP to assess, upon further instruction by Commerce, countervailing duties on all imports of the subject merchandise that are entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation, as discussed above in the "Continuation of Suspension of Liquidation" section.

Administrative Protective Order

In the event that the ITC issues a final negative injury determination, this notice will serve as the only reminder to parties subject to an APO of their responsibility concerning the destruction of proprietary information disclosed under APO, in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/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 violation which is subject to sanction.

Notification to Interested Parties

This determination is issued and published pursuant to sections 705(d) and 777(i) of the Act, and 19 CFR 351.210(c).

Dated: December 18, 2025.

Christopher Abbott,

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

Appendix I

Scope of the Investigation

The merchandise subject to the scope of this investigation is hard empty capsules, which are comprised of two prefabricated, hollowed cylindrical sections (cap and body). The cap and body pieces each have one closed and rounded end and one open end, and are constructed with different or equal diameters at their open ends.

Hard empty capsules are unfilled cylindrical shells composed of at least 80 percent by weight of a water soluble polymer that is considered non-toxic and appropriate for human or animal consumption by the United States Pharmacopeia—National Formulary (USP–NF), Food Chemical Codex (FCC), or equivalent standards. The most common polymer materials in HECs are gelatin derived from animal collagen (including, but not limited to, pig, cow, or fish collagen), hydroxypropyl methylcellulose (HPMC), and pullulan.

Hard empty capsules may also contain water and additives, such as opacifiers, colorants, processing aids, controlled release

agents, plasticizers, and preservatives. Hard empty capsules may also be imprinted or otherwise decorated with markings.

Hard empty capsules are covered by the scope of these investigations regardless of polymer material, additives, transparency, opacity, color, imprinting, or other markings.

Hard empty capsules are also covered by the scope of these investigations regardless of their size, weight, length, diameter, thickness, and filling capacity.

Cap and body pieces of hard empty capsules are covered by the scope of these investigations regardless of whether they are imported together or separately, and regardless of whether they are imported in attached or detached form.

Hard empty capsules covered by the scope of these investigations are those that disintegrate in water, simulated intestinal fluid, simulated gastric fluid, or other similar water-based (*i.e.*, aqueous) fluids within 2 hours under tests specified in Chapter 701 of the USP–NF, or equivalent disintegration tests.

Hard empty capsules are classifiable under subheadings 9602.00.1040 and 9602.00.5010 of the Harmonized Tariff Schedule of the United States (HTSUS). In addition, hard empty capsules may be imported under HTSUS subheading 1905.90.9090; gelatin hard empty capsules may be imported under HTSUS subheading 3503.00.5510; HPMC hard empty capsules may be imported under HTSUS subheading 3923.90.0080; and pullulan hard empty capsules may be imported under HTSUS subheading 2106.90.9998. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise covered by these investigations is dispositive.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Changes Since the *Preliminary Determination*
- IV. Scope of the Investigation
- V. Subsidies Valuation Information
- VI. Use of Facts Otherwise Available
- VII. Analysis of Programs
- VIII. Analysis of Comments
 - Comment 1: Whether Commerce Has the Legal Authority Under the World Trade Organization (WTO) Rules and U.S. Law to Investigate Transnational Subsidies
 - Comment 2: Whether the Export Import Bank of Korea (KEXIM) Overseas Business Loan Program is Specific
 - Comment 3: Whether to Revise the Benchmark for the KEXIM Overseas Business Loan Program
 - Comment 4: Whether the Refund for Import Duties on Raw Materials Used to Produce Exports Program is Countervailable
 - Comment 5: Whether the Income Tax Preferences for Enterprises in Special Zones Program Provides a Benefit During the Period of Investigation (POI)
 - Comment 6: Whether the Exemption or Reduction From Land and Water Rents

in Industrial Zones Program is
Countervailable

Comment 7: Whether Commerce Should
Apply Adverse Facts Available (AFA) to
Suheung Vietnam to Countervail Certain
Additional Loans

Comment 8: Whether Commerce Should
Treat Suheung Vietnam's Unreported
Import Duty Exemption as a Subsidy

IX. Recommendation

[FR Doc. 2025–23829 Filed 12–23–25; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–184]

Hard Empty Capsules From the People's Republic of China: Final Affirmative Determination of Sales at Less Than Fair Value

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

SUMMARY: The U.S. Department of
Commerce (Commerce) determines that
hard empty capsules (capsules) from the
People's Republic of China (China) are
being, or are likely to be, sold in the
United States at less than fair value
(LTFV) for the period of investigation
April 1, 2024, through September 30,
2024.

DATES: Applicable December 29, 2025.

FOR FURTHER INFORMATION CONTACT:
Rebecca Janz or Jerry Xiao, AD/CVD
Operations, Office II, Enforcement and
Compliance, International Trade
Administration, U.S. Department of
Commerce, 1401 Constitution Avenue
NW, Washington, DC 20230; telephone:
(202) 482–2972 or (202) 482–2273,
respectively.

SUPPLEMENTARY INFORMATION:

Background

On May 29, 2025, Commerce
published in the **Federal Register** its
preliminary affirmative determination
in the LTFV investigation of capsules
from China, in which it also postponed
the final determination until October 14,
2025.¹ On August 27, 2025, Commerce
issued a post-preliminary analysis
memorandum in which it made certain
changes to its differential pricing
analysis.² We invited interested parties

to comment on the *Preliminary
Determination* and changes to the
differential pricing analysis.³

Due to the lapse in appropriations and
Federal Government shutdown, on
November 14, 2025, Commerce tolled
all deadlines in administrative
proceedings by 47 days.⁴ Additionally,
due to a backlog of documents that were
electronically filed via Enforcement and
Compliance's Antidumping and
Countervailing Duty Centralized
Electronic Service System (ACCESS)
during the Federal Government
shutdown, on November 24, 2025,
Commerce tolled all deadlines in
administrative proceedings by an
additional 21 days.⁵ Accordingly, the
deadline for this final determination is
now December 18, 2025.

A summary of the events that
occurred since the *Preliminary
Determination*, as well as a full
discussion of the issues raised by parties
for this final determination, may be
found in the Issues and Decision
Memorandum.⁶ The Issues and Decision
Memorandum is a public document and
is on file electronically via ACCESS.
ACCESS is available to registered users
at <https://access.trade.gov>. In addition, a
complete version of the Issues and
Decision Memorandum can be accessed
directly at [https://access.trade.gov/
public/FRNoticesListLayout.aspx](https://access.trade.gov/public/FRNoticesListLayout.aspx).

Scope of the Investigation

The products covered by this
investigation are capsules from China.
For a complete description of the scope
of this investigation, *see* Appendix I.

Scope Comments

In the Preliminary Scope
Memorandum, we set aside a period of
time for parties to raise issues regarding
product coverage (*i.e.*, scope) in scope-
specific case briefs or other written
comments.⁷ We received scope case and

Fair-Value Investigation of Hard Empty Capsules
from the People's Republic of China," dated August
27, 2025 (Post-Preliminary Analysis).

³ See Memorandum, "Briefing Schedule," dated
August 28, 2025.

⁴ See Memorandum, "Deadlines Affected by the
Shutdown of the Federal Government," dated
November 14, 2025.

⁵ See Memorandum, "Tolling of all Case
Deadlines," dated November 24, 2025.

⁶ See Memorandum, "Issues and Decision
Memorandum for the Final Affirmative
Determination of Sales at Less Than Fair Value in
the Investigation of Hard Empty Capsules from the
People's Republic of China," dated concurrently
with, and hereby adopted by, this notice (Issues and
Decision Memorandum).

⁷ See Memorandum, "Less-Than-Fair-Value and
Countervailing Duty Investigations of Hard Empty
Capsules from Brazil, the People's Republic of
China, India, and the Socialist Republic of Vietnam:
Scope Comments Decision Memorandum for the

rebuttal briefs from multiple interested
parties. For a summary of the product
coverage comments and rebuttal
response submitted to the record for this
final determination, and accompanying
discussion and analysis of all comments
timely received, *see* the Final Scope
Memorandum.⁸ In the Final Scope
Memorandum, Commerce determined
that it is modifying the scope language
as it appeared in the *Initiation
Notice*.⁹ *See* Appendix I.

Verification

Commerce conducted verification of
the information relied upon in making
its final determination in this
investigation, in accordance with
section 782(i) of the Tariff Act of 1930,
as amended (the Act). Specifically, we
conducted on-site verifications of the
sales and cost information submitted by
Shandong Healsee Capsule Ltd.
(Shandong Healsee) and Shanxi JC
Biological Technology Co., Ltd. (Shanxi
JC) for use in our final determination.
We used standard verification
procedures, including an examination of
relevant sales and accounting records,
and original source documents provided
by Shandong Healsee and Shanxi JC.

Analysis of Comments Received

All issues raised in the case and
rebuttal briefs submitted by interested
parties in this investigation are
addressed in the Issues and Decision
Memorandum. A list of the issues
addressed in the Issues and Decision
Memorandum is attached to this notice
as Appendix II.

Changes Since the Preliminary Determination

We made certain changes to the
margin calculations for Shandong
Healsee and Shanxi JC since the
Preliminary Determination and Post-
Preliminary Analysis. For a discussion
of these changes, *see* the Issues and
Decision Memorandum.

Separate Rate Companies and the China-Wide Entity

We preliminarily granted a separate
rate to certain respondents that we did

Preliminary Determination," dated March 24, 2025
(Preliminary Scope Memorandum).

⁸ See Memorandum, "Less-Than-Fair-Value and
Countervailing Duty Investigations of Hard Empty
Capsules from Brazil, the People's Republic of
China, India, and the Socialist Republic of Vietnam:
Final Scope Decision Memorandum," dated
concurrently with this notice (Final Scope
Memorandum).

⁹ See *Hard Empty Capsules from Brazil, the
People's Republic of China, India, and the Socialist
Republic of Vietnam: Initiation of Countervailing
Duty Investigations*, 89 FR 91680 (November 20,
2024) (*Initiation Notice*).

¹ See *Hard Empty Capsules from the People's
Republic of China: Preliminary Affirmative
Determination of Sales at Less Than Fair Value,
Postponement of Final Determination, and
Extension of Provisional Measures*, 90 FR 22704
(May 29, 2025) (*Preliminary Determination*), and
accompanying Preliminary Decision Memorandum.

² See Memorandum, "Post-Preliminary Analysis
for the Affirmative Determination in the Less-Than-

not select for individual examination.¹⁰ Additionally, because we preliminarily did not find that the China-wide entity failed to cooperate in this investigation, we preliminarily assigned this same rate as the estimate weighted-average dumping margin for the China-wide entity.¹¹ No party commented on our preliminary separate rate determinations or our findings with respect to the China-wide entity.

Therefore, we continue to find that Shandong Healsee, Shanxi JC, and certain non-individually examined companies that are listed in the “Final Determination” rate table below, are eligible for a separate rate. We also continue to assign the same rate assigned to the non-individually examined companies to the China-wide entity.

Combination Rates

Consistent with the *Preliminary Determination* and Policy Bulletin 05.1,¹² Commerce calculated combination rates for the companies eligible for a separate rate.

Final Determination

Commerce determines that the following estimated weighted-average dumping margins exist:

Producer	Exporter	Weighted-average dumping margin (percent)	Cash deposit rate (percent) ¹³
Shandong Healsee Capsule Ltd	Shandong Healsee Capsule Ltd	18.71	18.71
Shanxi JC Biological Technology Co., Ltd	Shanxi JC Biological Technology Co., Ltd	0.00	0.00
Guizhou Guang De Li Pharmaceuticals Co., Ltd	Guizhou Guang De Li Pharmaceuticals Co., Ltd	18.71	18.71
Hebei Kangxin Plant Capsule Co., Ltd	Hebei Kangxin Plant Capsule Co., Ltd	18.71	18.71
Hubei Kornnac Pharmaceutical Co., Ltd ¹⁴	Hubei Kornnac Pharmaceutical Co., Ltd	18.71	18.71
Jiangsu Lefan Capsule Co., Ltd	Jiangsu Lefan Capsule Co., Ltd	18.71	18.71
Jiujiang Angtai Capsule Co., Ltd	Jiujiang Angtai Capsule Co., Ltd	18.71	18.71
Qingdao Yiqing Biotechnology Co., Ltd	Qingdao Yiqing Biotechnology Co., Ltd	18.71	18.71
Shaanxi Genex Bio-Tech Co., Ltd	Shaanxi Genex Bio-Tech Co., Ltd	18.71	18.71
Shanghai Guang De Li Capsule Co., Ltd	Shanghai Guang De Li Capsule Co., Ltd	18.71	18.71
Shanxi Guangsheng Medicinal Capsule Co., Ltd.; Shanxi Guangsheng Capsule Co., Ltd.	Shanxi Guangsheng Medicinal Capsule Co., Ltd.; Shanxi Guangsheng Capsule Co., Ltd ¹⁵ .	18.71	18.71
Shaoxing Kangke Capsule Co., Ltd	Shaoxing Kangke Capsule Co., Ltd	18.71	18.71
Shaoxing Renhe Capsule Co., Ltd	Shaoxing Renhe Capsule Co., Ltd	18.71	18.71
Xinchang County Hexin Capsule Co., Ltd	Xinchang County Hexin Capsule Co., Ltd	18.71	18.71
Xinchang County No.6 Capsule Factory	Xinchang Paulo Import And Export Co., Ltd	18.71	18.71
Shaoxing Kangke Capsule Co., Ltd	Xinchang Paulo Import And Export Co., Ltd	18.71	18.71
Zhejiang Huaguang Capsule Co., Ltd	Xinchang Paulo Import And Export Co., Ltd	18.71	18.71
Shanxi Guangsheng Capsule Co., Ltd	Xinchang Paulo Import And Export Co., Ltd	18.71	18.71
Zhejiang Pujiang Enerkang Capsule Co., Ltd	Xinchang Paulo Import And Export Co., Ltd	18.71	18.71
Yantai Oriental Pharmacap Co., Ltd	Yantai Oriental Pharmacap Co., Ltd	18.71	18.71
Ningbo Capsulcn Capsule Co., Ltd	Zhejiang Capsulcn Machinery Co., Ltd	18.71	18.71
Shaoxing Zhongya Capsules Industry Co., Ltd	Zhejiang Capsulcn Machinery Co., Ltd	18.71	18.71
Shandong Healsee Capsule Ltd	Zhejiang Capsulcn Machinery Co., Ltd	18.71	18.71
Zhejiang Guangjiyuan Biotechnology Co., Ltd	Zhejiang Capsulcn Machinery Co., Ltd	18.71	18.71
Zhejiang Huaguang Capsule Co., Ltd	Zhejiang Capsulcn Machinery Co., Ltd	18.71	18.71
Zhejiang Huaguang Capsule Co., Ltd	Zhejiang Huaguang Capsule Co., Ltd	18.71	18.71
Zhejiang Huili Capsules Co., Ltd	Zhejiang Huili Capsules Co., Ltd	18.71	18.71
Zhejiang Lujian Capsule Co., Ltd	Zhejiang Lujian Capsule Co., Ltd	18.71	18.71
China-Wide Entity		18.71	18.71

Disclosure

Commerce intends to disclose the calculations performed in connection with this final determination to interested parties within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this

notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, we instructed U.S. Customs and Border Protection (CBP) to suspend liquidation of subject merchandise entries, as described in Appendix I of

this notice, that were entered, or withdrawn from warehouse, for consumption on or after May 29, 2025, the date of publication of the *Preliminary Determination* in the **Federal Register**. In accordance with section 733(d) of the Act, we subsequently instructed CBP to discontinue the suspension of

¹⁰ See *Preliminary Determination*, 90 FR at 22705.

¹¹ *Id.*

¹² See Enforcement and Compliance's Policy Bulletin No. 05.1, regarding, “Separate-Rates Practice and Application of Combination Rates in Antidumping Investigations Involving Non-Market Economy Countries,” dated April 5, 2005 (Policy Bulletin 05.1), available on Commerce's website at <http://enforcement.trade.gov/policy/bull05-1.pdf>.

¹³ To determine the cash deposit rate, Commerce normally adjusts the estimated weighted-average dumping margin by the amount of export subsidies countervailed in a companion countervailing duty (CVD) proceeding, when CVD provisional measures are in effect. Accordingly, where Commerce has made a final affirmative determination for countervailable export subsidies, Commerce offsets

the estimated weighted-average dumping margin by the appropriate CVD rate. However, in the final determination of the companion CVD investigation of capsules from China, we found no export subsidies. See the unpublished **Federal Register** notice entitled “Hard Empty Capsules from the People's Republic of China: Final Affirmative Countervailing Duty Determination,” signed and dated concurrently with this **Federal Register** notice. Therefore, Commerce has not adjusted the cash deposit rate for export subsidies in the companion CVD investigation.

¹⁴ Hubei Kornnac Pharmaceutical Co., Ltd. (Hubei Kornnac) initially filed a separate rate application under the name “Hubei Humanwell Pharmaceutical Excipients Co., Ltd.” and subsequently notified Commerce that the company's name changed to

Hubei Kornnac. We preliminarily determined it was appropriate to allow the name change. See *Preliminary Determination*, 90 FR at 22705 n.13. No party commented on this determination; thus, we continue to find it is appropriate to allow the name change and grant Hubei Kornnac a separate rate.

¹⁵ In the *Preliminary Determination*, we listed the name of this company as “Shanxi Guangsheng Medicinal Capsule Co., Ltd. A.K.A. Shanxi Guangsheng Capsule Co., Ltd.” See *Preliminary Determination*, 90 FR at 22706. However, for customs purposes, the appropriate marker between a company's name and an “also known as” name is a semicolon; thus, we are correcting the format of the company's names for our final determination.

liquidation of all entries of subject merchandise entered or withdrawn from warehouse, on or after November 25, 2025, but to continue the suspension of liquidation of all entries of subject merchandise on or before November 24, 2025.

Because the estimated weighted-average dumping margin is zero for the Shanxi JC producer/exporter combination, we will discontinue the suspension of liquidation and refund all cash deposits already collected for this producer/exporter combination, pursuant to section 735(c)(2) of the Act, and we will exclude merchandise exported and produced by Shanxi JC from the antidumping duty order, in the event an order is instituted, in accordance with section 735(a)(4) of the Act and 19 CFR 351.204(e)(1). However, entries of shipments of subject merchandise from Shanxi JC in any other exporter/producer combination, or by third parties that sourced subject merchandise from the excluded producer/exporter combination, will be subject to suspension of liquidation at the China-wide entity rate.

Other than for entries produced and exported by Shanxi JC, if the U.S. International Trade Commission (ITC) issues a final affirmative injury determination, we will issue an antidumping duty order, reinstate the suspension of liquidation, and require a cash deposit for estimated weighted-average antidumping duties, in accordance with section 736(a) of the Act, as follows: (1) the cash deposit rate for the exporter/producer combinations listed in the table above will be the rate identified in the table; (2) for all combinations of Chinese exporters/producers of subject merchandise that have not received their own separate rate above, the cash deposit rate will be the cash deposit rate established for the China-wide entity; and (3) for all non-Chinese exporters of subject merchandise that have not received their own separate rate above, the cash deposit rate will be the cash deposit rate applicable to the Chinese exporter/producer combination that supplied that non-Chinese exporter.

If the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated, and all estimated duties deposited or securities posted as a result of the suspension of liquidation will be refunded or canceled.

ITC Notification

In accordance with section 735(d) of the Act, Commerce will notify the ITC of its final affirmative determination of sales at LTFV. Because Commerce's

final determination is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports, or sales (or the likelihood of sales) for importation, of capsules no later than 45 days after this final determination. If the ITC determines that material injury or threat of material injury does not exist, this proceeding will be terminated, all cash deposits will be refunded or canceled, and suspension of liquidation will be lifted. If the ITC determines that such injury does exist, Commerce will issue an antidumping duty order directing CBP to assess, upon further instructions by Commerce, antidumping duties on all imports of the subject merchandise that are entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation, as discussed above in the "Suspension of Liquidation" section above.

Administrative Protective Order (APO)

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

Notification to Interested Parties

This final determination is issued and published in accordance with sections 735(d) and 777(i) of the Act, and 19 CFR 351.210(c).

Dated: December 18, 2025.

Christopher Abbott,

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

Appendix I

Scope of the Investigation

The merchandise subject to the scope of the investigation is hard empty capsules, which are comprised of two prefabricated, hollowed cylindrical sections (cap and body). The cap and body pieces each have one closed and rounded end and one open end, and are constructed with different or equal diameters at their open ends.

Hard empty capsules are unfilled cylindrical shells composed of at least 80 percent by weight of a water soluble polymer that is considered non-toxic and appropriate for human or animal consumption by the United States Pharmacopeia—National

Formulary (USP–NF), Food Chemical Codex (FCC), or equivalent standards. The most common polymer materials in hard empty capsules are gelatin derived from animal collagen (including, but not limited to, pig, cow, or fish collagen), hydroxypropyl methylcellulose (HPMC), and pullulan.

Hard empty capsules may also contain water and additives, such as opacifiers, colorants, processing aids, controlled release agents, plasticizers, and preservatives. Hard empty capsules may also be imprinted or otherwise decorated with markings.

Hard empty capsules are covered by the scope of the investigation regardless of polymer material, additives, transparency, opacity, color, imprinting, or other markings.

Hard empty capsules are also covered by the scope of the investigation regardless of their size, weight, length, diameter, thickness, and filling capacity.

Cap and body pieces of hard empty capsules are covered by the scope of the investigation regardless of whether they are imported together or separately, and regardless of whether they are imported in attached or detached form.

Hard empty capsules covered by the scope of the investigation are those that disintegrate in water, simulated intestinal fluid, simulated gastric fluid, or other similar water-based (*i.e.*, aqueous) fluids within 2 hours under tests specified in Chapter 701 of the USP–NF, or equivalent disintegration tests.

Hard empty capsules are classifiable under subheadings 9602.00.1040 and 9602.00.5010 of the Harmonized Tariff Schedule of the United States (HTSUS). In addition, hard empty capsules may be imported under HTSUS subheading 1905.90.9090; gelatin hard empty capsules may be imported under HTSUS subheading 3503.00.5510; HPMC hard empty capsules may be imported under HTSUS subheading 3923.90.0080; and pullulan hard empty capsules may be imported under HTSUS subheading 2106.90.9998. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise covered by the investigation is dispositive.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Changes Since the *Preliminary Determination*
- IV. Application of Facts Available (AFA) and Use of Adverse Inference
- V. Discussion of the Issues
 - Comment 1: Application of AFA to Shandong Healsee's U.S. Expenses
 - Comment 2: Whether to Collapse Shandong Healsee with Its Affiliated Input Suppliers
 - Comment 3: Application of AFA to Shanxi JC
 - Comment 4: Whether to Include Freight Expenses in the Calculation of Shanxi JC's By-Product Input Costs
 - Comment 5: The Appropriate Short-Term Interest Rate for the Calculation of

Shanxi JC's Credit Expenses and Inventory Carrying Costs
 Comment 6: Whether the Turkish Starch Surrogate Value is Aberrational
 Comment 7: Selection of the Primary Surrogate Country
 Comment 8: Selection of Surrogate Financial Statements
 Comment 9: Differential Pricing Test
 VI. Recommendation

[FR Doc. 2025-23824 Filed 12-23-25; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-552-847]

Hard Empty Capsules From the Socialist Republic of Vietnam: Final Affirmative Determination of Sales at Less Than Fair Value

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

SUMMARY: The U.S. Department of Commerce (Commerce) determines that hard empty capsules (capsules) from the Socialist Republic of Vietnam (Vietnam) are being, or are likely to be, sold in the United States at less than fair value (LTFV) for the period of investigation April 1, 2024, through September 30, 2024.

DATES: Applicable December 29, 2025.

FOR FURTHER INFORMATION CONTACT:

Jinny Ahn or Harrison Tanchuck, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-0339 or (202) 482-7421, respectively.

SUPPLEMENTARY INFORMATION:

Background

On May 29, 2025, Commerce published in the **Federal Register** its preliminary affirmative determination in the LTFV investigation of capsules from Vietnam, in which it also postponed the final determination until October 14, 2025.¹ On July 23, 2025, Commerce issued a post-preliminary analysis memorandum in which it made certain changes to its differential pricing analysis.² We invited interested parties

to comment on the *Preliminary Determination* and changes to the differential pricing analysis.³

Due to the lapse in appropriations and Federal Government shutdown, on November 14, 2025, Commerce tolled all deadlines in administrative proceedings by 47 days.⁴ Additionally, due to a backlog of documents that were electronically filed via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS) during the Federal Government shutdown, on November 24, 2025, Commerce tolled all deadlines in administrative proceedings by an additional 21 days.⁵ Accordingly, the deadline for this final determination is now December 18, 2025.

A summary of the events that occurred since the *Preliminary Determination*, as well as a full discussion of the issues raised by parties for this final determination, may be found in the Issues and Decision Memorandum.⁶ The Issues and Decision Memorandum is a public document and is on file electronically via ACCESS. ACCESS is available to registered users at <http://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Scope of the Investigation

The products covered by this investigation are capsules from Vietnam. For a complete description of the scope of this investigation, see Appendix I.

Scope Comments

In the Preliminary Scope Memorandum, we set aside a period of time for parties to raise issues regarding product coverage (*i.e.*, scope) in scope-specific case briefs or other written comments.⁷ We received scope case and

Empty Capsules from the Socialist Republic of Vietnam," dated July 23, 2025 (Post-Preliminary Analysis).

³ See Memorandum, "Briefing Schedule," dated August 14, 2025.

⁴ See Memorandum, "Deadlines Affected by the Shutdown of the Federal Government," dated November 14, 2025.

⁵ See Memorandum, "Tolling of all Case Deadlines," dated November 24, 2025.

⁶ See Memorandum, "Issues and Decision Memorandum for the Final Affirmative Determination of Sales at Less Than Fair Value in the Investigation of Hard Empty Capsules from the Socialist Republic of Vietnam," dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

⁷ See Memorandum, "Less-Than-Fair-Value and Countervailing Duty Investigations of Hard Empty Capsules from Brazil, the People's Republic of China, India, and the Socialist Republic of Vietnam:

rebuttal briefs from multiple interested parties. For a summary of the product coverage comments and rebuttal response submitted to the record for this final determination, and accompanying discussion and analysis of all comments timely received, see the Final Scope Memorandum.⁸ In the Final Scope Memorandum, Commerce determined that it is modifying the scope language as it appeared in the *Initiation Notice*.⁹ See Appendix I.

Verification

Commerce conducted verification of the information relied upon in making its final determination in this investigation, in accordance with section 782(i) of the Tariff Act of 1930, as amended (the Act). Specifically, we conducted on-site verifications of sales and cost information submitted by Suheung Vietnam Co., Ltd. (SHVN) for use in our final determination. We used standard verification procedures, including an examination of relevant sales and accounting records, and original source documents provided by SHVN.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs submitted by interested parties in this investigation are addressed in the Issues and Decision Memorandum. A list of the issues addressed in the Issues and Decision Memorandum is attached to this notice as Appendix II.

Changes Since the Preliminary Determination

We made certain changes to the margin calculation for SHVN since the *Preliminary Determination* and Post-Preliminary Analysis. For a discussion of these changes, see the Issues and Decision Memorandum.

Use of Adverse Facts Available

Commerce finds that, pursuant to sections 776(a)(2)(B) and (C) of the Act, the use of partial adverse facts available is warranted in determining the

Scope Comments Decision Memorandum for the Preliminary Determination," dated March 24, 2025 (Preliminary Scope Memorandum).

⁸ See Memorandum, "Less-Than-Fair-Value Investigations of Hard Empty Capsules from Brazil, the People's Republic of China, India, and the Socialist Republic of Vietnam and Countervailing Duty Investigations from Brazil, the People's Republic of China, India, and the Socialist Republic of Vietnam: Final Scope Decision Memorandum," dated concurrently with this notice (Final Scope Memorandum).

⁹ See *Hard Empty Capsules From Brazil, the People's Republic of China, India, and the Socialist Republic of Vietnam: Initiation of Less-Than-Fair-Value Investigations*, 89 FR 91684 (November 20, 2024) (*Initiation Notice*).

¹ See *Hard Empty Capsules from the Socialist Republic of Vietnam: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Extension of Provisional Measures*, 90 FR 22708 (May 29, 2025) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum (PDM).

² See Memorandum, "Post-Preliminary Analysis in the Less-Than-Fair-Value Investigation of Hard

dumping rate for SHVN. For further discussion, see the Issues and Decision Memorandum.

Separate Rate Company and the Vietnam-Wide Entity

We preliminarily granted a separate rate to SHVN, the sole company that submitted a separate rate application in this investigation.¹⁰ We received no comments from interested parties on Commerce's preliminary separate rate determination for SHVN. Accordingly, we continue to find that SHVN is eligible for a separate rate. Additionally,

because we preliminarily did not find that the Vietnam-wide entity failed to cooperate in this investigation, we preliminarily assigned the estimated weighted-average dumping margins calculated for SHVN as the estimated weighted-average dumping margin for the Vietnam-wide entity. No party commented on our preliminary separate rate determination or our finding with respect to the Vietnam-wide entity. Therefore, we continue to find that SHVN is eligible for a separate rate. We also continue to assign the estimated

weighted-average dumping margins calculated for SHVN to the Vietnam-wide entity.

Combination Rates

Consistent with the *Preliminary Determination* and Policy Bulletin 05.1,¹¹ Commerce calculated combination rates for the company eligible for a separate rate.

Final Determination

Commerce determines that the following estimated weighted-average dumping margins exist:

Producer	Exporter	Weighted-average dumping margin (percent)	Cash deposit rate (adjusted for export subsidy offset) (percent) ¹²
Suheung Vietnam Co., Ltd	Suheung Vietnam Co., Ltd	47.12	46.24
Vietnam-Wide Entity		47.12	46.24

Disclosure

Commerce intends to disclose the calculations performed in connection with this final determination to interested parties within five days after public announcement or, if there is no public announcement, within five days of the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, we instructed U.S. Customs and Border Protection (CBP) to suspend liquidation of all entries of subject merchandise, as described in Appendix I of this notice, which are entered, or withdrawn from warehouse, for consumption on or after May 29, 2025, the date of publication of the *Preliminary Determination* in the **Federal Register**. In accordance with section 733(d) of the Act, we instructed CBP to discontinue the suspension of liquidation of all entries of subject merchandise entered or withdrawn from warehouse, on or after November 25, 2025, but to continue the suspension of liquidation of all entries of subject merchandise on or before November 24, 2025.

If the U.S. International Trade Commission (ITC) issues a final affirmative injury determination, we will issue an antidumping duty order,

reinstate the suspension of liquidation under section 736(a) of the Act, and require a cash deposit of estimated antidumping duties for such entries of subject merchandise in the amounts indicated above, in accordance with section 736(a) of the Act, as follows: (1) the cash deposit rate for the exporter/producer combinations listed in the table above will be the rate identified in the table; (2) for all combinations of Vietnamese exporters/producers of subject merchandise that have not received their own separate rate above, the cash deposit rate will be the cash deposit rate established for the Vietnam-wide entity; and (3) for all non-Vietnamese exporters of subject merchandise that have not received their own separate rate above, the cash deposit rate will be the cash deposit rate applicable to the Vietnamese exporter/producer combination that supplied that non-Vietnamese exporter.

If the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated, and all estimated duties deposited or securities posted as a result of the suspension of liquidation will be refunded or canceled.

To determine the cash deposit rate, Commerce normally adjusts the estimated weighted-average dumping margin by the amount of export subsidies countervailed in a companion countervailing duty (CVD) investigation,

when CVD provisional measures are in effect. Accordingly, where Commerce made an affirmative determination for countervailable export subsidies, Commerce would offset the estimated weighted-average dumping margins by the appropriate export subsidy rate.¹³ Any such adjusted cash deposit rates may be found in the "Final Determination" section above. If the U.S. International Trade Commission (ITC) makes a final affirmative determination of injury due to both dumping and subsidies, then the cash deposit rate will include the offsets for the export subsidies collected as part of the CVD final determination.

ITC Notification

In accordance with section 735(d) of the Act, Commerce will notify the ITC of its final affirmative determination of sales at LTFV. Because Commerce's final determination is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports, or sales (or the likelihood of sales) for importation, of capsules no later than 45 days after this final determination. If the ITC determines that material injury or threat of material injury does not exist, this proceeding will be terminated, all cash deposits will be refunded or

dated concurrently with this notice (CVD Final Determination). For the Vietnam-wide entity, we continue to calculate the adjusted cash deposit rate by deducting the export subsidy rate calculated for SHVN in the companion CVD Final Determination.

¹³ See *Preliminary Determination* PDM at 24–26.

¹⁰ See *Preliminary Determination*, 90 FR at 22708.

¹¹ See Enforcement and Compliance's Policy Bulletin No. 05.1, regarding, "Separate-Rates Practice and Application of Combination Rates in Antidumping Investigations Involving Non-Market Economy Countries," dated April 5, 2005 (Policy

Bulletin 05.1), available on Commerce's website at <http://enforcement.trade.gov/policy/bull05-1.pdf>.

¹² We are applying an export subsidy offset to the mandatory respondent. See unpublished **Federal Register** notice entitled, "Hard Empty Capsules from the Socialist Republic of Vietnam: Final Affirmative Countervailing Duty Determination,"

canceled, and suspension of liquidation will be lifted. If the ITC determines that such injury does exist, Commerce will issue an antidumping duty order directing CBP to assess, upon further instructions by Commerce, antidumping duties on all imports of the subject merchandise that are entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation, as discussed above in the “Suspension of Liquidation” section.

Administrative Protective Order (APO)

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

Notification to Interested Parties

This final determination is issued and published in accordance with sections 735(d) and 777(i) of the Act, and 19 CFR 351.210(c).

Dated: December 18, 2025.

Christopher Abbott,

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

Appendix I

Scope of the Investigation

The merchandise subject to the scope of this investigation is hard empty capsules, which are comprised of two prefabricated, hollowed cylindrical sections (cap and body). The cap and body pieces each have one closed and rounded end and one open end, and are constructed with different or equal diameters at their open ends.

Hard empty capsules are unfilled cylindrical shells composed of at least 80 percent by weight of a water soluble polymer that is considered non-toxic and appropriate for human or animal consumption by the United States Pharmacopeia—National Formulary (USP–NF), Food Chemical Codex (FCC), or equivalent standards. The most common polymer materials in hard empty capsules are gelatin derived from animal collagen (including, but not limited to, pig, cow, or fish collagen), hydroxypropyl methylcellulose (HPMC), and pullulan.

Hard empty capsules may also contain water and additives, such as opacifiers, colorants, processing aids, controlled release agents, plasticizers, and preservatives. Hard empty capsules may also be imprinted or otherwise decorated with markings.

Hard empty capsules are covered by the scope of this investigation regardless of

polymer material, additives, transparency, opacity, color, imprinting, or other markings.

Hard empty capsules are also covered by the scope of this investigation regardless of their size, weight, length, diameter, thickness, and filling capacity.

Cap and body pieces of hard empty capsules are covered by the scope of this investigation regardless of whether they are imported together or separately, and regardless of whether they are imported in attached or detached form.

Hard empty capsules covered by the scope of this investigation are those that disintegrate in water, simulated intestinal fluid, simulated gastric fluid, or other similar water-based (*i.e.*, aqueous) fluids within 2 hours under tests specified in Chapter 701 of the USP–NF, or equivalent disintegration tests.

Hard empty capsules are classifiable under subheadings 9602.00.1040 and 9602.00.5010 of the Harmonized Tariff Schedule of the United States (HTSUS). In addition, hard empty capsules may be imported under HTSUS subheading 1905.90.9090; gelatin hard empty capsules may be imported under HTSUS subheading 3503.00.5510; HPMC hard empty capsules may be imported under HTSUS subheading 3923.90.0080; and pullulan hard empty capsules may be imported under HTSUS subheading 2106.90.9998. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise covered by this investigation is dispositive.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Adjustment to Cash Deposit Rate for Export Subsidies
- IV. Changes Since the *Preliminary Determination*
- V. Application of Facts Available and Use of Adverse Inference
- VI. Discussion of the Issues
 - Comment 1: Total Adverse Facts Available (AFA)
 - Comment 2: Selection of the Primary Surrogate Country
 - Comment 3: Unreported Packing Inputs
 - Comment 4: Calculation of Surrogate Financial Ratios
 - Comment 5: Unreported Supplier Distances
- VII. Recommendation

[FR Doc. 2025–23828 Filed 12–23–25; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–185]

Hard Empty Capsules From the People’s Republic of China: Final Affirmative Countervailing Duty Determination

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

SUMMARY: The U.S. Department of Commerce (Commerce) determines that countervailable subsidies are being provided to producers and exporters of hard empty capsules (capsules) from the People’s Republic of China (China). The period of investigation is January 1, 2023, through December 31, 2023.

DATES: Applicable December 29, 2025.

FOR FURTHER INFORMATION CONTACT:

Laura Delgado or John Conniff, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1468 or (202) 482–1009, respectively.

SUPPLEMENTARY INFORMATION:

Background

On March 31, 2025, Commerce published the *Preliminary Determination* in the **Federal Register**, invited interested parties to comment.¹ In the *Preliminary Determination*, and in accordance with section 705(a)(1) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.210(b)(4), Commerce aligned the final CVD determination with the final investigation of capsules from China.²

Due to the lapse in appropriations and Federal Government shutdown, on November 14, 2025, Commerce tolled all deadlines in administrative proceedings by 47 days.³ Additionally, due to a backlog of documents that were electronically filed via Enforcement and Compliance’s Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS) during the Federal Government shutdown, on November 24, 2025,

¹ See *Hard Empty Capsules from the People’s Republic of China: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Determination with Final Antidumping Duty Determination*, 90 FR 14244 (March 31, 2025) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum (PDM).

² *Id.*

³ See Memorandum, “Deadlines Affected by the Shutdown of the Federal Government,” dated November 14, 2025.

Commerce tolled all deadlines in administrative proceedings by an additional 21 days.⁴ Accordingly, the deadline for this final determination is now December 18, 2025.

For a complete discussion of the events that followed the *Preliminary Determination*, see the Issues and Decision Memorandum.⁵ The Issues and Decision Memorandum is a public document and is made available to the public via ACCESS. ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Scope of the Investigation

The products covered by this investigation are capsules from China. For a complete description of the scope of this investigation, see Appendix I.

Scope Comments

In the Preliminary Scope Memorandum, we set aside a period of time for parties to raise issues regarding product coverage (*i.e.*, scope) in scope-specific case briefs or other written comments.⁶ We received scope case and rebuttal briefs from multiple interested parties. For a summary of the product coverage comments and rebuttal response submitted to the record for this final determination, and accompanying discussion and analysis of all comments timely received, see the Final Scope Memorandum.⁷ In the Final Scope Memorandum, Commerce determined that it is modifying the scope language as it appeared in the *Initiation Notice*.⁸ See Appendix I.

⁴ See Memorandum, "Tolling of all Case Deadlines," dated November 24, 2025.

⁵ See Memorandum, "Issues and Decision Memorandum for the Final Affirmative Determination of the Countervailing Duty Investigation of Hard Empty Capsules from the People's Republic of China," dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

⁶ See Memorandum, "Less-Than-Fair-Value Investigations of Hard Empty Capsules from Brazil, the People's Republic of China, India, and the Socialist Republic of Vietnam and Countervailing Duty Investigations from Brazil, the People's Republic of China, India, and the Socialist Republic of Vietnam: Preliminary Scope Decision Memorandum," dated March 24, 2025 (Preliminary Scope Memorandum).

⁷ See Memorandum, "Less-Than-Fair-Value Investigations of Hard Empty Capsules from Brazil, the People's Republic of China, India, and the Socialist Republic of Vietnam and Countervailing Duty Investigations from Brazil, the People's Republic of China, India, and the Socialist Republic of Vietnam: Final Scope Decision Memorandum," dated concurrently with this notice (Final Scope Memorandum).

⁸ See *Hard Empty Capsules from Brazil, the People's Republic of China, India, and the Socialist*

Verification

As provided in section 782(i) the Act, in April 2025, Commerce verified the information reported by Jiangsu Lefan Capsule Co., Ltd. (Jiangsu Lefan) and Shanxi JC Biological Technology Co., Ltd. (Shanxi JC) for use in our final determination. We used standard verification procedures, including an examination of relevant accounting records and original source documents provided at verification.⁹

Analysis of Subsidy Programs and Comments Received

The subsidy programs under investigation and the issues raised in the case and rebuttal briefs that were submitted by interested parties in this investigation are discussed in the Issues and Decision Memorandum. For a list of the issues raised by interested parties and addressed in the Issues and Decision Memorandum, see Appendix II to this notice.

Methodology

Commerce conducted this investigation in accordance with section 701 of the Act. For each of the subsidy programs found to be countervailable, Commerce determines that there is a subsidy, *i.e.*, a financial contribution by an "authority" that gives rise to a benefit to the recipient, and that the subsidy is specific.¹⁰ For a full description of the methodology underlying our final determination, see the Issues and Decision Memorandum.

In making this final determination, Commerce relied, in part, on facts otherwise available, including with an adverse inference, pursuant to sections 776(a) and (b) of the Act. For a full discussion of our application of adverse facts available (AFA), see the *Preliminary Determination*¹¹ and the Issues and Decision Memorandum at the section entitled "Use of Facts Available and Application of Adverse Inferences."

Changes Since the Preliminary Determination

Based on our review and analysis of the information received during verification and comments received from parties, for this final

Republic of Vietnam: Initiation of Countervailing Duty Investigations, 89 FR 91680 (November 20, 2024) (*Initiation Notice*).

⁹ See Memoranda, "Verification of the Questionnaire Responses of Jiangsu Lefan Capsule Co., Ltd.," dated May 29, 2025; and "Verification of the Questionnaire Responses of Shanxi JC Biological Technology," dated May 28, 2025.

¹⁰ See sections 771(5)(B) and (D) of the Act regarding financial contribution; see also section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

¹¹ See *Preliminary Determination PDM* at 6–16.

determination, we made certain changes to the countervailable subsidy rate calculations for Jiangsu Lefan, Shanxi JC, and for all other producers/exporters.¹² For a discussion of these changes, see the Issues and Decision Memorandum.

All-Others Rate

Section 705(c)(5)(A)(i) of the Act states that, for companies not individually investigated, Commerce will determine an all-others rate equal to the weighted-average countervailable subsidy rates established for exporters and/or producers individually investigated, excluding any zero and *de minimis* countervailable subsidy rates, and any rates determined entirely under section 776 of the Act.

Commerce calculated individual estimated countervailable subsidy rates for Jiangsu Lefan and Shanxi JC that are not zero, *de minimis*, or based entirely on facts otherwise available. Commerce calculated the all-others rate using a weighted average of the individual estimated subsidy rates calculated for the examined respondents using each company's publicly-ranged values for the merchandise under consideration.¹³

Final Determination

Commerce determines that the following estimated countervailable subsidy rates exist for the period January 1, 2023, through December 31, 2023:

Company	Subsidy rate (percent <i>ad valorem</i>)
Jiangsu Lefan Capsule Co., Ltd	3.14
Shanxi JC Biological Co. Ltd	8.81
All Others	6.90

¹² See Issues and Decision Memorandum at 3.

¹³ With two respondents under examination, Commerce normally calculates: (A) a weighted-average of the estimated subsidy rates calculated for the examined respondents; (B) a simple average of the estimated subsidy rates calculated for the examined respondents; and (C) a weighted-average of the estimated subsidy rates calculated for the examined respondents using each company's publicly-ranged U.S. sale values for the merchandise under consideration. Commerce then compares (B) and (C) to (A) and selects the rate closest to (A) as the most appropriate rate for all other producers and exporters. See, *e.g.*, *Ball Bearings and Parts Thereof from France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews, Final Results of Changed-Circumstances Review, and Revocation of an Order in Part*, 75 FR 53661, 53662 (September 1, 2010), and accompanying Issues and Decision Memorandum at Comment 1. As complete publicly ranged sales data were available, Commerce based the all-others rate on the publicly ranged sales data of the mandatory respondents. For a complete analysis of the data, see Memorandum, "Calculation of Subsidy Rate for All Others," dated concurrently with this notice.

Disclosure

Commerce intends to disclose its calculations performed to interested parties in this final determination within five days of its public announcement or, if there is no public announcement, within five days of the date of the publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Suspension of Liquidation

As a result of our *Preliminary Determination*, and pursuant to sections 703(d)(1)(B) and (d)(2) of the Act, we instructed U.S. Customs and Border Protection (CBP) to collect cash deposits and suspend liquidation of entries of subject merchandise from China that were entered, or withdrawn from warehouse, for consumption, on or after March 31, 2025, the date of the publication of the *Preliminary Determination* in the **Federal Register**.¹⁴ In accordance with section 703(d) of the Act, we instructed CBP to discontinue the suspension of liquidation of all entries of subject merchandise entered or withdrawn from warehouse, on or after July 29, 2025 but to continue the suspension of liquidation of all entries of subject merchandise on or before July 28, 2025.

If the U.S. International Trade Commission (ITC) issues a final affirmative injury determination, we will issue a countervailing duty (CVD) order, reinstate the suspension of liquidation under section 706(a) of the Act, and require a cash deposit of estimated countervailing duties for entries of subject merchandise in the amounts indicated above. Pursuant to section 705(c)(2) of the Act, if the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated, and all estimated duties deposited or securities posted as a result of the suspension of liquidation will be refunded or cancelled.

U.S. International Trade Commission Notification

In accordance with section 705(d) of the Act, Commerce will notify the ITC of its final affirmative determination that countervailable subsidies are being provided to producers and exporters of capsules from China. As Commerce's final determination is affirmative, in accordance with section 705(b) of the Act, the ITC will determine, within 45 days, whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of import of capsules from China.

In addition, we are making available to the ITC all non-privileged and non-proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under administrative protective order (APO), without the written consent of the Assistant Secretary for Enforcement and Compliance. If the ITC determines that material injury or threat of material injury does not exist, this proceeding will be terminated, and all cash deposits will be refunded. If the ITC determines that such injury does exist, Commerce will issue a CVD order directing CBP to assess, upon further instruction by Commerce, countervailing duties on all imports of the subject merchandise that are entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation, as discussed above in the "Suspension of Liquidation" section.

Administrative Protective Order

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

Notification to Interested Parties

This determination is issued and published in accordance with sections 705(d) and 777(i) of the Act, and 19 CFR 351.210(c).

Dated: December 18, 2025.

Christopher Abbott,

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

Appendix I

Scope of the Investigation

The merchandise subject to the scope of this investigation is hard empty capsules, which are comprised of two prefabricated, hollowed cylindrical sections (cap and body). The cap and body pieces each have one closed and rounded end and one open end, and are constructed with different or equal diameters at their open ends.

Hard empty capsules are unfilled cylindrical shells composed of at least 80 percent by weight of a water soluble polymer that is considered non-toxic and appropriate for human or animal consumption by the United States Pharmacopeia—National Formulary (USP—NF), Food Chemical Codex (FCC), or equivalent standards. The most

common polymer materials in hard empty capsules are gelatin derived from animal collagen (including, but not limited to, pig, cow, or fish collagen), hydroxypropyl methylcellulose (HPMC), and pullulan.

Hard empty capsules may also contain water and additives, such as opacifiers, colorants, processing aids, controlled release agents, plasticizers, and preservatives. Hard empty capsules may also be imprinted or otherwise decorated with markings.

Hard empty capsules are covered by the scope of this investigation regardless of polymer material, additives, transparency, opacity, color, imprinting, or other markings.

Hard empty capsules are also covered by the scope of this investigation regardless of their size, weight, length, diameter, thickness, and filling capacity.

Cap and body pieces of hard empty capsules are covered by the scope of this investigation regardless of whether they are imported together or separately, and regardless of whether they are imported in attached or detached form.

Hard empty capsules covered by the scope of this investigation are those that disintegrate in water, simulated intestinal fluid, simulated gastric fluid, or other similar water-based (*i.e.*, aqueous) fluids within 2 hours under tests specified in Chapter 701 of the USP—NF, or equivalent disintegration tests.

Hard empty capsules are classifiable under subheadings 9602.00.1040 and 9602.00.5010 of the Harmonized Tariff Schedule of the United States (HTSUS). In addition, hard empty capsules may be imported under HTSUS subheading 1905.90.9090; gelatin hard empty capsules may be imported under HTSUS subheading 3503.00.5510; HPMC hard empty capsules may be imported under HTSUS subheading 3923.90.0080; and pullulan hard empty capsules may be imported under HTSUS subheading 2106.90.9998. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise covered by this investigation is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Investigation
- IV. Subsidies Valuation
- V. Use of Facts Otherwise Available and Application of Adverse Inferences
- VI. Changes Since the *Preliminary Determination*
- VII. Analysis of Programs
- VIII. Discussion of the Issues
 - Comment 1: Whether Commerce Should Apply Total Adverse Facts Available (AFA) to Shanxi JC
 - Comment 2: Whether Commerce Should Apply AFA in Determining the Benefit to Shanxi JC from the Provision of Land-Use Rights for Less Than Adequate Remuneration (LTAR)
 - Comment 3: Whether Commerce Should Continue to Countervail the Provision of Electricity for LTAR

¹⁴ See *Preliminary Determination*, 90 FR at 14245.

Comment 4: Whether Commerce Should Change the Benchmarks for Electricity for LTAR

Comment 5: Whether Commerce Miscalculated Electricity for LTAR for Jiangsu Lefan

Comment 6: Whether Commerce Should Continue to Countervail the Provision of Land-Use Rights for LTAR

Comment 7: Whether Commerce Should Continue to Countervail Other Subsidies

Comment 8: Whether Commerce Has or Should Countervail Grants Received Before the Average Useful Life Period

Comment 9: Whether Commerce Should Correct an Erroneously Deducted Benchmark Payment When Calculating Loan Benefits

IX. Recommendation

[FR Doc. 2025–23825 Filed 12–23–25; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–555–006]

Paper File Folders From the Kingdom of Cambodia: Final Affirmative Countervailing Duty Determination

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

SUMMARY: The U.S. Department of Commerce (Commerce) determines that countervailable subsidies are being provided to producers and exporters of paper file folders from the Kingdom of Cambodia (Cambodia). The period of investigation (POI) is January 1, 2023, through December 31, 2023.

DATES: Applicable December 29, 2025.

FOR FURTHER INFORMATION CONTACT:

Shane Subler or Brandon James, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–6241 and (202) 482–7472, respectively.

SUPPLEMENTARY INFORMATION:

Background

On March 28, 2025, Commerce published the *Preliminary Determination* in the **Federal Register**, invited interested parties to comment on the *Preliminary Determination*, and aligned this countervailing duty investigation with the final determination in the less-than-fair value investigation of paper file folders from Cambodia, in accordance with section 705(a)(1) of the Tariff Act of 1930, as amended (the Act), and 19 CFR

351.210(b)(4).¹ On August 27, 2025, Commerce released its Post-Preliminary Analysis.²

Due to the lapse in appropriations and Federal Government shutdown, on November 14, 2025, Commerce tolled all deadlines in administrative proceedings by 47 days.³ Additionally, due to a backlog of documents that were electronically filed via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS) during the Federal Government shutdown, on November 24, 2025, Commerce tolled all deadlines in administrative proceedings by an additional 21 days.⁴ Accordingly, the deadline for this final determination is now December 18, 2025.

For a complete discussion of the events that followed the *Preliminary Determination*, see the Issues and Decision Memorandum.⁵ The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Scope of the Investigation

The products covered by this investigation are paper file folders. For a complete description of the scope of this investigation, see Appendix I.

Scope Comments

No interested party commented on the scope of the investigation as it appeared in the *Preliminary Determination*.

¹ See *Paper File Folders From the Kingdom of Cambodia: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Determination With Final Antidumping Duty Determination*, 90 FR 14110 (March 28, 2025) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum (PDM).

² See Memorandum, “Decision Memorandum for the Post-Preliminary Analysis in the Countervailing Duty Investigation of Paper File Folders from the Kingdom of Cambodia,” dated August 27, 2025 (Post-Preliminary Analysis).

³ See Memorandum, “Deadlines Affected by the Shutdown of the Federal Government,” dated November 14, 2025.

⁴ See Memorandum, “Tolling of All Case Deadlines,” dated November 24, 2025.

⁵ See Memorandum, “Issues and Decision Memorandum for the Final Affirmative Determination of the Countervailing Duty Investigation of Paper File Folders from the Kingdom of Cambodia,” dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

Therefore, no changes were made to the scope of the investigation.

Verification

As provided in section 782(i) of the Act, in July 2025, Commerce conducted on-site verification of the subsidy information reported by the Royal Government of Cambodia (RCG) and Three Color Stone Stationery (Cambodia) Co., Ltd. (TCS). We used standard verification procedures, including an examination of relevant accounting records and original source documents provided by the RGC and TCS.⁶

Analysis of Subsidy Programs and Comments Received

The subsidy programs under investigation and the issues raised in the case and rebuttal briefs submitted by interested parties in this investigation are discussed in the Issues and Decision Memorandum. For a list of the issues raised by interested parties and addressed in the Issues and Decision Memorandum, see Appendix II.

Methodology

Commerce conducted this investigation in accordance with section 701 of the Act. For each of the subsidy programs found to be countervailable, Commerce determines that there is a subsidy, *i.e.*, a financial contribution by an “authority” that gives rise to a benefit to the recipient, and that the subsidy is specific.⁷ For a full description of the methodology underlying our final determination, see the Issues and Decision Memorandum.

In making this final determination, Commerce relied, in part, on facts otherwise available, including with adverse inferences, pursuant to sections 776(a) and (b) of the Act. For a full discussion of our application of adverse facts available (AFA), see the Issues and Decision Memorandum at the section entitled “Use of Facts Otherwise Available and Application of Adverse Inferences.”

Changes Since the Preliminary Determination

For this final determination, we have included an additional subsidy program addressed in the Post-Preliminary

⁶ See Memorandum, “Verification of the Questionnaire Responses of Three Color Stone Stationery (Cambodia) Co., Ltd.,” dated August 11, 2025; see also Memorandum, “Verification of the Questionnaire Responses of the Royal Government of Cambodia,” dated August 18, 2025.

⁷ See sections 771(5)(B) and (D) of the Act regarding financial contribution; see also section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

Analysis.⁸ Based on our review and analysis of the information at verification and comments received from interested parties, we made no changes to the subsidy rate calculations for TCS and all other producers and/or exporters from the *Preliminary Determination* and Post-Preliminary Analysis. For further discussion, see the Issues and Decision Memorandum.

All-Others Rate

In accordance with section 705(c)(1)(B)(i) of the Act, we calculated an individual estimated countervailable subsidy rate for the mandatory respondent, TCS. Section 705(c)(5)(A)(i) of the Act states that, for companies not individually investigated, Commerce will determine an all-others rate equal to the weighted-average countervailable subsidy rates established for exporters and/or producers individually investigated, excluding any zero and *de minimis* countervailable subsidy rates, and any rates determined entirely under section 776 of the Act. For this final determination, TCS’s subsidy rate is not zero, *de minimis*, or determined entirely under section 776 of the Act. Consequently, we have assigned the subsidy rate calculated for TCS as the rate for all other producers and/or exporters.

Final Determination

Commerce determines that the following estimated countervailable subsidy rates exist for the period January 1, 2023, through December 31, 2023:

Company	Subsidy rate (percent <i>ad valorem</i>)
Three Color Stone Stationery (Cambodia) Co., Ltd	930.38
All Others	30.38

Disclosure

Commerce normally discloses the calculations for a final determination to interested parties within five days of any public announcement or, if there is no public announcement, within five days of the date of the publication of the notice in the **Federal Register**, in accordance with 19 CFR 351.224(b). However, because we have made no changes to the calculations from the

⁸ See Post-Preliminary Analysis at 14–15.
⁹ TCS’s subsidy rate in the *Preliminary Determination* was 21.53 percent *ad valorem*. The subsidy rate for the additional program addressed in the Post-Preliminary Analysis was 8.85 percent *ad valorem*. See *Preliminary Determination*, 90 FR at 14111; see also Post-Preliminary Analysis at 15. The sum of these two rates is 30.38 percent *ad valorem*.

Preliminary Determination and Post-Preliminary Analysis, there are no new calculations to disclose.

Suspension of Liquidation

As a result of our *Preliminary Determination*, and pursuant to sections 703(d)(1)(B) and (d)(2) of the Act, Commerce instructed U.S. Customs and Border Protection (CBP) to collect cash deposits and suspend liquidation of entries of subject merchandise as described in the scope of the investigation section entered, or withdrawn from warehouse, for consumption on or after March 28, 2025, the date of publication of the *Preliminary Determination* in the **Federal Register**. In accordance with section 703(d) of the Act, on July 28, 2025, we instructed CBP to discontinue the suspension of liquidation of all entries of subject merchandise entered or withdrawn from warehouse on or after July 26, 2025, but to continue the suspension of liquidation of all entries of subject merchandise on or after March 28, 2025, to on or before July 25, 2025.

If the U.S. International Trade Commission (ITC) issues a final affirmative injury determination, we will issue a countervailing duty order, reinstate the suspension of liquidation under section 706(a) of the Act, and require a cash deposit of estimated countervailing duties for such entries of subject merchandise in the amounts indicated above, in accordance with section 706(a) of the Act. If the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated, and all estimated duties deposited or securities posted as a result of the suspension of liquidation will be refunded or canceled.

ITC Notification

In accordance with section 705(d) of the Act, Commerce will notify the ITC of its final affirmative determination that countervailable subsidies are being provided to producers and exporters of paper file folders from Cambodia. As Commerce’s final determination is affirmative, in accordance with section 705(b) of the Act, the ITC will determine, within 45 days, whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of paper file folders from Cambodia. In addition, we are making available to the ITC all non-privileged and non-proprietary information related to this investigation. We will allow the ITC access to all privileged and business proprietary information in our files,

provided the ITC confirms that it will not disclose such information, either publicly or under an administrative protective order, without the written consent of the Assistant Secretary for Enforcement and Compliance. If the ITC determines that material injury does not exist, this proceeding will be terminated and all cash deposits will be refunded.

If the ITC determines that such injury does exist, Commerce will issue a countervailing duty order directing CBP to assess, upon further instruction by Commerce, countervailing duties on all imports of the subject merchandise that are entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation, as discussed above in the “Continuation of Suspension of Liquidation” section.

Administrative Protective Order (APO)

In the event that the ITC issues a final negative injury determination, this notice will serve as the only reminder to parties subject to an APO of their responsibility concerning the destruction of proprietary information disclosed under APO, in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/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 violation which is subject to sanction.

Notification to Interested Parties

This determination is issued and published in accordance with sections 705(d) and 777(i) of the Act, and 19 CFR 351.210(c).

Dated: December 18, 2025.

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

Appendix I

Scope of the Investigation

The products within the scope of this investigation are file folders consisting primarily of paper, paperboard, pressboard, or other cellulose material, whether coated or uncoated, that has been folded (or creased in preparation to be folded), glued, taped, bound, or otherwise assembled to be suitable for holding documents. The scope includes all such folders, regardless of color, whether or not expanding, whether or not laminated, and with or without tabs, fasteners, closures, hooks, rods, hangers, pockets, gussets, or internal dividers. The term “primarily” as used in the first sentence of this scope means 50 percent or more of the total product weight, exclusive of the weight of fasteners, closures, hooks, rods, hangers, removable

tabs, and similar accessories, and exclusive of the weight of the packaging.

Subject folders have the following dimensions in their folded and closed position: lengths and widths of at least 8 inches and no greater than 17 inches, regardless of depth.

The scope covers all varieties of folders, including but not limited to manila folders, hanging folders, fastener folders, classification folders, expanding folders, pockets, jackets, and wallets.

Excluded from the scope are:

- mailing envelopes with a flap bearing one or more adhesive strips that can be used permanently to seal the entire length of a side such that, when sealed, the folder is closed on all four sides;

- binders, with two or more rings to hold documents in place, made of paperboard or pressboard encased entirely in plastic;

- binders consisting of a front cover, back cover, and spine, with or without a flap; to be excluded, a mechanism with two or more metal rings must be included on or adjacent to the interior spine;

- non-expanding folders with a depth exceeding 2.5 inches and that are closed or closeable on the top, bottom, and all four sides (e.g., boxes or cartons);

- expanding folders that have: (1) 13 or more pockets; (2) a flap covering the top; (3) a latching mechanism made of plastic and/or metal to close the flap; and (4) an affixed plastic or metal carry handle;

- folders that have an outer surface (other than the gusset, handles, and/or closing mechanisms, if any) that is covered entirely with fabric, leather, and/or faux leather;

- fashion folders, which are defined as folders with all of the following characteristics: (1) plastic lamination covering the entire exterior of the folder; (2) printing, foil stamping, embossing (*i.e.*, raised relief patterns that are recessed on the opposite side), and/or debossing (*i.e.*, recessed relief patterns that are raised on the opposite side), covering the entire exterior surface area of the folder; (3) at least two visible and printed or foil stamped colors (other than the color of the base paper), each of which separately covers no less than 10 percent of the entire exterior surface area; and (4) patterns, pictures, designs, or artwork covering no less than thirty percent of the exterior surface area of the folder;

- portfolios, which are folders having: (1) a width of at least 16 inches when open flat; (2) no tabs or dividers; and (3) one or more pockets that are suitable for holding letter size documents and that cover at least 15 percent of the surface area of the relevant interior side or sides; and

- report covers, which are folders having: (1) no tabs, dividers, or pockets; and (2) one or more fasteners or clips, each of which is permanently affixed to the center fold, to hold papers securely in place.

Imports of the subject merchandise are provided for under Harmonized Tariff Schedule of the United States (HTSUS) category 4820.30.0040. Subject imports may also enter under other HTSUS classifications. While the HTSUS subheading is provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary

II. Background

III. Changes Since the Preliminary Determination

IV. Subsidies Valuation Information

V. Use of Facts Otherwise Available and Application of Adverse Inferences

VI. Benchmarks for Measuring the Adequacy of Remuneration

VII. Analysis of Programs

VIII. Discussion of the Issues

Comment 1: Whether World Trade Organization Rules Grant Commerce Authority to Investigate Transnational Subsidies

Comment 2: Whether Commerce Has Statutory Authority to Countervail Alleged Transnational Subsidies

Comment 3: Whether Commerce's Determinations Regarding the Cross-Border Provision of Chinese-Origin Inputs for Less Than Adequate Remuneration Are Based on Substantial Evidence and Otherwise in Accordance with Law

Comment 4: Whether Record Evidence Establishes that the Cambodian Kraft Paper and Pulp Markets Are Distorted

Comment 5: Whether Commerce Should Revise the Partial Adverse Facts Available (AFA) Rate Applied to Vietnamese Purchases of Kraft Paper

Comment 6: Whether Commerce Should Remove Import Duties and Value-Added Taxes from the Kraft Paper and Pulp Benchmarks

Comment 7: Whether Commerce Should Revise the Ocean Freight Benchmarks

Comment 8: Whether Commerce Should Correct Its Market Distortion Calculations for Pulp

Comment 9: Whether Commerce Should Apply AFA Because TCS Failed to Report Income Tax Exemptions Under the Qualified Investment Project Program

Comment 10: Whether the Royal Government of Cambodia's Customs Duty Exemptions for Imported Raw Materials Are Countervailable

Comment 11: Whether the Business Recovery Guarantee Scheme Program Is Specific

Comment 12: Whether the Electricity Fee Reduction Program Was Used During the POI and Is Specific

IX. Recommendation

[FR Doc. 2025–23780 Filed 12–23–25; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XF393]

Gulf Fishery Management Council; Public Meetings

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

Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; public hearings and webinars.

SUMMARY: The Gulf Fishery Management Council (Gulf Council) will hold three in-person public hearings and one webinar to solicit public comments on Shallow-water Grouper.

DATES: The public hearings will take place January 8–21, 2026. The in-person public hearings and webinar will begin at 6 p.m. and will conclude no later than 8 p.m. local time. For specific dates and times, see **SUPPLEMENTARY INFORMATION**. Written public comments must be received on or before 5 p.m. EST on January 20, 2026.

ADDRESSES: Please visit the Gulf Council website at www.gulfcouncil.org for meeting materials and webinar registration information.

Meeting addresses: The public hearings will be held in Madeira Beach, Galveston, TX and Lafayette, LA; and one virtual webinar. For specific locations, dates and times see **SUPPLEMENTARY INFORMATION** below.

Council address: Gulf Fishery Management Council, 4107 W Spruce Street, Suite 200, Tampa, FL 33607; telephone: (813) 348–1630.

FOR FURTHER INFORMATION CONTACT: Emily Muehlstein; Public Information Officer; emily.muehlstein@gulfcouncil.org, Gulf Fishery Management Council; telephone: (813) 348–1630.

SUPPLEMENTARY INFORMATION: The agenda for the following three in-person public hearings and webinar is as follows: Council staff will begin with a presentation on the purpose, need, and proposed management alternatives in Shallow-water Grouper Amendment 58A.

Staff and a Council member will be available to answer any questions, and the public will have the opportunity to provide testimony on the amendment and other related testimony.

In-Person Locations and Webinars

Thursday, January 8, 2026; Maderia Beach City Hall, 300 Municipal Drive, Madeira Beach, FL 33708, (727) 391–9951.

Monday, January 12, 2026; Hilton Galveston Island, 5400 Seawall Boulevard, Galveston, TX 77551, (409) 744–5000.

Tuesday, January 13, 2026; Louisiana Department of Wildlife and Fisheries (LDWF) Lafayette Office Large Conference Room #2039, 2000 Dulles Drive, Lafayette, LA 70508.

Wednesday, January 21, 2026; via webinar.

Visit www.gulfcouncil.org website and click on the “meetings and public hearings” tab for registration information. After registering, you will receive a confirmation email containing information about joining the webinar.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kathy Pereira (see **ADDRESSES**), at least 10 working days prior to the meeting date.

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

Dated: December 19, 2025.

Anna Michelle Harrison,

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

[FR Doc. 2025–23779 Filed 12–23–25; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XF408]

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

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

ACTION: Notice; 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 America, originally published as “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 revised Letter of Authorization (LOA) to WesternGeco LLC (WesternGeco), in place of Viridien, for the take of marine mammals incidental to geophysical survey activity in the Gulf of America (GOA).

DATES: The LOA is effective 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-america. In case of problems accessing these documents, please call the contact listed below (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Jenna Harlacher, 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 GOA¹ 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 50 CFR 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.

¹ Pursuant to Executive Order 14172, “Restoring Names That Honor American Greatness,” and Department of the Interior Secretarial Order 3423, “The Gulf of America,” the body of water formerly known as the Gulf of Mexico is now called the Gulf of America. Accordingly, NMFS amended the incidental take regulations to reflect the change. See 90 FR 38001 (August 7, 2025).

Summary of Request and Analysis

On August 1, 2025, NMFS issued an LOA to Viridien (90 FR 37842, August 6, 2025) to take marine mammals incidental to a three-dimensional (3D) ocean bottom node (OBN) survey over 2,023 lease blocks in the Garden Banks, Keathley Canyon, East Breaks, and Alaminos Canyon areas, with water depths ranging from approximately 185 to 2,095 meters (m). See section F of the LOA application for a map of the area. Additional description of the planned survey, as well as analysis related to the issuance of that LOA, is available in Viridien's LOA application and the aforementioned **Federal Register** notice of issuance.

On December 9, 2025, Viridien requested the transfer of the LOA to its partner in the planned survey effort (WesternGeco). WesternGeco confirmed to NMFS that it similarly requested transfer of the LOA. With the transfer of the LOA, WesternGeco agrees to comply with the associated terms, conditions, stipulations, and restrictions of the original LOA. No other changes were requested. The revised LOA remains effective through April 19, 2026.

The revised LOA sets forth only a change in the LOA holder. There are no other changes to the LOA as described in the August 6, 2025, **Federal Register** notice of issuance (90 FR 37842): the specified activity; estimated take by incidental harassment; and small numbers analysis and determination; and the period of effectiveness remain unchanged and are herein incorporated by reference.

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 WesternGeco authorizing the take of marine mammals incidental to its geophysical survey activity, as described above.

Dated: December 19, 2025.

Kimberly Damon-Randall,

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

[FR Doc. 2025-23782 Filed 12-23-25; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XF272]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Pacific Gas & Electric Sediment Remediation Project, Remedial Response Area C, San Francisco Bay

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

ACTION: Notice; proposed incidental harassment authorization; request for comments on proposed authorization and possible renewal.

SUMMARY: NMFS has received a request from Pacific Gas & Electric (PG&E) for authorization to take marine mammals incidental to construction for a sediment remediation project in San Francisco Bay, CA. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an incidental harassment authorization (IHA) to incidentally take marine mammals during the specified activities. NMFS is also requesting comments on a possible one-time, 1-year renewal that could be issued under certain circumstances and if all requirements are met, as described in Request for Public Comments at the end of this notice. NMFS will consider public comments prior to making any final decision on the issuance of the requested MMPA authorization and agency responses will be summarized in the final notice of our decision.

DATES: Comments and information must be received no later than January 28, 2026.

ADDRESSES: Comments should be addressed to Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service, and should be submitted via email to ITP.jacobus@noaa.gov. Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities>. In case of problems accessing these documents, please call the contact listed below.

Instructions: NMFS is not responsible for comments sent by any other method, to any other address or individual, or received after the end of the comment

period. Comments, including all attachments, must not exceed a 25-megabyte file size. All comments received are a part of the public record and will generally be posted online at <https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act> without change. All personal identifying information (e.g., name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

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

SUPPLEMENTARY INFORMATION:

Background

The MMPA prohibits the "take" of marine mammals, with certain exceptions. Section 101(a)(5) (D) of the MMPA (16 U.S.C. 1361 *et seq.*) directs 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 proposed or, if the taking is limited to harassment, a notice of a proposed IHA is provided to the public for review.

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 the species or stocks for taking for certain subsistence uses (collectively referred to as "mitigation"); and requirements pertaining to the monitoring and reporting of the takings. The definitions of all applicable MMPA statutory terms used above are included in the relevant sections below and can be found in section 3 of the MMPA (16 U.S.C. 1362) and NMFS regulations at 50 CFR 216.103.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and

NOAA Administrative Order (NAO) 216–6A, NMFS must review our proposed action (*i.e.*, the issuance of an IHA) with respect to potential impacts on the human environment. This action is consistent with categories of activities identified in Categorical Exclusion B4 (IHAs with no anticipated serious injury or mortality) of the Companion Manual for NAO 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS has preliminarily determined that the issuance of the proposed IHA qualifies to be categorically excluded from further NEPA review.

Summary of Request

On May 4, 2023, NMFS received an application from PG&E requesting the take of marine mammals incidental to construction of a Sediment Remediation Project in Remedial Response Areas A and B, Piers 39 to 43½, San Francisco Bay. NMFS published a notice of a proposed IHA and request for comments in the **Federal Register** on December 27, 2023 (88 FR 82836). We subsequently published the final notice of our issuance of the IHA on January 30, 2024 (89 FR 5865), making the IHA valid from May 1, 2024 through April 30, 2025. Following a request from PG&E, NMFS published a notice of proposed renewal IHA on October 16, 2024 (89 FR 83459) and issued the renewal IHA on November 22, 2024 (89 FR 92649), making the renewal IHA valid from May 1, 2025 to April 30, 2026. The specified activities were expected to result in the take of seven species of marine mammal including the bottlenose dolphin (*Tursiops truncatus*), harbor porpoise (*Phocoena phocoena*), California sea lion (*Zalophus californianus*), northern fur seal (*Callorhinus ursinus*), Steller sea lion (*Eumetopias jubatus*), harbor seal (*Phoca vitulina*), and northern elephant seal (*Mirounga angustirostris*).

On August 11, 2025, NMFS received a request from PG&E for an IHA to take marine mammals incidental to construction in Remedial Response Area C, Pier 41½, San Francisco Bay, as a

part of a continuation of the Sediment Remediation Project. Following NMFS' review of the application, PG&E submitted a revised version on December 18, 2025, which was deemed adequate and complete. PG&E's request is for take of eight species (nine stocks) by Level B harassment only. Neither PG&E nor NMFS expect serious injury or mortality to result from this activity and, therefore, an IHA is appropriate. NMFS previously issued an IHA and renewal IHA to PG&E (herein referred to as the 2024 IHA and 2025 renewal IHA) (89 FR 5865, January 30, 2024; 89 FR 92649, November 24, 2024) to incidentally take marine mammals, by Level B harassment, for similar construction activities in San Francisco Bay, as part of the larger sediment remediation project. Although PG&E is proposing to install many of the same pile types as the 2024 IHA, some pile types differ. In addition, some source levels and harassment distances have been adjusted based on hydroacoustic measurements conducted by PG&E. PG&E is also requesting take of gray whale (*Eschrichtius robustus*) based on recent marine mammal monitoring in San Francisco Bay. The proposed mitigation, monitoring, and reporting measures remain the same as prescribed in the 2024 IHA with slight modifications (*e.g.*, shut down zones distance changes) as described below.

PG&E complied with all the requirements (*e.g.*, mitigation, monitoring, and reporting) of the previous IHA, and information regarding their monitoring results may be found in the Estimated Take of Marine Mammals section.

This proposed IHA would cover 1 year of a larger project for which PG&E obtained prior IHAs and intends to request take authorization for subsequent facets of the project. The larger 5–7 year project involves construction to remediate contaminated sediment.

Description of Proposed Activity

Overview

PG&E is proposing to conduct pile driving to remediate sediments impacted by polycyclic aromatic hydrocarbons (PAHs) around the area

offshore and under Pier 41½ in San Francisco Bay, CA. PG&E would install piles for a turbidity curtain, the temporary relocation of the Blue and Gold Fleet (BGF), and sediment pins for slope stabilization. PG&E plans to use primarily vibratory pile driving. Impact pile driving would only be used as needed to seat piles. Vibratory and impact pile driving would introduce underwater sounds that may result in take, by Level B harassment, of marine mammals. Level A harassment of marine mammals is not expected, and none is proposed for authorization.

Dates and Duration

The proposed IHA would be valid for the statutory maximum of 1 year from the date of effectiveness. It will become effective upon written notification from the applicant to NMFS, but not beginning later than 1 year from the date of issuance or extending beyond 2 years from the date of issuance. In-water construction is anticipated to occur over 62 construction days between March and November. However, project delays may occur due to a number of factors, including availability of equipment and/or materials, weather-related delays, equipment maintenance and/or repair, and other contingencies. Pile driving will occur during daylight hours. Any impact pile driving would occur from June 1 to November 30 to protect sensitive life stages of Endangered Species Act (ESA)-listed fish species in the area.

Specific Geographic Region

PG&E's proposed construction activities would occur in San Francisco Bay, CA, about 3.7 miles (mi) (6 kilometers [km]) from the entrance. PG&E's sediment remediation project area encompasses Pier 39, both the Pier 39 East and West Basins, defined by existing breakwaters, and the intertidal and subtidal areas between Pier 39 and 45 along the margin of San Francisco Bay. The project area is divided into five remedial response areas. All pile driving during the timeframe of this proposed IHA would be in Remedial Response Area C, which is the Pier 41½ offshore area and the area under Pier 41½. See figure 1.



Figure 1—Project Location

Detailed Description of the Specified Activity

PG&E proposes to conduct construction in San Francisco Bay to remediate sediments impacted with PAHs. Construction components include installation of piles to attach a turbidity curtain; installation of sediment pins to promote slope stability; removal and installation of piles to relocate the Blue and Gold Fleet (BGF); removal of impacted sediment using mechanical dredges; and capping and armoring of sediment left in place.

Underwater noise generated by dredging, capping, and armoring are within range of other background noise in San Francisco Bay and are not

anticipated to result in take of marine mammals.

Pile driving to install and remove piles is expected to result in take of marine mammals and these activities are described below in detail.

Turbidity curtain—Because increased water turbidity might occur during dredging and capping activities, a turbidity curtain would be installed across the full depth of the water column extending to the sediment surface. The turbidity curtain would be attached to 20 temporary steel shell piles less than 12 inches (30.5 centimeters [cm]) in diameter. The piles would be installed with primarily vibratory methods. Impact pile driving would be used as needed to seat the piles. The piles would be removed using vibratory methods.

Slope stabilization—In order to prevent rotational or sliding failure in dredged and capped areas, approximately 500 18-inch (45.7-cm) diameter tapered timber piles (referred to as sediment pins) would be installed using vibratory and impact hammers.

BGF Relocation—Relocation of the BGF would require removal of piles and overwater structures at the current location and reinstallation after remediation actions are complete. Eight 24-inch (61-cm) steel shell piles, two 42-inch (106.7-cm) steel shell piles, and five 30-inch (76.2-cm) steel shell piles would be removed using vibratory methods. These piles would then be replaced by eight 30-inch (76.2-cm) steel shell piles, five 36-inch (91.4-cm) steel shell piles, four 24-inch (61-cm) steel shell piles, and four 36-inch (91.4-cm)

steel shell piles. These piles would all be installed using primarily vibratory methods. An impact hammer would be

used only to seat the piles to the required tip elevation.

TABLE 1—OVERVIEW OF PILES FOR INSTALLATION AND REMOVAL

Pile size and type	Hammer type	Total number of piles
Turbidity Curtain		
Steel shell piles <12 inches (30.5 cm)	Vibratory and impact	40 (20 installed, 20 removed).
Slope Stabilization		
18-inch (45.7-cm) tapered timber	Vibratory and impact	500.
BGF Relocation		
24-inch (61-cm) steel shell piles	Vibratory removal	8.
	Vibratory and impact installation	4.
30-inch (76.2 cm) steel shell piles	Vibratory removal	5.
	Vibratory and impact installation	8.
36-inch (91.4-cm) steel shell piles	Vibratory and impact installation	9.
42-inch steel shell piles	Vibratory removal	2.

TABLE 2—ESTIMATED DAYS OF PILE DRIVING

Activity	Total number of piles	Number of piles installed/ removed per day	Days of pile driving
Turbidity Curtain	40 (20 installed, 20 removed)	4	10
Slope stabilization	500	15	* 34
BGF Temporary Relocation	25 (<36 inches [91.4 cm]) (13 removed, 12 installed)	4	* 6
	11 (≥36 inches [91.4 cm])	2	* 6
Total			56
Total +10% buffer			* 62

* Rounded to the nearest whole number.

Proposed mitigation, monitoring, and reporting measures are described in detail later in this document (please see Proposed Mitigation and Proposed Monitoring and Reporting sections).

Description of Marine Mammals in the Area of Specified Activities

Sections 3 and 4 of the application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history of the potentially affected species. NMFS fully considered all of this information, and we refer the reader to these descriptions, instead of reprinting the information. Additional information regarding population trends and threats may be found in NMFS’ Stock Assessment Reports (SARs; <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments>) and more general information about

these species (*e.g.*, physical and behavioral descriptions) may be found on NMFS’ website (<https://www.fisheries.noaa.gov/find-species>).

Table 3 lists all species or stocks for which take is expected and proposed to be authorized for this activity and summarizes information related to the population or stock, including regulatory status under the MMPA and ESA and potential biological removal (PBR), where known. PBR is defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population (as described in NMFS’ SARs). While no serious injury or mortality is anticipated or proposed to be authorized here, PBR and annual serious injury and mortality (M/SI) from anthropogenic sources are included here as gross indicators of the

status of the species or stocks and other threats.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study or survey area. NMFS’ stock abundance estimates for most species represent the total estimate of individuals within the geographic area, if known, that comprises that stock. For some species, this geographic area may extend beyond U.S. waters. All managed stocks in this region are assessed in NMFS’ U.S. Pacific and Alaska SARs. All values presented in table 3 are the most recent available at the time of publication (including from the draft 2024 SARs) and are available online at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments>.

TABLE 3—SPECIES ¹ WITH ESTIMATED TAKE FROM THE SPECIFIED ACTIVITIES

Common name	Scientific name	Stock	ESA/ MMPA status; strategic (Y/N) ²	Stock abundance (CV, N _{min} , most recent abundance survey) ³	PBR	Annual M/SI ⁴
Order Artiodactyla—Cetacea—Mysticeti (baleen whales)						
<i>Family Eschrichtiidae:</i>						
Gray whale	<i>Eschrichtius robustus</i>	Eastern North Pacific	-,N	26,960 (0.05, 25,849, 2016) ..	801	131
<i>Family Delphinidae:</i>						
Bottlenose Dolphin	<i>Tursiops truncatus</i>	California Coastal	-,N	453 (0.06, 346, 2011)	2.7	≥2
Harbor porpoise	<i>Phocoena phocoena</i>	San Francisco/Russian River	-,N	7,777 (0.62, 4,811, 2017)	73	≥0.4
Order Carnivora—Pinnipedia						
<i>Family Otariidae (eared seals and sea lions):</i>						
California sea lion	<i>Zalophus californianus</i>	United States	-,N	257,606 (N/A, 233,515, 2014)	14,011	>321
Northern fur seal	<i>Callorhinus ursinus</i>	Eastern Pacific	-, D,Y	626,618 (0.2, 530,376, 2019)	11,403	373
Northern fur seal	<i>Callorhinus ursinus</i>	California	-,N	14,050 (N/A, 7,524, 2013)	451	1.8
Steller sea lion	<i>Eumetopias jubatus</i>	Eastern	-,N	36,308 (N/A, 36,308, 2022) ...	2,178	93.2
<i>Family Phocidae (earless seals):</i>						
Harbor seal	<i>Phoca vitulina</i>	California	-,N	30,968 (N/A, 27,348, 2012) ...	1,641	43
Northern elephant seal	<i>Mirounga angustirostris</i>	California breeding	-, -, N	187,386 (N/A, 85,369, 2013)	5,122	13.7

¹ Information on the classification of marine mammal species can be found on the web page for The Society for Marine Mammalogy's Committee on Taxonomy (<https://marinemammalscience.org/science-and-publications/list-marine-mammal-species-subspecies>).

² ESA status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

³ NMFS marine mammal stock assessment reports online at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessment-reports-region>. CV is coefficient of variation; N_{min} is the minimum estimate of stock abundance.

⁴ These values, found in NMFS's SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (e.g., commercial fisheries, ship strike). Annual M/SI often cannot be determined precisely and is in some cases presented as a minimum value or range. A CV associated with estimated mortality due to commercial fisheries is presented in some cases.

As indicated above, all eight species (with nine managed stocks) in table 3 temporally and spatially co-occur with the activity to the degree that take is reasonably likely to occur. While the humpback whale occasionally enters San Francisco Bay, if this species is to approach the Level B harassment zone, construction will be shutdown. Therefore, no take is expected of humpback whale and the species will not be discussed further.

With the exception of the gray whale, a description of all marine mammals proposed for take in this IHA can be found in the notice of the proposed 2024 IHA (88 FR 82836, November 11, 2023), and the information remains applicable to this proposed IHA as well. NMFS has reviewed recent draft Stock Assessment Reports, information on relevant Unusual Mortality Events, and recent scientific literature, and determined that no new information affects our original analysis of impacts to these species under this proposed IHA.

For the 2024 IHA, no take was authorized for gray whales, and PG&E shut down if gray whales approached the estimated Level B harassment isopleth. During construction conducted

under the 2024 IHA, gray whales were present in San Francisco Bay more than expected, resulting in multiple instances of shutdown. Therefore, PG&E is requesting take for small numbers of gray whales by Level B harassment in this IHA. Gray whales will be discussed below.

Gray Whale

During the summer and fall most Eastern North Pacific gray whales feed in the Chukchi, Beaufort, and northwestern Bering Seas, with a small number that summer and feed along the Pacific coast between Kodiak Island, Alaska and northern California. The southward migration generally occurs from December through February and peaks in January, and the northward migration generally occurs from February through May and peaks in March (NOAA National Centers for Coastal Ocean Science, 2007). Although their presence in San Francisco Bay is generally considered uncommon, increased numbers of gray whales have been seen in San Francisco Bay in recent years, and gray whales were observed in San Francisco Bay more often than expected during PG&E's construction under the 2024 IHA (Integral Consulting Inc., 2025a).

Marine Mammal Hearing

Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals are able to hear. Not all marine mammal species have equal hearing capabilities (e.g., Au and Hastings, 2008; Richardson *et al.*, 1995; Wartzok and Ketten, 1999). To reflect this, Southall *et al.* (2007, 2019) recommended that marine mammals be divided into hearing groups based on directly measured (behavioral or auditory evoked potential techniques) or estimated hearing ranges (behavioral response data, anatomical modeling, *etc.*). Generalized hearing ranges were chosen based on the ~65 decibel (dB) threshold from composite audiograms, previous analyses in NMFS (2018), and/or data from Southall *et al.* (2007, 2019). We note that the names of two hearing groups and the generalized hearing ranges of all marine mammal hearing groups have been recently updated (NMFS, 2024) as reflected below in table 4.

TABLE 4—MARINE MAMMAL HEARING GROUPS (NMFS, 2024)

Hearing group	Generalized hearing range *
Low-frequency (LF) cetaceans (baleen whales)	7 Hz to 36 kHz.
High-frequency (HF) cetaceans (dolphins, toothed whales, beaked whales, bottlenose whales)	150 Hz to 160 kHz.
Very High-frequency (VHF) cetaceans (true porpoises, <i>Kogia</i> , river dolphins, Cephalorhynchid, <i>Lagenorhynchus cruciger</i> & <i>L. australis</i>).	200 Hz to 165 kHz.
Phocid pinnipeds (PW) (underwater) (true seals)	40 Hz to 90 kHz.
Otariid pinnipeds (OW) (underwater) (sea lions and fur seals)	60 Hz to 68 kHz.

* Represents the generalized hearing range for the entire group as a composite (*i.e.*, all species within the group), where individual species' hearing ranges may not be as broad. Generalized hearing range chosen based on approximately 65 dB threshold from composite audiogram, previous analysis in NMFS (2018), and/or data from Southall *et al.* (2007, 2019). Additionally, animals are able to detect very loud sounds above and below that "generalized" hearing range.

For more detail concerning these groups and associated frequency ranges, please see NMFS (2024) for a review of available information.

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

A description of the potential effects of the specified activities on marine mammals and their habitat may be found in the notice of the proposed 2024 IHA (88 FR 82836, November 27, 2023).

Estimated Take of Marine Mammals

This section provides an estimate of the number of incidental takes proposed for authorization through the IHA, which will inform NMFS' consideration of "small numbers," the negligible impact determinations, and impacts on subsistence uses.

Harassment is the only type of take expected to result from these activities. Except with respect to certain activities not pertinent here, section 3(18) of 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).

Authorized takes would be by Level B harassment only, in the form of behavioral reactions and/or temporary threshold shift (TTS) for individual marine mammals resulting from exposure to pile driving. Based on the nature of the activity and the anticipated effectiveness of the mitigation measures (*i.e.*, shutdown at the Level A harassment isopleth) discussed in detail below in the Proposed Mitigation section, Level A harassment is neither anticipated nor proposed to be authorized.

As described previously, no serious injury or mortality is anticipated or proposed to be authorized for this activity. Below we describe how the proposed take numbers are estimated.

For acoustic impacts, generally speaking, we estimate take by considering: (1) acoustic criteria above which NMFS believes there is some reasonable potential for marine mammals to be behaviorally harassed or incur some degree of auditory injury (AUD INJ); (2) the area or volume of water that will be ensonified above these levels in a day; (3) the density or occurrence of marine mammals within these ensonified areas; and, (4) the number of days of activities. We note that while these factors can contribute to a basic calculation to provide an initial prediction of potential takes, additional information that can qualitatively inform take estimates is also sometimes available (*e.g.*, previous monitoring results or average group size). Below, we describe the factors considered here in more detail and present the proposed take estimates.

Acoustic Criteria

NMFS recommends the use of acoustic criteria that identify the received level of underwater sound above which exposed marine mammals would be reasonably expected to be behaviorally harassed (equated to Level B harassment) or to incur AUD INJ of some degree (equated to Level A harassment).

Level B Harassment—Though significantly driven by received level, the onset of behavioral disturbance from anthropogenic noise exposure is also informed to varying degrees by other factors related to the source or exposure context (*e.g.*, frequency, predictability, duty cycle, duration of the exposure, signal-to-noise ratio, distance to the source), the environment (*e.g.*, bathymetry, other noises in the area, predators in the area), and the receiving animals (hearing, motivation, experience, demography, life stage,

depth) and can be difficult to predict (*e.g.*, Southall *et al.*, 2007, 2021; Ellison *et al.*, 2012). Based on what the available science indicates and the practical need to use a threshold based on a metric that is both predictable and measurable for most activities, NMFS typically uses a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment. NMFS generally predicts that marine mammals are likely to be behaviorally harassed in a manner considered to be Level B harassment when exposed to underwater anthropogenic noise above root-mean-squared pressure received levels (RMS SPL) of 120 dB (referenced to 1 micropascal (re 1 μ Pa)) for continuous (*e.g.*, vibratory pile driving, drilling) and above RMS SPL 160 dB re 1 μ Pa for non-explosive impulsive (*e.g.*, seismic airguns) or intermittent (*e.g.*, scientific sonar) sources. Generally speaking, Level B harassment take estimates based on these behavioral harassment thresholds are expected to include any likely takes by TTS as, in most cases, the likelihood of TTS occurs at distances from the source less than those at which behavioral harassment is likely. TTS of a sufficient degree can manifest as behavioral harassment, as reduced hearing sensitivity and the potential reduced opportunities to detect important signals (conspecific communication, predators, prey) may result in changes in behavior patterns that would not otherwise occur.

PG&E's proposed construction activity includes the use of continuous (vibratory pile driving) and impulsive (impact pile driving) sources, and therefore the RMS SPL thresholds of 120 and 160 dB re 1 μ Pa are applicable.

Level A harassment—NMFS' Updated Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Version 3.0) (Updated Technical Guidance, 2024) identifies dual criteria to assess AUD INJ (Level A harassment) to five different underwater marine mammal

groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive). PG&E's proposed construction includes the use of impulsive (impact pile driving) and non-impulsive (vibratory pile driving) sources.

The 2024 Updated Technical Guidance criteria include both updated thresholds and updated weighting functions for each hearing group. The thresholds are provided in the table below. The references, analysis, and methodology used in the development of the criteria are described in NMFS'

2024 Updated Technical Guidance, which may be accessed at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance-other-acoustic-tools>.

TABLE 5—THRESHOLDS IDENTIFYING THE ONSET OF AUDITORY INJURY

Hearing group	AUD INJ onset acoustic thresholds * (received level)	
	Impulsive	Non-impulsive
Low-Frequency (LF) Cetaceans	Cell 1: $L_{pk,flat}$: 222 dB; $L_{E,LF,24h}$: 183 dB	Cell 2: $L_{E,LF,24h}$: 197 dB.
High-Frequency (HF) Cetaceans	Cell 3: $L_{pk,flat}$: 230 dB; $L_{E,HF,24h}$: 193 dB	Cell 4: $L_{E,HF,24h}$: 201 dB.
Very High-Frequency (VHF) Cetaceans	Cell 5: $L_{pk,flat}$: 202 dB; $L_{E,VHF,24h}$: 159 dB	Cell 6: $L_{E,VHF,24h}$: 181 dB.
Phocid Pinnipeds (PW) (Underwater)	Cell 7: $L_{pk,flat}$: 223 dB; $L_{E,PW,24h}$: 183 dB	Cell 8: $L_{E,PW,24h}$: 195 dB.
Otariid Pinnipeds (OW) (Underwater)	Cell 9: $L_{pk,flat}$: 230 dB; $L_{E,OW,24h}$: 185 dB	Cell 10: $L_{E,OW,24h}$: 199 dB.

*Dual metric criteria for impulsive sounds: Use whichever criteria results in the larger isopleth for calculating AUD INJ onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level criteria associated with impulsive sounds, the PK SPL criteria are recommended for consideration for non-impulsive sources.

Note: Peak sound pressure level ($L_{p,0-pk}$) has a reference value of 1 μ Pa, and weighted cumulative sound exposure level ($L_{E,p}$) has a reference value of 1 μ Pa²s. In this table, criteria are abbreviated to be more reflective of International Organization for Standardization standards (ISO, 2017). The subscript "flat" is being included to indicate peak sound pressure are flat weighted or unweighted within the generalized hearing range of marine mammals underwater (*i.e.*, 7 Hz to 165 kHz). The subscript associated with cumulative sound exposure level criteria indicates the designated marine mammal auditory weighting function (LF, HF, and VHF cetaceans, and PW and OW pinnipeds) and that the recommended accumulation period is 24 hours. The weighted cumulative sound exposure level criteria could be exceeded in a multitude of ways (*i.e.*, varying exposure levels and durations, duty cycle). When possible, it is valuable for action proponents to indicate the conditions under which these criteria will be exceeded.

Ensonified Area

Here, we describe operational and environmental parameters of the activity that are used in estimating the area ensonified above the acoustic thresholds, including source levels and transmission loss coefficient.

The sound field in the project area is the existing background noise plus additional construction noise from the proposed project. Marine mammals are expected to be affected via sound

generated by the primary components of the project (*i.e.*, pile driving and removal).

The project includes vibratory pile installation and removal and impact pile installation. Source levels for these activities are based on hydroacoustic monitoring conducted under the 2024 IHA (Reyff and Ambaskar, 2025) and 2025 renewal IHA (Illingworth & Rodkin, 2025) and on reviews of measurements of the same or similar

types and dimensions of piles available in the literature. Source levels for each pile size are presented in table 6. Source levels for vibratory installation and removal of piles of the same diameter are assumed to be the same. PG&E plans to use a bubble curtain for all impact pile driving, and a 5 dB reduction in source level is assumed from those presented in table 6 for impact pile driving due to the use of a bubble curtain.

TABLE 6—SOUND SOURCE LEVELS FOR PILE DRIVING

Pile	Hammer	Source level (at 10 meters [m])			Source
		Peak sound pressure (dB re 1 μPa)	RMS (dB re 1 μPa)	SEL (dB re 1 μPa2 sec)	
Turbidity Curtain					
Steel shell piles <12 inches (30.5 cm)	Vibratory	N/A	157.3	N/A	Illingworth & Rodkin (2025). Caltrans (2015, 2020).
Steel shell piles <12 inches (30.5 cm)	Impact *	192	177	167	
Slope Stabilization					
18-inch (45.7-cm) tapered timber	Vibratory	N/A	158	N/A	Greenbusch Group (2018), Illingworth & Rodkin (2017), Laughlin, (2011), U.S. Navy (2016). Caltrans (2020).
	Impact *	184	157	145	
BGF Relocation					
24-inch (61-cm) steel shell	Vibratory	N/A	160.4	N/A	Reyff and Ambaskar (2025).
	Impact *	208	193	178	Illingworth & Rodkin (2014).
30-inch (76.2-cm) steel shell	Vibratory	N/A	171.8	N/A	Reyff and Ambaskar (2025).
	Impact *	210	190	177	Caltrans (2015).
36-inch (91.4-cm) steel shell	Vibratory	N/A	169.4	N/A	Reyff and Ambaskar (2025).
	Impact *	210	193	183	Caltrans, (2015, 2020).
42-inch (106.7-cm) steel shell	Vibratory	N/A	170	N/A	NMFS 2025 analysis.

*PG&E would use a bubble curtain attenuation system for all impact pile, and NMFS assumes a 5 dB reduction in source level from those presented here due to use of the attenuation system.

Level B Harassment Zones— Transmission loss (TL) is the decrease in acoustic intensity as an acoustic pressure wave propagates out from a source. TL parameters vary with frequency, temperature, sea conditions, current, source and receiver depth, water depth, water chemistry, and bottom composition topography. The general formula for underwater TL is: $TL = B * \log_{10} (R_1/R_2)$,

Where:

TL = transmission loss in dB;

B = transmission loss coefficient;

R_1 = the distance of the modeled SPL from the driven pile; and

R_2 = the distance from the driven pile of the initial measurement.

Absent site-specific data, the recommended TL coefficient for most nearshore environments is the practical spreading value of 15. This value results in an expected propagation environment that would lie between spherical and cylindrical spreading loss conditions, known as practical spreading. As is common practice in coastal waters, here

we assume practical spreading (4.5 dB reduction in sound level for each doubling of distance) for all impact and vibratory installation of piles without site-specific acoustical monitoring (*i.e.*, impact installation of 12-, 24-, 30-, and 36-inch [30.5-, 61-, 76.2-, and 91.4-cm] steel shell piles, vibratory and impact installation of 18-inch [45.7-cm] tapered timber piles, and vibratory installation of 42-inch [106.7-cm] steel shell piles).

As described above, PG&E conducted hydroacoustic monitoring for the vibratory installation of 12-, 24-, 30-, and 36-inch (61-, 76.2-, and 91.4-cm) steel shell piles, and the TL coefficients were 22, 24.9, 22.5, and 23.9, respectively (Reyff and Ambaskar, 2025, Illingworth & Rodkin, 2025). PG&E proposes to use these site specific TL coefficients for the respective piles, and NMFS concurs.

The ensounded area associated with Level A harassment is more technically challenging to predict due to the need to account for a duration component. Therefore, NMFS developed an optional User Spreadsheet tool to accompany the

2024 Updated Technical Guidance that can be used to relatively simply predict an isopleth distance for use in conjunction with marine mammal density or occurrence to help predict potential takes. We note that because of some of the assumptions included in the methods underlying this optional tool, we anticipate that the resulting isopleth estimates are typically going to be overestimates of some degree, which may result in an overestimate of potential take by Level A harassment. However, this optional tool offers the best way to estimate isopleth distances when more sophisticated modeling methods are not available or practical. For stationary sources, such as pile driving, the optional User Spreadsheet tool predicts the distance at which, if a marine mammal remained at that distance for the duration of the activity, it would be expected to incur AUD INJ. Inputs used in the NMFS User Spreadsheet are provided in table 7. Level A and Level B harassment isopleths are provided in table 8.

TABLE 7—NMFS USER SPREADSHEET INPUTS

Pile size/type	Hammer type	Piles per day	Strikes per pile	Duration to drive pile (min)	TL coefficient	Weighting factor adjustment (WFA)
Turbidity Curtain						
Steel shell piles <12 inches (30.5 cm)	Vibratory	4	N/A	20	22	2.5
	Impact	4	25	N/A	15	2
Slope Stabilization						
18-inch (45.7-cm) tapered timber	Vibratory	15	N/A	20	15	2.5
	Impact	15	400	N/A	15	2
BGF Relocation						
24-inch (61-cm) steel shell	Vibratory	4	N/A	20	24.9	2.5
	Impact	4	25	N/A	15	2
30-inch (76.2-cm) steel shell	Vibratory	4	N/A	20	22.5	2.5
	Impact	4	25	N/A	15	2
36-inch (91.4 cm) steel shell	Vibratory	2	N/A	20	23.9	2.5
	Impact	2	50	N/A	15	2
42-inch (106.7-cm) steel shell	Vibratory	2	N/A	20	15	2.5

TABLE 8—LEVEL A AND LEVEL B HARASSMENT ISOPLETHS

Pile	Level A harassment isopleth (m)					Level B harassment isopleth (m)
	LF	HF	VHF	Phocids	Otariid	
Turbidity Curtain						
Steel shell pile <12 inch (30.5 cm) (vibratory)	7	4	6	9	4	496
Steel shell pile <12 inch (30.5 cm) (impact, attenuated) *	10	1	13	8	3	63
Slope Stabilization						
18-inch (45.7-cm) tapered timber (vibratory)	17	7	14	22	7	3,415
18-inch (45.7-cm) tapered timber (impact, attenuated) *	5	1	7	4	2	3

TABLE 8—LEVEL A AND LEVEL B HARASSMENT ISOPLETHS—Continued

Pile	Level A harassment isopleth (m)					Level B harassment isopleth (m)
	LF	HF	VHF	Phocids	Otariid	
BGF Relocation						
24-inch (61-cm) steel shell (vibratory)	10	6	9	12	6	419
24-inch (61-cm) steel shell (impact, attenuated) *	46	6	72	41	15	736
30-inch (76.2-cm) steel shell (vibratory)	33	17	28	39	19	2,006
30-inch (76.2-cm) steel shell (impact, attenuated) *	40	5	61	35	13	464
36-inch (91.4-cm) steel shell (vibratory)	18	10	16	21	11	1,167
36-inch (91.4-cm) steel shell (impact, attenuated) *	100	13	154	88	33	736
42-inch (106.7-cm) steel shell (vibratory)	28	11	23	36	12	21,544

* 5 dB reduction in sound assumed due to use of bubble curtain.

Marine Mammal Occurrence

In this section we provide information about the occurrence of marine mammals, including density or other relevant information which will inform the take calculations.

Because reliable marine mammal density information is not available for San Francisco Bay, PG&E reviewed several resources and datasets to estimate marine mammal occurrence. These datasets include (but are not limited to):

- 5 years of sighting and stranding data from The Marine Mammal Center (TMMC) (NMFS, 2021b as cited by Integral Consulting Inc., 2025a) and California Academy of Sciences (CAS) (NMFS, 2021a as cited by Integral Consulting Inc., 2025a);
- Monitoring data collected over 5 days in Remedial Response Areas A, B, and C in 2020 during sediment investigations in the initial phase of the sediment remediation project (Haase, 2021);
- Monitoring data collected over 11 days of construction in Remedial Response Areas A and B in the Spring of 2025 (Integral Consulting Inc., 2025b);

- Counts from nearby haulouts; and
- Citizen-reported live sightings from <https://www.iNaturalist.org>;

Depending on the distribution of sightings and granularity of data, different sources have been used to estimate the number of individuals of each species with the potential to occur in the vicinity of the project.

Gray Whale

Gray whales may enter the Bay in late winter and early spring or in the fall during their migrations and, in recent years, there have been an increased number of gray whales in the western and Central Bay (Integral Consulting Inc., 2025a). During construction in March-April 2025, multiple gray whales were observed in San Francisco Bay

(Integral Consulting Inc., 2025b).

According to TMMC, in June 2025, 9 individual gray whales were observed in June over 14 days (TMMC, unpublished data). PG&E estimates that one gray whale will occur in the project area every other day (0.5 whales/day), and NMFS concurs with this approach.

Bottlenose Dolphin

Historically, observations of bottlenose dolphins have occurred west of Treasure Island and were concentrated along the nearshore area of San Francisco south to Redwood City. Since 2016, one individual has been regularly seen near the former Alameda Air Station, and five animals were regularly seen in the summer and fall of 2018 in the same location (Integral Consulting Inc., 2025a). In February 2019, an adult and juvenile were seen on two separate occasions northwest of the Oakland Inner Harbor, approximately 4 mi (6.4 km) from PG&E's proposed project area (Integral Consulting Inc., 2025a). No bottlenose dolphins were observed during pre-construction monitoring in 2020 (Haase, 2021) or during construction in the spring of 2025 (Integral Consulting Inc., 2025b). Although bottlenose dolphins are relatively uncommon in San Francisco Bay, NMFS conservatively assumes that one group of bottlenose dolphins will be present in the project area per month of construction. A group size is estimated to be five animals based on sightings of bottlenose dolphins in San Francisco Bay (Integral Consulting Inc., 2025a).

Harbor Porpoise

Harbor porpoise are primarily seen near the Golden Gate Bridge, Marin County, and the city of San Francisco on the northwest side of San Francisco Bay (Keener *et al.*, 2012; Stern *et al.*, 2017). CAS recorded 29 harbor porpoises (only 2 of which were alive) over the past 5 years, and <https://www.iNaturalist.org>

recorded 11 harbor porpoise in San Francisco Bay over the past 2 years. During 2020 monitoring, an individual harbor porpoise was seen within the project area on 2 of the 5 monitoring days (Haase, 2021), and a single harbor porpoise was observed within the Level B harassment zone during 11 days of monitoring in the spring of 2025 (Integral Consulting Inc., 2025b). PG&E estimates that two harbor porpoises will occur within the project area per day, and NMFS concurs.

California Sea Lion

Remedial Response Area C, where PG&E proposes to conduct construction, is adjacent to the Pier 39 K-Dock where California sea lions regularly haul out. The Sea Lion Center at Pier 39 regularly counted the sea lions at K-Dock from 1991 through 2018, and from 2016 through 2018, the yearly average ranged from 89 to 229 animals per day, and the average over all 3 years was 191 (Integral Consulting Inc., 2025a). Over 5 days of monitoring in 2020, a total of 463 sea lions were observed, ranging from 56 to 129 per day (Haase, 2021). During construction in March and April 2025, California sea lions were seen on each of 11 monitoring days, with a total of 92 California sea lions seen, ranging from 3 to 18 California sea lions per day (Integral Consulting Inc., 2025b). Although there are times of year when the K-Dock is unoccupied or there are few individuals present, it is difficult to predict abundance based on the time of year. Therefore, PG&E is conservatively assuming 191 sea lions per day, based on the average K-dock counts, and NMFS concurs.

Northern Fur Seal

TMMC recorded 44 northern fur seals in San Francisco Bay from 2016 to 2021 (NMFS, 2021b). CAS recorded an additional 3 for a total of 47 over 5 years (NMFS, 2021a), yielding 0.03 northern fur seals per day, or approximately 10

northern fur seals per year. No fur seals were observed during monitoring efforts in 2020 and 2025 (Integral Consulting Inc., 2025b; Haase, 2021). In the fall and winter, northern fur seals occasionally strand on Yerba Buena Island and Treasure Island (Integral Consulting Inc., 2025a), approximately 2 mi (3.2 km) from PG&E’s proposed project area. Using PG&E’s assumption of approximately 0.03 fur seals per day over the course of 62 days of pile driving plus a history of known fur seal strandings near the project area, NMFS has determined it appropriate to assume 5 fur seals in the project area over the course of construction.

Steller Sea Lion

Steller sea lions are rare in San Francisco Bay. TMMC recorded four Steller sea lions in San Francisco Bay from 2016 to 2021 (NMFS, 2021b), and CAS recorded no Steller sea lions over the same time frame (NMFS, 2021a). On rare occasions, Steller sea lions are seen on the Pier 39 K-Dock haulout. An adult male was spotted there in May 2023 (Segura, 2023), and, in previous years, a single male Steller sea lion had been observed using the Pier 39 K-Dock haulout intermittently during July and August and occasionally September (Integral Consulting Inc., 2025a). No Steller sea lions were observed during the 2020 or 2025 monitoring (Haase, 2021; Integral Consulting Inc., 2025b). Given the known occasional occurrences of Steller sea lions at Pier 39, NMFS feels it is appropriate to assume five Steller sea lions in PG&E’s proposed project area during the time period of construction.

Harbor Seal

Harbor seals in San Francisco Bay forage mainly within 7 mi (11.3 km) of their primary haulout site (Grigg *et al.*, 2012) and often within just 1–3 mi (1.6–4.8 km) (Torok, 1994). The only harbor seal haulout within 7 mi (11.3 km) of the project site is Yerba Buena Island, which is 3.1 mi (5 km) to the east of the Project Area. Aside from the vibratory

removal of 42-inch (106.7-cm) steel shell piles, the largest Level B harassment zone is 2,006 m (vibratory installation of 30-inch [76.2 cm]), and the Level B harassment isopleths are not expected to reach the Yerba Buena haulout. However, harbor seals that use this haulout are likely to forage within ensonified areas from the project. During 5 days of monitoring in 2020, 60 harbor seals were observed, with a maximum of 20 seals observed in one day (Haase, 2021). During 11 days of monitoring in 2025, two harbor seals were observed in the project area (Integral Consulting Inc., 2025b). Based on this data, PG&E assumes 20 harbor seals will be within the Level B harassment isopleth per day, and NMFS concurs.

PG&E proposes to conduct vibratory removal of 42-inch (106.7-cm) steel shell piles over 2 days (one pile per day). The Level B harassment isopleth for the vibratory removal of the 42-inch (106.7-cm) steel shell pile is 21,544 m. This isopleth would extend to Castro Rocks in northern San Francisco Bay, which is a well-known harbor seal haulout, and therefore, PG&E proposes to add harbor seals from Castro Rocks haulout to the take determined by the daily occurrence estimate described above. The National Park Service conducts annual surveys of haulouts in San Francisco Bay. Over the past 10 years of surveys, the highest mean number of harbor seals observed at Castro Rocks was 237 seals (in 2019) (Codde, 2020; Codde & Allen, 2017, 2018, 2020, 2025). The vibratory removal of 42-inch (106.7-cm) steel shell piles is expected to last approximately 20 minutes each day. PG&E estimates that 50 harbor seals from Castro Rocks will occur within the Level B harassment isopleth during each day of vibratory removal of 42-inch (106.7-cm) steel shell piles, resulting in 100 harbor seals.

Northern Elephant Seal

TMMC recorded 903 northern elephant seals in San Francisco Bay

from 2016 to 2021 (NMFS, 2021b). The CAS reported an additional 6 northern elephant seals over the same time frame (NMFS, 2021a), for a total of 909 seals, yielding an average of 0.5 elephant seals per day. No northern elephant seals were observed during monitoring efforts conducted in 2020 and 2025 (Haase, 2021; Integral Consulting Inc., 2025b). In order to ensure sufficient authorization of northern elephant seal takes, PG&E assumed 0.5 elephant seals will occur in the proposed project area per day (*i.e.*, one elephant seal every 2 days). NMFS concurs with this assumption.

Take Estimation

Here we describe how the information provided above is synthesized to produce a quantitative estimate of the take that is reasonably likely to occur and proposed for authorization.

To estimate take by Level B harassment for gray whale, harbor porpoise, California sea lion, and northern elephant seal the expected daily occurrence was multiplied by the estimated number of 62 pile driving days (see table 9). Similarly, for harbor seals, the expected daily occurrence was multiplied by the estimated number of 62 pile driving days and 100 harbor seals was added to this number to account for take of harbor seals at Castro Rocks during 2 days of vibratory removal of 42-inch (106.7-cm) steel shell piles (50 harbor seals per day) (see table 9). For northern fur seals and Steller sea lions, PG&E is assuming five animals of each species will occur in the proposed project area during the course of PG&E’s construction (see table 9). For bottlenose dolphins, PG&E estimates that one group of five bottlenose dolphins will occur in the proposed project area per month of pile driving. Based on 5 months of pile driving, NMFS proposes to authorize 25 takes of bottlenose dolphins by Level B harassment (table 9).

TABLE 9—ESTIMATED TAKE BY LEVEL B HARASSMENT PROPOSED FOR AUTHORIZATION

Species	Stock	Expected occurrence	Estimated take by Level B harassment	Stock abundance	Percent of stock
Gray whale	Eastern North Pacific	0.5 whales/day	31	26,960	0.1
Bottlenose dolphin	California coastal	5 dolphins/month of construction	25	453	5.5
Harbor porpoise	San Francisco/Russian River.	2 porpoises/day	124	7,777	1.6
California sea lion	United States	191 sea lions/day	11,842	257,606	4.6
Northern fur seal	Eastern Pacific	5 seals over project duration	5	626,618	<0.1
	California			14,050	<0.1
Steller sea lion	Eastern	5 sea lions over project duration	5	36,308	<0.1

TABLE 9—ESTIMATED TAKE BY LEVEL B HARASSMENT PROPOSED FOR AUTHORIZATION—Continued

Species	Stock	Expected occurrence	Estimated take by Level B harassment	Stock abundance	Percent of stock
Harbor seal	California	20 harbor seals/day for 62 days +50 seals/day for 2 days of vibratory removal of 42-inch steel shell piles (see <i>Marine Mammal Occurrence</i> section above).	1,340	30,968	4.3
Northern elephant seal ..	California breeding	0.5 seals/day	31	187,386	<0.1

Proposed Mitigation

In order to issue an IHA under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to the activity, and other means of effecting the least practicable impact on the species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stock for taking for certain subsistence uses (latter not applicable for this action). NMFS regulations require applicants for incidental take authorizations (ITAs) to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting the activity or other means of effecting the least practicable adverse impact upon the affected species or stocks, and their habitat (50 CFR 216.104(a)(11)).

In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where applicable, NMFS considers two primary factors:

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if implemented as planned), the likelihood of effective implementation (probability implemented as planned), and;

(2) The practicability of the measures for applicant implementation, which may consider such things as cost, and impact on operations.

The mitigation requirements described in the following were proposed by PG&E in its adequate and complete application or are the result of subsequent coordination between NMFS and PG&E. PG&E has agreed that all of the mitigation measures are practicable. NMFS has fully reviewed the specified activities and the mitigation measures to determine if the mitigation measures would result in the least practicable

adverse impact on marine mammals and their habitat, as required by the MMPA, and has determined the proposed measures are appropriate. NMFS describes these below as proposed mitigation requirements, and has included them in the proposed IHA.

Shutdown Zones

PG&E must establish shutdown zones for all pile driving activities. The purpose of a shutdown zones is generally to define an area within which shutdown of the activity would occur upon sighting of a marine mammal (or in anticipation of an animal entering the defined area). Shutdown zones will vary based on the activity type and marine mammal hearing group (see table 10). Specifically, PG&E will establish shutdown zones for otariids based on the otariid Level A harassment zone and shutdown zones for all other marine mammals based on the largest Level A harassment zone for each pile size/type and driving method, as shown in table 10. A minimum shutdown zone of 10 m would be required for all in-water construction activities to avoid physical interaction with marine mammals.

TABLE 10—PROPOSED SHUTDOWN ZONES

Pile type	Hammer type	Otariid shutdown zone (m)	Shutdown zone for all other marine mammals (m)
Turbidity Curtain			
Steel shell pile <12 inch	Vibratory	10	10
Steel shell pile <12 inch	Impact (attenuated)	10	15
Slope Stabilization			
18-inch tapered timber	Vibratory	10	25
18-inch tapered timber	Impact (attenuated)	10	10
BGF Relocation			
24-inch steel shell	Vibratory	10	15
24-inch steel shell	Impact (attenuated)	15	75
30-inch steel shell	Vibratory	20	40
30-inch steel shell	Impact (attenuated)	15	65
36-inch steel shell	Vibratory	15	25
36-inch steel shell	Impact (attenuated)	35	155
42-inch steel shell	Vibratory	15	40

Prior to pile driving, shutdown zones will be established based on zones represented in table 10. Protected species observers (PSOs) will survey the shutdown zones for at least 30 minutes before pile driving activities start. If marine mammals are found within the shutdown zone, pile driving will be delayed until the animal has moved out of the shutdown zone, either verified by a PSO or by waiting until 15 minutes has elapsed without a sighting. If a marine mammal approaches or enters the shutdown zone during pile driving, the activity will be halted. Pile driving may resume after the animal has moved out of and is moving away from the shutdown zone or after at least 15 minutes has passed since the last observation of the animal.

If a species for which authorization has not been granted, or a species which has been granted but the authorized takes are met, is observed approaching or within the Level B harassment zone, pile driving activities will be shutdown. Activities will not resume until the animal has been confirmed to have left the area or 15 minutes has elapsed with no sighting of the animal.

Protected Species Observers

The placement of PSOs during all pile driving activities (described in the *Proposed Monitoring and Reporting* section) would ensure that the entire shutdown zone is visible. Should environmental conditions deteriorate such that the entire shutdown zone would not be visible (e.g., fog, heavy rain), pile driving would be delayed until the PSO is confident marine mammals within the shutdown zone could be detected. PSOs would monitor the full shutdown zones and as much of the Level B harassment zones as possible.

Pre- and Post-Activity Monitoring

Monitoring must take place from 30 minutes prior to initiation of pile driving activities (i.e., pre-clearance monitoring) through 30 minutes post-completion of pile driving. Prior to the start of daily in-water construction activity, or whenever a break in pile driving of 30 minutes or longer occurs, PSOs would observe the shutdown zones for a period of 30 minutes. The shutdown zone would be considered cleared when a marine mammal has not been observed within the zone for a 30-minute period. If a marine mammal is observed within shutdown zones, pile driving activity would be delayed or halted. When a marine mammal for which take by Level B harassment is authorized is present in the Level B harassment zone, activities may begin

and take by Level B harassment will be recorded. If work ceases for more than 30 minutes, the pre-activity monitoring of the shutdown zones would commence. A determination that the shutdown zone is clear must be made during a period of good visibility (i.e., the entire shutdown zone and surrounding waters must be visible to the naked eye).

Soft-Start Procedures

Soft-start procedures are used to provide additional protection to marine mammals by providing warning and/or giving marine mammals a chance to leave the area prior to the hammer operating at full capacity. For impact pile driving, contractors would be required to provide an initial set of three strikes from the hammer at reduced energy, followed by a 30-second waiting period, then two subsequent reduced-energy strike sets. Soft start would be implemented at the start of each day's impact pile driving and at any time following cessation of impact pile driving for a period of 30 minutes or longer.

Bubble Curtain

A bubble curtain must be employed during all impact pile driving. The bubble curtain must distribute air bubbles around 100 percent of the piling circumference for the full depth of the water column. The lowest bubble ring must be in contact with the mudline for the full circumference of the ring. The weights attached to the bottom ring must ensure 100 percent substrate contact. No parts of the ring or other objects may prevent full substrate contact. Air flow to the bubble rings must be balanced around the circumference of the pile.

NMFS conducted an independent evaluation of the proposed measures, and has preliminarily determined that the proposed mitigation measures provide the means of effecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Proposed Monitoring and Reporting

In order to issue an IHA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge

of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present while conducting the activities. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

- Occurrence of marine mammal species or stocks in the area in which take is anticipated (e.g., presence, abundance, distribution, density);
- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) action or environment (e.g., source characterization, propagation, ambient noise); (2) affected species (e.g., life history, dive patterns); (3) co-occurrence of marine mammal species with the activity; or (4) biological or behavioral context of exposure (e.g., age, calving or feeding areas);
- Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors;
- How anticipated responses to stressors impact either: (1) long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks;
- Effects on marine mammal habitat (e.g., marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat); and
- Mitigation and monitoring effectiveness.

The monitoring and reporting requirements described in the following were proposed by PG&E in its adequate and complete application and/or are the result of subsequent coordination between NMFS and PG&E. PG&E has agreed to the requirements. NMFS describes these below as requirements and has included them in the proposed IHA.

Visual Monitoring

Marine mammal monitoring must be conducted in accordance with the conditions in this section and the IHA. Marine mammal monitoring during pile driving and removal must be conducted by NMFS-approved PSOs in a manner consistent with the following:

- PSOs must be independent of the activity contractor (for example,

employed by a subcontractor) and have no other assigned tasks during monitoring periods;

- At least one PSO would have prior experience performing the duties of a PSO during construction activity pursuant to a NMFS' issued ITA;
- Other PSOs may substitute education (degree in biological science or related field) or training for experience;
- Where a team of three or more PSOs is required, a lead observer or monitoring coordinator would be designated. The lead observer would be required to have prior experience working as a marine mammal observer during construction;
- PSOs must be approved by NMFS prior to beginning any activity subject to the IHA.

PSOs should have the following additional qualifications:

- Ability to conduct field observations and collect data according to assigned protocols;
- Experience or training in the field identification of marine mammals, including the identification of behavior;
- Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations;
- Writing skills sufficient to prepare a report of observations including but not limited to the number and species of marine mammals observed; dates and times when in-water construction activities were conducted; dates, times, and reason for implementation of mitigation (or why mitigation was not implemented when required); and marine mammal behavior; and
- Ability to communicate orally, by radio or in person, with project personnel to provide real-time information on marine mammals observed in the area as necessary.

PG&E would have between one and three PSOs on site at all times during pile driving activities. One PSO would be designated as the Lead PSO and would receive updates from the other PSOs. The Lead PSO would be stationed at the active pile driving rig or at the best vantage point practicable to monitor the shutdown zones and implement shutdown and delay procedures. The other PSOs would be stationed at the best vantage points practicable to observe the monitoring zones. Exact locations would be determined in the field based on the pile driving site, field conditions, and in coordination with contractors, but may include docks, barges, and tower structures. PSOs would be equipped with high quality binoculars or spotting scopes for monitoring and radios and

cell phones for maintaining contact with other observers and work crew.

Monitoring would be conducted 30 minutes before, during, and 30 minutes after all in-water construction activities. PSOs would record all incidents of marine mammal occurrence, regardless of distance from activity, and would document any behavioral reactions in concert with distance from piles being driven or removed. Pile driving activities include the time to install or remove a single pile or series of piles, as long as the time elapsed between uses of the pile driving equipment is no more than 30 minutes.

Hydroacoustic Monitoring

Hydroacoustic monitoring, to be conducted for purposes of measuring sound source levels and sound propagation, will be conducted in accordance with a NMFS-approved acoustic monitoring plan. PG&E plans to conduct hydroacoustic monitoring throughout the entirety of the sediment remediation project, which is expected to span over multiple ITAs. Across the entire project, PG&E will collect data on a representative number of piles (at least 10 percent of each pile type and installation method). Given that PG&E's proposed hydroacoustic monitoring effort would span multiple IHAs, specific effort under any given IHA may vary. Therefore, under this proposed IHA, PG&E will only conduct hydroacoustic monitoring for pile types/installation methods for which hydroacoustic monitoring has not been previously conducted. PG&E may request that NMFS adjust the shutdown zones and revise the Level A and Level B harassment zones, as appropriate, pending NMFS' review and approval of the results of acoustic monitoring.

Reporting

Marine Mammal Monitoring Report

PG&E must submit a draft marine mammal monitoring report to NMFS within 90 days after the completion of pile driving activities, or 60 days prior to the requested issuance of any future IHAs for the project, or other projects at the same location, whichever comes first. A final report must be prepared and submitted within 30 calendar days of following receipt of any NMFS comments on the draft report. If no comments are received from NMFS within 30 calendar days of receipt of the draft report, the report shall be considered final. The marine mammal report would include an overall description of work completed, a narrative regarding marine mammal sightings, and associated PSO data

sheets and/or raw sighting data.

Specifically, the report would include:

- Dates and times (begin and end) of all marine mammal monitoring;
- Construction activities occurring during each daily observation period, including: (a) the number and type of piles that were driven and the method (e.g., impact, vibratory); and (b) total duration of driving time for each pile (vibratory driving) and number of strikes for each pile (impact driving);
- PSO locations during marine mammal monitoring;
- Environmental conditions during monitoring periods (at beginning and end of PSO shift and whenever conditions change significantly), including Beaufort sea state and any other relevant weather conditions including cloud cover, fog, sun glare, and overall visibility to the horizon, and estimated observable distance;
- Upon observation of a marine mammal, the following information must be recorded: (a) name of PSO who sighted the animal(s) and PSO location and activity at time of sighting; (b) time of sighting; (c) identification of the animal(s) (e.g., genus/species, lowest possible taxonomic level, or unidentified), PSO confidence in identification, and the composition of the group if there is a mix of species; (d) distance and location of each observed marine mammal relative to the pile being driven for each sighting; (e) estimated number of animals (min/max/best estimate); (f) estimated number of animals by cohort (adults, juveniles, neonates, group composition, etc.); (g) animal's closest point of approach and estimated time spent within the harassment zone; (h) description of any marine mammal behavioral observations (e.g., observed behaviors such as feeding or traveling), including an assessment of behavioral responses thought to have resulted from the activity (e.g., no response or changes in behavioral state such as ceasing feeding, changing direction, flushing, or breaching); and (i) description of any actions implemented in response to the sighting (e.g., delays, shutdown) and time and location of the action;
- Number of marine mammals detected within the harassment zones, by species; and
- Summary information about implementation of any mitigation (e.g., shutdowns and delays), a description of specific actions that ensued, and resulting changes in behavior of the animal(s), if any.

Hydroacoustic Monitoring Report

The hydroacoustic monitoring report must, at minimum, include the following:

- Hydrophone equipment and methods, recording device, sampling rate, distance (m) from the pile where recordings were made; depth of water and recordings device(s);
- Type and size of pile being driven, substrate type, method of driving during recordings (e.g., hammer model and energy), and total pile driving duration;
- Whether a sound attenuation device is used and, if so, a detailed description of the device used and the duration of its use per pile;
- For impact pile driving (per pile): Number of strikes and strike rate; depth of substrate to penetrate; pulse duration and mean, median, and maximum sound levels (dB re: 1 μ Pa); root mean square sound pressure level (SPL_{rms}); cumulative sound exposure level (SEL_{cum}), peak sound pressure level (SPL_{peak}), and single-strike sound exposure level (SEL_{ss});
- For vibratory driving/removal (per pile): Duration of driving per pile; mean, median, and maximum sound levels (dB re: 1 μ Pa); root mean square sound pressure level (SPL_{rms}), cumulative sound exposure level (SEL_{cum}) (and timeframe over which the sound is averaged);
- One-third octave band spectrum and power spectral density plot; and
- Transmission loss values for each pile size and type and installation method, when appropriate.

Reporting Injured or Dead Marine Mammals

In the event that personnel involved in the construction activities discover an injured or dead marine mammal, PG&E must report the incident to the Office of Protected Resources, NMFS (PR.ITP.MonitoringReports@noaa.gov) and to the West Coast regional stranding network (866-767-6114) as soon as feasible. If the death or injury was clearly caused by the specified activity, PG&E would immediately cease the specified activities until NMFS is able to review the circumstances of the incident and determine what, if any, additional measures are appropriate to ensure compliance with the terms of the IHA. PG&E would not resume their activities until notified by NMFS. The report would include the following information:

- Time, date, and location (latitude/longitude) of the first discovery (and updated location information if known and applicable);
- Species identification (if known) or description of the animal(s) involved;

- Condition of the animal(s) (including carcass condition if the animal is dead);
- Observed behaviors of the animal(s), if alive;
- If available, photographs or video footage of the animal(s); and
- General circumstances under which the animal was discovered.

Negligible Impact Analysis and Determination

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.*, population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be “taken” through harassment, NMFS considers other factors, such as the likely nature of any impacts or responses (*e.g.*, intensity, duration), the context of any impacts or responses (*e.g.*, critical reproductive time or location, foraging impacts affecting energetics), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS’ implementing regulations (54 FR 40338, September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the baseline (*e.g.*, as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

To avoid repetition, the discussion of our analysis applies to all the species listed in table 3, given that the anticipated effects of this activity on these different marine mammal stocks are expected to be similar. There is little information about the nature or severity of the impacts, or the size, status, or structure of any of these species or stocks that would lead to a different analysis for this activity.

Level A harassment is extremely unlikely given the small size of the Level A harassment isopleths and the required mitigation measures designed to minimize the possibility of injury to

marine mammals. No serious injury or mortality is anticipated given the nature of the activity.

Pile driving activities have the potential to disturb or displace marine mammals. Specifically, the project activities may result in take, in the form of Level B harassment from underwater sounds generated from impact and vibratory pile driving activities. Potential takes could occur if individuals move into the ensonified zones when these activities are underway.

The takes by Level B harassment would be due to potential behavioral disturbances. The potential for harassment is minimized through construction methods and the implementation of planned mitigation strategies (see Proposed Mitigation section).

Behavioral responses of marine mammals to pile driving at the project site, if any, are expected to be mild and temporary. Marine mammals within the Level B harassment zone may not show any visual cues they are disturbed by activities or could become alert, avoid the area, leave the area, or display other mild responses that are not observable such as changes in vocalization patterns. Given the short duration of noise-generating activities per day and that pile driving and removal would occur over approximately 62 days during a span of 5 months, any harassment would be temporary. There are no other areas or times of known biological importance for any of the affected species.

Take would occur within a limited, confined area of each stock’s range. Further, the amount of take authorized is extremely small when compared to stock abundance.

No marine mammal stocks for which incidental take authorization is proposed are listed as threatened or endangered under the ESA. Only one stock, the Eastern North Pacific Stock of the northern fur seal, is listed as depleted under the MMPA. However, we do not expect the proposed authorizations in this action to affect the stock. No injury or mortality is proposed for authorization, take by Level B harassment is limited (five takes over the duration of the project), and the proposed action should have no effect on the reproduction of this species. In addition, the five authorized takes for the northern fur seal include both the depleted Eastern North Pacific Stock and the California stock, which is not depleted.

The relatively low marine mammal occurrences in the area, shutdown zones, and planned monitoring make

injury of marine mammals unlikely. The shutdown zones would be thoroughly monitored before the pile driving activities begin, and activities would be postponed if a marine mammal is sighted within the shutdown zone. There is a high likelihood that marine mammals would be detected by trained observers under environmental conditions described for the project. Limiting pile driving activities to daylight hours would also increase detectability of marine mammals in the area. Therefore, the mitigation and monitoring measures are expected to eliminate the potential for injury and Level A harassment as well as reduce the amount and intensity of Level B behavioral harassment. Furthermore, the pile driving activities analyzed here are similar to, or less impactful than, numerous construction activities conducted in other similar locations which have occurred with no reported injuries or mortality to marine mammals, and no known long-term adverse consequences from behavioral harassment.

The project is not expected to have significant adverse effects on marine mammal habitat. There are no known Biologically Important Areas (BIAs) or ESA-designated critical habitat within the project area, and the activities would not permanently modify existing marine mammal habitat.

In summary and as described above, the following factors primarily support our preliminary determination that the impacts resulting from this activity are not expected to adversely affect any of the species or stocks through effects on annual rates of recruitment or survival:

- No serious injury or mortality is anticipated or authorized;
- The specified activities and associated ensounded areas are very small relative to the overall habitat ranges of all species;
- The project area does not overlap known BIAs or ESA-designated critical habitat;
- The lack of anticipated significant or long-term effects or marine mammal habitat; and
- The presumed efficacy of the mitigation measures in reducing the effects of the specified activity.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the proposed monitoring and mitigation measures, NMFS preliminarily finds that the total marine mammal take from the proposed activity will have a negligible impact on all affected marine mammal species or stocks.

Small Numbers

As noted previously, only take of small numbers of marine mammals may be authorized under section 101(a)(5)(A) and (D) of the MMPA for specified activities other than military readiness activities. The MMPA does not define small numbers and so, in practice, where estimated numbers are available, NMFS compares the number of individuals taken to the most appropriate estimation of abundance of the relevant species or stock in our determination of whether an authorization is limited to small numbers of marine mammals. When the predicted number of individuals to be taken is fewer than one-third of the species or stock abundance, the take is considered to be of small numbers (see 86 FR 5322, January 19, 2021). Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

The amount of take NMFS proposes to authorize is below one-third of the estimated stock abundances for all stocks (table 9). These are all likely conservative estimates because they assume all takes are of different individual animals which is likely not the case. Some individuals may return multiple times in a day, but PSOs would count them as separate takes if they cannot be individually identified.

Based on the analysis contained herein of the proposed activity (including the proposed mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS preliminarily finds that small numbers of marine mammals would be taken relative to the population size of the affected species or stocks.

Unmitigable Adverse Impact Analysis and Determination

There are no relevant subsistence uses of the affected marine mammal stocks or species implicated by this action. Therefore, NMFS has determined that the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

Endangered Species Act

Section 7(a)(2) of the ESA of 1973 (16 U.S.C. 1531 *et seq.*) requires that each Federal agency ensures that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure

ESA compliance for the issuance of ITAs, NMFS consults internally whenever we propose to authorize take for ESA-listed species.

No incidental take of ESA-listed species is proposed for authorization or expected to result from this activity. Therefore, NMFS has determined that formal consultation under section 7 of the ESA is not required for this action.

Proposed Authorization

As a result of these preliminary determinations, NMFS proposes to issue an IHA to PG&E for conducting pile driving activities in San Francisco Bay, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated. A draft of the proposed IHA can be found at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities>.

Request for Public Comments

We request comment on our analyses, the proposed authorization, and any other aspect of this notice of proposed IHA for the proposed construction. We also request comment on the potential renewal of this proposed IHA as described in the paragraph below. Please include with your comments any supporting data or literature citations to help inform decisions on the request for this IHA or a subsequent renewal IHA.

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 Description of Proposed Activity section of this notice is planned or (2) the activities as described in the Description of Proposed Activity section of this notice would not be completed by the time the IHA expires and a renewal would allow for completion of the activities beyond that described in the *Dates and Duration* section of this notice, provided all of the following conditions are met:

- 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).
- The request for renewal must include the following:

1. 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).

2. 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.

- 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.

Dated: December 19, 2025.

Kimberly Damon-Randall,

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

[FR Doc. 2025–23798 Filed 12–23–25; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

U.S. Integrated Ocean Observing System (IOOS®) Advisory Committee Public Meeting

AGENCY: U.S. Integrated Ocean Observing System (IOOS®), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce.

ACTION: Notice of open meeting; opportunity for public comment.

SUMMARY: Notice is hereby given of a hybrid meeting of the U.S. Integrated Ocean Observing System (IOOS®) Advisory Committee (Committee). The meeting is open to the public and an opportunity for oral and written comments will be provided.

DATES: The meeting will be held virtually and in-person on January 20, 2026 from 8:45 a.m. to 5 p.m. Eastern Standard Time (EST) and January 21, 2026 from 8:45 a.m. to 12 p.m. (EST). Registration is required to attend either virtually or in person; please register online at <https://forms.gle/J514DTapodxShqFC8> or email laura.gewain@noaa.gov. If attending in-person, registration is required by 5 p.m. EST on January 13, 2026 to meet security requirements for visitor access at this location. If attending virtually, registration is required by 5 p.m. EST on January 16, 2026.

ADDRESSES: The meeting will be held in-person at 1315 East-West Hwy., Silver Spring, MD, 4th Floor Conference Room. To register for the meeting and/or submit public comments, use this link <https://forms.gle/J514DTapodxShqFC8> or email laura.gewain@noaa.gov. See **SUPPLEMENTARY INFORMATION** for instructions and other information about public participation and special accommodations.

FOR FURTHER INFORMATION CONTACT:

Krisa Arzayus, Designated Federal Official, U.S. IOOS Advisory Committee, U.S. IOOS Program, 240–533–9455, krisa.arzayus@noaa.gov or visit the U.S. IOOS Advisory Committee website at <http://ioos.noaa.gov/community/u-s-ioos-advisory-committee/>.

SUPPLEMENTARY INFORMATION:

I. Background

The Committee was established by the NOAA Administrator as directed by section 12304(d) of the Integrated Coastal and Ocean Observation System Act (the Act) as amended by Section 103 of the Coordinated Ocean Observations and Research Act of 2020 (COORA) (Pub. L. 116–271, Title I). 33 U.S.C. 3603(d). The Committee advises the NOAA Administrator and the Interagency Ocean Observation Committee (IOOC) on matters related to the responsibilities and authorities set forth in the Act and other appropriate matters as the Administrator, the Ocean Policy Committee described at 33 U.S.C. 3603(c)(1), and IOOC may refer to the Committee for review and advice. The charter and summaries of prior meetings can be found online at <https://ioos.noaa.gov/community/u-s-ioos-advisory-committee/>.

II. Matters To Be Considered

The meeting will focus on: (1) updates from NOAA and key partners, including the NOAA Administrator, and (2) working sessions on work plan topics. The latest version of the agenda will be posted at <http://ioos.noaa.gov/community/u-s-ioos-advisory-committee/>. The times and the agenda topics described here are subject to change.

III. Public Comment Instructions

The meeting will be open to public participation (check agenda on website to confirm time). The Committee expects that public statements presented at its meetings will not be repetitive of previously submitted verbal or written statements. In general, each individual or group making a verbal presentation

will be limited to a total time of three (3) minutes. Written comments should be received by January 12, 2026 11:59 p.m. EST, to provide sufficient time for Committee review. Written comments received after January 12, 2026 11:59 p.m. EST, will be distributed to the Committee, but may not be reviewed prior to the meeting date. To submit written comments, please fill out the brief form at <https://forms.gle/J514DTapodxShqFC8> or email your comments and your organization/company affiliation to laura.gewain@noaa.gov. All comments received are a part of the public record. All personally identifiable information (name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the commenter will be publicly accessible. The written comment is considered the official comment and should include discussion of all points you wish to make. The Federal agencies 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). Comments that are not responsive or contain profanity, vulgarity, threats, or other inappropriate language will not be considered. This NOAA public meeting will be recorded for use in preparation of minutes. If you have a public comment, you acknowledge that you will be recorded and are aware you can opt out of the meeting. Participation in the meeting constitutes consent to the recording.

IV. Special accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Krisa Arzayus, Designated Federal Official by phone (240–533–9455) or email (krisa.arzayus@noaa.gov) or to Laura Gewain (laura.gewain@noaa.gov) by January 6, 2026 11:59 p.m.

Authority: Integrated Coastal and Ocean Observation System Act, part of the Omnibus Public Land Management Act of 2009 (Pub. L. 111–11), and the Coordinated Ocean Observations and Research Act of 2020 (Pub. L. No. 116–271).

Jeffrey L. Payne,

Acting Director, U.S. IOOS Program National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2025–23793 Filed 12–23–25; 8:45 am]

BILLING CODE 3510–NE–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XF367]

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to Geophysical Surveys Related to Oil and Gas Activities in the Gulf of America (Formerly 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 America (GOA), originally published as "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 modified the Letter of Authorization (LOA) issued to TGS for the taking of marine mammals incidental to geophysical survey activity in the GOA.

DATES: This LOA is effective through April 19, 2026.

ADDRESSES: The LOA, LOA request, and supporting documentation are available online at: <https://www.fisheries.noaa.gov/marine-mammal-protection/issued-letters-authorization-oil-and-gas-industry-geophysical-survey>. In case of problems accessing these documents, please call the contact listed below (**FOR FURTHER INFORMATION CONTACT**).

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

SUPPLEMENTARY INFORMATION:**Background**

Section 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 (Gulf of America) GOA¹ 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. The rule 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 50 CFR 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 affirmance 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 (LPAI) standard of the MMPA.

NMFS issued a LOA to TGS on December 20, 2024, for the take of marine mammals incidental to a three-dimensional (3D) ocean bottom node survey in the East Breaks area, effective December 20, 2024, through December 19, 2025. Please see the **Federal Register** notice of issuance (89 FR 105536, December 27, 2024) for additional detail regarding the LOA and the survey activity.

On July 22, 2025, TGS informed NMFS that its planned survey area and timing had shifted and, accordingly, they requested a modification to the LOA to reflect the new survey area and dates. No survey activity had begun. TGS requested the expiration date be extended to April 19, 2026, and increase the survey to 105 total days of sound source operation in Zone 6. On August 19, 2025, NMFS issued a modified LOA to TGS (90 FR 41060; August 22, 2025).

On November 26, 2025, TGS notified NMFS that the survey area had changed again based on market interest. TGS is now requesting 140 total days of sound source operation with 139 days in zone 6 and 1 day in zone 7. The monthly

¹ Pursuant to Executive Order 14172, "Restoring Names That Honor American Greatness," and Department of the Interior Secretarial Order 3423, "The Gulf of America," the body of water formerly known as the Gulf of Mexico is now called the Gulf of America. Accordingly, NMFS amended the incidental take regulations to reflect the change. See 90 FR 38001 (August 7, 2025).

distribution of survey days is not known in advance, though we assume that the planned 140 days of source operation would occur contiguously. Take estimates for each species are based on the time period that produces the greatest value and have been updated based on the revised survey plan. There are no other changes to the planned survey.

For the Rice’s whale, recent survey data, sightings, and acoustic data support Rice’s whale occurrence in waters throughout the GOA between approximately 100 meters (m) and 400 m depth along the continental shelf break, and associated habitat-based density modeling has identified similar habitat (*i.e.*, approximately 100 to 400 m water depths along the continental shelf break) as being Rice’s whale habitat (Garrison *et al.*, 2023; Soldevilla *et al.*, 2022, 2024). NMFS’ 2024 final rule provided detailed discussion regarding Rice’s whale habitat (see, *e.g.*, 89 FR 31508, 31519).

TGS’s planned activities will overlap with this depth range, with approximately 10 percent of the area expected to be ensonified by the survey above root-mean-squared pressure received levels (RMS SPL) of 160 decibel (dB) (referenced to 1 micropascal (re 1 μPa)) overlapping the 100–400 m isobaths. Therefore, there is some reasonable potential for take of Rice’s whale to occur in association

with this survey. The generic acoustic exposure modeling results in one take of Rice’s whales and we have rounded that up to a group size, authorizing two Rice’s whale takes.

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 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 (see 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 and in the **Federal Register** notice of issuances (90 FR 41060, August 22,

2025; 89 FR 105536, December 27, 2024). Subsequently, the total incidents of harassment for each species are multiplied by scalar ratios (except in the cases where the take estimate has been rounded up to reflect a group size) to produce a derived product that better reflects the number of individuals likely to be taken within a survey (as compared to the total number of instances of take), accounting for the likelihood that some individual marine mammals may be taken on more than 1 day (see 86 FR 5404, January 19, 2021). The output of this scaling, where appropriate, is incorporated into adjusted total take estimates that are the basis for NMFS’ small numbers determinations, as depicted in table 1.

This product is used by NMFS in making the necessary small numbers determinations through comparison with the best available abundance estimates (see discussion at 86 FR 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

Species	Authorized take	Scaled take ¹	Abundance ²	Percent abundance
Rice’s whale	³ 2	NA	51	3.9
Sperm whale	716	303	2,451	12.4
<i>Kogia spp</i>	⁴ 404	123	1,385	10.3
Beaked whales	259	26	1,038	2.5
Rough-toothed dolphin	2,856	820	4,853	16.9
Bottlenose dolphin	3,160	907	151,886	0.5
Clymene dolphin	4,917	1,411	6,136	23.0
Atlantic spotted dolphin	6,604	1,895	21,506	8.8
Pantropical spotted dolphin	15,683	4,501	50,209	9.0
Spinner dolphin	⁵ 152	NA	2,199	5.1
Striped dolphin	2,755	791	16,102	4.9
Fraser’s dolphin	1,140	327	1,665	19.6
Risso’s dolphin	465	137	1,974	6.9
Blackfish ⁶	7,665	2,261	9,535	23.7
Short-finned pilot whale	2,543	750	3,277	22.9

¹ Scalar ratios were applied to “Authorized Take” values as described at 86 FR 5322 and 86 FR 5404 (January 19, 2021) to derive scaled take numbers shown here.

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 SAR abundance estimate is used.

³ Modeled take of 1 increased to account for potential encounter with a group of average size (Maze-Foley and Mullin, 2006).

⁴ Includes 20 takes by Level A harassment and 384 takes by Level B harassment. Scalar ratio is applied to takes by Level B harassment only; small numbers determination made on basis of scaled Level B harassment take plus authorized Level A harassment take.

⁵ Modeled take of 12 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 TGS's proposed survey activity described in its LOA application, as subsequently modified by TGS, 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 a modification to the LOA to TGS authorizing the take of marine mammals incidental to its geophysical survey activity, as described above.

Dated: December 22, 2025.

Michael P. Ruccio,

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

[FR Doc. 2025-23842 Filed 12-23-25; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XF215]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to the Alaska Department of Transportation and Public Facilities' Cold Bay Ferry Terminal Reconstruction Project in Cold Bay, Alaska

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

ACTION: Notice; proposed incidental harassment authorization; request for comments on proposed authorization and possible renewal.

SUMMARY: NMFS has received a request from the Alaska Department of Transportation and Public Facilities (ADOT&PF) for authorization to take marine mammals incidental to the Cold Bay Ferry Terminal Reconstruction Project in Cold Bay, Alaska. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an incidental harassment authorization (IHA) to incidentally take marine mammals

during the specified activities. NMFS is also requesting comments on a possible one-time, 1-year renewal that could be issued under certain circumstances and if all requirements are met, as described in Request for Public Comments at the end of this notice. NMFS will consider public comments prior to making any final decision on the issuance of the requested MMPA authorization and agency responses will be summarized in the final notice of our decision.

DATES: Comments and information must be received no later than January 28, 2026.

ADDRESSES: Comments should be addressed to Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service and should be submitted via email to ITP.Potlock@noaa.gov. Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities>. In case of problems accessing these documents, please call the contact listed below.

Instructions: NMFS is not responsible for comments sent by any other method, to any other address or individual, or received after the end of the comment period. Comments, including all attachments, must not exceed a 25-megabyte file size. All comments received are a part of the public record and will generally be posted online at <https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act> without change. All personal identifying information (*e.g.*, name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

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

SUPPLEMENTARY INFORMATION:

Background

The MMPA prohibits the “take” of marine mammals, with certain exceptions. Section 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) directs 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 proposed or, if the taking is limited to harassment, a notice of a proposed IHA is provided to the public for review.

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 the species or stocks for taking for certain subsistence uses (collectively referred to as “mitigation”); and requirements pertaining to the monitoring and reporting of the takings. The definitions of all applicable MMPA statutory terms used above are included in the relevant sections below and can be found in section 3 of the MMPA (16 U.S.C. 1362) and NMFS regulations at 50 CFR 216.103.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216-6A, NMFS must review our proposed action (*i.e.*, the issuance of an IHA) with respect to potential impacts on the human environment.

This action is consistent with categories of activities identified in Categorical Exclusion B4 (IHAs with no anticipated serious injury or mortality) of the Companion Manual for NAO 216-6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS has preliminarily determined that the issuance of the proposed IHA qualifies to be categorically excluded from further NEPA review.

Summary of Request

On July 30, 2025, NMFS received a request from ADOT&PF for an IHA to take marine mammals incidental to pile-driving activities for the Cold Bay Ferry Terminal Reconstruction Project in Cold Bay, Alaska. Following NMFS' review of the application, ADOT&PF submitted revised versions on November 14, 2025, November 21, 2025, December 11, 2025, and December 19, 2025. The application was deemed adequate and complete on

December 12, 2025. ADOT&PF’s request is for take of six species (eight stocks) of marine mammals by Level B harassment and, for a subset of these species, Level A harassment. Neither ADOT&PF nor NMFS expect serious injury or mortality to result from this activity and, therefore, an IHA is appropriate.

NMFS previously issued several IHAs to ADOT&PF for similar coastal construction work between 2018 and 2025 (e.g., 83 FR 5063, February 5, 2018; 83 FR 29749, June 26, 2018; July 19, 2023, 88 FR 46145; 90 FR 24385, June 10, 2025; 90 FR 38134, August 7, 2025). To date, ADOT&PF has complied with all the requirements (e.g., mitigation, monitoring, and reporting) of the previous IHAs.

Description of Proposed Activity

Overview

ADOT&PF has requested an IHA to take marine mammals incidental to in-water construction activities. The original Cold Bay Dock was constructed by the State of Alaska in 1978, expanded in 1993, and then refurbished in 2015. Currently, the structure is nearing the end of serviceable life and is at risk of failing, which would be detrimental for the communities that so heavily rely on this infrastructure. At present, use restrictions are currently in place that limit axel loads and gross vehicle weights until the dock can be fully replaced. Given the receipt of additional funding, ADOT&PF plans to replace the aging public dock to

improve accessibility; support commercial, subsistence, and recreation users; continue uninterrupted ferry service; secure cargo delivery and bulk materials offloading; ensure public safety; and safeguard vessel moorage. Additionally, this project would maintain access to essential services for surrounding communities that rely on Cold Bay as a hub for fuel, goods, cargo, and potable drinking water. The new dock would be designed and built to accommodate commercial use, freight and fuel transportation, private vessel use, and public uses like emergency medical services and public transportation through the Alaska Marine Highway System (AMHS).

Given the proposed use of vibratory and impact pile driving to remove and install piles, there is potential of the take of marine mammals by Level B harassment and, for a subset of the species, Level A harassment. No serious injury and/or mortality is expected or proposed for this project.

Dates and Duration

ADOT&PF has been awarded funds by the U.S. Department of Transportation’s (DOT) Maritime Administration (MARAD) under the Port Infrastructure Development Program (via the Infrastructure Investment and Jobs Act (Pub. L. 117–58, November 15, 2021)), a discretionary grant program awarded on a competitive basis to projects that improve the safety, efficiency, or reliability of the movement of goods into, out of, around, or within a port

(<https://www.maritime.dot.gov/PIDPgrants>). These grants are awarded to improve port and related freight infrastructure to meet the nation’s freight transport needs and ensure that port infrastructure can keep up with the growth of freight volume as it continues to increase.

ADOT&PF intends to begin their project on May 1, 2028, and continue for one year through April 30, 2029. The entire project is anticipated to consist of 18 months of activities (in-water and on-shore), whereas the in-water activities (i.e., pile driving) are expected to occur for 12 months, consisting of 231 (not necessarily consecutive) days requiring 10 to 12 hours of activities per day, following the general schedule of events described in table 1. In-water pile driving is expected to occur near-continuously for the first 7 months (May through November with an estimated driving duration of 165 days), which would allow for the installation of the trestle and dock piles. For the next 3 months (December through February), limited in-water pile driving is expected to occur as the dock superstructure is completed. Likely activities during these months include fender and dolphin installation (estimated 21 days of in-water pile driving). After this is completed, demolition activities on the existing dock would be performed, estimated to require non-continuous in-water pile driving over approximately 45 days within a 2-month period (March to April).

TABLE 1—ANTICIPATED SCHEDULE OF ACTIVITIES

Phase	Tasks
Mobilize to site	The contractor would mobilize the necessary equipment and personnel.
Install Trestle ^a	• Install temporary work trestle and pile driving templates. • Drive and proof foundation pile. • Remove templates and template support piles. • Install precast concrete caps. • Set trestle superstructure. • Grout deck joints and place and cast-in-place concrete in closure pours.
Install Dock	• Install temporary work trestle and pile driving templates. • Drive and proof foundation pile. • Remove templates and template support piles. • Install precast concrete caps. • Set precast concrete deck panels. • Grout deck joints and place and cast-in-place concrete in closure pours. • Install on-dock appurtenances (bullrails, ladders, cleats, bollards, <i>etc.</i>).
Install Dolphins	• Install pile driving template. • Drive and proof foundation piles. • Remove template and extract template support piles. • Install pile caps. • Set catwalks.
Install Fendering	• Install pile driving template. • Drive and proof fender piles. • Install fender panels.
Utility Installation	• Install onshore utility service as required. • Install trestle supported service lines. • Install dock-mounted headers and service connections.

TABLE 1—ANTICIPATED SCHEDULE OF ACTIVITIES—Continued

Phase	Tasks
Existing Dock Demolition	• Remove appurtenances and utilities located on the dock and trestle. • Demolish and remove existing superstructure. • Extract existing piles.
Demobilization	• All demolished existing materials staged on the uplands would be removed from the site.

^a Installation of the trestle would likely progress from shore, seaward to the dock location.

However, project delays may occur due to a number of factors, including other permitting requirements, availability of equipment and/or materials, weather-related delays, equipment maintenance and/or repair, transit to and from ports to survey locations, and other contingencies. Therefore, the analysis herein represents a best estimate of activities and timeframe and does not imply limits to activities in a given month.

Specific Geographic Region

The proposed project is located within southwestern tip of the Alaska Peninsula (Township 57 South, Range 89 West of the Seward Meridian; U.S. Geological Survey Quadrangle COLD BAY A-3) (see figure 1). Situated at approximately Latitude 55°12' N, Longitude 162°42' W, the city encompasses 53.41 square miles (mi²; 138 square kilometers (km²)) of land and 14.64 mi² (38 km²) of water. Per the United States 2020 census, approximately 50 people live within Cold Bay (U.S. Census Bureau, 2025). The City of Cold Bay sits approximately

138 feet (ft; 42 meters (m)) above mean sea level.

Geologically, the region is part of the Aleutian arc, a highly active segment of the Pacific Ring of Fire. The landscape is dominated by prominent volcanic features, including Frosty Peak and Mount Simeon nearby, with the more distant and active Pavlof and Shishaldin Volcanoes. The region contains complex geology, which is shaped by a long history of volcanic, glacial, and tectonic processes. The immediate topography of Cold Bay is characterized by a rolling, treeless tundra dotted with numerous lakes and swamps. This landscape is part of a broad coastal lowland on the northern side of the peninsula, which generally lies less than 100 ft (30.5 m) above sea level. Cold Bay's most defining physical characteristic is its location on a narrow isthmus separating two great marine ecosystems: the cold, shallow, and enclosed Bering Sea to the north, and the deep, warmer, and open North Pacific Ocean to the south. This unique geographical position creates a convergence zone of powerful ocean currents, temperature gradients, and

salinities, resulting in one of the most biologically productive marine environments on the planet. The City of Cold Bay lies on the shore of Cold Bay, a large Pacific Ocean embayment, and is adjacent to the Izembek Lagoon (a shallow, 30-mi (48-km) coastal ecosystem that contains one of the world's largest beds of eelgrass (*Zostera marina*) (Rice and Hogan, 1995)) on the Bering Sea side.

Cold Bay serves as a primary commercial and transportation hub for the Alaska Peninsula and a gateway to the Aleutian Islands. It is the headquarters for the Izembek National Wildlife Refuge (see U.S. Fish and Wildlife Service (2025a)) and a key logistics and support center for the commercial fishing industry in the region. The city's primary infrastructure includes the Port of Cold Bay, which serves the state ferry system, and the Cold Bay Airport, a critical regional hub and emergency diversion airport for trans-Pacific flights with one of the longest runways in Alaska.

BILLING CODE 3510-22-P

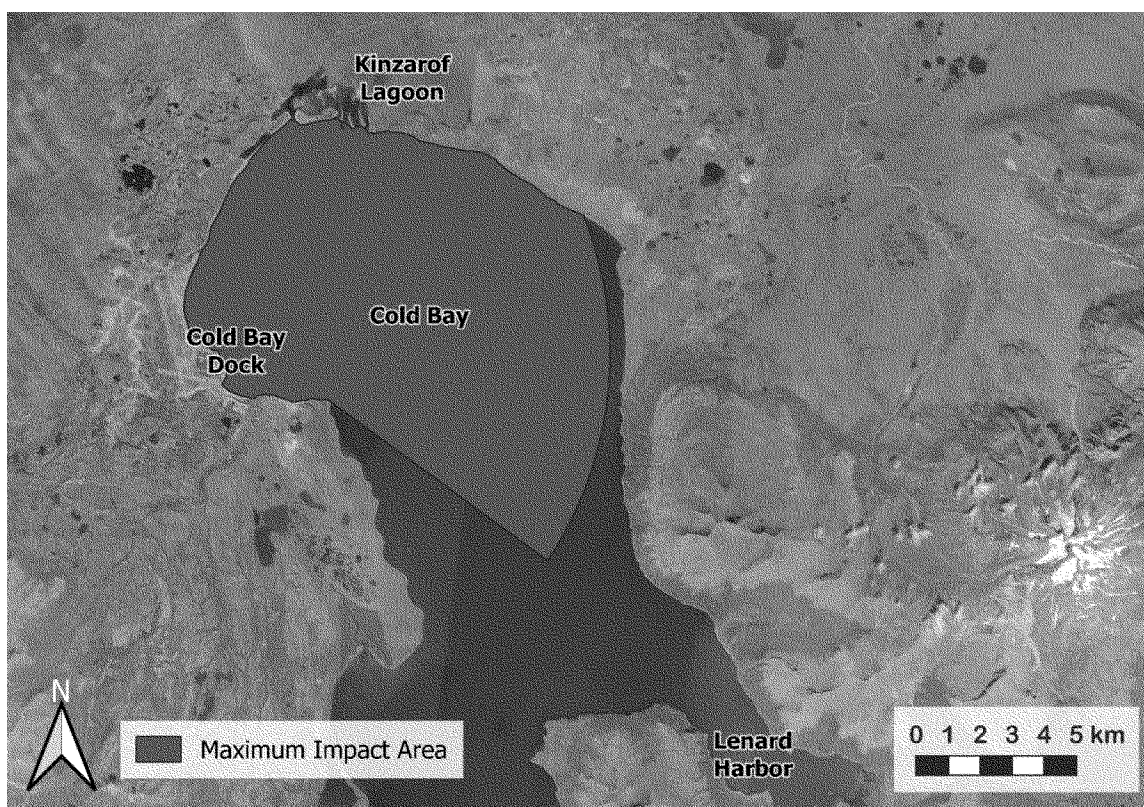


Figure 1 -- Proposed Project Location and Vicinity Map for the Cold Bay Ferry Terminal Reconstruction Project

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Detailed Description of the Specified Activity

ADOT&PF has proposed to remove components of the existing and aging structure and install new components to better serve the Cold Bay community. The existing Cold Bay Dock is a critical facility for the community and surrounding areas, serving as the sole location for the sea-based delivery of fuel, goods, cargo, and potable drinking water. Per the 2022–2027 Alaska Statewide Comprehensive Economic Development Strategy, officials have highlighted that coastal communities, such as Cold Bay, depend on efficient and well-functioning waterfront infrastructure to receive goods. Currently, the dock is nearing the end of its serviceable life and is at risk of failing. Use restrictions are in place that limit axle loads and gross vehicle weights until the dock can be replaced. The new dock would be designed and built to accommodate a variety of uses, including commercial use, freight and fuel transportation, private vessel uses, and public uses like emergency medical services and public transportation through the AMHS.

The project would be completed in stages, depending on the structure being constructed, including development of a trestle and abutment, a dock, dolphin piles, and then demolition/removal of old structures (*i.e.*, trestle, dock, dolphins, and fenders). For all in-water work, the project would require the mobilization of barges and support vessels, all of which are likely to come from different communities within Alaska. The number of vessels is not currently known as the construction contractor has not been chosen but all support vessels, support barges, material barges, and construction barges would follow known routes when transiting to the construction site.

To develop the new infrastructure, a 360 ft (109.7 m) by 54 ft (16.5 m) pile-supported dock with adjacent mooring dolphins would be developed. The applicant would also develop fendering (both heavy-duty on the primary face and light-duty fenders on opposite faces) around the new dock. All access to the dock would be made available by a 22 ft (6.7 m) by 1,800 ft (548.6 m) pile-supported trestle. The trestle and dock would be constructed using pre-cast concrete elements, supported by pile-driven steel foundation piles. For the

trestle and dock construction, vibratory pile driving would be used whenever feasible, but impact pile driving likely would be needed to proof piles. The trestle would be constructed using prefabricated sections supported by pile bents. A pile-supported abutment would support the nearshore end of the trestle. All pier-support piles would be installed first, followed by the pre-cast concrete caps, and then the superstructure would be set. The trestle piles would require both vibratory and impact pile driving methods, to install and (in some cases remove) a total of 208 temporary piles, 261 new permanent piles, and 322 existing piles. No simultaneous pile driving is planned. Pile specifics for the dock trestle are described here:

- Vibratory and impact installation of 113 permanent trestle support piles (36-inch (in); 91.44-centimeter (cm) pipe piles);
- Vibratory and impact installation and vibratory removal of 150 temporary trestle piles (24-in (60.96-cm) to 36-in (91.44-cm) pipe or H-piles);
- Vibratory and impact installation of 80 permanent dock support piles (36-in (91.44-cm) pipe piles);

- Vibratory and impact installation and vibratory removal of 50 temporary dock piles (24-in (60.96-cm) to 36-in (91.44-cm) pipe piles);

- Vibratory installation of 20 fender piles (30-in (76.2-cm) pipe piles); and

- Vibratory installation of 40 fender piles (24-in (60.96-cm) pipe piles).

The construction of the dock would proceed similarly to trestle construction, where the dock piles would be installed using both vibratory and impact methods. All permanent piles would be driven at their pre-planned locations, which would be followed by a setting of pre-cast concrete caps and structural panel systems that make up the superstructure of the dock. Piles would be set and driven using a crane either located on a barge or working on a temporary structure. Fenders (using two fender piles) would be installed along the offshore dock face to protect the dock from moored vessels. Single pile fenders would be installed on the shoreward dock face. Installation would only be by vibratory pile driving. Lastly, various dock appurtenances and utilities would be installed, although these would not necessitate any pile driving. These would serve the current and future needs of the dock and consist of water, electrical, and fuel piping, such as the installation of utility lines and diesel/gasoline fuel lines, a portable

water supply line, and new lighting along the new trestle and dock.

Upon completion of the dock and trestle structures, the applicant would install two dolphins at opposite ends, using four temporary pile templates initially driven for the installation of each dolphin and removed following completion. Temporary piles would be installed using vibratory pile driving, and impact pile driving would be used to proof the vertical load supporting piles or in the case of obstructions. All temporary piles would be extracted using vibratory pile driving. Pile specifics for the dolphins are described here:

- Vibratory and impact installation of eight permanent dolphin piles (36-in (76.2-cm) pipe piles); and

- Vibratory installation and removal of eight temporary dolphin piles (24-in (60.96-cm) to 36-in (76.2-cm) pipe piles).

During all the construction, demolition and removal of the existing older dock structure would be coordinated with the installation of the new structure to minimize any potential disturbance to users of the facility. Trestle demolition would not be performed until the new trestle is completed. Demolition for the dock and trestle would include removal of the concrete superstructure, support piles,

fenders and all dock utilities and appurtenances. Removal of the superstructure would be accomplished by first saw-cutting and pulling the concrete deck panels. The existing pile caps would then be cut, while the supporting piles would be cut at the pile/cap interface and then the caps would be lifted and removed. Pile extraction would proceed following the removal of the superstructure. All piles would be removed using vibratory pile driving equipment or cut off at the mudline. Piles removed during demolition would include:

- 180 trestle piles (16-in (40.64-cm) pipe piles);
- 24 dock piles (16-in (40.64-cm) pipe piles);
- 65 dock piles (26-in (66-cm) pipe piles);
- 9 dolphin piles (16-in (40.64-cm) pipe piles);
- 13 fender piles (20-in (50.8-cm) pipe piles); and
- 31 fender piles (16-in (40.64-cm) timber piles).

Upon completion, refuse and excess materials from the project would be either reclaimed, recycled, or disposed of and all project equipment would be demobilized to the port of origin.

A summary of all piles planned to be installed or removed and their specific attributes are included in table 2 below.

TABLE 2—PILE PARAMETERS FOR THE PROPOSED COLD BAY FERRY TERMINAL RECONSTRUCTION PROJECT

Specific activity	Pile information	Pile material	Installation and/or removal approach	Number of piles
Permanent Removal Activities				
Trestle removal	16-inch pipe pile	Steel	Vibratory	180
Dock removal	16-inch pipe pile	Steel	Vibratory	24
Dock removal	26-inch pipe pile	Steel	Vibratory	65
Dolphin removal	16-inch pipe pile	Steel	Vibratory	9
Fender removal	20-inch pipe pile	Steel	Vibratory	13
Fender removal	16-inch pipe pile	Timber	Vibratory	31
Removal total				322
Temporary installation and subsequent removal				
Temporary trestle pile	24-inch to 36-inch pipe pile or H-pile	Steel	Vibratory installation, impact installation, vibratory removal.	240
Temporary dock pile	24-inch to 36-inch pipe pile	Steel	Vibratory installation, impact installation, vibratory removal.	50
Temporary dolphin pile	24-inch to 36-inch pipe pile	Steel	Vibratory installation, impact installation, vibratory removal.	8
Temporary installation and removal total.				298
Permanent Installation Activities				
Trestle support piles	36-inch pipe piles	Steel	Vibratory and impact installation	113
Dock support pile	36-inch pipe pile	Steel	Vibratory and impact installation	80
Fender pile	30-inch pipe pile	Steel	Vibratory installation	20
Fender pile	24-inch pipe pile	Steel	Vibratory installation	40
Dolphin pile	36-inch pipe pile	Steel	Vibratory and impact installation	8

TABLE 2—PILE PARAMETERS FOR THE PROPOSED COLD BAY FERRY TERMINAL RECONSTRUCTION PROJECT—Continued

Specific activity	Pile information	Pile material	Installation and/or removal approach	Number of piles
Installation total				269
In-water total				889

Proposed mitigation, monitoring, and reporting measures are described in detail later in this document (please see Proposed Mitigation and Proposed Monitoring and Reporting).

Description of Marine Mammals in the Area of Specified Activities

Sections 3 and 4 of the application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history of the potentially affected species. NMFS fully considered all of this information, and we refer the reader to these descriptions, instead of reprinting the information. Additional information regarding population trends and threats may be found in NMFS' Stock Assessment Reports (SARs; <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments>) and more general information about

these species (*e.g.*, physical and behavioral descriptions) may be found on NMFS' website (<https://www.fisheries.noaa.gov/find-species>).

Table 3 lists all species or stocks for which take is expected and proposed to be authorized for this activity and summarizes information related to the population or stock, including regulatory status under the MMPA and Endangered Species Act (ESA) and potential biological removal (PBR), where known. PBR is defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population (as described in NMFS' SARs). While no serious injury or mortality is anticipated or proposed to be authorized here, PBR and annual serious injury and mortality (M/SI) from anthropogenic sources are

included here as gross indicators of the status of the species or stocks and other threats.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study or survey area. NMFS' stock abundance estimates for most species represent the total estimate of individuals within the geographic area, if known, that comprises that stock. For some species, this geographic area may extend beyond U.S. waters. All managed stocks in this region are assessed in NMFS' Alaska SARs. All values presented in table 3 are the most recent available at the time of publication (including from the draft 2024 SARs) and are available online at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments>.

TABLE 3—SPECIES ^a WITH ESTIMATED TAKE FROM THE SPECIFIED ACTIVITIES

Common name	Scientific name	Stock	ESA/ MMPA status; strategic (Y/N) ^b	Stock abundance (CV; N _{min} ; most recent abundance survey) ^c	PBR	Annual M/SI ^d
Order Artiodactyla—Infraorder Cetacea—Mysticeti (baleen whales)						
<i>Family Eschrichtiidae:</i> Gray whale	<i>Eschrichtius robustus</i>	Eastern North Pacific	-, -, N	26,960 (0.05; 25,849; 2016) ..	801	131
<i>Family Balaenopteridae</i> (rorquals): Humpback whale	<i>Megaptera novaeangliae</i>	Hawai'i	-, -, N	11,278 (0.56; 7,265; 2020)	127	27.09
		Mexico-North Pacific	T, D, Y	N/A (N/A; N/A; 2006) ^e	UND	0.6
		Western North Pacific	E, D, Y	1,084 (0.88; 1,007; 2022)	3.4	5.82
Odontoceti (toothed whales, dolphins, and porpoises)						
<i>Family Delphinidae:</i> Killer whale	<i>Orcinus orca</i>	Eastern North Pacific Gulf of Alaska, Aleutian Islands, and Bering Sea Transient.	-, -, N	587 (N/A; 587; 2012)	5.9	0.8
<i>Family Phocoenidae</i> (por- poises): Harbor porpoise	<i>Phocoena phocoena</i>	Gulf of Alaska	-, -, Y	31,046 (0.21; N/A; 1998)	UND	72
Order—Carnivora—Pinnipedia						
<i>Family Otariidae</i> (eared seals and sea lions): Steller sea lion	<i>Eumetopias jubatus</i>	Western	E, D, Y	49,837 (N/A; 49,837; 2023) ^f ..	299	267
<i>Family Phocidae</i> (earless seals): Harbor seal	<i>Phoca vitulina</i>	Cook Inlet/Shelikof Strait	-, -, N	28,411 (N/A; 26,907; 2018) ...	807	107

^a Information on the classification of marine mammal species can be found on the web page for The Society for Marine Mammalogy's Committee on Taxonomy (<https://marinemammalscience.org/science-and-publications/list-marine-mammal-species-subspecies/>).

^b Endangered Species Act (ESA) status: Endangered (E), Threatened (T); MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR or is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

^cNMFS marine mammal stock assessment reports online at <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments>. CV is the coefficient of variation; N_{min} is the minimum estimate of stock abundance. In some cases, a CV is not applicable. N/A indicates data are unknown. UND (undetermined) PBR indicates data are available to calculate a PBR level, but a determination has been made that calculating a PBR level using those data is inappropriate (see the SAR for details).

^dThese values, found in NMFS's SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (e.g., commercial fisheries, ship strikes). Annual M/SI often cannot be determined precisely and is sometimes presented as a minimum value or range. A CV associated with estimated mortality due to commercial fisheries is presented in some cases.

^eAbundance estimates are currently considered unknown.

^f N_{est} is best estimate of counts, which have not been corrected for animals at sea during abundance surveys.

As indicated above, all six species (with eight managed stocks) in table 3 temporally and spatially co-occur with the activity to the degree that take is reasonably likely to occur.

For all marine mammal species, there are no known biologically important areas (BIA) within the coastal site that ADOT&PF's proposed activities would be expected to impact. For fin whales (*Balaenoptera physalus*), gray whales, humpback whales, North Pacific right whales (*Eubalaena japonica*), and sperm whales (*Physeter macrocephalus*), while these have been sighted near Cold Bay historically or could be encountered along anticipated vessel transit routes, these are not expected within the Bay itself, where the construction would be occurring and acoustic disturbance could occur, given its relatively shallow depths. Furthermore, any feeding or migratory BIAs exist outside of the project area in more offshore areas

(Brower *et al.*, 2022). Given the inshore and sheltered nature of the project, NMFS does not expect that any acoustic influence would transmit outside of Cold Bay. Furthermore, the area where the proposed project would occur represents a small portion of the available habitat for these species.

In addition, northern sea otters may (*Enhydra lutris kenyoni*) be found in Cold Bay (Alaska Department of Fish and Game, 2025). However, this species and its stocks are managed by the U.S. Fish and Wildlife Service and are not considered further in this notice.

Marine Mammal Hearing

Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals

are able to hear. Not all marine mammal species have equal hearing capabilities or hear over the same frequency range (e.g., Richardson *et al.*, 1995; Wartzok and Ketten, 1999; Au and Hastings, 2008). To reflect this, Southall *et al.* (2007, 2019) recommended that marine mammals be divided into hearing groups based on directly measured (behavioral or auditory evoked potential techniques) or estimated hearing ranges (behavioral response data, anatomical modeling, *etc.*). Generalized hearing ranges were chosen based on the ~65 decibel (dB) threshold from composite audiograms, previous analyses in NMFS (2018), and/or data from Southall *et al.* (2007) and Southall *et al.* (2019). We note that the names of two hearing groups and the generalized hearing ranges of all marine mammal hearing groups have been recently updated (NMFS, 2024) as reflected below in table 4.

TABLE 4—MARINE MAMMAL HEARING GROUPS
[NMFS, 2024]

Hearing group	Generalized hearing range *
Low-frequency (LF) cetaceans (baleen whales)	7 Hz to 36 kHz.
High-frequency (HF) cetaceans (dolphins, toothed whales, beaked whales, bottlenose whales)	150 Hz to 160 kHz.
Very High-frequency (VHF) cetaceans (true porpoises, <i>Kogia</i> , river dolphins, Cephalorhynchid, <i>Lagenorhynchus cruciger</i> & <i>L. australis</i>).	200 Hz to 165 kHz.
Phocid pinnipeds (PW) (underwater) (true seals)	40 Hz to 90 kHz.
Otariid pinnipeds (OW) (underwater) (sea lions and fur seals)	60 Hz to 68 kHz.

* Represents the generalized hearing range for the entire group as a composite (*i.e.*, all species within the group), where individual species' hearing ranges may not be as broad. Generalized hearing range chosen based on ~65 dB threshold from composite audiogram, previous analysis in NMFS (2018), and/or data from Southall *et al.* (2007) and Southall *et al.* (2019). Additionally, animals are able to detect very loud sounds above and below that "generalized" hearing range.

Of the species potentially present in the action area, two are considered low-frequency (LF) cetaceans (*i.e.*, gray whales and humpback whales), one is considered a high-frequency (HF) cetacean (*i.e.*, killer whale), one is considered a very high-frequency (VHF) cetacean (*i.e.*, harbor porpoise), one is an otariid pinniped (*i.e.*, Steller sea lion), and one is a phocid pinniped (*i.e.*, harbor seal).

For more detail concerning these groups and associated frequency ranges, please see NMFS (2024) for a review of available information.

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

This section includes a summary and provides a discussion of the ways in which components of the specified activity may impact marine mammals and their habitat. The Estimated Take of Marine Mammals section later in this document includes a quantitative analysis of the number of individuals that are expected to be taken by this activity. The Negligible Impact Analysis and Determination section considers the content of this section, the Estimated Take of Marine Mammals section, and the Proposed Mitigation section, to draw conclusions regarding the likely impacts

of these activities on the reproductive success or survivorship of individuals and whether those impacts are reasonably expected to, or reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

Acoustic effects on marine mammals during the specified activity are expected to potentially occur from impact and vibratory pile installation and removal. The effects of underwater noise from ADOT&PF's proposed activities have the potential to result in Level B harassment of marine mammals in the action area and, for some species as a result of certain activities, Level A harassment.

Overall, the proposed activities include the removal and installation of old, temporary, and permanent piles in Cold Bay, Alaska. There are a variety of types and degrees of effects to marine mammals, prey species, and habitat that could occur as a result of the project. Below we provide a brief description of the types of sound sources that would be generated by the project, the general impacts from these types of activities, and an analysis of the anticipated impacts on marine mammals from the project, with consideration of the proposed mitigation measures.

Description of Sound Sources for the Specified Activities

Activities associated with the project that have the potential to incidentally take marine mammals through exposure to sound would include impact pile driving for installation, and vibratory pile driving for installation and removal. Impact hammers typically operate by repeatedly dropping and/or pushing a heavy piston onto a pile to drive the pile into the substrate. Sound generated by impact hammers is impulsive, characterized by rapid rise

times and high peak levels, a potentially injurious combination (Hastings and Popper, 2005). Vibratory hammers install piles by vibrating them and allowing the weight of the hammer to push them into the substrate. Vibratory hammers typically produce less sound (*i.e.*, lower levels) than impact hammers. Peak sound pressure levels (SPLs) may be 180 dB or greater but are generally 10 to 20 dB lower than SPLs generated during impact pile driving of the same-sized pile (Oestman *et al.*, 2009; California Department of Transportation (CALTRANS), 2015, 2020). Sounds produced by vibratory hammers are non-impulsive; compared to sounds produced by impact hammers, the rise time is slower, reducing the probability and severity of injury, and the sound energy is distributed over more time (Nedwell and Edwards, 2002; Carlson *et al.*, 2005).

The likely or possible impacts of ADOT&PF’s proposed activities on marine mammals could involve both non-acoustic and acoustic stressors. Potential non-acoustic stressors could

result from the physical presence of the equipment and personnel. However, given there are no known pinniped haul-out sites in the vicinity of the project site, visual and other non-acoustic stressors would be limited, and any impacts to marine mammals are expected to primarily be acoustic in nature. While there are known rookeries for Steller sea lions at Clubbing Rocks North (57 km (35.4 mi) to the south), Clubbing Rocks South (58 km (36 mi) to the south), and Pinnacle Rock (76 km (47.2 mi) to the southeast), no Steller sea lion haulouts have been reported in Cold Bay (Fritz *et al.*, 2015). Additionally, while harbor seals are known to haul out at the mouth of Kinzarof Lagoon, the mouth of the Lagoon is approximately 8.35 km (5.2 mi) away the existing Cold Bay dock and the largest isopleth for any in-air noises from construction is 0.152 km (0.09 mi), meaning that any harbor seals near the Lagoon would not be affected by in-air noises (table 5). Therefore, NMFS considers take from in-air exposures to be unlikely, and it is not considered further in this notice.

TABLE 5—CALCULATED ISOPLETHS IN KILOMETERS FOR POTENTIAL IN-AIR SOURCES ^a

Installation details			Harbor seal		Other pinnipeds	
Structure	Installation approach	Source level (dB) ^a	Isopleths (m)	Isopleths (km)	Isopleths (m)	Isopleths (km)
36-in round steel	Vibratory	95	27.0	0.0	8.5	0.0
	Impact	112	191.4	0.2	60.6	0.1
24-in round steel	Vibratory	92	19.1	0.0	6.1	0.0
	Impact	110	152.0	0.2	48.1	0.0
16-in round steel	Vibratory	87.5	11.4	0.0	3.6	0.0
	Impact	110	152.0	0.2	48.1	0.0
Gravity fill	Vibratory	n/a				

^a Impulsive RMS L_{max} (Unweighted), Non-Impulsive RMS Leq (Unweighted). All values are relative to 20 μPa and at 15 m (50 ft) from the pile.

Potential Effects of Underwater Sound on Marine Mammals

The introduction of anthropogenic noise into the aquatic environment from impact and vibratory pile driving is the primary means by which marine mammals may be harassed from ADOT&PF’s specified activity. Anthropogenic sounds cover a broad range of frequencies and sound levels and can have a range of highly variable impacts on marine life from none or minor to potentially severe responses depending on received levels, duration of exposure, behavioral context, and various other factors. Broadly, underwater sound from active acoustic sources, such as those in the project, can potentially result in one or more of the following: temporary or permanent hearing impairment, non-auditory physical or physiological effects,

behavioral disturbance, stress, and masking (Richardson *et al.*, 1995; Gordon *et al.*, 2003; Nowacek *et al.*, 2007; Southall *et al.*, 2007; Götz *et al.*, 2009). We describe the more severe effects of certain non-auditory physical or physiological effects only briefly as we do not expect that use of impact and vibratory hammers are reasonably likely to result in such effects (see below for further discussion). Potential effects from impulsive sound sources can range in severity from effects such as behavioral disturbance or tactile perception to physical discomfort, slight injury of the internal organs and the auditory system, or mortality (Yelverton *et al.*, 1973). Non-auditory physiological effects or injuries that theoretically might occur in marine mammals exposed to high level underwater sound or as a secondary effect of extreme

behavioral reactions (*e.g.*, change in dive profile as a result of an avoidance reaction) caused by exposure to sound include neurological effects, bubble formation, resonance effects, and other types of organ or tissue damage (Cox *et al.*, 2006; Southall *et al.*, 2007; Zimmer and Tyack, 2007; Tal *et al.*, 2015). The proposed project activities considered here do not involve the use of devices such as explosives or mid-frequency tactical sonar that are associated with these types of effects. In general, animals exposed to natural or anthropogenic sound may experience physical and psychological effects, ranging in magnitude from none to severe (Southall *et al.*, 2007, 2019). Exposure to anthropogenic noise has the potential to result in auditory threshold shifts and behavioral reactions (*e.g.*, avoidance, temporary cessation of foraging and vocalizing, changes in dive

behavior). It can also lead to non-observable physiological responses, such as an increase in stress hormones. Additional noise in a marine mammal's habitat can mask acoustic cues used by marine mammals to carry out daily functions, such as communication and predator and prey detection.

The degree of effect of an acoustic exposure on marine mammals is dependent on several factors, including, but not limited to, sound type (*e.g.*, impulsive vs. non-impulsive), signal characteristics, the species, age and sex class (*e.g.*, adult male vs. mom with calf), duration of exposure, the distance between the noise source and the animal, received levels, behavioral state at time of exposure, and previous history with exposure (Wartzok *et al.*, 2004; Southall *et al.*, 2007). In general, sudden, high-intensity sounds can cause hearing loss, as can longer exposures to lower-intensity sounds. Moreover, any temporary or permanent loss of hearing, if it occurs at all, would occur almost exclusively for noise within an animal's hearing range. We describe below the specific manifestations of acoustic effects that may occur based on the activities proposed by ADOT&PF.

Richardson *et al.* (1995) described zones of increasing intensity of effect that might be expected to occur in relation to distance from a source and assuming that the signal is within an animal's hearing range. First (at the greatest distance) is the area within which the acoustic signal would be audible (potentially perceived) to the animal but not strong enough to elicit any overt behavioral or physiological response. The next zone (closer to the receiving animal) corresponds with the area where the signal is audible to the animal and of sufficient intensity to elicit behavioral or physiological responsiveness. The third is a zone within which, for signals of high intensity, the received level is sufficient to potentially cause discomfort or tissue damage to auditory or other systems. Overlaying these zones to a certain extent is the area within which masking (*i.e.*, when a sound interferes with or masks the ability of an animal to detect a signal of interest that is above the absolute hearing threshold) may occur; the masking zone may be highly variable in size.

Below, we provide additional detail regarding potential impacts on marine mammals and their habitat from noise in general, starting with hearing impairment, as well as from the specific activities ADOT&PF plans to conduct, to the degree it is available.

Hearing Threshold Shifts—NMFS defines a noise-induced threshold shift

(TS) as a change, usually an increase, in the threshold of audibility at a specified frequency or portion of an individual's hearing range above a previously established reference level (NMFS, 2018, 2024). The amount of threshold shift is customarily expressed in dB. TS can be permanent or temporary. As described in NMFS (2018, 2024) there are numerous factors to consider when examining the consequence of TS, including, but not limited to, the signal temporal pattern (*e.g.*, impulsive or non-impulsive), likelihood an individual would be exposed for a long enough duration or to a high enough level to induce a TS, the magnitude of the TS, time to recovery (seconds to minutes or hours to days), the frequency range of the exposure (*i.e.*, spectral content), the hearing frequency range of the exposed species relative to the signal's frequency spectrum (*i.e.*, how animal uses sound within the frequency band of the signal; *e.g.*, Kastelein *et al.*, 2014), and the overlap between the animal and the source (*e.g.*, spatial, temporal, and spectral).

Auditory Injury (AUD INJ)—NMFS (2024) defines AUD INJ as damage to the inner ear that can result in destruction of tissue, such as the loss of cochlear neuron synapses or auditory neuropathy (Houser, 2021; Finneran, 2024). AUD INJ may or may not result in a permanent threshold shift (PTS). PTS is subsequently defined as a permanent, irreversible increase in the threshold of audibility at a specified frequency or portion of an individual's hearing range above a previously established reference level (NMFS, 2024). PTS does not generally affect more than a limited frequency range, and an animal that has incurred PTS has some level of hearing loss at the relevant frequencies; typically, animals with PTS or other AUD INJ are not functionally deaf (Au and Hastings, 2008; Finneran, 2016). Available data from humans and other terrestrial mammals indicate that a 40-dB threshold shift approximates AUD INJ onset (see Ward *et al.*, 1958, 1959; Ward, 1960; Kryter *et al.*, 1966; Miller, 1974; Ahroon *et al.*, 1996; Henderson *et al.*, 2008). AUD INJ levels for marine mammals are estimates, as with the exception of a single study unintentionally inducing PTS in a harbor seal (Kastak *et al.*, 2008), there are no empirical data measuring AUD INJ in marine mammals largely due to the fact that, for various ethical reasons, experiments involving anthropogenic noise exposure at levels inducing AUD INJ are not typically pursued or authorized (NMFS, 2024).

Temporary Threshold Shift (TTS)—TTS is a temporary, reversible increase

in the threshold of audibility at a specified frequency or portion of an individual's hearing range above a previously established reference level (NMFS, 2024), and is not considered an AUD INJ. Based on data from marine mammal TTS measurements (see Southall *et al.*, 2007, 2019), a TTS of 6 dB is considered the minimum threshold shift clearly larger than any day-to-day or session-to-session variation in a subject's normal hearing ability (Finneran *et al.*, 2000, 2002; Schlundt *et al.*, 2000). As described in Finneran (2015), marine mammal studies have shown the amount of TTS increases with the 24-hour cumulative sound exposure level (SEL₂₄) in an accelerating fashion: at low exposures with lower SEL₂₄, the amount of TTS is typically small and the growth curves have shallow slopes. At exposures with higher SEL₂₄, the growth curves become steeper and approach linear relationships with the sound exposure level (SEL).

Depending on the degree (elevation of threshold in dB), duration (*i.e.*, recovery time), and frequency range of TTS, and the context in which it is experienced, TTS can have effects on marine mammals ranging from discountable to more impactful (similar to those discussed in auditory masking, below). For example, a marine mammal may be able to readily compensate for a brief, relatively small amount of TTS in a non-critical frequency range that takes place during a time when the animal is traveling through the open ocean, where ambient noise is lower and there are not as many competing sounds present. Alternatively, a larger amount and longer duration of TTS sustained during time when communication is critical for successful mother/calf interactions could have more severe impacts. We note that reduced hearing sensitivity as a simple function of aging has been observed in marine mammals, as well as humans and other taxa (Southall *et al.*, 2007), so we can infer that strategies exist for coping with this condition to some degree, though likely not without cost.

Many studies have examined noise-induced hearing loss in marine mammals (see Finneran (2015) and Southall *et al.* (2019) for summaries). TTS is the mildest form of hearing impairment that can occur during exposure to sound (Kryter, 2013). While experiencing TTS, the hearing threshold rises, and a sound must be at a higher level in order to be heard. In terrestrial and marine mammals, TTS can last from minutes or hours to days (in cases of strong TTS). In many cases, hearing sensitivity recovers rapidly after

exposure to the sound ends. For cetaceans, published data on the onset of TTS are limited to captive bottlenose dolphin (*Tursiops truncatus*), beluga whale (*Delphinapterus leucas*), harbor porpoise, and Yangtze finless porpoise (*Neophocoena asiakororientalis*) (Southall *et al.*, 2019). For pinnipeds in water, measurements of TTS are limited to harbor seals, elephant seals (*Mirounga angustirostris*), bearded seals (*Erignathus barbatus*) and California sea lions (*Zalophus californianus*) (Kastak *et al.*, 1999, 2007; Kastelein *et al.*, 2019b, 2019c, 2021, 2022a, 2022b; Reichmuth *et al.*, 2019; Sills *et al.*, 2020). TTS was not observed in spotted (*Phoca largha*) and ringed (*Pusa hispida*) seals exposed to single airgun impulse sounds at levels matching previous predictions of TTS onset (Reichmuth *et al.*, 2016). These studies examine hearing thresholds measured in marine mammals before and after exposure to intense or long-duration sound exposures. The difference between the pre-exposure and post-exposure thresholds can be used to determine the amount of threshold shift at various post-exposure times.

The amount and onset of TTS depends on the exposure frequency. Sounds below the region of best sensitivity for a species or hearing group are less hazardous than those near the region of best sensitivity (Finneran and Schlundt, 2013). At low frequencies, onset-TTS exposure levels are higher compared to those in the region of best sensitivity (*i.e.*, a low frequency noise would need to be louder to cause TTS onset when TTS exposure level is higher), as shown for harbor porpoises and harbor seals (Kastelein *et al.*, 2019a, 2019c). Note that in general, harbor seals and harbor porpoises have a lower TTS onset than other measured pinniped or cetacean species (Finneran, 2015). In addition, TTS can accumulate across multiple exposures, but the resulting TTS would be less than the TTS from a single, continuous exposure with the same SEL (Mooney *et al.*, 2009; Finneran *et al.*, 2010; Kastelein *et al.*, 2014, 2015). This means that TTS predictions based on the total, SEL₂₄ would overestimate the amount of TTS from intermittent exposures, such as sonars and impulsive sources. Nachtigall *et al.* (2018) describe measurements of hearing sensitivity of multiple odontocete species (bottlenose dolphin, harbor porpoise, beluga, and false killer whale (*Pseudorca crassidens*)) when a relatively loud sound was preceded by a warning sound. These captive animals were shown to reduce hearing sensitivity

when warned of an impending intense sound. Based on these experimental observations of captive animals, the authors suggest that wild animals may dampen their hearing during prolonged exposures or if conditioned to anticipate intense sounds. Another study showed that echolocating animals (including odontocetes) might have anatomical specializations that might allow for conditioned hearing reduction and filtering of low-frequency ambient noise, including increased stiffness and control of middle ear structures and placement of inner ear structures (Ketten *et al.*, 2021). Data available on noise-induced hearing loss for mysticetes are currently lacking (NMFS, 2024). Additionally, the existing marine mammal TTS data come from a limited number of individuals within these species.

Relationships between TTS and AUD INJ thresholds have not been studied in marine mammals, and there are no measured PTS data for cetaceans, but such relationships are assumed to be similar to those in humans and other terrestrial mammals. AUD INJ typically occurs at exposure levels at least several dB above that inducing mild TTS (*e.g.*, a 40-dB threshold shift approximates AUD INJ onset (Kryter *et al.*, 1966; Miller, 1974), while a 6-dB threshold shift approximates TTS onset (Southall *et al.*, 2007, 2019). Based on data from terrestrial mammals, a precautionary assumption is that the AUD INJ thresholds for impulsive sounds (such as impact pile driving pulses as received close to the source) are at least 6 dB higher than the TTS threshold on a peak-pressure basis and AUD INJ cumulative sound exposure level thresholds are 15 to 20 dB higher than TTS cumulative sound exposure level thresholds (Southall *et al.*, 2007, 2019). Given the higher level of sound or longer exposure duration necessary to cause AUD INJ as compared with TTS, it is considerably less likely that AUD INJ could occur. Given the stationary nature of the construction activities, the fact that Cold Bay is relatively sheltered (*i.e.*, not located in the open ocean), and the fact that many marine mammals are likely moving through the project areas and not remaining for extended periods of time, the potential for threshold shift is low for most species.

Behavioral Effects—Exposure to noise also has the potential to behaviorally disturb marine mammal response—in other words, not every response qualifies as behavioral disturbance, and for responses that do, those of a higher level, or accrued across a longer duration, have the potential to affect foraging, reproduction, or survival.

Behavioral disturbance may include a variety of effects, including subtle changes in behavior (*e.g.*, minor or brief avoidance of an area or changes in vocalizations), more conspicuous changes in similar behavioral activities, and more sustained and/or potentially severe reactions, such as displacement from or abandonment of high-quality habitat. Behavioral responses may include changing durations of surfacing and dives, changing direction and/or speed; reducing/increasing vocal activities; changing/cessation of certain behavioral activities (such as socializing or feeding); eliciting a visible startle response or aggressive behavior (such as tail/fin slapping or jaw clapping); and avoidance of areas where sound sources are located. In addition, pinnipeds may increase their haul out time, possibly to avoid in-water disturbance (Thorson and Reyff, 2006).

Behavioral responses to sound are highly variable and context-specific and any reactions depend on numerous intrinsic and extrinsic factors (*e.g.*, species, state of maturity, experience, current activity, reproductive state, auditory sensitivity, time of day), as well as the interplay between factors (*e.g.*, Richardson *et al.*, 1995; Wartzok *et al.*, 2004; Southall *et al.*, 2007, 2019; Weilgart, 2007; Archer *et al.*, 2010). Behavioral reactions can vary not only among individuals but also within an individual, depending on previous experience with a sound source, context, and numerous other factors (Ellison *et al.*, 2012), and can vary depending on characteristics associated with the sound source (*e.g.*, whether it is moving or stationary, number of sources, distance from the source). In general, pinnipeds seem more tolerant of, or at least habituate more quickly to, potentially disturbing underwater sound than do cetaceans, and generally seem to be less responsive to exposure to industrial sound than most cetaceans. Please see Appendices B and C of Southall *et al.* (2007) and Gomez *et al.* (2016) for reviews of studies involving marine mammal behavioral responses to sound.

Habituation can occur when an animal's response to a stimulus wanes with repeated exposure, usually in the absence of unpleasant associated events (Wartzok *et al.*, 2004). Animals are most likely to habituate to sounds that are predictable and unvarying. It is important to note that habituation is appropriately considered as a “progressive reduction in response to stimuli that are perceived as neither aversive nor beneficial,” rather than as, more generally, moderation in response to human disturbance (Bejder *et al.*,

2009). The opposite process is sensitization, when an unpleasant experience leads to subsequent responses, often in the form of avoidance, at a lower level of exposure.

As noted above, behavioral state may affect the type of response. For example, animals that are resting may show greater behavioral change in response to disturbing sound levels than animals that are highly motivated to remain in an area for feeding (Richardson *et al.*, 1995; Wartzok *et al.*, 2004; National Research Council (NRC), 2005). Controlled experiments with captive marine mammals have shown pronounced behavioral reactions, including avoidance of loud sound sources (Ridgway *et al.*, 1997; Finneran *et al.*, 2003). Observed responses of wild marine mammals to loud-pulsed sound sources (e.g., seismic airguns) have been varied but often consist of avoidance behavior or other behavioral changes (Richardson *et al.*, 1995; Morton and Symonds, 2002; Nowacek *et al.*, 2007).

Available studies show wide variation in response to underwater sound; therefore, it is difficult to predict specifically how any given sound in a particular instance might affect marine mammals perceiving the signal (e.g., Erbe *et al.*, 2019). If a marine mammal does react briefly to an underwater sound by changing its behavior or moving a small distance, the impacts of the change are unlikely to be significant to the individual, let alone the stock or population. If a sound source displaces marine mammals from an important feeding or breeding area for a prolonged period, impacts on individuals and populations could be significant (e.g., Lusseau and Bejder, 2007; Weilgart, 2007; NRC, 2005). However, there are broad categories of potential response, which we describe in greater detail here, that include alteration of dive behavior, alteration of foraging behavior, effects to breathing, interference with or alteration of vocalization, avoidance, and flight.

Avoidance and displacement—Changes in dive behavior can vary widely and may consist of increased or decreased dive times and surface intervals as well as changes in the rates of ascent and descent during a dive (e.g., Frankel and Clark, 2000; Costa *et al.*, 2003; Ng and Leung, 2003; Nowacek *et al.*, 2004; Goldbogen *et al.*, 2013a, 2013b, Blair *et al.*, 2016). Variations in dive behavior may reflect interruptions in biologically significant activities (e.g., foraging) or they may be of little biological significance. The impact of an alteration to dive behavior resulting from an acoustic exposure depends on what the animal is doing at the time of

the exposure and the type and magnitude of the response.

Disruption of feeding behavior can be difficult to correlate with anthropogenic sound exposure, so it is usually inferred by observed displacement from known foraging areas, the appearance of secondary indicators (e.g., bubble nets or sediment plumes), or changes in dive behavior. Acoustic and movement bi-logging tools also have been used in some cases to infer responses to anthropogenic noise. For example, Blair *et al.* (2015) reported significant effects on humpback whale foraging behavior in Stellwagen Bank in response to ship noise including slower descent rates, and fewer side-rolling events per dive with increasing ship noise. In addition, Wisniewska *et al.* (2018) reported that tagged harbor porpoises demonstrated fewer prey capture attempts when encountering occasional high-noise levels resulting from vessel noise as well as more vigorous fluking, interrupted foraging, and cessation of echolocation signals observed in response to some high-noise vessel passes. As for other types of behavioral response, the frequency, duration, and temporal pattern of signal presentation, as well as differences in species sensitivity, are likely contributing factors to differences in response in any given circumstance (e.g., Croll *et al.*, 2001; Nowacek *et al.*, 2004; Madsen *et al.*, 2006; Yazvenko *et al.*, 2007). A determination of whether foraging disruptions incur fitness consequences would require information on or estimates of the energetic requirements of the affected individuals and the relationship between prey availability, foraging effort and success, and the life history stage of the animal.

Respiration rates vary naturally with different behaviors and alterations to breathing rate as a function of acoustic exposure can be expected to co-occur with other behavioral reactions, such as a flight response or an alteration in diving. However, respiration rates in and of themselves may be representative of annoyance or an acute stress response. Various studies have shown that respiration rates may either be unaffected or could increase, depending on the species and signal characteristics, again highlighting the importance in understanding species differences in the tolerance of underwater noise when determining the potential for impacts resulting from anthropogenic sound exposure (e.g., Kastelein *et al.*, 2001; 2005; 2006; Gailey *et al.*, 2007). For example, harbor porpoise respiration rates increased in response to pile driving sounds at and above a received broadband SPL of 136 dB (zero-peak

SPL: 151 dB re 1 μ Pa; SEL of a single strike (SEL_{ss}): 127 dB re 1 μ Pa²-s) (Kastelein *et al.*, 2013).

Avoidance is the displacement of an individual from an area or migration path as a result of the presence of a sound or other stressors, and is one of the most obvious manifestations of disturbance in marine mammals (Richardson *et al.*, 1995). For example, gray whales are known to change direction—deflecting from customary migratory paths—in order to avoid noise from seismic surveys (Malme *et al.*, 1984). Harbor porpoises, Atlantic white-sided dolphins (*Lagenorhynchus actus*), and minke whales (*Balaenoptera acutorostrata*) have demonstrated avoidance in response to vessels during line transect surveys (Palka and Hammond, 2001). In addition, beluga whales in the St. Lawrence Estuary in Canada have been reported to increase levels of avoidance with increased boat presence by way of increased dive durations and swim speeds, decreased surfacing intervals, and by bunching together into groups (Blane and Jaakson, 1994). Avoidance may be short-term, with animals returning to the area once the noise has ceased (e.g., Bowles *et al.*, 1994; Goold, 1996; Stone *et al.*, 2000; Morton and Symonds, 2002; Gailey *et al.*, 2007). Longer-term displacement is possible, however, which may lead to changes in abundance or distribution patterns of the affected species in the affected region if habituation to the presence of the sound does not occur (e.g., Blackwell *et al.*, 2004; Bejder *et al.*, 2006; Teilmann *et al.*, 2006).

A flight response is a dramatic change in normal movement to a directed and rapid movement away from the perceived location of a sound source. The flight response differs from other avoidance responses in the intensity of the response (e.g., directed movement, rate of travel). Relatively little information on flight responses of marine mammals to anthropogenic signals exist, although observations of flight responses to the presence of predators have occurred (Connor and Heithaus, 1996; Bowers *et al.*, 2018). The result of a flight response could range from brief, temporary exertion and displacement from the area where the signal provokes flight to, in extreme cases, marine mammal strandings (England *et al.*, 2001). However, it should be noted that response to a perceived predator does not necessarily invoke flight (Ford and Reeves, 2008), and whether individuals are solitary or in groups may influence the response.

Behavioral disturbance can also impact marine mammals in more subtle

ways. Increased vigilance may result in costs related to diversion of focus and attention (*i.e.*, when a response consists of increased vigilance, it may come at the cost of decreased attention to other critical behaviors such as foraging or resting). These effects have generally not been demonstrated for marine mammals, but studies involving fishes and terrestrial animals have shown that increased vigilance may substantially reduce feeding rates (*e.g.*, Beauchamp and Livoreil, 1997; Fritz *et al.*, 2002; Purser and Radford, 2011). In addition, chronic disturbance can cause population declines through reduction of fitness (*e.g.*, decline in body condition) and subsequent reduction in reproductive success, survival, or both (*e.g.*, Harrington and Veitch, 1992; Daan *et al.*, 1996; Bradshaw *et al.*, 1998). However, Ridgway *et al.* (2006) reported that increased vigilance in bottlenose dolphins exposed to sound over a 5-day period did not cause any sleep deprivation or stress effects.

Many animals perform vital functions, such as feeding, resting, traveling, and socializing, on a diel cycle (24-hour cycle). Disruption of such functions resulting from reactions to stressors such as sound exposure are more likely to be significant if they last more than one diel cycle or recur on subsequent days (Southall *et al.*, 2007). Consequently, a behavioral response lasting less than 1 day and not recurring on subsequent days is not considered particularly severe unless it could directly affect reproduction or survival (Southall *et al.*, 2007). Note that there is a difference between multi-day substantive (*i.e.*, meaningful) behavioral reactions and multi-day anthropogenic activities. For example, just because an activity lasts for multiple days does not necessarily mean that individual animals are either exposed to activity-related stressors for multiple days or, further, exposed in a manner resulting in sustained multi-day substantive behavioral responses.

Physiological stress responses—An animal's perception of a threat may be sufficient to trigger stress responses consisting of some combination of behavioral responses, autonomic nervous system responses, neuroendocrine responses, or immune responses (*e.g.*, Selye, 1950; Moberg, 2000). In many cases, an animal's first and sometimes most economical (in terms of energetic costs) response is behavioral avoidance of the potential stressor. Autonomic nervous system responses to stress typically involve changes in heart rate, blood pressure, and gastrointestinal activity. These responses have a relatively short

duration and may or may not have a significant long-term effect on an animal's fitness.

Neuroendocrine stress responses often involve the hypothalamus-pituitary-adrenal system. Virtually all neuroendocrine functions that are affected by stress—including immune competence, reproduction, metabolism, and behavior—are regulated by pituitary hormones. Stress-induced changes in the secretion of pituitary hormones have been implicated in failed reproduction, altered metabolism, reduced immune competence, and behavioral disturbance (*e.g.*, Moberg, 1987; Blecha, 2000). Increases in the circulation of glucocorticoids are also equated with stress (Romano *et al.*, 2004).

The primary distinction between stress (which is adaptive and does not normally place an animal at risk) and “distress” is the cost of the response. During a stress response, an animal uses glycogen stores that can be quickly replenished once the stress is alleviated. In such circumstances, the cost of the stress response would not pose serious fitness consequences. However, when an animal does not have sufficient energy reserves to satisfy the energetic costs of a stress response, energy resources must be diverted from other functions. This state of distress would last until the animal replenishes its energetic reserves sufficient to restore normal function.

Relationships between these physiological mechanisms, animal behavior, and the costs of stress responses are well studied through controlled experiments and for both laboratory and free-ranging animals (*e.g.*, Holberton *et al.*, 1996; Hood *et al.*, 1998; Jessop *et al.*, 2003; Krausman *et al.*, 2004; Lankford *et al.*, 2005; Ayres *et al.*, 2012; Yang *et al.*, 2022). Stress responses due to exposure to anthropogenic sounds or other stressors and their effects on marine mammals have also been reviewed (Fair and Becker, 2000; Romano *et al.*, 2002b) and, more rarely, studied in wild populations (*e.g.*, Romano *et al.*, 2002a). For example, Rolland *et al.* (2012) found that noise reduction from reduced ship traffic in the Bay of Fundy was associated with decreased stress in North Atlantic right whales. In addition, Lemos *et al.* (2022) observed a correlation between higher levels of fecal glucocorticoid metabolite concentrations (indicative of a stress response) and vessel traffic in gray whales. Yang *et al.* (2022) studied behavioral and physiological responses in captive bottlenose dolphins exposed to playbacks of “pile-driving-like” impulsive sounds, finding significant

changes in cortisol and other physiological indicators but only minor behavioral changes. These and other studies lead to a reasonable expectation that some marine mammals would experience physiological stress responses upon exposure to acoustic stressors and that it is possible that some of these would be classified as “distress.” In addition, any animal experiencing TTS would likely also experience stress responses (NRC, 2005), however distress is an unlikely result of this project based on observations of marine mammals during previous, similar construction projects.

Vocalizations and Auditory

Masking—Since many marine mammals rely on sound to find prey, moderate social interactions, and facilitate mating (Tyack, 2008), noise from anthropogenic sound sources can interfere with these functions, but only if the noise spectrum overlaps with the hearing sensitivity of the receiving marine mammal (Southall *et al.*, 2007; Clark *et al.*, 2009; Hatch *et al.*, 2012). Chronic exposure to excessive, though not high-intensity, noise could cause masking at particular frequencies for marine mammals that utilize sound for vital biological functions (Clark *et al.*, 2009). Acoustic masking is when other noises such as from human sources interfere with an animal's ability to detect, recognize, or discriminate between acoustic signals of interest (*e.g.*, those used for intraspecific communication and social interactions, prey detection, predator avoidance, navigation) (Richardson *et al.*, 1995; Erbe *et al.*, 2016). Therefore, under certain circumstances, for marine mammals whose acoustic sensors or environment are being severely masked could also be impaired from maximizing their performance fitness in survival and reproduction. The ability of a noise source to mask biologically important sounds depends on the characteristics of both the noise source and the signal of interest (*e.g.*, signal-to-noise ratio, temporal variability, direction), in relation to each other and to an animal's hearing abilities (*e.g.*, sensitivity, frequency range, critical ratios, frequency discrimination, directional discrimination, age or TTS hearing loss), and existing ambient noise and propagation conditions (Hotchkiss and Parks, 2013).

Marine mammals vocalize for different purposes and across multiple modes, such as whistling, echolocation click production, calling, and singing. Changes in vocalization behavior in response to anthropogenic noise can occur for any of these modes and may result from a need to compete with an increase in background noise or may

reflect increased vigilance or a startle response. For example, in the presence of potentially masking signals, humpback whales and killer whales have been observed to increase the length of their songs (Miller *et al.*, 2000; Fristrup *et al.*, 2003) or vocalizations (Foote *et al.*, 2004), respectively, while North Atlantic right whales (*Eubalaena glacialis*) have been observed to shift the frequency content of their calls upward while reducing the rate of calling in areas of increased anthropogenic noise (Parks *et al.*, 2007). Fin whales (*Balaenoptera physalus*) have also been documented lowering the bandwidth, peak frequency, and center frequency of their vocalizations under increased levels of background noise from large vessels (Castellote *et al.* 2012). Other alterations to communication signals have also been observed. For example, gray whales, in response to playback experiments exposing them to vessel noise, have been observed increasing their vocalization rate and producing louder signals at times of increased outboard engine noise (Dahlheim and Castellote, 2016). Alternatively, in some cases, animals may cease sound production during production of aversive signals (Bowles *et al.*, 1994, Wisniewska *et al.*, 2018).

Under certain circumstances, marine mammals experiencing significant masking could also be impaired from maximizing their performance fitness in survival and reproduction. Therefore, when the coincident (masking) sound is human-made, it may be considered harassment when disrupting or altering critical behaviors. It is important to distinguish TTS and PTS, which persist after the sound exposure, from masking, which occurs during the sound exposure. Because masking (without resulting in TS) is not associated with abnormal physiological function, it is not considered a physiological effect, but rather a potential behavioral effect (though not necessarily one that would be associated with harassment).

The frequency range of the potentially masking sound is important in determining any potential behavioral impacts. For example, low-frequency signals may have less effect on high-frequency echolocation sounds produced by odontocetes but are more likely to affect detection of mysticete communication calls and other potentially important natural sounds such as those produced by surf and some prey species. The masking of communication signals by anthropogenic noise may be considered as a reduction in the communication space of animals (e.g., Clark *et al.*, 2009) and may result in energetic or other

costs as animals change their vocalization behavior (e.g., Miller *et al.*, 2000; Foote *et al.*, 2004; Parks *et al.*, 2007; Di Iorio and Clark, 2010; Holt *et al.*, 2009). Masking can be reduced in situations where the signal and noise come from different directions (Richardson *et al.*, 1995), through amplitude modulation of the signal, or through other compensatory behaviors, including modifications of the acoustic properties of the signal or the signaling behavior (Hotchkiss and Parks, 2013). Masking can be tested directly in captive species (e.g., Erbe, 2008), but in wild populations it must be either modeled or inferred from evidence of masking compensation. There are few studies addressing real-world masking sounds likely to be experienced by marine mammals in the wild (e.g., Branstetter *et al.*, 2013).

Masking occurs in the frequency band that the animals utilize and is more likely to occur in the presence of broadband, relatively continuous noise sources such as vibratory pile driving. Energy distribution of vibratory pile driving sound covers a broad frequency spectrum and is anticipated to be within the audible range of marine mammals present in the proposed action area. Since noises generated from the proposed construction activities are mostly concentrated at low frequencies (<2 kHz), these activities likely have less effect on mid-frequency echolocation sounds produced by odontocetes (toothed whales). However, lower frequency noises are more likely to affect detection of communication calls and other potentially important natural sounds such as surf and prey noise. Low-frequency noise may also affect communication signals when they occur near the frequency band for noise and thus reduce the communication space of animals (e.g., Clark *et al.*, 2009) and cause increased stress levels (e.g., Holt *et al.*, 2009). Unlike TS, masking, which can occur over large temporal and spatial scales, can potentially affect the species at population, community, or even ecosystem levels, in addition to individual levels. Masking affects both senders and receivers of the signals, and at higher levels for longer durations, could have long-term chronic effects on marine mammal species and populations. However, the noise generated by ADOT&PF's proposed activities would only occur intermittently, across an estimated 231 (not necessarily consecutive) days during the proposed authorization period in a relatively small area focused around the proposed construction site. Thus, while the ADOT&PF's proposed

activities may mask some acoustic signals that are relevant to the daily behavior of marine mammals, the short-term duration and limited areas affected make it very unlikely that the fitness of individual marine mammals would be impacted.

While in some cases marine mammals have exhibited little to no obviously detectable response to certain common or routine industrialized activities (Cornick *et al.*, 2011; Horley and Larson, 2023), it is possible some animals may at times be exposed to received levels of sound above the AUD INJ and Level B harassment thresholds during the proposed project. This potential exposure in combination with the nature of planned activity (e.g., vibratory pile driving, impact pile driving) means it is possible that take by Level A and Level B harassment could occur over the total estimated period of activities; therefore, NMFS, in response to ADOT&PF's IHA application, proposes to authorize take by Level A and Level B harassment from ADOT&PF's proposed construction activities.

Airborne Acoustic Effects—Pinnipeds that occur near the project site could be exposed to airborne sounds associated with construction activities that have the potential to cause behavioral harassment, depending on their distance from these activities. Airborne noise would primarily be an issue for pinnipeds that are swimming or hauled out near the project site within the range of noise levels elevated above airborne acoustic harassment criteria. As described above in *Description of Sound Sources for the Specified Activities*, although pinnipeds are known to haul-out regularly on man-made objects, we believe that incidents of take resulting solely from airborne sound are unlikely due to the proximity between the proposed project area and the known haulout sites (refer back to table 5). Cetaceans are not expected to be exposed to airborne sounds that would result in harassment as defined under the MMPA.

We recognize that pinnipeds in the water could be exposed to airborne sound that may result in behavioral harassment when looking with their heads above water. Most likely, airborne sound would cause behavioral responses similar to those discussed above in relation to underwater sound. For instance, anthropogenic sound could cause hauled out pinnipeds to exhibit changes in their normal behavior, such as reduction in vocalizations, or cause them to flush from haulouts, temporarily abandon the area, and or move further from the

source. However, these animals would previously have been “taken” because of exposure to underwater sound above the behavioral harassment thresholds, which are in all cases larger than those associated with airborne sound. Thus, the behavioral harassment of these animals is already accounted for in these estimates of potential take. Therefore, we do not believe that authorization of incidental take resulting from airborne sound for pinnipeds is warranted, and airborne sound is not discussed further here.

Potential Effects on Marine Mammal Habitat

ADOT&PF’s proposed activities could have localized, temporary impacts on marine mammal habitat, including prey, by increasing in-water SPLs. Increased noise levels may affect acoustic habitat and adversely affect marine mammal prey in the vicinity of the project areas (see discussion below). Elevated levels of underwater noise would ensonify the project areas where both fishes and mammals occur and could affect foraging success. Additionally, marine mammals may avoid the area during the proposed construction activities; however, displacement due to noise is expected to be temporary and is not expected to result in long-term effects to the individuals or populations.

The total area likely impacted by ADOT&PF’s activities is relatively small compared to the available habitat in and around Cold Bay. Avoidance by potential prey (*i.e.*, fish) of the immediate area due to increased noise is possible. The duration of fish and marine mammal avoidance of this area after tugging stops is unknown, but a rapid return to normal recruitment, distribution, and behavior is anticipated. Any behavioral avoidance by fish or marine mammals of the disturbed area would still leave significantly large areas of fish and marine mammal foraging habitat in the nearby vicinity.

The proposed project would occur within the same general footprint as the existing marine infrastructure. The nearshore and intertidal habitat where the proposed project would occur is an area of relatively high marine vessel traffic. Most marine mammals do not generally use the area within the footprint of the project area. Temporary, intermittent, and short-term habitat alteration may result from increased noise levels during the proposed construction activities. Effects on marine mammals would be limited to temporary displacement from pile installation and removal noise, and

effects on prey species would be similarly limited in time and space.

Water quality—Temporary and localized reduction in water quality would occur as a result of in-water construction activities. Most of this effect would occur during the installation and removal of piles when bottom sediments are disturbed. The installation and removal of piles would disturb bottom sediments and may cause a temporary increase in suspended sediment in the project area. During pile extraction, sediment attached to the pile moves vertically through the water column until gravitational forces cause it to slough off under its own weight. The small resulting sediment plume is expected to settle out of the water column within a few hours. Studies of the effects of turbid water on fish (marine mammal prey) suggest that concentrations of suspended sediment can reach thousands of milligrams per liter before an acute toxic reaction is expected (Burton, 1993).

Effects to turbidity and sedimentation are expected to be short-term, minor, and localized. Turbidity within the water column has the potential to reduce the level of oxygen in the water and irritate the gills of prey fish species in the proposed project area. However, turbidity plumes associated with the project would be temporary and localized, and fish in the proposed project area would be able to move away from and avoid the areas where plumes may occur. Therefore, it is expected that the impacts on prey fish species from turbidity, and therefore on marine mammals, would be minimal and temporary. In general, the area likely impacted by the proposed construction activities is relatively small compared to the available marine mammal habitat in Cold Bay.

Potential Effects on Prey—Sound may affect marine mammals through impacts on the abundance, behavior, or distribution of prey species (*e.g.*, crustaceans, cephalopods, fishes, zooplankton). Marine mammal prey varies by species, season, and location and, for some, is not well documented. Studies regarding the effects of noise on known marine mammal prey are described here.

Fishes utilize the soundscape and components of sound in their environment to perform important functions such as foraging, predator avoidance, mating, and spawning (*e.g.*, Zelick *et al.*, 1999; Fay, 2009). Depending on their hearing anatomy and peripheral sensory structures, which vary among species, fishes hear sounds using pressure and particle

motion sensitivity capabilities and detect the motion of surrounding water (Fay *et al.*, 2008). The potential effects of noise on fishes depends on the overlapping frequency range, distance from the sound source, water depth of exposure, and species-specific hearing sensitivity, anatomy, and physiology. Key impacts to fishes may include behavioral responses, hearing damage, barotrauma (pressure-related injuries), and mortality.

Fish react to sounds that are especially strong and/or intermittent low-frequency sounds, and behavioral responses such as flight or avoidance are the most likely effects. Short duration, sharp sounds can cause overt or subtle changes in fish behavior and local distribution. The reaction of fish to noise depends on the physiological state of the fish, past exposures, motivation (*e.g.*, feeding, spawning, migration), and other environmental factors. (Hastings and Popper, 2005) identified several studies that suggest fish may relocate to avoid certain areas of sound energy. Additional studies have documented effects of pile driving on fishes (*e.g.*, Scholik and Yan, 2001, 2002; Popper and Hastings, 2009). Several studies have demonstrated that impulse sounds might affect the distribution and behavior of some fishes, potentially impacting foraging opportunities or increasing energetic costs (*e.g.*, Fewtrell and McCauley, 2012; Pearson *et al.*, 1992; Skalski *et al.*, 1992; Santulli *et al.*, 1999; Paxton *et al.*, 2017). However, some studies have shown no or slight reaction to impulse sounds (*e.g.*, Peña *et al.*, 2013; Wardle *et al.*, 2001; Jorgenson and Gyselman, 2009; Cott *et al.*, 2012). More commonly, though, the impacts of noise on fishes are temporary. For example, during the Port of Alaska’s Marine Terminal Redevelopment Project, the effects of impact and vibratory installation of 30-in (76-cm) steel sheet piles at the POA on 133 caged juvenile coho salmon (*Oncorhynchus kisutch*) in Knik Arm were studied (Hart Crowser Incorporated *et al.*, 2009; Houghton *et al.*, 2010). Acute or delayed mortalities, or behavioral abnormalities were not observed in any of the coho salmon. Furthermore, results indicated that the pile driving had no adverse effect on feeding ability or the ability of the fish to respond normally to threatening stimuli (Hart Crowser Incorporated *et al.*, 2009; Houghton *et al.*, 2010).

SPLs of sufficient strength have been known to cause injury to fishes and fish mortality (summarized in Popper *et al.*, 2014). However, in most fish species, hair cells in the ear continuously regenerate and loss of auditory function

is likely restored when damaged cells are replaced with new cells. Halvorsen *et al.* (2012b) showed that a TTS of 4 to 6 dB was recoverable within 24 hours for one species. Impacts would be most severe when the individual fish is close to the source and when the duration of exposure is long. Injury caused by barotrauma can range from slight to severe and can cause death, and is most likely for fish with swim bladders. Barotrauma injuries have been documented during controlled exposure to impact pile driving (Halvorsen *et al.*, 2012a; Casper *et al.*, 2013, 2017).

Fish populations in the proposed project area that serve as marine mammal prey could be temporarily affected by noise from pile installation and removal. The frequency range in which fishes generally perceive underwater sounds is 50 to 2,000 Hz, with peak sensitivities below 800 Hz (Popper and Hastings, 2009). Fish behavior or distribution may change, especially with strong and/or intermittent sounds that could harm fishes. High underwater SPLs have been documented to alter behavior, cause hearing loss, and injure or kill individual fish by causing serious internal injury (Hastings and Popper, 2005).

Zooplankton is a food source for several marine mammal species, as well as a food source for fish that are then preyed upon by marine mammals. Population effects on zooplankton could have indirect effects on marine mammals. Data are limited on the effects of underwater sound on zooplankton species, particularly sound from construction (Erbe *et al.*, 2019). Popper and Hastings (2009) reviewed information on the effects of human-generated sound and concluded that no substantive data are available on whether the sound levels from pile driving, seismic activity, or any human-made sound would have physiological effects on invertebrates. Any such effects would be limited to the area very near (1 to 5 m (3.28 to 16.4 ft)) to the sound source and would result in no population effects because of the relatively small area affected at any one time and the reproductive strategy of most zooplankton species (short generation, high fecundity, and very high natural mortality). No adverse impact on zooplankton populations is expected to occur from the specified activity due in part to large reproductive capacities and naturally high levels of predation and mortality of these populations. Any mortalities or impacts that might occur would be negligible.

The Essential Fish Habitat (EFH) designation for the Cold Bay, Alaska

region is fundamentally driven by the Izembek Lagoon complex, which harbors one of the world's most extensive and productive eelgrass (*Zostera marina*) beds (Ward *et al.*, 1997; Ward and Amundson, 2019; Douglas *et al.*, 2024). This submerged aquatic vegetation serves as the ecological foundation, acting as a critical nursery EFH by providing abundant food resources, crucial shelter from predators, and favorable hydrological conditions necessary for the feeding and growth to maturity life stages of marine species. The adjacent coastal waters also serve as habitat for various marine mammals, including harbor seals, Steller sea lions, and cetaceans such as gray, minke, killer, and humpback whales.

The habitat is vital for sustaining major regional fisheries, serving as an important area for all five species of Pacific salmon (genus *Oncorhynchus*) which utilize the lagoon and associated streams for migration and spawning. Crucially, the Izembek Lagoon nursery supports federally managed crustaceans, including juvenile red king crab (*Paralithodes camtschaticus*) and tanner crab (*Chionoecetes bairdi*), whose survival is dependent on the shallow, protected environment before they move to deeper Cold Bay areas as adults (U.S. Fish and Wildlife Service, 2024). Additionally, the system sustains large populations of forage fish (such as capelin (*Mallotus villosus*), sand lance (family *Ammodytidae*), and herring (*Clupea pallasii*)), Pacific halibut (*Hippoglossus stenolepis*), and Walleye Pollack (*Gadus chalcogrammus*), which in turn support high concentrations of apex predators (U.S. Fish and Wildlife Service, 2024). However, based on the potential effects of the proposed project, adverse effects on EFH in this area are not expected.

The greatest potential impact to marine mammal prey during construction would occur during impact pile driving. However, in most cases, the duration of impact pile driving would be limited to the final stage of installation (proofing) after the pile has been driven as close as practicable to the design depth with a vibratory driver. In-water construction activities would only occur during daylight hours, allowing fish to forage and transit the project area in the evening. Vibratory pile driving could possibly elicit behavioral reactions from fishes, such as temporary avoidance of the area, but is unlikely to cause injuries to fishes or have persistent effects on local fish populations. Construction also would have minimal permanent and temporary impacts on benthic invertebrate species,

a marine mammal prey source. In addition, it should be noted that the area in question is low-quality habitat since it is already highly developed and experiences a high level of anthropogenic noise from normal operations and other vessel traffic.

Potential Effects on Foraging Habitat

The proposed project is not expected to result in any habitat related effects that could cause significant or long-term negative consequences for individual marine mammals or their populations, since installation and removal of in-water piles would be temporary and intermittent. The total seafloor area affected by pile installation and removal is a very small area compared to the vast foraging area available to marine mammals outside this project area. For marine mammals, while the area is commonly used or traversed by some species, the proposed project area does not contain any particularly high-value habitat and is not usually important to any of the other species potentially affected by ADOT&PF's proposed activities. While opportunistic foraging could occur, more foraging habitat is available outside the Bay, in more open ocean waters. Overall, the area impacted by the project is relatively small compared to the available habitat just outside the project area, and there are no areas of particular importance that would be impacted by this project during the period planned for activities to occur. Any behavioral avoidance by fish of the disturbed area would still leave significantly large areas of fish and marine mammal foraging habitat in the nearby vicinity. As described in the preceding, the potential for the ADOT&PF's construction to affect the availability of prey to marine mammals or to meaningfully impact the quality of physical or acoustic habitat is considered insignificant. Therefore, impacts of the project are not likely to have adverse effects on marine mammal foraging habitat in the proposed project area.

In summary, given the relatively small areas being affected, as well as the temporary and mostly transitory nature of the proposed construction activities, any adverse effects from ADOT&PF's activities on prey habitat or prey populations are expected to be minor and temporary. The most likely impact to fishes at the project site would be temporary avoidance of the area. Any behavioral avoidance by fish of the disturbed area would still leave significantly large areas of fish and marine mammal foraging habitat in the nearby vicinity. Thus, we preliminarily conclude that impacts of the specified

activities are not likely to have more than short-term adverse effects on any prey habitat or populations of prey species. Further, any impacts to marine mammal habitat are not expected to result in significant or long-term consequences for individual marine mammals, or to contribute to adverse impacts on their populations.

Estimated Take of Marine Mammals

This section provides an estimate of the number of incidental takes proposed for authorization through the IHA, which will inform NMFS' consideration of "small numbers," the negligible impact determinations, and impacts on subsistence uses.

Harassment is the only type of take expected to result from these activities. Except with respect to certain activities not pertinent here, section 3(18) of 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).

Authorized takes would primarily be by Level B harassment, as use of the acoustic sources (*i.e.*, impact pile driving, vibratory pile driving) has the potential to result in disruption of behavioral patterns for individual marine mammals. There is also some potential for auditory injury (AUD INJ) (Level A harassment) to result, primarily for mysticetes, very high-frequency cetaceans, phocids, and otariids because predicted AUD INJ zones are larger than for high-frequency species. AUD INJ is unlikely to occur for high-frequency cetaceans. The proposed mitigation and monitoring measures are expected to minimize the severity of the taking to the extent practicable.

As described previously, no serious injury or mortality is anticipated or proposed to be authorized for this activity. Below we describe how the proposed take numbers are estimated.

For acoustic impacts, generally speaking, we estimate take by considering: (1) acoustic criteria above which NMFS believes there is some

reasonable potential for marine mammals to be behaviorally harassed or incur some degree of AUD INJ; (2) the area or volume of water that would be ensonified above these levels in a day; (3) the density or occurrence of marine mammals within these ensonified areas; and, (4) the number of days of activities. We note that while these factors can contribute to a basic calculation to provide an initial prediction of potential takes, additional information that can qualitatively inform take estimates is also sometimes available (*e.g.*, previous monitoring results or average group size). Below, we describe the factors considered here in more detail and present the proposed take estimates.

Acoustic Criteria

NMFS recommends the use of acoustic criteria that identify the received level of underwater sound above which exposed marine mammals would be reasonably expected to be behaviorally harassed (equated to Level B harassment) or to incur AUD INJ of some degree (equated to Level A harassment). We note that the criteria for AUD INJ, as well as the names of two hearing groups, have been recently updated (NMFS, 2024) as reflected below in the Level A harassment section.

Level B Harassment—Though significantly driven by received level, the onset of behavioral disturbance from anthropogenic noise exposure is also informed to varying degrees by other factors related to the source or exposure context (*e.g.*, frequency, predictability, duty cycle, duration of the exposure, signal-to-noise ratio, distance to the source), the environment (*e.g.*, bathymetry, other noises in the area, predators in the area), and the receiving animals (hearing, motivation, experience, demography, life stage, depth) and can be difficult to predict (*e.g.*, Southall *et al.*, 2007, 2021, Ellison *et al.*, 2012). Based on what the available science indicates and the practical need to use a threshold based on a metric that is both predictable and measurable for most activities, NMFS typically uses a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment. NMFS generally predicts that marine mammals are likely to be behaviorally harassed in a manner

considered to be Level B harassment when exposed to underwater anthropogenic noise above root-mean-squared pressure received levels (RMS SPL) of 120 dB (referenced to 1 micropascal (re 1 μ Pa)) for continuous (*e.g.*, vibratory pile driving, drilling) and above RMS SPL 160 dB re 1 μ Pa for non-explosive impulsive (*e.g.*, seismic airguns) or intermittent (*e.g.*, scientific sonar) sources. Generally speaking, Level B harassment take estimates based on these behavioral harassment thresholds are expected to include any likely takes by TTS as, in most cases, the likelihood of TTS occurs at distances from the source less than those at which behavioral harassment is likely. TTS of a sufficient degree can manifest as behavioral harassment, as reduced hearing sensitivity and the potential reduced opportunities to detect important signals (conspecific communication, predators, prey) may result in changes in behavior patterns that would not otherwise occur.

ADOT&PF's proposed pile driving includes the use of continuous (vibratory hammer) and impulsive (impact hammer) sources, and therefore the RMS SPL thresholds of 120 and 160 dB re 1 μ Pa are applicable.

Level A harassment—NMFS' Updated Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Version 3.0) (Updated Technical Guidance, 2024) identifies dual criteria to assess AUD INJ (Level A harassment) to five different underwater marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive). ADOT&PF's proposed pile driving includes the use of impulsive (impact hammer) and non-impulsive (vibratory hammer) sources.

The 2024 Updated Technical Guidance criteria include both updated thresholds and updated weighting functions for each hearing group (table 6). The thresholds are provided in the table below. The references, analysis, and methodology used in the development of the criteria are described in NMFS' 2024 Updated Technical Guidance, which may be accessed at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance-other-acoustic-tools>.

TABLE 6—THRESHOLDS IDENTIFYING THE ONSET OF AUDITORY INJURY

Hearing group	AUD INJ onset acoustic thresholds* (received level)	
	Impulsive	Non-impulsive
Low-Frequency (LF) Cetaceans	Cell 1: $L_{pk,flat}$: 222 dB; $L_{E,LF,24h}$: 183 dB	Cell 2: $L_{E,LF,24h}$: 197 dB.
High-Frequency (HF) Cetaceans	Cell 3: $L_{pk,flat}$: 230 dB; $L_{E,HF,24h}$: 193 dB	Cell 4: $L_{E,HF,24h}$: 201 dB.
Very High-Frequency (VHF) Cetaceans	Cell 5: $L_{pk,flat}$: 202 dB; $L_{E,VHF,24h}$: 159 dB	Cell 6: $L_{E,VHF,24h}$: 181 dB.
Phocid Pinnipeds (PW) (Underwater)	Cell 7: $L_{pk,flat}$: 223 dB; $L_{E,PW,24h}$: 183 dB	Cell 8: $L_{E,PW,24h}$: 195 dB.
Otariid Pinnipeds (OW) (Underwater)	Cell 9: $L_{pk,flat}$: 230 dB; $L_{E,OW,24h}$: 185 dB	Cell 10: $L_{E,OW,24h}$: 199 dB.

* Dual metric criteria for impulsive sounds: Use whichever criteria results in the larger isopleth for calculating AUD INJ onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level criteria associated with impulsive sounds, the PK SPL criteria are recommended for consideration for non-impulsive sources.

Note: Peak sound pressure level ($L_{p,0-pk}$) has a reference value of 1 μ Pa, and weighted cumulative sound exposure level ($L_{E,p}$) has a reference value of 1 μ Pa²s. In this table, criteria are abbreviated to be more reflective of International Organization for Standardization standards (ISO, 2017). The subscript “flat” is being included to indicate peak sound pressure are flat weighted or unweighted within the generalized hearing range of marine mammals underwater (*i.e.*, 7 Hz to 165 kHz). The subscript associated with cumulative sound exposure level criteria indicates the designated marine mammal auditory weighting function (LF, HF, and VHF cetaceans, and PW and OW pinnipeds) and that the recommended accumulation period is 24 hours. The weighted cumulative sound exposure level criteria could be exceeded in a multitude of ways (*i.e.*, varying exposure levels and durations, duty cycle). When possible, it is valuable for action proponents to indicate the conditions under which these criteria will be exceeded.

Ensonified Area

Here, we describe operational and environmental parameters of the activity that are used in estimating the area ensonified above the acoustic thresholds, including source levels and transmission loss coefficient.

The sound field in the project area is the existing background noise plus additional construction noise from the

proposed project. Marine mammals are expected to be affected via sound generated by the primary components of the project (*i.e.*, impact pile driving and vibratory pile driving). The source levels assumed for both removal and installation activities are based on reviews of measurements of the same or similar types and dimensions of piles available in the scientific literature and from similar coastal construction

projects. Derived by the applicant using Geographic Information System software, the source levels for the piles and activities (*i.e.*, installation and/or removal), and the information and literature used to determine appropriate proxy sources, where applicable, are presented in table 7. The source levels for vibratory removal and installation of piles of the same material and diameter are assumed to be the same.

TABLE 7—SOUND SOURCE LEVELS INCORPORATED INTO THE ANALYSIS AT 10 METERS (M)

Activity	Pile type	Installation method	Sound pressure level (SPL RMS) ^a	Sound exposure level (SEL)	Peak source level (SPL PK)
Trestle and Abutment					
Trestle support pile	36-in steel pipe piles	Vibratory Installation ^b	166.0		
		Impact Installation ^c	193.0	183.0	210.0
Temporary trestle pile	24-in to 36-in steel pipe or H-pile	Vibratory Installation and Removal ^{b,e} ..	166.0		
		Impact Installation ^c	193.0	183.0	210.0
Dock					
Dock support pile	36-in steel pipe pile	Vibratory Installation ^b	166.0		
		Impact Installation ^c	193.0	183.0	210.0
Temporary dock pile	24-in to 36-in steel pipe pile	Vibratory Installation and Removal ^{b,e} ..	166.0		
		Impact Installation ^c	193.0	183.0	210.0
Fender pile	30-in steel pipe pile	Vibratory Installation ^d	166.0		
Fender pile	24-in steel pipe pile	Vibratory Installation	161.0		
Dolphin					
Dolphin pile	36-in steel pipe pile	Vibratory Installation ^b	166.0		
		Impact Installation ^c	193.0	183.0	210.0
Temporary dolphin pile	24-in to 36-in steel pipe pile	Vibratory installation and removal ^{b,e}	166.0		
Demolition (Removal)					
Trestle removal	16-in steel pipe pile	Vibratory removal ^e	161.0		
Dock removal	16-in steel pipe pile	Vibratory removal ^e	161.0		
Dock removal	26-in steel pipe pile	Vibratory removal ^d	166.0		
Dolphin removal	16-in steel pipe pile	Vibratory removal ^e	161.0		
Fender removal	20-in steel pipe pile	Vibratory removal ^e	161.0		
Fender removal	16-in timber pile	Vibratory removal ^f	162.0		

^a All values relative to 1 μ Pa.

^b Navy (2012, 2013), Sexton (2007), Laughlin (2011, 2017), Miner (2020), CALTRANS (2020).

^c CALTRANS (2015, 2020).

^d Denes et al. (2016), Laughlin (2011, 2012, 2017), PND Engineering (2015), CALTRANS (2020).

^e NAVFAC (2015), CALTRANS (2020); fillingworth and Rodkin (2017).

Level B Harassment

Transmission Loss (*TL*) is the decrease in acoustic intensity as an acoustic pressure wave propagates out from a source. *TL* parameters vary with frequency, temperature, sea conditions, current, source and receiver depth, water depth, water chemistry, and bottom composition and topography. The general formula for underwater *TL* is:

$$TL = B \times \log_{10}(R1/R2),$$

Where:

TL = transmission loss in dB,

B = transmission loss coefficient,

R1 = the distance of the modeled SPL from the driven pile, and

R2 = the distance from the driven pile of the initial measurement.

This formula neglects loss due to scattering and absorption, which is assumed to be zero in this case. The degree to which underwater sound propagates away from a sound source depends on various factors, most notably the water bathymetry and the presence or absence of reflective or absorptive conditions, including in-water structures and sediments. Spherical spreading occurs in a perfectly unobstructed (free-field) environment not limited by depth or water surface, resulting in a 6 dB reduction in sound level for each

doubling of distance from the source ($20 \times \log_{10}[\text{range}]$). Cylindrical spreading occurs in an environment in which sound propagation is bounded by the water surface and sea bottom, resulting in a reduction of 3 dB in sound level for each doubling of distance from the source ($10 \times \log_{10}[\text{range}]$). A practical spreading value of 15 is often used under conditions where water increases with depth as the receiver moves away from the shoreline, resulting in an expected propagation environment that would lie between spherical and cylindrical spreading loss conditions. Absent site-specific acoustic monitoring with differing measured *TL*, practical spreading is used. Site-specific *TL* data for Cold Bay is not available; therefore, the default coefficient of 15 is used to determine the distances to the Level A harassment and Level B harassment thresholds.

Level A Harassment

The ensonified area associated with Level A harassment is more technically challenging to predict due to the need to account for a duration component. Therefore, NMFS developed an optional User Spreadsheet tool to accompany the 2024 Updated Technical Guidance that can be used to relatively simply predict an isopleth distance for use in conjunction with marine mammal

density or occurrence to help predict potential takes (found on our website here: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance-other-acoustic-tools>).

We note that because of some of the assumptions included in the methods underlying this optional tool, we anticipate that the resulting isopleth estimates are typically going to be overestimates of some degree, which may result in an overestimate of potential take by Level A harassment. However, this optional tool offers the best way to estimate isopleth distances when more sophisticated modeling methods are not available or practical. For stationary sources, such as vibratory pile driving and impact pile driving, the optional User Spreadsheet tool predicts the distance at which, if a marine mammal remained at that distance for the duration of the activity, it would be expected to incur AUD INJ. Inputs used in the optional User Spreadsheet tool, and the resulting estimated isopleths, are reported below in tables 8 and 9. Using the practical spreading model, NMFS determined that the underwater noise would yield the calculated distances to the Level A harassment and Level B harassment thresholds for marine mammals shown in table 10.

TABLE 9—USER SPREADSHEET INPUTS FOR IMPACT PILE DRIVING

User spreadsheet variables					
Structure	Trestle and abutment		Dock		Dolphin
	Trestle support pile	Temporary trestle	Dock support pile	Temporary dock pile	Dolphin pile
	36-inch steel pile	24-inch to 36-inch steel pipe or H-pile	36-inch steel pipe pile	24-inch to 36-inch steel pipe pile	36-inch steel pipe pile
Pile information					
Tab of User Spreadsheet		E.1: Impact pile driving (Stationary Source: Impulsive, Intermittent)			
Unweighted SEL _{cum}		209.8	219.8	219.8	222.0
SEL					
Single Strike SEL _{ss} at "X" distance (meters)	183	183	183	183	183
Number of strikes per pile	60	600	600	600	1,000
Number of piles per day	8	8	8	8	8
Transmission loss coefficient	15	15	15	15	15
Distance of single strike SEL _{ss} (meters)	10	10	10	10	10
Weighting Factor Adjustment (kHz)	2	2	2	2	2
PK (single strike)					
L _{p,0-pk} at "X" distance (meters)	210	210	210	210	210
Distance of L _{p,0-pk} measurements (meters)	10	10	10	10	10
L _{p,0-pk} source level	225.0	225.0	225.0	225.0	225.0

TABLE 10—CALCULATED ISOPLETHS (IN METERS (M)) AND AREAS (IN KILOMETERS (Km²)) TO NMFS' THRESHOLDS [NMFS, 2024]

Installation details			Level A harassment (PTS)										Level B harassment	
Structure	Pile parameters	Installation approach	LFC		HFC		VHFC		PW		OW		All species	
			Isopleth	Area	Isopleth	Area	Isopleth	Area	Isopleth	Area	Isopleth	Area		
													Isopleth	Area
Trestle and Abutment														
Trestle Support Pile.	36-in steel pipe pile.	Vibratory installation.	50.1	0.1	19.2	0.0	40.9	0.1	64.4	0.1	21.7	0.0	11,659.2	116.9
		Impact installation.	610.0	1.4	77.8	0.1	944.0	2.8	541.9	1.2	202.0	0.4	1,584.9	6.4
Temporary Trestle Pile.	24-in to 36-in steel pipe or H-pile.	Vibratory installation.	79.5	0.1	30.5	0.1	64.9	0.1	102.3	0.2	34.4	0.1	11,659.2	116.9
		Impact installation.	2,831.3	14.9	361.2	0.7	4,381.4	28.0	2,515.2	12.5	937.6	2.8	1,584.9	6.4
Dock														
Dock Support Pile.	36-in steel pipe piles.	Vibratory installation.	50.1	0.1	19.2	0.0	40.9	0.1	64.4	0.1	21.7	0.0	11,659.2	116.9
		Impact installation.	2,831.3	14.9	361.2	0.7	4,381.4	28.0	2,515.2	12.5	937.6	2.8	1,584.9	6.4
Temporary Dock Pile.	24-in to 36-in steel pipe piles.	Vibratory installation and removal.	79.5	0.1	30.5	0.1	64.9	0.1	102.3	0.2	34.4	0.1	11,659.2	116.9
		Impact installation.	2,831.3	14.9	361.2	0.7	4,381.4	28.0	2,515.2	12.5	937.6	2.8	1,584.9	6.4
Fender Pile	30-in steel pipe piles.	Vibratory installation.	44.3	0.1	17.0	0.0	36.2	0.1	57.1	0.1	19.2	0.0	11,659.2	116.9
Fender Pile	24-in steel pipe piles.	Vibratory installation.	20.6	0.0	7.9	0.0	16.8	0.0	26.5	0.0	8.9	0.0	5,411.7	39.0
Dolphin														
Dolphin Pile	36-in steel pipe piles.	Vibratory installation.	79.5	0.1	30.5	0.1	64.9	0.1	102.3	0.2	34.4	0.1	11,659.2	116.9
		Impact installation.	3,980.0	24.2	507.8	1.1	6,159.1	47.8	3,535.7	20.3	1,318.0	4.8	1,584.9	6.4

TABLE 10—CALCULATED ISOPLETHS (IN METERS (M)) AND AREAS (IN KILOMETERS (Km²)) TO NMFS' THRESHOLDS—
Continued
[NMFS, 2024]

Installation details			Level A harassment (PTS)										Level B harassment	
Structure	Pile parameters	Installation approach	LFC		HFC		VHFC		PW		OW		All species	
			Isopleth	Area	Isopleth	Area	Isopleth	Area	Isopleth	Area	Isopleth	Area	Isopleth	Area
Temporary Dolphin Pile.	24-in to 36-in steel pipe piles.	Vibratory installation and removal.	50.1	0.1	19.2	0.0	40.9	0.1	64.4	0.1	21.7	0.0	11,659.2	116.9
Demolition (Removal)														
Trestle Removal.	16-in steel pipe piles.	Vibratory removal.	35.3	0.1	13.6	0.0	28.9	0.0	45.5	0.1	15.3	0.0	5,411.7	39.0
Dock Removal	16-in steel pipe piles.	Vibratory removal.	35.3	0.1	13.6	0.0	28.9	0.0	45.5	0.1	15.3	0.0	5,411.7	39.0
Dock Removal	26-in steel pipe piles.	Vibratory removal.	76.1	0.1	29.2	0.0	62.2	0.1	98.0	0.0	33.0	0.1	11,659.2	116.9
Dolphin Removal.	16-in steel pipe piles.	Vibratory removal.	23.2	0.0	8.9	0.0	19.0	0.0	29.9	0.0	10.1	0.0	5,411.7	39.0
Fender Removal.	20-in steel pipe piles.	Vibratory removal.	35.3	0.1	13.6	0.0	28.9	0.0	45.5	0.1	15.3	0.0	5,411.7	39.0
Fender Removal.	16-in timber piles.	Vibratory removal.	41.2	0.1	15.8	0.0	33.7	0.1	53.0	0.1	17.8	0.0	6,309.6	49.7

Note: LFC = low-frequency cetaceans; HFC = high-frequency cetaceans; VHFC = very high-frequency cetaceans; PW = phocid pinnipeds (in-water); OW = otariids pinnipeds (in-water).

It should be noted that, based on the geography of Cold Bay and the surrounding islands outside of the mouth of the Bay, the sound would not reach the entire distance of the Level B harassment isopleths. The size and shape of the Bay are expected to truncate the largest Level B harassment isopleths.

Marine Mammal Occurrence and Take Estimation

In this section, we provide information about the occurrence of marine mammals, including density or other relevant information, which will inform the take calculations. Then, we describe how all of the information detailed above is synthesized to produce

a quantitative estimate of the take that is reasonably likely to occur and proposed for authorization.

In their ITA application, ADOT&PF calculated their requested take based on the synthetization of different resources, including websites from state and Federal agencies (*i.e.*, Alaska Department of Fish & Game, NMFS, U.S. Fish and Wildlife Service), data from aerial survey performed by the National Marine Mammal Laboratory, information gleaned from scientific literature (*i.e.*, Zerbini *et al.*, 2007, Rone *et al.*, 2017, and McInnes *et al.*, 2024b), and information from non-profits (*i.e.*, iNaturalist) with both relevant species-specific and site-specific information. Given the secluded and sheltered nature

of Cold Bay's geographic location, these resources provide the most appropriate information for which to determine estimated species densities/occurrences and group sizes.

Estimated take was calculated different for each species, depending on the likely occurrence of the species in the proposed project area (see table 11). This means that some occurrences were calculated on a daily basis, some on a weekly, or some on a monthly (or multi-monthly) basis. This is all assumed to occur within 231 days of project activities requiring the use of in-water pile driving, consisting of both vibratory and impact approaches, which can vary in total number of days based on the specific construction activity.

TABLE 11—ESTIMATED SPECIES OCCURRENCE

Species	Abundance estimate assumed	Estimated occurrence
Humpback whale	Group size of 2 individuals per month	0.067 ^a per workday.
Gray whale	Group size of 5.7 individuals per 3 months	0.03 per workday.
Killer whale	Group size of 3 individuals per group, assuming 1 group per week	0.43 per workday.
Harbor porpoise	Group size of 3 individuals per week	0.43 per workday.
Steller sea lion	Group size of 15 individuals per day	15.
Harbor seal	Group size of 10 individuals per day	10.

^a This was assumed for the entire species and then, based on NMFS (2021), was split further for each stock/Distinct Population Segment (DPS).

After reviewing the available resources to determine an appropriate occurrence level (*i.e.*, daily, weekly, monthly, multi-monthly) and group size, these were multiplied together to yield the overall estimated take (combined Level A harassment and Level B harassment). These were then

split using two different methods. Potential takes by Level A harassment were calculated if 1) some of the Level A harassment zones were estimated to exceed the practicable shutdown zone for a given hearing group, or 2) if the species could be difficult to see due to its small size or cryptic behavior. To

calculate the proposed takes by Level A harassment, "areal calculations" were performed for three species (Steller sea lion, harbor seal, and harbor porpoise) where the calculated area of each hearing group's Level A harassment zone was divided by the area of the largest predicted Level B harassment

zone to result in an “areal percentage”. This was then multiplied by both the number of days determined necessary to complete the construction task and then by unique species occurrence. To calculate the number of estimated takes proposed for authorization by Level B harassment, the calculated takes by Level A harassment were subtracted from the total number of calculated takes, with the remaining assumed to be taken by Level B harassment only.

Humpback whales are common in the general region during the summer

months; however, their presence within the project area is uncommon due to the shallow and sheltered nature of Cold Bay. Given that all work and noise are expected to be confined to the Bay, but in some cases, exceed the practicable shutdown zone, NMFS proposes to conservatively authorize two groups of two humpback whales for take by Level A harassment.

More specific information on species/stock occurrence, which was incorporated into the analysis, can be found in section 6 of ADOT&PF’s

application and is not repeated here; instead, we reference the reader to the application for this additional information. Below, we provide the areal calculations (table 12), and we summarize the relevant group sizes and information presented on the occurrence of each species/stock and provide the numerical values proposed for authorization in the table below (table 13).

TABLE 12—AREAL CALCULATIONS FOR THREE MARINE MAMMAL SPECIES TO ESTIMATE PROPOSED TAKES BY LEVEL A HARASSMENT

Source	Source type	Species	Maximum Level B harassment area (km ²) ^a	Level A harassment area (km ²)	Level A area to maximum Level B area ratio (%)	Takes assumed per day	Days of effort planned	Calculated proposed takes by Level A harassment
Trestle and Abutment								
Trestle support pile (36-inch steel pipe pile).	Impact pile driving (installation).	Harbor porpoise	116.9	2.82	2.41	0.43	8	0
		Steller sea lion	116.9	0.35	0.30	15	8	0
		Harbor seal	116.9	12.55	10.74	10	8	9
Temporary trestle pile (24-inch to 36-inch steel pipe or H-pile).	Impact pile driving (installation).	Harbor porpoise	116.9	28.02	23.97	0.43	8	1
		Steller sea lion	116.9	2.78	2.38	15	8	3
		Harbor seal	116.9	12.55	10.74	10	8	9
Dock								
Dock support pile (36-inch steel pipe pile).	Impact pile driving (installation).	Harbor porpoise	116.9	28.02	23.97	0.43	8	1
		Steller sea lion	116.9	2.78	2.38	15	8	3
		Harbor seal	116.9	12.55	10.74	10	8	9
Temporary dock pile (24-inch to 36-inch steel pile).	Impact pile driving (installation).	Harbor porpoise	116.9	28.02	23.97	0.43	8	1
		Steller sea lion	116.9	2.78	2.38	15	8	3
		Harbor seal	116.9	12.55	10.74	10	8	9
Dolphin								
Dolphin pile (36-inch steel pipe pile).	Impact pile driving (installation).	Harbor porpoise	116.9	47.85	40.93	0.43	8	1
		Steller sea lion	116.9	4.79	4.10	15	8	5
		Harbor seal	116.9	20.33	17.39	10	8	14

^a The largest behavioral isopleth (*i.e.*, 116.9 km²) was calculated based on vibratory driving of 36-in pipe piles.

TABLE 13—PROPOSED TAKE, BY LEVEL A HARASSMENT AND/OR LEVEL B HARASSMENT, BY STOCK, HARASSMENT TYPE, TAKES ESTIMATED PER DAY, TOTAL PROPOSED TAKES, AND AS A PERCENTAGE OF STOCK ABUNDANCE

Species	Stock	N _{EST} ^a	Takes per day (total)	Takes per day (by stock)	Estimated number of pile driving days	Takes proposed for authorization			Proposed percentage to be taken ^b	
						Level A harassment	Level B harassment	Total	By species	By stock
Gray whale	Eastern North Pacific	26,960	0.03		231	2	13	15	0.06	
Humpback whale ^c ...	Hawai'i	11,278	0.067	0.061	231	4	11	15	0.16	0.13
	Mexico-North Pacific	n/a		0.005	231	0	2	2	n/a	n/a
	Western North Pacific	1,084		0.001	231	0	1	1	1.66	0.09
Killer whale	Eastern North Pacific Gulf of Alaska, Aleutian Islands, and Bering Sea Transient.	587	0.43		231	0	99	99	16.87	
Harbor porpoise	Gulf of Alaska	31,046	0.43		231	4	26	30	0.10	
Steller sea lion	Western	49,837	15		231	14	3,211	3,225	6.47	
Harbor seal	Cook Inlet/Shelikof Strait	28,411	10		231	50	1,566	1,616	5.69	

^a Stock estimates from the most recent NMFS stock assessment reports, unless otherwise noted.

^b Proposed percentage to be taken refers to combined take by both Level B harassment and Level A harassment (where requested) for each individual species/stock. If there is more than one stock of a species, the percent of stock is also calculated as if all takes occurred to a single stock.

^c Although different stocks of humpback whales could be present, PSOs would likely be unable to identify to the stock-level. Given this, NMFS will count any takes for humpback whales as a single group, not by stocks.

Proposed Mitigation

In order to issue an IHA under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to the activity, and other means of effecting the least practicable impact on the species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stock for taking for certain subsistence. NMFS regulations require applicants for incidental take authorizations (ITA) to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting the activity or other means of effecting the least practicable adverse impact upon the affected species or stocks, and their habitat (50 CFR 216.104(a)(11)).

In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where applicable, NMFS considers two primary factors:

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat, as well as subsistence uses. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if implemented as planned), the likelihood of effective implementation (probability implemented as planned), and;

(2) The practicability of the measures for applicant implementation, which may consider such things as cost, and impact on operations.

The mitigation requirements described in the following were proposed by ADOT&PF in its adequate and complete application or are the result of subsequent coordination between NMFS and ADOT&PF. ADOT&PF has agreed that all of the mitigation measures are practicable.

NMFS has fully reviewed the specified activities and the mitigation measures to determine if the mitigation measures would result in the least practicable adverse impact on marine mammals and their habitat, as required by the MMPA, and has determined the proposed measures are appropriate. NMFS describes these below as proposed mitigation requirements and has included them in the proposed IHA.

In addition to the measures described later in this section, ADOT&PF would be required to follow these general mitigation measures:

- Takes proposed for authorization, by Level A harassment and Level B harassment only, would be limited to the species and numbers listed in table 14. Construction activities would be required to be halted upon observation of either a species for which incidental take was not authorized or for a species for which incidental take has been authorized but the number of takes has been met, entering or is within the harassment zone, if the IHA is issued.

- The taking by serious injury or death of any of the species listed in table 14 or any taking of any other species of marine mammal would be prohibited and would result in the modification, suspension, or revocation of the IHA, if issued. Any taking exceeding the amounts proposed for authorization listed in table 14 would be prohibited and would result in the modification, suspension, or revocation of the IHA, if issued;

- Ensure that construction supervisors and crews, the marine mammal monitoring team, and relevant ADOT&PF staff are trained prior to the start of all construction activities, so that responsibilities, communication procedures, marine mammal monitoring protocol, and operational procedures are clearly understood. New personnel joining during the project must be trained prior to commencing work;

- ADOT&PF, construction supervisors and crews, PSOs, and relevant ADOT&PF staff must avoid direct physical interaction with marine mammals during construction activities. If a marine mammal comes within 10 m (32.8 ft) of such activity, operations must cease and vessels must reduce

speed to the minimum level required to maintain steerage and safe working conditions, as necessary to avoid direct physical interaction;

- Employ PSOs and establish monitoring locations as described in the Protected Species Monitoring and Mitigation Plan (PSMMP) (see NMFS' website). ADOT&PF must monitor the project area to the maximum extent possible based on the required number of PSOs, required monitoring locations, and environmental conditions;

- ADOT&PF also would abide by the reasonable and prudent measures and terms and conditions of a Biological Opinion and Incidental Take Statement, if issued by NMFS, pursuant to Section 7 of the ESA; and

- ADOT&PF, in alignment with the PSMMP, would abide by vessel measures related to North Pacific right whales (50 CFR 224.103(c)), Steller sea lions (50 CFR 224.103(d)), and humpback whales (50 CFR 224.103(b), 50 CFR 223.214).

Additionally, the following mitigation measures apply to ADOT&PF's in-water construction activities.

Pre- and Post-Activity Monitoring

ADOT&PF would be required to establish pre- and post-monitoring zones with radial distances (based on the distances to the Level B harassment threshold and feasibility for PSOs in the field) for all construction activities (see table 14). Monitoring would take place from 30 minutes prior to initiation of any pile driving activity (*i.e.*, pre-start clearance monitoring) through 30 minutes post-completion of pile driving activity. In addition, monitoring for 30 minutes would take place whenever a break in the specified activity (*i.e.*, impact pile driving, vibratory pile driving) of 30 minutes or longer occurs. Pre-start clearance monitoring would be conducted during periods of visibility sufficient for the Lead PSO to determine that the shutdown zones (indicated further below) are clear of marine mammals. Pile driving may commence following 30 minutes of observation when the determination is made that the shutdown zones are clear of marine mammals.

TABLE 14—PROPOSED MONITORING ZONES (IN METERS) FOR ALL MARINE MAMMAL SPECIES

Activity	Pile type	Installation method	Largest Level B harassment monitoring zone ^a
Trestle and Abutment			
Trestle support pile	36-in steel pipe piles	Vibratory Installation	11,659.2 m.
		Impact Installation	1,584.9 m.

TABLE 14—PROPOSED MONITORING ZONES (IN METERS) FOR ALL MARINE MAMMAL SPECIES—Continued

Activity	Pile type	Installation method	Largest Level B harassment monitoring zone ^a
Temporary trestle pile	24-in to 36-in steel pipe or H-pile	Vibratory Installation and Removal	11,659.2 m.
		Impact Installation	1,584.9 m.
Dock			
Dock support pile	36-in steel pipe pile	Vibratory Installation	11,659.2 m.
		Impact Installation	1,584.9 m.
Temporary dock pile	24-in to 36-in steel pipe pile	Vibratory Installation and Removal	11,659.2 m.
		Impact Installation	1,584.9 m.
Fender pile	30-in steel pipe pile	Vibratory Installation	11,659.2 m.
Fender pile	24-in steel pipe pile	Vibratory Installation	5,411.7 m.
Dolphin			
Dolphin pile	36-in steel pipe pile	Vibratory Installation	11,659.2 m.
		Impact Installation	1,584.9 m.
Temporary dolphin pile	24-in to 36-in steel pipe pile	Vibratory installation and removal	11,659.2 m.
Demolition (Removal)			
Trestle removal	16-in steel pipe pile	Vibratory removal	5,411.7 m.
Dock removal	16-in steel pipe pile	Vibratory removal	5,411.7 m.
Dock removal	26-in steel pipe pile	Vibratory removal	11,659.2 m.
Dolphin removal	16-in steel pipe pile	Vibratory removal	5,411.7 m.
Fender removal	20-in steel pipe pile	Vibratory removal	5,411.7 m.
Fender removal	16-in timber pile	Vibratory removal	6,309.6 m.

^a Monitoring zones are measured from shore (where PSOs would be located) outward from each monitoring station.

Soft-Start

ADOT&PF would use soft start techniques when impact pile driving. Soft-start requires contractors to provide an initial set of three strikes at reduced energy, followed by a 30-second waiting period, then two subsequent reduced-energy strike sets. A soft-start would be implemented at the start of each day's impact pile driving and at any time following cessation of impact pile driving for a period of 30 minutes or longer. Soft-start procedures are used to provide additional protection to marine mammals by providing warning and/or giving marine mammals a chance to leave the area prior to the hammer operating at full capacity.

Establishment of Shutdown Zones

ADOT&PF would be required to establish shutdown zones with radial distances, as identified in table 15 for all construction activities. The purpose of a shutdown zone is generally to define an area within which shutdown of the activity would occur upon sighting of a marine mammal (or in anticipation of an animal entering the defined area). Additionally, ADOT&PF would be required to shutdown in the event an unauthorized species is present, to avoid take of that unauthorized species. Shutdown zones would vary based on the activity type and marine mammal hearing group.

If a marine mammal is observed entering or within the shutdown zones indicated in table 15, pile driving activities must be delayed or halted. If pile driving is delayed or halted due to the presence of a marine mammal, the activity may not commence or resume until either the animal has voluntarily exited and been visually confirmed beyond the shutdown zones or a specific time period has passed without re-detection of the animal (*i.e.*, 30 minutes for cetaceans, 15 minutes for pinnipeds). If a marine mammal comes within or approaches the shutdown zone indicated in table 15, such operations must cease.

TABLE 15—PROPOSED SHUTDOWN ZONES (IN METERS) FOR ALL MARINE MAMMAL SPECIES

Activity	Pile type	Installation method	Shutdown zones ^a				
			Humpback whales, gray whales	Killer whales	Harbor porpoise	Harbor seals	Steller sea lions
Trestle and Abutment							
Trestle support pile	36-in steel pipe piles	Vibratory Installation	60	20	50	70	30
		Impact Installation	610	80	300	500	210
Temporary trestle pile	24-in to 36-in steel pipe or H-pile.	Vibratory Installation and Removal.	80	40	70	110	40
		Impact Installation	^b 2,000	370	300	500	^b 300
Dock							
Dock support pile	36-in steel pipe pile	Vibratory Installation	60	20	50	70	30
		Impact Installation	^b 2,000	370	300	500	^c 300

TABLE 15—PROPOSED SHUTDOWN ZONES (IN METERS) FOR ALL MARINE MAMMAL SPECIES—Continued

Activity	Pile type	Installation method	Shutdown zones ^a				
			Humpback whales, gray whales	Killer whales	Harbor porpoise	Harbor seals	Steller sea lions
Temporary dock pile	24-in to 36-in steel pipe pile.	Vibratory Installation and Removal.	80	40	70	110	40
Fender pile	30-in steel pipe pile	Impact Installation	^b 2,000	370	300	500	^c 300
Fender pile	24-in steel pipe pile	Vibratory Installation	50	20	40	60	20
Fender pile	24-in steel pipe pile	Vibratory Installation	30	10	20	30	10
Dolphin							
Dolphin pile	36-in steel pipe pile	Vibratory Installation	80	40	70	110	40
Temporary dolphin pile	24-in to 36-in steel pipe pile.	Impact Installation	^b 2,000	510	300	500	^d 300
Temporary dolphin pile	24-in to 36-in steel pipe pile.	Vibratory installation and removal.	60	20	50	70	30
Demolition (Removal)							
Trestle removal	16-in steel pipe pile	Vibratory removal	40	20	30	50	20
Dock removal	16-in steel pipe pile	Vibratory removal	440	20	30	50	20
Dock removal	26-in steel pipe pile	Vibratory removal	80	30	70	100	40
Dolphin removal	16-in steel pipe pile	Vibratory removal	30	10	20	30	20
Fender removal	20-in steel pipe pile	Vibratory removal	40	20	30	50	20
Fender removal	16-in timber pile	Vibratory removal	50	20	40	60	20

^a A minimum shutdown zone of 10 m (32.8 ft) would be enforced to ensure animals are not endangered by any physical interaction with the construction equipment (*i.e.*, barge positioning operations, the positioning of piles via a crane ("stabbing" the pile), the removal of piles via a crane (deadpull), or the overwater slinging of construction materials).

^b While NMFS acknowledges that the Level A harassment zones are larger than the 2,000-meter monitoring zone, NMFS considers 2,000 meters a practicable shutdown zone distance for LF cetaceans.

^c NMFS notes that this value was original 940 m (3,084 ft); however, given the size of Steller sea lions, NMFS suggested and the applicant accepted, a more realistic shutdown zone for 300 m (984.3 ft) for these activities.

^d NMFS notes that this value was original 1,320 m (4,330.7 ft); however, given the size of Steller sea lions, NMFS suggested and the applicant accepted, a more realistic shutdown zone for 300 m (984.3 ft) for these activities.

Bubble Curtain

ADOT&PF has not proposed, to utilize a bubble curtain during any of the proposed pile driving activities presented herein due to feasibility concerns related to the costs and time necessary to install and operate the curtains. Time delays are impractical for the proposed project due to the short field season available in the extreme environment of the Aleutian Islands.

NMFS conducted an independent evaluation of the proposed measures, and has preliminarily determined that the proposed mitigation measures provide the means of effecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, areas of similar significance, and on the availability of such species or stock for subsistence uses.

Proposed Monitoring and Reporting

In order to issue an IHA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for authorizations must include

the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present while conducting the activities. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

- Occurrence of marine mammal species or stocks in the area in which take is anticipated (*e.g.*, presence, abundance, distribution, density);
- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) action or environment (*e.g.*, source characterization, propagation, ambient noise); (2) affected species (*e.g.*, life history, dive patterns); (3) co-occurrence of marine mammal species with the activity; or (4) biological or behavioral context of exposure (*e.g.*, age, calving or feeding areas);

- Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors;

- How anticipated responses to stressors impact either: (1) long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks;

- Effects on marine mammal habitat (*e.g.*, marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat); and

- Mitigation and monitoring effectiveness.

ADOT&PF would abide by all monitoring and reporting measures contained within the IHA, if issued, and their PSMMP (see NMFS' website). The monitoring and reporting requirements described in the following were proposed by ADOT&PF in its adequate and complete application and/or are the result of subsequent coordination between NMFS and ADOT&PF. ADOT&PF has agreed to the requirements. NMFS describes these below as requirements and has included them in the proposed IHA.

Visual Monitoring

All PSOs must be NMFS-approved. PSOs would be independent of the activity contractor (for example, employed by a subcontractor) and have no other assigned tasks during monitoring periods. At least one PSO would have prior experience performing the duties of a PSO during an activity pursuant to a NMFS-issued ITA. Other PSOs may substitute other relevant experience (including relevant Alaska Native traditional knowledge), education (degree in biological science or related field), or training for prior experience performing the duties of a PSO during construction activity pursuant to a NMFS-issued ITA.

Additionally, PSOs would be required to meet the following qualifications:

- The ability to conduct field observations and collect data according to assigned protocols;
- Experience or training in the field identification of marine mammals, including the identification of behaviors;
- Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations;
- Writing skills sufficient to prepare a report of observations including but not limited to:

- (1) Number and species of marine mammals observed;
 - (2) Dates and times when in-water construction activities were conducted;
 - (3) Dates, times, and reason for implementation of mitigation (or why mitigation was not implemented when required); and
 - (4) Marine mammal behavior.
- The ability to communicate orally, by radio or in person, with project personnel to provide real-time information on marine mammals observed in the area as necessary.

ADOT&PF must establish monitoring locations, as described in PSMMP (see NMFS' website). ADOT&PF must use a minimum of two PSOs. Where a team of three or more PSOs is required, a lead observer ("Lead PSO") or monitoring coordinator would be designated. The lead observer must have prior experience performing the duties of a PSO during construction activity pursuant to a NMFS-issued ITA or Letter of Concurrence.

For all pile driving activities, a minimum of one PSO must be assigned to each active pile driving location to monitor the applicable shutdown zones for the entirety of active construction operations (see PSMMP). Given the maximum effective observation distance, PSOs would be required to

continuously monitor the entirety of the shutdown zones and as much as possible of the Level B harassment zones given visibility constraints, using binoculars and other resources to aid in observation. At all locations, all PSOs, to the extent practicable, must use an elevator platform at observation points to enhance observation ability. PSOs would be required to record all observations of marine mammals, regardless of distance from the pile being driven, as well as the additional data indicated below and in section 6 of the IHA, if issued.

Proposed Reporting

ADOT&PF would be required to submit an annual draft summary report on all construction activities and marine mammal monitoring results to NMFS within 90 days following the end of construction or 60 calendar days prior to the requested issuance of any subsequent IHA for similar activity at the same location, whichever comes first. The draft summary report would include an overall description of construction work completed, a narrative regarding marine mammal sightings, and associated raw PSO data sheets (in electronic spreadsheet format). Specifically, the report must include:

- Dates and times (begin and end) of all marine mammal monitoring;
- Construction activities occurring during each daily observation period, including: (a) how many and what type of piles were driven or removed and the method (*i.e.*, impact and vibratory); and (b) the total duration of time for each pile (vibratory driving) or number of strikes for each pile (impact driving);
- PSO locations during marine mammal monitoring; and
- Environmental conditions during monitoring periods (at beginning and end of PSO shift and whenever conditions change significantly), including Beaufort sea state and any other relevant weather conditions including cloud cover, fog, sun glare, and overall visibility to the horizon, and estimated observable distance.

Upon observation of a marine mammal, the following information must be reported:

- Name of PSO who sighted the animal(s) and PSO location and activity at the time of the sighting;
- Time of the sighting;
- Identification of the animal(s) (*e.g.*, genus/species, lowest possible taxonomic level, or unidentified), PSO confidence in identification, and the composition of the group if there is a mix of species;

- Distance and bearing of each observed marine mammal relative to the pile being driven or removed for each sighting;

- Estimated number of animals (min/max/best estimate);
- Estimated number of animals by cohort (*e.g.*, adults, juveniles, neonates, group composition, *etc.*);
- Animal's closest point of approach and estimated time spent within the estimated harassment zone(s);
- Description of any marine mammal behavioral observations (*e.g.*, observed behaviors such as feeding or traveling), including an assessment of behavioral responses thought to have resulted from the activity (*e.g.*, no response or changes in behavioral state such as ceasing feeding, changing direction, flushing, or breaching);
- Number of marine mammals detected within the estimated harassment zones, by species; and
- Detailed information about implementation of any mitigation (*e.g.*, shutdowns and delays), a description of specified actions that occurred, and resulting changes in behavior of the animal(s), if any.

If no comments are received from NMFS within 30 days after the submission of the draft summary report, the draft report would constitute the final report. If ADOT&PF received comments from NMFS, a final summary report addressing NMFS' comments would be submitted within 30 days after receipt of comments.

Reporting Injured or Dead Marine Mammals

In the event that personnel involved in ADOT&PF's activities discover an injured or dead marine mammal, ADOT&PF would report the incident to the NMFS Office of Protected Resources (OPR) (PR.ITP.MonitoringReports@noaa.gov, ITP.Potlock@noaa.gov) and to the Alaska Regional Stranding Coordinator (877-925-7773) as soon as feasible. If the death or injury was clearly caused by the specified activity, ADOT&PF would immediately cease the specified activities until NMFS is able to review the circumstances of the incident and determine what, if any, additional measures are appropriate to ensure compliance with the IHA. ADOT&PF would not resume their activities until notified by NMFS. The report would include the following information:

- Description of the incident;
- Environmental conditions (*e.g.*, Beaufort sea state, visibility);
- Description of all marine mammal observations in the 24 hours preceding the incident;

- Photographs or video footage of the animal(s) (if equipment is available).
- Time, date, and location (latitude/longitude) of the first discovery (and updated location information if known and applicable);
- Species identification (if known) or description of the animal(s) involved;
- Condition of the animal(s) (including carcass condition if the animal is dead);
- Observed behaviors of the animal(s), if alive; and
- General circumstances under which the animal was discovered.

Negligible Impact Analysis and Determination

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.*, population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be “*taken*” through harassment, NMFS considers other factors, such as the likely nature of any impacts or responses (*e.g.*, intensity, duration), the context of any impacts or responses (*e.g.*, critical reproductive time or location, foraging impacts affecting energetics), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS’ implementing regulations (54 FR 40338, September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the baseline (*e.g.*, as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

To avoid repetition, the discussion of our analysis applies to all of the species listed in table 3, given that the anticipated effects of this activity on these different marine mammal stocks are expected to be similar. There is little information about the nature or severity of the impacts, or the size, status, or structure of any of these species or

stocks that would lead to a different analysis for these activities.

Impact pile driving for installation and vibratory pile driving for installation and/or removal activities associated with the proposed project, as outlined previously, have the potential to disturb or displace marine mammals. Specifically, the specified activities may result in take in the form of Level A harassment and/or Level B harassment from underwater sounds generated from pile driving installation and removal. Potential takes could occur if individuals of these species are present in zones ensounded above the thresholds for Level A harassment or Level B harassment identified above when these activities are underway.

Given the nature of the proposed activities, NMFS does not anticipate serious injury or mortality due to ADOT&PF’s proposed project, even in the absence of required mitigation. The Level A harassment zones identified in table 10 are based upon an animal exposed to vibratory pile driving and/or impact pile driving for periods ranging from 20 to 60 minutes for in-water pile driving per day. Overall, construction activities are not expected to exceed 12 hours per day (likely ranging between 10–12 hours but not all of that would be spent actively pile driving). Exposures of this length are, however, unlikely for vibratory driving for installation and/or removal, given marine mammal movement throughout the area. Even during impact driving scenarios, an animal exposed to the accumulated sound energy would likely only experience limited AUD INJ at the lower frequencies where pile driving energy is concentrated.

As stated in the Proposed Mitigation section, ADOT&PF would implement shutdown zones that equal or exceed many of the Level A harassment isopleths shown in table 15. Take by Level A harassment is proposed for five marine mammal species/stocks. This is precautionary to account for the potential that an animal could enter and remain within the area between a Level A harassment zone and the shutdown zone for long enough to be taken by Level A harassment. Additionally, in some cases, this precaution would account for the possibility that an animal could enter a shutdown zone without detection and remain in the Level A harassment zone for a duration long enough to be taken by Level A harassment before being observed and a shutdown occurring. That said, any take by Level A harassment is expected to arise from, at most, a small degree of AUD INJ because animals would need to be exposed to higher levels and/or

longer duration than are expected to occur here to incur any more than a small degree of AUD INJ. Given the proximity to shore and the secluded nature of the Bay, exposure over extended periods of time are not considered likely to occur before the animal is observed by PSO’s and the proposed mitigation measures are implemented. Additionally, and as noted previously, some subset of the individuals that are behaviorally harassed could also simultaneously incur some small degree of TTS for a short duration of time. Because of the small degree anticipated, any AUD INJ or TTS potentially incurred here is not expected to adversely affect an animal’s individual fitness, let alone annual rates of recruitment or survival.

For all species and stocks, take is expected to occur within a limited, confined area (adjacent to the project site) of the stock’s range. The intensity and duration of take by Level A harassment and Level B harassment would be expected to be minimized through the proposed mitigation measures described herein. Furthermore, the amount of take proposed for authorization is small compared to the relative stock’s abundance, even assuming that every take for any particular species could wholly occur to individuals of an individual stock (where estimates of the stocks population are available).

Behavioral responses of marine mammals to pile driving for pile installation and/or pile removal at the project site, if any, are expected to be mild, short-term, and temporary. Given that old piles would be removed, temporary piles would be installed and then subsequently removed, and new piles would be permanently installed over 231 days in total (not necessarily be consecutive) over 10 to 12 hours per day, any harassment is expected to be temporary and intermittent. Marine mammals within the Level B harassment zones may not show any visual cues they are disturbed by activities or they could become alert, avoid the area, leave the area, or display other mild responses that are not observable, such as changes in vocalization patterns. Additionally, many of the species present in this region would only be present temporarily based on seasonal patterns or during active transit between other habitats. Most likely, during pile driving, individuals would be expected to move away from the sound source and be temporarily displaced from the areas of pile driving throughout the duration of pile driving activities. However, this reaction has been

observed primarily associated with impact pile driving. While vibratory driving associated with the proposed project may produce sound at distances of many kilometers from the project site, thus overlapping with some likely less-disturbed habitat, the project site itself is located in a busy harbor, and the majority of sound fields produced by the specified activities are close to the harbor. Animals disturbed by project sounds would be expected to avoid the area and use nearby higher-quality habitats. Pinnipeds in the area would have the ability to haul-out on shorelines and floating structures to avoid the activities (noting that the only regular haul-outs are located much further away from the project area) and no additional in-air harassment is anticipated from the construction activities.

The potential for harassment is minimized by implementing the proposed mitigation measures. During all impact driving, implementation of soft-start procedures and monitoring of established shutdown zones by trained and qualified PSOs shall be required, significantly reducing any possibility of injury. Given sufficient notice through soft-start (for impact driving), marine mammals are expected to move away from an irritating sound source before it becomes potentially injurious.

Any impacts on marine mammal prey that would occur during ADOT&PF's proposed activities would have, at most, short-term effects on foraging of individual marine mammals, and likely no effect on the populations of marine mammals as a whole. Indirect effects on marine mammal prey during the construction are expected to be minor, and these effects are unlikely to cause substantial effects on marine mammals at the individual level, with no expected effect on annual rates of recruitment or survival.

The area likely impacted by the project is relatively small compared to the available habitat in the surrounding waters of the Aleutian Islands. Although the Aleutian Islands are part of several identified BIAs (*i.e.*, fin whale, gray whale, humpback whale, North Pacific right whale, and sperm whale), none of the BIAs themselves enter the Bay (NOAA, 2023; Wild *et al.*, 2023). As all sound produced from the proposed activity is not expected to leave the mouth of the Bay, NMFS does not expect any spatial overlap with the proposed timing of the in-water construction.

In addition, it is unlikely that minor noise effects in a small, localized area of habitat would have any effect on the reproduction or survival of any

individuals, much less the stocks' annual rates of recruitment or survival. In combination, we believe that these factors, as well as the available body of evidence from other similar activities, demonstrate that the potential effects of the specified activities would have only minor, short-term effects on individuals. As already said, the specified activities are not expected to impact rates of recruitment or survival; therefore, these effects would not be expected to result in population-level impacts.

In summary and as described above, the following factors primarily support our preliminary determination that the impacts resulting from this activity are not expected to adversely affect any of the species or stocks through effects on annual rates of recruitment or survival:

- No serious injury or mortality is anticipated or proposed for authorization;
- Any Level A harassment exposures are anticipated to result in slight AUD INJ (*i.e.*, of a few decibels) within the lower frequencies associated with pile driving;
- The anticipated incidents of Level B harassment would consist of, at worst, temporary modifications in behavior that would not result in fitness impacts to individuals;
- The area affected by the specified activity is very small relative to the overall habitat ranges of all species, does not include any rookeries, and does not spatially overlap with any BIAs;
- Effects on species that serve as prey for marine mammals from the activities are expected to be short-term and, therefore, any associated impacts on marine mammal feeding are not expected to result in significant or long-term consequences for individuals, or to accrue to adverse impacts on their populations;
- There are no known haulout locations for Steller sea lions near the proposed project site;
- While harbor seals are known to haul out near the mouth of Kinzarof Lagoon (located approximately 4.5 mi (7.2 km) from the City of Cold Bay's coastal infrastructure, at the closest point), all activities are occurring in-water, and any harbor seals hauled out would not be expected to be affected by in-water noise. Any seals in the water would have the ability to surface as this in-air habitat is expected to be unaffected at distance by the proposed in-water activities;
- The project area is located in an industrialized and commercial dock; and
- The proposed mitigation measures, such as employing vibratory driving to

the maximum extent practicable, soft-starts, and shutdowns, are expected to reduce the effects of the specified activity to the least practicable adverse impact level.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the proposed monitoring and mitigation measures, NMFS preliminarily finds that the total marine mammal take from the proposed activity would have a negligible impact on all affected marine mammal species or stocks.

Small Numbers

As noted previously, only take of small numbers of marine mammals may be authorized under section 101(a)(5)(A) and (D) of the MMPA for specified activities other than military readiness activities. The MMPA does not define small numbers and so, in practice, where estimated numbers are available, NMFS compares the number of individuals taken to the most appropriate estimation of abundance of the relevant species or stock in our determination of whether an authorization is limited to small numbers of marine mammals. When the predicted number of individuals to be taken is fewer than one-third of the species or stock abundance, the take is considered to be of small numbers (86 FR 5322, January 19, 2021). Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

NMFS is proposing to authorize incidental take by Level A harassment and/or Level B harassment of six species (eight stocks) of marine mammals. No mortality or serious injury has been requested, nor is it anticipated to occur from the activities described herein. The maximum number of instances of takes by Level A harassment and/or Level B harassment, relative to the best available population abundance, is less than one-third for all species and stocks potentially impacted (see table 13).

Based on the analysis contained herein of the proposed activity (including the proposed mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS preliminarily finds that small numbers of marine mammals would be taken relative to the population size of the affected species or stocks.

Unmitigable Adverse Impact Analysis and Determination

In order to issue an IHA, NMFS must find that the specified activity would

not have an “*unmitigable adverse impact*” on the subsistence uses of the affected marine mammal species or stocks by Alaskan Natives. NMFS has defined “*unmitigable adverse impact*” in 50 CFR 216.103 as an impact resulting from the specified activity: (1) that is likely to reduce the availability of the species to a level insufficient for a harvest to meet subsistence needs by: (i) causing the marine mammals to abandon or avoid hunting areas; (ii) directly displacing subsistence users; or (iii) placing physical barriers between the marine mammals and the subsistence hunters; and (2) that cannot be sufficiently mitigated by other measures to increase the availability of marine mammals to allow subsistence needs to be met.

Hunting and fishing for the purpose of subsistence has been a critical component of the history and culture of Alaska, including the Aleutian Islands. The Unangan have displayed highly skilled techniques for fishing, hunting of marine mammals, and gathering and usage of shellfish and plants for thousands of years (Keating *et al.*, 2022). Historically, the Unangan relied on harbor seals, Steller sea lions, and sea otters for subsistence. Not only did they provide a source of food, which was shared between households, but also a source for oil, decoration, and clothing (Haynes and Mishler, 1991). However, very little information is available regarding subsistence hunting of marine mammals in Cold Bay, with most information coming from nearby communities (False Pass, King Cove, and Unalaska). Based on subsistence records from 2016, tracked by the Alaska Department of Fish and Game’s (ADF&G) Division of Subsistence, Cold Bay has shown a higher preference for fishing than subsistence hunting of marine mammals, catching 9,253 pounds (lbs; 4,197.1 kilograms (kg)) of salmon compared to only 54 lbs (24.5 kg) of marine mammals. Since 2016, no data are available on the number Steller sea lions or harbor seals harvested in Cold Bay. Even when looking at the nearby communities, Steller sea lions were harvested at low levels (one at False Pass in 1985 (40 mi (64.4 km) from Cold Bay), none at False Pass in 2007, 1.3 at King Cove (20 mi (32.2 km) from Cold Bay) in 2007, and none in 2020 at Unalaska (170 mi (273.6 km) from Cold Bay). Comparatively, harbor seals made up a significant amount of the harvest at Unalaska in 2020 (74 percent) at 35 harbor seals. At closer locations, between False Pass and King Cove, respectively, the annual harvest was made up of one and five harbor seals,

demonstrating a low harvest rate. Between 2014 and 2024, a total of 25 sea otters were reported as harvested from Cold Bay (U.S. Fish and Wildlife Service, 2025b). The annual harvest ranged from zero to nine sea otters in Cold Bay (at an average of 2.5 sea otters per year).

Therefore, NMFS preliminarily determines that the proposed project is not likely to adversely affect the availability of any marine mammal species/stock that would traditionally be used for subsistence purposes, and would only minimally affect any subsistence harvest in the region because of the following reasons:

- There are minimal recorded subsistence harvests of marine mammals in the area;
- The construction activities would be localized and temporary in nature in a sheltered Bay;
- Harbor seals and Steller sea lions do not have dedicated haul outs in Cold Bay, meaning their numbers are not occurring regularly enough to be a dependable resource, unlike the abundant rivers and streams, which provide ample fishing opportunities and is a more popular source of subsistence for local residents;
- The proposed mitigation measures would minimize any disturbances of marine mammals in the area;
- NMFS expects that the majority of effects on marine mammals would not rise above behavioral impacts and would be temporary in nature; and
- No serious injury or mortality is expected to result from the project activities; therefore, the project would not result in a significant change to the availability of subsistence resources.

Based on the description of the specified activity, the measures described to minimize adverse effects on the availability of marine mammals for subsistence purposes, and the proposed mitigation and monitoring measures, NMFS has preliminarily determined that there would not be an unmitigable adverse impact on subsistence uses from ADOT&PF’s proposed activities.

Endangered Species Act

Section 7(a)(2) of the ESA of 1973 (16 U.S.C. 1531 *et seq.*) requires that each Federal agency ensures that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of incidental take authorizations, NMFS consults internally whenever we

propose to authorize take for ESA-listed species, in this case with NMFS’ Alaska Regional Office.

NMFS is proposing to authorize take of humpback whales (Mexico-North Pacific stock), humpback whales (Western North Pacific stock), and Steller sea lions (Western stock), which are all listed under the ESA. The Permits and Conservation Division has requested initiation of section 7 consultation with NMFS’ Alaska Regional Office for the issuance of this IHA. NMFS would conclude the ESA consultation prior to reaching a determination regarding the proposed issuance of the authorization.

Proposed Authorization

As a result of these preliminary determinations, NMFS proposes to issue an IHA to ADOT&PF for conducting construction work for the Cold Bay Ferry Terminal Reconstruction Project in Cold Bay, Alaska, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated. A draft of the proposed IHA can be found at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities>.

Request for Public Comments

We request comment on our analyses, the proposed authorization, and any other aspect of this notice of proposed IHA for the proposed construction project. We also request comment on the potential renewal of this proposed IHA as described in the paragraph below. Please include with your comments any supporting data or literature citations to help inform decisions on the request for this IHA or a subsequent renewal IHA.

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 Description of Proposed Activity section of this notice is planned or (2) the activities as described in the Description of Proposed Activity section of this notice would not be completed by the time the IHA expires and a renewal would allow for completion of the activities beyond that described in the *Dates and Duration* section of this notice, provided all of the following conditions are met:

- 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).

• The request for renewal must include the following:

1. 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).

2. 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.

• 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.

Dated: December 22, 2025.

Kimberly Damon-Randall,

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

[FR Doc. 2025-23894 Filed 12-23-25; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XF278]

Fisheries Off West Coast States; Pacific Coast Groundfish Fishery; Trawl Rationalization Program; 2026 Cost Recovery Fee Notice

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

ACTION: Notice, 2026 cost recovery fee percentages and average mothership cooperative program pricing.

SUMMARY: This action provides participants in the Pacific Coast Groundfish Trawl Rationalization Program with the 2026 cost recovery fee percentages and the average mothership (MS) price per pound to be used in the catcher/processor (C/P) Co-op program to calculate the fee amount for the upcoming calendar year. For the 2026 calendar year, NMFS announces the following fee percentages by sector specific program: 3.0 percent for the

Shorebased Individual Fishing Quota (IFQ) Program; 0.3 percent for the C/P Co-op Program; and 3.0 percent for the MS Co-op Program. For 2026, the MS pricing to be used as a proxy by the C/P Co-op Program is \$0.10/pound (lb) for Pacific whiting.

DATES: Applicable January 1, 2026.

FOR FURTHER INFORMATION CONTACT: Christopher Biegel, (503) 231-6291, christopher.biegel@noaa.gov.

SUPPLEMENTARY INFORMATION: Section 304(d)(2)(A) of the Magnuson-Stevens Fishery Conservation and Management Act (MSA) authorizes and requires NMFS to collect fees to recover the costs directly related to the management, data collection and analysis, and enforcement connected to and in support of a limited access privilege program (LAPP) (16 U.S.C. 1854(d)(2)), also called “cost recovery.” Cost recovery fees recover the actual costs directly related to the management, data collection and analysis, and enforcement of the programs (MSA Section 303A(e), 16 U.S.C. 1853a(e)). Section 304(d)(2)(B) of the MSA mandates that cost recovery fees not exceed 3 percent of the annual ex-vessel value of fish harvested by a program subject to a cost recovery fee, and that the fee be collected either at the time of landing, filing of a landing report, or sale of such fish during a fishing season or in the last quarter of the calendar year in which the fish is harvested.

The Pacific Coast Groundfish Trawl Rationalization Program is a LAPP, implemented in 2011, and consists of three sector-specific programs: the Shorebased IFQ Program, the MS Co-op Program, and the C/P Co-op Program. In accordance with the MSA and based on a recommended structure and methodology developed in coordination with the Pacific Fishery Management Council (Council), NMFS began collecting mandatory fees of up to 3 percent of the ex-vessel value of groundfish from each program (Shorebased IFQ Program, MS Co-op Program, and C/P Co-op Program) in 2014. NMFS collects the fees to recover the incremental costs of management, data collection and analysis, and enforcement of the Groundfish Trawl Rationalization Program. Additional background can be found in the cost recovery proposed rule (78 FR 7371, February 1, 2013) and final rule (78 FR 75268, December 11, 2013). The details of cost recovery for the Groundfish Trawl Rationalization Program are in regulation at 50 CFR 660.115 (Trawl fishery—cost recovery program), 660.140 (Shorebased IFQ Program),

660.150 (MS Co-op Program), and 660.160 (C/P Co-op Program).

By December 31 of each year, NMFS announces the next year’s fee percentages and the applicable MS pricing for the C/P Co-op Program. To calculate the fee percentages, NMFS used the formula specified in regulation at § 660.115(b)(1), where the fee percentage by sector equals the lower of 3 percent or direct program costs (DPC) for that sector divided by total ex-vessel value (V) for that sector multiplied by 100 (Fee percentage = the lower of 3 percent or (DPC/V) × 100).

“DPC” as defined in the regulations at § 660.115(b)(1)(i), are the actual incremental costs for the previous fiscal year directly related to the management, data collection and analysis, and enforcement of each program (Shorebased IFQ Program, MS Co-op Program, and C/P Co-op Program). Actual incremental costs means those net costs that would not have been incurred but for the implementation of the Groundfish Trawl Rationalization Program, including both increased costs for new requirements of the program and reduced costs resulting from any program efficiencies or adjustments to costs from previous years.

“V”, as specified at § 660.115(b)(1)(ii), is the total ex-vessel value, as defined at § 660.111, for each sector from the previous calendar year. To determine the ex-vessel value for the Shorebased IFQ Program, NMFS used the ex-vessel value for calendar year 2024 as reported in the Pacific Fisheries Information Network (PacFIN) from Shorebased IFQ electronic fish tickets as this was the most recent complete set of data. To determine the ex-vessel value for the MS Co-op Program and the C/P Co-op Program, NMFS used the retained catch estimates (weight) for each sector as reported in the North Pacific Observer Program database multiplied by the average price of Pacific whiting as reported by participants in the MS Co-op program for 2024.

The fee calculations for the 2026 fee percentages are described below.

IFQ Program:

• 5.1 percent = (\$2,110,933.27 / \$41,126,145.00) × 100.

C/P Co-op Program:

• 0.3 percent = (\$50,758.19 / \$15,663,157.09) × 100.

MS Co-op Program:

• 4.2 percent = (\$218,726.38 / \$5,208,949.27) × 100.

However, the calculated fee percentage cannot exceed the statutory limit of 3.0 percent. Both the IFQ Program (5.1 percent) and MS Co-op Program (4.2 percent) fee calculations exceed this limit, therefore, the 2026 fee

percentages for these Programs are 3.0 percent. The final 2026 fee percentages are 3.0 percent for the IFQ Program, 0.3 percent for the C/P Co-op Program, and 3.0 percent for the MS Co-op Program.

MS Average Pricing

MS pricing is the average price per pound that the C/P Co-op Program will use to determine the fee amount due for that sector. The C/P sector value (V) is calculated by multiplying the retained catch estimates (weight) of Pacific whiting harvested by the vessel registered to a C/P-endorsed limited entry trawl permit by the MS pricing. NMFS has calculated the 2026 MS pricing to be used as a proxy by the CP Co-op Program as: \$0.10/lb for Pacific whiting.

Cost recovery fees are submitted to NMFS by fish buyers via *Pay.gov* (<https://www.pay.gov/>). Fees are only accepted at *Pay.gov* by credit/debit card or bank transfers. Cash or checks cannot be accepted. Fish buyers registered with *Pay.gov* can login in the upper right-hand corner of the screen. Fish buyers not registered with *Pay.gov* can go to the cost recovery forms directly from the website below. The links to the *Pay.gov* forms for each program (IFQ, MS, or C/P) are listed below:

IFQ: <https://www.pay.gov/public/form/start/58062865>;

MS: <https://www.pay.gov/public/form/start/58378422>; and

C/P: <https://www.pay.gov/public/form/start/58102817>.

As stated in the preamble to the cost recovery proposed and final rules, in the spring of each year, NMFS will release an annual report documenting the details and data used for the fee percentage calculations. Annual reports are available at: <https://www.fisheries.noaa.gov/west-coast/sustainable-fisheries/west-coast-groundfish-trawl-catch-share-program#cost-recovery>.

Authority: 16 U.S.C. 1801 *et seq.*, 16 U.S.C. 773 *et seq.*, and 16 U.S.C. 7001 *et seq.*

Dated: December 19, 2025.

Kelly Denit,

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

[FR Doc. 2025-23841 Filed 12-23-25; 8:45 am]

BILLING CODE 3510-22-P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions

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

ACTION: Proposed additions to the Procurement List.

SUMMARY: The Committee is proposing to add service(s) to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: Comments must be received on or before: January 28, 2026.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 355 E Street SW, Suite 325, Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 489-1322, or email CMTEFedReg@AbilityOne.gov.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51-2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

In accordance with 41 CFR 51-5.3(b), the Committee intends to add the service requirements listed below to the Procurement List as a mandatory purchase only for the contracting activities at the locations listed with the proposed qualified nonprofit agency as the authorized source of supply. Prior to adding the service to the Procurement List, the Committee will consider other pertinent information, including information from Government personnel and relevant comments from interested parties regarding the Committee's intent to geographically limit this services requirement.

Services(s)

Service Type: Document Destruction

Mandatory for: US Air Force, Oklahoma City-Air Logistics Complex, 7858 5th Street, Tinker, AFB, OK

Authorized Source of Supply: The Meadows Center for Opportunity, Inc., Edmond, OK

Contracting Activity: DEPT OF DEFENSE, FA8132 AFSC PZIMC

Service Type: Laundry & Linen Services

Mandatory for: Department of Veterans Affairs, Memphis VA Medical Center and Outpatient Clinics, Memphis, TN, 116 N. Pauline Street, Memphis, TN

Designated Source of Supply: Wiregrass Rehabilitation Center, Inc., Dothan, AL
Contracting Activity: VETERANS AFFAIRS, DEPARTMENT OF, 249-NETWORK CONTRACT OFC 9(00249)

Service Type: Janitorial Service

Mandatory for: National Park Service, Golden Gate National Recreation Area, Marin County Administrative Buildings and Public Restrooms, and San Francisco County Public Restrooms, San Francisco, CA

Authorized Source of Supply: Toolworks, San Francisco, CA

Contracting Activity: National Park Service, San Francisco Golden Gate National Recreation Area

Michael R. Jurkowski,

Director, Business Operations.

[FR Doc. 2025-23893 Filed 12-23-25; 8:45 am]

BILLING CODE 6353-01-P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions and Deletions

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

ACTION: Additions to and deletions from the Procurement List.

SUMMARY: This action adds product(s) and service(s) to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes product(s) and service(s) from the Procurement List previously furnished by such agencies.

DATES: *Date added to and deleted from the Procurement List:* January 29, 2026.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 355 E Street SW, Suite 325, Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 489-1322 or email CMTEFedReg@AbilityOne.gov.

SUPPLEMENTARY INFORMATION:

Additions

On September 18, 2026 (90 FR 45023) and November 20, 2025 (90 FR 52358), the Committee for Purchase From People Who Are Blind or Severely Disabled (operating as the U.S. AbilityOne Commission) published an initial notice of proposed additions to the Procurement List. This final notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51-2.3. The Committee has determined that the product(s) and service(s) listed below are suitable for procurement by the Federal Government and has added these product(s) and service(s) to the Procurement List as a mandatory purchase for Federal entities. In accordance with 41 CFR 51-5.2, the Committee has authorized the qualified nonprofit agencies described with the product(s) and service(s) as the mandatory source(s) of supply.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the product(s) and impact of the additions on the current or most recent contractors, the Committee has determined that the product(s) listed below are suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the product(s) and service(s) to the Government.

2. The action will result in authorizing small entities to furnish the product(s) and service(s) to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the product(s) and service(s) proposed for addition to the Procurement List.

End of Certification

Accordingly, the following product(s) are added to the Procurement List:

Product(s)

NSN(s)—Product Name(s): 6510–01–598–8418—Bandage, Compression, I, Flat Fold

Authorized Source of Supply: Alphapointe, Kansas City, MO

Mandatory For: DEPARTMENT OF DEFENSE

Contracting Activity: DEFENSE LOGISTICS AGENCY, DLA TROOP SUPPORT, MEDICAL SUPPLY CHAIN FSF

Distribution: C-List 1005–01–706–2547—Buttstock, Subassembly, Black

Authorized Source of Supply: DePaul Industries, Portland, OR

Mandatory For: DEPARTMENT OF DEFENSE

Contracting Activity: DLA LAND AND MARITIME, LAND SUPPLIER OPERATIONS SMS

Distribution: C-List

Service(s)

Service Type: Laundry and Linen Service

Mandatory for: Department of Veteran Affairs, VISN 7, Multiple Locations, GA, SC

Authorized Source of Supply: Wiregrass Rehabilitation Center, Inc.

Contracting Activity: DEPARTMENT OF VETERANS AFFAIRS, 247–NETWORK CONTRACT OFC 7(00247)

The Committee finds good cause to dispense with the 30-day delay in the

effective date normally required by the Administrative Procedure Act. See 5 U.S.C. 553(d). This addition to the Committee's Procurement List is effectuated because of the expiration of the Department of Veteran Affairs, VISN 7, Multiple Locations, GA, SC Laundry and Linen Service contract. The Federal customer contacted and has worked diligently with the AbilityOne Program to fulfill this service need under the AbilityOne Program. To avoid performance disruption, and the possibility that the Department of Veteran Affairs will refer its business elsewhere, this addition must be effective on January 12, 2026, ensuring timely execution for a January 12, 2026 start date. The Committee published an initial notice of proposed Procurement List addition in the **Federal Register** on September 18, 2026 (90 FR 45023) but did not receive any comments. This addition will not create a public hardship and has limited effect on the public at large. Rather, this addition will create new jobs for other affected parties—people with significant disabilities in the AbilityOne program who otherwise face challenges locating employment. Moreover, this addition enables the Federal customer to continue operations without interruption.

Deletions

On November 20, 2026 (90 FR 52358), the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed deletions from the Procurement List. This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51–2.3. After consideration of the relevant matter presented, the Committee has determined that the product(s) and service(s) listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the product(s) and service(s) to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in

connection with the product(s) and service(s) deleted from the Procurement List.

End of Certification

Accordingly, the following product(s) and service(s) are deleted from the Procurement List:

Product(s)

NSN(s)—Product Name(s): 8520–00–NIB–0134—Purell Instant Hand Sanitizer, Green-Certified, 8 oz. Bottle

Authorized Source of Supply: Travis Association for the Blind, Austin, TX

Contracting Activity: DEPARTMENT OF HOMELAND SECURITY, OFFICE OF PROCUREMENT OPERATIONS

NSN(s)—Product Name(s): 7045–01–568–9695—USB 2.0 Hard Drive, Portable, 500G

Authorized Source of Supply: North Central Sight Services, Inc., Williamsport, PA

Contracting Activity: GSA/FAS ADMIN SVCS ACQUISITION BR(2)

NSN(s)—Product Name(s):

890008300S—Breakfast Burrito and Drink

890008301S—Cold Sandwich With Chips and Drink

890008302S—Dinner Burrito With Fruit Cup and Drink

890008303S—Vegetarian Burrito With Chips and Drink

890008304S—Cheeseburger Meal With Chips and Drink

890008305S—Chicken Salad With Chip and Drink

890008306S—Chicken Teriyaki Bowl and Drink

890008307S—Snack

890008308S—Water, 16.9 oz. bottle

890008309S—Milk, 8 oz. box

890008310S—Juice, 6 oz. box

890008311S—Cold Vegetarian Sandwich With Chips and Drink

890008312S—Vegetarian Cheeseburger Meal With Chips and Drink

Authorized Source of Supply: ARC-Imperial Valley, El Centro, CA

Contracting Activity: U.S. CUSTOMS AND BORDER PROTECTION, BORDER ENFORCEMENT CTR DIV

NSN(s)—Product Name(s):

8950–01–E60–7766—Pepper, Black, Ground, Gourmet, 12/16 oz. Metal Cans

8950–01–E60–7768—Pepper, Black, Ground, Gourmet, 6/18 oz. Metal Cans

8950–01–E60–8234—Pepper, Black, Cracked 16 Mesh, 6/18 oz. Metal Cans

8950–01–E60–8236—Pepper, Black, Cracked 16 Mesh, 6/16 oz. Metal Cans

8950–01–E60–8238—Pepper, Black, Whole, 6/16 oz. Metal Cans

8950–01–E60–8240—Pepper, Black, Whole, 6/18 oz. Metal Cans

Authorized Source of Supply: CDS Monarch, Webster, NY

Contracting Activity: DEFENSE LOGISTICS AGENCY, DLA TROOP SUPPORT

NSN(s)—Product Name(s): 4240–01–469–8738—Hearing Protection, Over-The-Head Earmuff, NRR 27dB

Authorized Source of Supply: Access: Supports for Living Inc., Middletown, NY

Contracting Activity: DEFENSE LOGISTICS AGENCY, DLA TROOP SUPPORT

NSN(s)—Product Name(s):

7290-00-633-9124—Pad, Ironing Board
7290-00-946-7905—Cover, Ironing Board

Authorized Source of Supply: NuVisions Center, a Not for Profit Corporation, Lewistown, PA

Contracting Activity: GSA/FSS GREATER SOUTHWEST ACQUISITI, FEDERAL ACQUISITION SERVICE

NSN(s)—Product Name(s):

7510-01-664-8787—DAYMAX System, 2024 Calendar Pad, Type I
7510-01-664-8808—DAYMAX System, 2024, Calendar Pad, Type II

Authorized Source of Supply: Anthony Wayne Rehabilitation Ctr for Handicapped and Blind, Inc., Fort Wayne, IN

Contracting Activity: GSA/FSS GREATER SOUTHWEST ACQUISITI, FEDERAL

NSN(s)—Product Name(s): 5340-00-454-5969—Strap, Webbing, 180" x 1"

Authorized Source of Supply: The Charles Lea Center, Inc., Spartanburg, SC

Contracting Activity: DEFENSE LOGISTICS AGENCY, DLA LAND AND MARITIME

NSN(s)—Product Name(s):

8415-01-092-7529—Coveralls, Disposable, Small

8415-01-092-7531—Coverall, Disposable, with Attached Hood & Booties for Asbestos/Fiberglass Handlers, Navy, White, L

8415-01-092-7533—Coverall, Disposable, Asbestos and Fiberglass, U.S. Navy, White Main Body, XX-Large

Authorized Source of Supply: TradeWinds Services, Inc., Merrillville, IN

Authorized Source of Supply: ASPIRO, Inc., Green Bay, WI

Contracting Activity: DEFENSE LOGISTICS AGENCY, DLA TROOP SUPPORT

NSN(s)—Product Name(s):

8415-00-NSH-0608—Pocket, Radio, AN/PRC-126

8415-00-NSH-0612—Suspenders, Sub-Belt

8415-00-NSH-0613—Pocket, Shotgun Launched Riot Control Canister

8415-00-NSH-0614—Pocket, Administrative

8415-00-NSH-0617—Insert, Medical, Trauma, Ranger

8415-00-NSH-0620—Modular Assault Pack

8415-00-NSH-0621—Load Carriage System Bag

8415-00-NSH-0623—Load Carriage System Harness (CV-420)

8415-00-NSH-0624—Mission Tether Belt

8415-00-NSH-0625—Mission Tether

8415-00-NSH-0684—FSBE Deployment Bag

8415-00-NSH-0685—Repair Kit

Authorized Source of Supply: Chautauqua County Chapter, NYSARC, Jamestown, NY

Contracting Activity: DEPT OF THE ARMY, W6QK ACC-APG NATICK

NSN(s)—Product Name(s):

6190-09-000-0279—Kit, Martial Arms Training (Battalion Kit)

7810-00-NSH-0002—Kit, Martial Arms Training (School of Infantry Kit)

7810-00-NSH-0003—Kit, Martial Arms Training (Recruit Depot Kit)

Authorized Source of Supply: Chautauqua County Chapter, NYSARC, Jamestown, NY

Contracting Activity: DEPT OF THE ARMY, W6QK ACC-APG NATICK

NSN(s)—Product Name(s):

1375-00-NSH-0001—Kit, Marine Corps Demolition, Advanced

Authorized Source of Supply: Chautauqua County Chapter, NYSARC, Jamestown, NY

Contracting Activity: DEPT OF THE ARMY, W6QK ACC-APG NATICK

NSN(s)—Product Name(s): 5340-00-454-5963—Strap, Webbing, 100" x 1"

Authorized Source of Supply: The Charles Lea Center, Inc., Spartanburg, SC

Contracting Activity: DEFENSE LOGISTICS AGENCY, DLA LAND AND MARITIME

NSN(s)—Product Name(s): 5340-00-126-9011—Strap, Webbing, 144" x 1"

Authorized Source of Supply: The Charles Lea Center, Inc., Spartanburg, SC

Contracting Activity: DEFENSE LOGISTICS AGENCY, DLA LAND AND MARITIME

NSN(s)—Product Name(s): 5340-00-854-6736—Strap, Webbing, 174" x 1"

Authorized Source of Supply: The Charles Lea Center, Inc., Spartanburg, SC

Contracting Activity: DEFENSE LOGISTICS AGENCY, DLA LAND AND MARITIME

NSN(s)—Product Name(s): 8970-01-321-9153—Heater, Flameless

Authorized Source of Supply: Work, Incorporated, Dorchester, MA

Contracting Activity: DEFENSE LOGISTICS AGENCY, DLA TROOP SUPPORT

NSN(s)—Product Name(s): EIRS 74, PSIN3916—Tray, MM, Fiberboard

Authorized Source of Supply: ReadyOne Industries, Inc., El Paso, TX

Contracting Activity: U.S. Postal Service, Washington, DC

NSN(s)—Product Name(s):

8415-00-NSH-0398—Trousers, Wind Resistant, Army, Urban Camouflage, XS-XS

8415-00-NSH-0399—Trousers, Wind Resistant, Army, Urban Camouflage, XS-S

8415-00-NSH-0400—Trousers, Wind Resistant, Army, Urban Camouflage, XS-R

8415-00-NSH-0401—Trousers, Wind Resistant, Army, Urban Camouflage, XS-L

8415-00-NSH-0402—Trousers, Wind Resistant, Army, Urban Camouflage, S-XS

8415-00-NSH-0403—Trousers, Wind Resistant, Army, Urban Camouflage, S-S

8415-00-NSH-0404—Trousers, Wind Resistant, Army, Urban Camouflage, S-R

8415-00-NSH-0405—Trousers, Wind Resistant, Army, Urban Camouflage, S-L

8415-00-NSH-0406—Trousers, Wind Resistant, Army, Urban Camouflage, S-XL

8415-00-NSH-0407—Trousers, Wind Resistant, Army, Urban Camouflage, M-XS

8415-00-NSH-0408—Trousers, Wind Resistant, Army, Urban Camouflage, M-S

8415-00-NSH-0409—Trousers, Wind Resistant, Army, Urban Camouflage, M-R

8415-00-NSH-0410—Trousers, Wind Resistant, Army, Urban Camouflage, M-L

8415-00-NSH-0411—Trousers, Wind Resistant, Army, Urban Camouflage, M-XL

8415-00-NSH-0412—Trousers, Wind Resistant, Army, Urban Camouflage, L-S

8415-00-NSH-0413—Trousers, Wind Resistant, Army, Urban Camouflage, L-R

8415-00-NSH-0414—Trousers, Wind Resistant, Army, Urban Camouflage, L-L

8415-00-NSH-0415—Trousers, Wind Resistant, Army, Urban Camouflage, L-XL

8415-00-NSH-0416—Trousers, Wind Resistant, Army, Urban Camouflage, XL-S

8415-00-NSH-0417—Trousers, Wind Resistant, Army, Urban Camouflage, XL-R

8415-00-NSH-0418—Trousers, Wind Resistant, Army, Urban Camouflage, XL-LL

8415-00-NSH-0419—Trousers, Wind Resistant, Army, Urban Camouflage, M-XXL

8415-00-NSH-0420—Trousers, Wind Resistant, Army, Urban Camouflage, L-XXL

8415-00-NSH-0421—Trousers, Wind Resistant, Army, Urban Camouflage, XXL-XXL

Authorized Source of Supply: Goodwill Industries of South Florida, Inc., Miami, FL

Contracting Activity: DEPT OF THE ARMY, W6QK ACC-APG NATICK

NSN(s)—Product Name(s):

8415-00-NSH-0425—Jacket, Fleece, with Hood, Wind and Water Resistant, Type 1, Army, Green, S

8415-00-NSH-0426—Jacket, Fleece, with Hood, Wind and Water Resistant, Type 1, Army, Green, M

8415-00-NSH-0427—Jacket, Fleece, with Hood, Wind and Water Resistant, Army, Green, L

8415-00-NSH-0428—Jacket, Fleece, with Hood, Wind and Water Resistant, Army, Green, XL

8415-00-NSH-0429—Jacket, Fleece, with Hood, Wind and Water Resistant, Army, Black, S

8415-00-NSH-0430—Jacket, Fleece, with Hood, Wind and Water Resistant, Army, Black, M

8415-00-NSH-0431—Jacket, Fleece, with Hood, Wind and Water Resistant, Army, Black, L

8415-00-NSH-0432—Jacket, Fleece, with Hood, Wind and Water Resistant, Army, Black, XL

8415-01-476-6425—Jacket, Wind Resistant Fleece with Hood, SPEAR, Army, Green, LR

8415-01-476-6428—Jacket, Wind Resistant Fleece with Hood, SPEAR, Army, Green, MR

8415-01-476-6429—Jacket, Wind Resistant Fleece with Hood, SPEAR, Army, Green, SR
8415-01-476-6431—Jacket, Wind Resistant Fleece, SPEAR, Army, Green, XLR

8415-01-476-6560—Jacket, Wind Resistant Fleece, SPEAR, Army, Black, XLR

8415-01-476-6573—Jacket, Wind Resistant Fleece, SPEAR, Army, Black, LL

8415-01-476-6574—Jacket, Wind Resistant Fleece with Hood, SPEAR, Army, Green, SR

8415-01-476-6576—Jacket, Wind Resistant Fleece, SPEAR, Army, Black, MR

8415-01-476-6577—Jacket, Wind Resistant Fleece with Hood, SPEAR, Army, Black, SR

8415-01-476-6578—Jacket, Wind Resistant Fleece, SPEAR, Army, Black, XLL

Authorized Source of Supply: Peckham Vocational Industries, Inc., Lansing, MI
Contracting Activity: DEPT OF THE ARMY, W6QK ACC-APG NATICK

NSN(s)—Product Name(s):

8415-00-NSH-0341—Shirt, Underlayer for Fleece Jacket, 200 Weight, Army, Long Sleeved, Black, XS

8415-01-470-1130—Jacket, 100 Weight Fleece, Extreme Cold Weather Clothing System (ECWCS), S

8415-01-470-1135—Jacket, 100 Weight Fleece, Extreme Cold Weather Clothing System (ECWCS), M

8415-01-470-1136—Jacket, 100 Weight Fleece, Extreme Cold Weather Clothing System (ECWCS), L

8415-01-470-1137—Jacket, 100 Weight Fleece, Extreme Cold Weather Clothing System (ECWCS), XL

Authorized Source of Supply: Peckham Vocational Industries, Inc., Lansing, MI
Contracting Activity: DEPT OF THE ARMY, W6QK ACC-APG NATICK

NSN(s)—Product Name(s):

8415-00-NSH-0422—Cover, Parachutists' Helmet, Army, Urban Camouflage, X Small-Small

8415-00-NSH-0423—Cover, Parachutists' Helmet, Army, Urban Camouflage, Medium—Large

8415-00-NSH-0424—Cover, Parachutists' Helmet, Army, Urban Camouflage, X Large

Authorized Source of Supply: Mount Rogers Community Services Board, Wytheville, VA

Contracting Activity: DEPT OF THE ARMY, W6QK ACC-APG NATICK

NSN(s)—Product Name(s):

8415-00-NSH-0333—Overalls, Bib, 100

Weight, Army, Black, Medium

8415-00-NSH-0351—Overalls, Bib, 100

Weight, Army, Black, Small

8415-00-NSH-0352—Overalls, Bib, 100

Weight, Army, Black, Small Long

8415-00-NSH-0353—Overalls, Bib, 100

Weight, Army, Black, Medium Long

8415-00-NSH-0354—Overalls, Bib, 100

Weight, Army, Black, Large

8415-00-NSH-0355—Overalls, Bib, 100

Weight, Army, Black, Large/Long

8415-00-NSH-0356—Overalls, Bib, 100

Weight, Army, Black, X Large

Authorized Source of Supply: Peckham Vocational Industries, Inc., Lansing, MI
Contracting Activity: DEPT OF THE ARMY, W6QK ACC-APG NATICK

NSN(s)—Product Name(s):

8415-00-NSH-0335—Trousers, 100 Weight Polyester Pile Fleece, Extreme Cold Weather Clothing System (ECWCS), M

8415-00-NSH-0362—Trousers, 100 Weight Polyester Pile Fleece, Extreme Cold Weather Clothing System (ECWCS), S

8415-00-NSH-0363—Trousers, 100 Weight Polyester Pile Fleece, Extreme Cold Weather Clothing System (ECWCS), L

8415-00-NSH-0364—Trousers, 100 Weight Polyester Pile Fleece, Extreme Cold Weather Clothing System (ECWCS), SL

Authorized Source of Supply: Peckham Vocational Industries, Inc., Lansing, MI
Contracting Activity: DEPT OF THE ARMY, W6QK ACC-APG NATICK

NSN(s)—Product Name(s):

8415-00-NSH-0334—Jacket, 200 Weight Polyester Pile Fleece, Extreme Cold Weather Clothing System (ECWCS), M

8415-00-NSH-0357—Jacket, 200 Weight Polyester Pile Fleece, Extreme Cold Weather Clothing System (ECWCS), S

8415-00-NSH-0358—Jacket, 200 Weight Polyester Pile Fleece, Extreme Cold Weather Clothing System (ECWCS), L

8415-00-NSH-0359—Jacket, 200 Weight Polyester Pile Fleece, Extreme Cold Weather Clothing System (ECWCS), L-L

8415-00-NSH-0360—Jacket, 200 Weight Polyester Pile Fleece, Extreme Cold Weather Clothing System (ECWCS), XL

8415-00-NSH-0361—Jacket, 200 Weight Polyester Pile Fleece, Extreme Cold Weather Clothing System (ECWCS), XL-L

Authorized Source of Supply: Peckham Vocational Industries, Inc., Lansing, MI
Contracting Activity: DEPT OF THE ARMY, W6QK ACC-APG NATICK

NSN(s)—Product Name(s):

1560-01-509-2216FX—#1 Fuel Tank

Foam Kit, F-15A/B Eagle

1560-01-509-2219FX—#3A Fuel Tank

Foam Kit, F-15A/B Eagle

Authorized Source of Supply: Middle Georgia Diversified Industries, Inc., Dublin, GA
Contracting Activity: DEFENSE LOGISTICS AGENCY, DLA AVIATION

NSN(s)—Product Name(s):

8415-00-NSH-0639—Overalls, Fire Retardant 200 Fleece, SPEAR, Army, Black, SR

8415-00-NSH-0640—Overalls, Fire Retardant 200 Fleece, SPEAR, Army, Black, MR

8415-00-NSH-0641—Overalls, Fire Retardant 200 Fleece, SPEAR, Army, Black, LR

8415-00-NSH-0642—Overalls, Fire Retardant 200 Fleece, SPEAR, Army, Black, LL

8415-00-NSH-0643—Overalls, Fire Retardant 200 Fleece, SPEAR, Army, Black, XLR

8415-00-NSH-0644—Overalls, Fire Retardant 200 Fleece, SPEAR, Army, Black, XLL

8415-00-NSH-0645—Overalls, Fire Retardant 200 Fleece, SPEAR, Army, Green, SR

8415-00-NSH-0646—Overalls, Fire Retardant 200 Fleece, SPEAR, Army, Green, MR

8415-00-NSH-0647—Overalls, Fire Retardant 200 Fleece, SPEAR, Army, Green, LR

8415-00-NSH-0648—Overalls, Fire Retardant 200 Fleece, SPEAR, Army, Green, LL

8415-00-NSH-0649—Overalls, Fire Retardant 200 Fleece, SPEAR, Army, Green, XLR

8415-00-NSH-0650—Overalls, Fire Retardant 200 Fleece, SPEAR, Army, Green, XLL

8415-00-NSH-0651—Jacket, Fire Retardant 200 Fleece, SPEAR, Army, Black, SR

8415-00-NSH-0652—Jacket, Fire Retardant 200 Fleece, SPEAR, Army, Black, MR

8415-00-NSH-0653—Jacket, Fire Retardant 200 Fleece, SPEAR, Army, Black, LR

8415-00-NSH-0654—Jacket, Fire Retardant 200 Fleece, SPEAR, Army, Black, LL

8415-00-NSH-0655—Jacket, Fire Retardant 200 Fleece, SPEAR, Army, Black, XLR

8415-00-NSH-0656—Jacket, Fire Retardant 200 Fleece, SPEAR, Army, Black, XLL

8415-01-476-6199—Jacket, Heavy Weight Fleece, Army, Black, LR

8415-01-476-6201—Jacket, Heavy Weight Fleece, Army, Black, MR

8415-01-476-6206—Jacket, Heavy Weight Fleece, Army, Black, SR

8415-01-476-6215—Jacket, Heavy Weight Fleece, Army, Black, XLL

8415-01-476-6217—Jacket, Heavy Weight Fleece, Army, Black, XLR

8415-01-476-6218—Shirt, Underwear, Midweight, Army, Black, L

8415-01-476-6223—Shirt, Underwear, Midweight, Army, Black, LR

8415-01-476-6224—Shirt, Underwear, Midweight, Army, Black, MR

8415-01-476-6227—Shirt, Underwear, Midweight, Army, Black, XLL

8415-01-476-6228—Shirt, Underwear, Midweight, Army, Black, SR

8415-01-476-6237—Shirt, Underwear, Midweight, Army, Black, LR

8415-01-476-6241—Overalls, Bib, Stretch, SPEAR, Army, Unisex, Black, LL

8415-01-476-6260—Overalls, Bib, Stretch, SPEAR, Army, Unisex, Black, LR

8415-01-476-6261—Overalls, Bib, Stretch, SPEAR, Army, Unisex, Black, MR

8415-01-476-6263—Overalls, Bib, Stretch, SPEAR, Army, Unisex, Black, SR

8415-01-476-6264—Overalls, Bib, Stretch, SPEAR, Army, Unisex, Black, XLL

8415-01-476-6265—Overalls, Bib, Stretch, SPEAR, Army, Unisex, Black, LLR

8415-01-F01-0215—Shirt, Underwear, Midweight, SPEAR, Army, Green

Authorized Source of Supply: Peckham

Vocational Industries, Inc., Lansing, MI
Contracting Activity: DEPT OF THE ARMY,
 W6QK ACC-APG NATICK

NSN(s)—Product Name(s):

8415-01-490-1900—Shirt, Chemical
 Protective Undergarment, Collarless,
 CPU, Navy, Long Sleeved, Black, 30
 8415-01-490-1901—Shirt, Chemical
 Protective Undergarment, Collarless,
 CPU, Navy, Long Sleeved, Black, 32
 8415-01-490-1902—Shirt, Chemical
 Protective Undergarment, Collarless,
 CPU, Navy, Long Sleeved, Black, 34
 8415-01-490-1903—Shirt, Chemical
 Protective Undergarment, Collarless,
 CPU, Navy, Long Sleeved, Black, 36
 8415-01-490-1904—Shirt, Chemical
 Protective Undergarment, Collarless,
 CPU, Navy, Long Sleeved, Black, 38
 8415-01-490-1908—Shirt, Chemical
 Protective Undergarment, Collarless,
 CPU, Navy, Long Sleeved, Black, 40
 8415-01-490-1910—Shirt, Chemical
 Protective Undergarment, Collarless,
 CPU, Navy, Long Sleeved, Black, 42
 8415-01-490-1911—Shirt, Chemical
 Protective Undergarment, Collarless,
 CPU, Navy, Long Sleeved, Black, 44
 8415-01-490-1913—Shirt, Chemical
 Protective Undergarment, Collarless,
 CPU, Navy, Long Sleeved, Black, 46
 8415-01-490-1914—Shirt, Chemical
 Protective Undergarment, Collarless,
 CPU, Navy, Long Sleeved, Black, 28
 8415-01-490-1915—Shirt, Chemical
 Protective Undergarment, Collarless,
 CPU, Navy, Long Sleeved, Black, 50
 8415-01-490-1917—Shirt, Chemical
 Protective Undergarment, Collarless,
 CPU, Navy, Long Sleeved, Black, 52

Authorized Source of Supply: Peckham
 Vocational Industries, Inc., Lansing, MI
Contracting Activity: DEFENSE LOGISTICS
 AGENCY, DLA TROOP SUPPORT

NSN(s)—Product Name(s):

2530-00-277-2689—Steering Wheel
Authorized Source of Supply: Opportunities,
 Inc. of Jefferson County, Fort Atkinson,
 WI

Contracting Activity: DEFENSE LOGISTICS
 AGENCY, DLA LAND AND MARITIME

NSN(s)—Product Name(s): 2510-01-210-
 2748—Door Assembly, Heater/Defroster,
 HMMWV series M998

Authorized Source of Supply: Opportunities,
 Inc. of Jefferson County, Fort Atkinson,
 WI

Contracting Activity: DEFENSE LOGISTICS
 AGENCY, DLA LAND AND MARITIME

NSN(s)—Product Name(s): 2590-01-265-
 3185—Parking (Rear Left)

Authorized Source of Supply: Opportunities,
 Inc. of Jefferson County, Fort Atkinson,
 WI

Contracting Activity: DEFENSE LOGISTICS
 AGENCY, DLA LAND AND MARITIME

SN(s)—Product Name(s):

8415-00-NSH-0925—Shirt, Underwear,
 No Lycra, MPS, Navy, Men's, Black, X
 Small Short
 8415-00-NSH-0926—Shirt, Underwear,
 No Lycra, MPS, Navy, Men's, Black, X
 Small Regular
 8415-00-NSH-0927—Shirt, Underwear,
 No Lycra, MPS, Navy, Men's, Black, X
 Small Long

8415-00-NSH-0928—Shirt, Underwear,
 No Lycra, MPS, Navy, Men's, Black,
 Small Short

8415-00-NSH-0929—Shirt, Underwear,
 No Lycra, MPS, Navy, Men's, Black,
 Small Regular

8415-00-NSH-0930—Shirt, Underwear,
 No Lycra, MPS, Navy, Men's, Black,
 Small Long

8415-00-NSH-0931—Shirt, Underwear,
 No Lycra, MPS, Navy, Men's, Black,
 Medium Short

8415-00-NSH-0932—Shirt, Underwear,
 No Lycra, MPS, Navy, Men's, Black,
 Medium Regular

8415-00-NSH-0933—Shirt, Underwear,
 No Lycra, MPS, Navy, Men's, Black,
 Medium Long

8415-00-NSH-0934—Shirt, Underwear,
 No Lycra, MPS, Navy, Men's, Black,
 Large Short

8415-00-NSH-0935—Shirt, Underwear,
 No Lycra, MPS, Navy, Men's, Black,
 Large Regular

8415-00-NSH-0936—Shirt, Underwear,
 No Lycra, MPS, Navy, Men's, Black,
 Large Long

8415-00-NSH-0937—Shirt, Underwear,
 No Lycra, MPS, Navy, Men's, Black, X
 Large Short

8415-00-NSH-0938—Shirt, Underwear,
 No Lycra, MPS, Navy, Men's, Black, X
 Large Regular

8415-00-NSH-0939—Shirt, Underwear,
 No Lycra, MPS, Navy, Men's, Black, X
 Large Long

8415-00-NSH-0940—Shirt, Underwear,
 No Lycra, MPS, Navy, Women's, Black,
 X Small Short

8415-00-NSH-0941—Shirt, Underwear,
 No Lycra, MPS, Navy, Women's, Black,
 X Small Regular

8415-00-NSH-0942—Shirt, Underwear,
 No Lycra, MPS, Navy, Women's, Black,
 X Small Long

8415-00-NSH-0943—Shirt, Underwear,
 No Lycra, MPS, Navy, Women's, Black,
 Small Short

8415-00-NSH-0944—Shirt, Underwear,
 No Lycra, MPS, Navy, Women's, Black,
 Small Regular

8415-00-NSH-0945—Shirt, Underwear,
 No Lycra, MPS, Navy, Women's, Black,
 Small Long

8415-00-NSH-0946—Shirt, Underwear,
 No Lycra, MPS, Navy, Women's, Black,
 Medium Short

8415-00-NSH-0947—Shirt, Underwear,
 No Lycra, MPS, Navy, Women's, Black,
 Medium Regular

8415-00-NSH-0948—Shirt, Underwear,
 No Lycra, MPS, Navy, Women's, Black,
 Medium Long

8415-00-NSH-0949—Shirt, Underwear,
 No Lycra, MPS, Navy, Women's, Black,
 Large Short

8415-00-NSH-0950—Shirt, Underwear,
 No Lycra, MPS, Navy, Women's, Black,
 Large Regular

8415-00-NSH-0951—Shirt, Underwear,
 No Lycra, MPS, Navy, Women's, Black,
 Large Long

8415-00-NSH-0952—Shirt, Underwear,
 No Lycra, MPS, Navy, Women's, Black,
 X Large Short

8415-00-NSH-0953—Shirt, Underwear,
 No Lycra, MPS, Navy, Women's, Black,
 X Large Regular

8415-00-NSH-0954—Shirt, Underwear,
 No Lycra, MPS, Navy, Women's, Black,
 X Large Long

8415-00-NSH-0955—Drawers, Underwear
 Power Stretch, Fire Resistant, No Lycra,
 Navy, Men's, Black, X Small Short

8415-00-NSH-0956—Drawers, Underwear
 Power Stretch, Fire Resistant, No Lycra,
 Navy, Men's, Black, X Small Regular

8415-00-NSH-0957—Drawers, Underwear
 Power Stretch, Fire Resistant, No Lycra,
 Navy, Men's, Black, X Small Long

8415-00-NSH-0958—Drawers, Underwear
 Power Stretch, Fire Resistant, No Lycra,
 Navy, Men's, Black, Small Short

8415-00-NSH-0959—Drawers, Underwear
 Power Stretch, Fire Resistant, No Lycra,
 Navy, Men's, Black, Small Regular

8415-00-NSH-0960—Drawers, Underwear
 Power Stretch, Fire Resistant, No Lycra,
 Navy, Men's, Black, Small Long

8415-00-NSH-0961—Drawers, Underwear
 Power Stretch, Fire Resistant, No Lycra,
 Navy, Men's, Black, Medium Short

8415-00-NSH-0962—Drawers, Underwear
 Power Stretch, Fire Resistant, No Lycra,
 Navy, Men's, Black, Medium Regular

8415-00-NSH-0963—Drawers, Underwear
 Power Stretch, Fire Resistant, No Lycra,
 Navy, Men's, Black, Medium Long

8415-00-NSH-0964—Drawers, Underwear
 Power Stretch, Fire Resistant, No Lycra,
 Navy, Men's, Black, Large Short

8415-00-NSH-0965—Drawers, Underwear
 Power Stretch, Fire Resistant, No Lycra,
 Navy, Men's, Black, Large Regular

8415-00-NSH-0966—Drawers, Underwear
 Power Stretch, Fire Resistant, No Lycra,
 Navy, Men's, Black, Large Long

8415-00-NSH-0967—Drawers, Underwear
 Power Stretch, Fire Resistant, No Lycra,
 Navy, Men's, Black, X Large Short

8415-00-NSH-0968—Drawers, Underwear
 Power Stretch, Fire Resistant, No Lycra,
 Navy, Men's, Black, X Large Regular

8415-00-NSH-0969—Drawers, Underwear
 Power Stretch, Fire Resistant, No Lycra,
 Navy, Men's, Black, X Large Long

8415-00-NSH-0970—Drawers, Underwear
 Power Stretch, Fire Resistant, No Lycra,
 Navy, Women's, Black, X Small Short

8415-00-NSH-0971—Drawers, Underwear
 Power Stretch, Fire Resistant, No Lycra,
 Navy, Women's, Black, X Small Regular

8415-00-NSH-0972—Drawers, Underwear
 Power Stretch, Fire Resistant, No Lycra,
 Navy, Women's, Black, X Small Long

8415-00-NSH-0973—Drawers, Underwear
 Power Stretch, Fire Resistant, No Lycra,
 Navy, Women's, Black, Small Short

8415-00-NSH-0974—Drawers, Underwear
 Power Stretch, Fire Resistant, No Lycra,
 Navy, Women's, Black, Small Regular

8415-00-NSH-0975—Drawers, Underwear
 Power Stretch, Fire Resistant, No Lycra,
 Navy, Women's, Black, Small Long

8415-00-NSH-0976—Drawers, Underwear
 Power Stretch, Fire Resistant, No Lycra,
 Navy, Women's, Black, Medium Short

8415-00-NSH-0977—Drawers, Underwear
 Power Stretch, Fire Resistant, No Lycra,
 Navy, Women's, Black, Medium Regular

8415-00-NSH-0978—Drawers, Underwear Power Stretch, Fire Resistant, No Lycra, Navy, Women's, Black, Medium Long

8415-00-NSH-0979—Drawers, Underwear Power Stretch, Fire Resistant, No Lycra, Navy, Women's, Black, Large Short

8415-00-NSH-0980—Drawers, Underwear Power Stretch, Fire Resistant, No Lycra, Navy, Women's, Black, Large Regular

8415-00-NSH-0981—Drawers, Underwear Power Stretch, Fire Resistant, No Lycra, Navy, Women's, Black, Large Long

8415-00-NSH-0982—Drawers, Underwear Power Stretch, Fire Resistant, No Lycra, Navy, Women's, Black, X Large Short

8415-00-NSH-0983—Drawers, Underwear Power Stretch, Fire Resistant, No Lycra, Navy, Women's, Black, X Large Regular

8415-00-NSH-0984—Drawers, Underwear Power Stretch, Fire Resistant, No Lycra, Navy, Women's, Black, X Large Long

8415-00-NSH-1272—Xsmall/Long

8415-00-NSH-1273—Small/Short

8415-00-NSH-1274—Small/Long

8415-00-NSH-1275—Medium/Short

Authorized Source of Supply: Peckham Vocational Industries, Inc., Lansing, MI

Contracting Activity: DEPT OF THE ARMY, W6QK ACC-APG NATICK

Contracting Activity: DEPT OF THE NAVY, NAVAL AIR SYSTEMS COMMAND

NSN(s)—Product Name(s):

8415-01-503-0222—Shirt, Cold Weather 300 Weight, Synthetic Fleece, Marine Corps, Unisex, Coyote Brown, S

8415-01-503-0223—Shirt, Cold Weather 300 Weight, Synthetic Fleece, Marine Corps, Unisex, Coyote Brown, M

8415-01-503-0224—Shirt, Cold Weather 300 Weight, Synthetic Fleece, Marine Corps, Unisex, Coyote Brown, L

8415-01-503-0225—Shirt, Cold Weather 300 Weight, Synthetic Fleece, Marine Corps, Unisex, Coyote Brown, XL

Authorized Source of Supply: Peckham Vocational Industries, Inc., Lansing, MI

Contracting Activity: DEFENSE LOGISTICS AGENCY, DLA TROOP SUPPORT

Service(s)

Service Type: Janitorial/Custodial

Mandatory for: U.S. Army Reserve Center: Mifflin County, Lewistown, PA

Contracting Activity: DEPT OF THE ARMY, W6QM MICC CTR-FT DIX (RC)

Service Type: Custodial Service

Mandatory for: US Navy, NAVFAC Southwest, Navy Operational Support Center, Salt Lake City, UT

Contracting Activity: DEPT OF THE NAVY, NAVFAC SOUTHWEST

Service Type: Sourcing, Cutting, Kitting and Fulfillment Service

Mandatory for: Federal Prison Industries, Washington, DC—Pre-Cut Kit, Groin Protector, Flame Retardant

Contracting Activity: FEDERAL PRISON SYSTEM/BUREAU OF PRISONS, CO BUSINESS OFFICE

Service Type: Dining Facility Attendant

Mandatory for: US Army, Mission and Installation Contracting Command, Fort Riley, KS

Contracting Activity: DEPT OF THE ARMY, W6QM MICC-FT RILEY

Service Type: Switchboard Operation

Mandatory for: Department of Veterans Affairs, VA Medical Center, San Francisco, CA

Contracting Activity: DEPT OF VETERANS AFFAIRS, 261-NETWORK CONTRACT OFC21 (00261)

Service Type: Grounds Maintenance

Mandatory for: US Army, Pueblo Chemical Depot, Installation Acreage, Pueblo, CO

Contracting Activity: DEPT OF THE ARMY, W6QK ACC-RI

Service Type: Food Service Attendant

Mandatory for: US Air Force, 103 AW/MS, 103rd Captain Joseph Wadsworth Airlift Dining Hall, East Granby, CT

Contracting Activity: DEPT OF THE ARMY, W7MZ USPFO ACTIVITY CT ARNG

Service Type: Custodial and Related Services

Mandatory for: GSA PBS Region 5, Senator Paul Simon Federal Building, Carbondale, IL

Contracting Activity: GENERAL SERVICES ADMINISTRATION, PUBLIC BUILDINGS SERVICE, PBS R5

Service Type: Custodial and Grounds Maintenance

Mandatory for: Multiple Locations St. Thomas and St. Johns, Virgin Islands

Contracting Activity: DEPT OF THE INTERIOR, NATIONAL PARK SERVICE, SER REGIONAL CONTRACTING OPO TID 60397

Service Type: Janitorial Service

Mandatory for: US Coast Guard, Air Station Atlantic City, William J. Hughes Federal Aviation Administration Technical Center, Atlantic City International Airport, Egg Harbor Township, NJ

Contracting Activity: DEPT OF HOMELAND SECURITY, U.S. COAST GUARD, BASE PORTSMOUTH

Service Type: Food Service Attendant

Mandatory for: US Air Force, 103AW/MS, 103rd Air Control Squadron Dining Hall, Orange, CT

Contracting Activity: DEPT OF THE ARMY, W7MZ USPFO ACTIVITY CT ARNG

Service Type: Document Management

Mandatory for: USDA Forest Service, Region 6, Edith Green-Wendell Wyatt Federal Building, Portland, OR

Contracting Activity: DEPT OF AGRICULTURE, FOREST SERVICE, NORTHWEST OREGON CONTRACTING AREA

Michael R. Jurkowski,

Director, Business Operations.

[FR Doc. 2025-23895 Filed 12-23-25; 8:45 am]

BILLING CODE 6353-01-P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID: USA-2025-HQ-0136]

Submission for OMB Review; Comment Request

AGENCY: Department of the Army, 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 January 28, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT:

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

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Exchange Security Verification for Contractors/Vendors; Exchange Forms 3900-002, 3900-006, and 3900-013; OMB Control Number 0702-0135.

Type of Request: Extension.

Number of Respondents: 2,900.

Responses per Respondent: 1.

Annual Responses: 2,900.

Average Burden per Response: 30 minutes.

Annual Burden Hours: 1,450.

Needs and Uses: The information collection requirement is necessary for the processing of all Army and Air Force Exchange Service (Exchange) security clearance actions, to record security clearances issued or denied, and to verify eligibility for access to classified information or assignments to sensitive positions. Respondents are individuals or businesses affiliated with the Exchange by assignment, employment contractual relationship, or because of an inter-service support agreement on which personnel security clearance determination has been completed or is pending. In addition to utilizing the information for processing security clearances, the information may be used by Exchange executives for adverse personnel actions such as removal from sensitive duties, removal from contract agreement, denial to a restricted or sensitive area, and revocation of security clearance.

Affected Public: Individuals or households; business or other for-profit.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

DoD Clearance Officer: Mr. Reginald Lucas.

Dated: December 19, 2025.

Stephanie J. Bost,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2025–23787 Filed 12–23–25; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID: USA–2025–HQ–0135]

Submission for OMB Review; Comment Request

AGENCY: Department of the Army, 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 January 28, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT:

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

SUPPLEMENTARY INFORMATION: *Title; Associated Form; and OMB Number:* Exchange Employee and Retirement Benefit System; Exchange Forms 1450–011 and 1700–012; OMB Control Number 0702–0139.

Type of Request: Extension.

Number of Respondents: 10,530.

Responses per Respondent: 1.

Annual Responses: 10,530.

Average Burden per Response: 20 minutes.

Annual Burden Hours: 3,510.

Needs and Uses: The information collection requirement is necessary to administer several different benefits, pay, and retirement entitlements to eligible Exchange associates, former associates (retirees), their dependents, beneficiaries, spouses, and ex-spouses.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

DoD Clearance Officer: Mr. Reginald Lucas.

Dated: December 19, 2025.

Stephanie J. Bost,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2025–23788 Filed 12–23–25; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Department of the Army

Record of Decision for Real Property Master Plan Implementation at Military Ocean Terminal Sunny Point, North Carolina (ID# EISX–007–21–001–1751989587)

AGENCY: Department of the Army, DoD.

ACTION: Notice of availability.

SUMMARY: The Department of the Army (Army) announces the availability of a Record of Decision (ROD) regarding the proposed implementation of real property actions at Military Ocean Terminal Sunny Point (MOTSU), North Carolina. In accordance with the National Environmental Policy Act (NEPA), the ROD identifies the Army's selected alternative, the basis for its selection, the environmentally preferred alternative, and the mitigation and protective measures the Army commits to implement with the selected alternative. The ROD is based on the results of the Army's Final Environmental Impact Statement (EIS), which analyzed the potential effects of the implementation of various projects needed for the safety and mission of the facility and provides an analysis of the effects of implementing real property maintenance, repair, upgrade, and development actions. The proposed action is needed to address improvements to real property related to explosive safety, waterfront maintenance, security, and linear infrastructure. The projects and programs address compliance with federal, state, DoD, and Army standards vital to safety, security, and other mission needs. The EIS includes a final Finding of No Practicable Alternative (FONPA) prepared because portions of the proposed action occur in floodplains or involve construction in wetlands, or both.

FOR FURTHER INFORMATION CONTACT:

Frederick Rice, Director, Public and Congressional Affairs Office, Military Surface Deployment and Distribution Command; telephone: (618) 220–6284; email: frederick.l.rice.civ@army.mil.

SUPPLEMENTARY INFORMATION: MOTSU is the Army Transportation Command's East Coast strategic ammunition port and is among DoD's seaports supporting

global operations. The proposed action includes barricade safety, waterfront maintenance, Pleasure Island Explosive Safety Clear Zone security, linear infrastructure (e.g., roads, rail, utilities, firebreaks), stormwater mitigation, and cantonment area infill. The proposed action also includes modernizing operation areas and general repair and maintenance of infrastructure, to include facilities, wharves, roads, rail, utilities, and perimeter security. The proposed projects address critical mission requirements and are planned for fiscal years 2026 through 2031.

The FEIS—published on July 9, 2025, and prepared in parallel with federal consultation processes (e.g., section 106 of the National Historic Preservation Act and section 7 of the Endangered Species Act)—evaluated the potential effects associated with implementing the proposed activities. The Army evaluated two alternatives that would meet the Proposed Action's purpose and need:

1. *Full Implementation Alternative (Preferred Alternative):* This alternative would implement the complete suite of 14 projects that are required improvements to real property related to explosive safety, waterfront maintenance, security, and linear infrastructure.

2. *Partial Implementation Alternative:* This alternative would implement a reduced set of 12 projects. Although the Partial Implementation Alternative would not address all requirements as comprehensively as the Full Implementation Alternative, it would substantially improve conditions and adequately address immediate installation needs.

Under the No-Action Alternative, the projects would not be implemented. While the No-Action Alternative would not satisfy the Proposed Action's purpose and need, in accordance with NEPA regulations, the No-Action Alternative provides a comparative baseline for gauging the Action Alternatives' potential effects.

The Final EIS determined the Full Implementation Alternative and Partial Implementation Alternatives would have potentially significant adverse effects on wetlands. The Army prepared a Finding of No Practicable Alternative (FONPA) addressing potential effects on wetlands and floodplains. The FONPA is included as an appendix to the Final EIS. The Final EIS concluded the adverse effects on all analyzed resources other than wetlands would be less than significant under either action alternative.

Based on the analysis presented in the Final EIS, the Full Implementation Alternative is the Army's selected

alternative because it provides the improvements necessary to support MOTSU's mission and ensure safety.

The ROD adopts multiple mitigation and protective measures to prevent or minimize the potential adverse environmental effects of the Full Implementation Alternative. The Army is using all practicable means to avoid or minimize environmental harm caused by the selected alternative. MOTSU Department of Public Works Environmental personnel will review the planning documents for each of the proposed projects prior to initiation to ensure compatibility with applicable regulatory requirements, best management practices, and minimization measures. Additional surveys, sampling, or testing may be required.

The ROD is available on the project website at: <https://www.army.mil/artrans#org-about>. Publication of the ROD formally concludes the NEPA process for this Proposed Action. The Army will proceed with the Full Implementation Alternative described in the Final EIS and will execute the mitigation and protective measures identified in the ROD.

(Authority: 42 U.S.C. 4321 *et seq.* (1969)).

James W. Satterwhite Jr.,
U.S. Army Federal Register Liaison Officer.
[FR Doc. 2025-23876 Filed 12-23-25; 8:45 am]
BILLING CODE 3711-CC-P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD-2025-OS-0573]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness (OUSDP&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 January 28, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting

“Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT: Reginald Lucas, (571) 372-7574, whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Qualitative and Quantitative Data Collection on Independent Review Commission Recommendation Evaluation; OMB Control Number 0704-0644.

Type of Request: Extension.
Number of Respondents: 72,000.
Responses per Respondent: 1.
Annual Responses: 72,000.
Average Burden per Response: 37.5 minutes.

Annual Burden Hours: 45,000 hours.
Needs and Uses: This information collection activity provides a means to garner DoD-wide quantitative and qualitative data in support of the implementation and evaluation of the Secretary of Defense approved Independent Review Commission's (IRC) 82 recommendations. These information collections will be conducted by the OUSD (P&R), Office of General Counsel, Military Departments, Military Services, and/or National Guard Bureau (hereafter referred to as DoD). DoD will collect quantitative and qualitative data through data calls, surveys, interviews, site visits and other validated methods. Information collection efforts will align to the four IRC Lines of Effort (LOE): LOE 1—Accountability; LOE 2—Prevention; LOE 3: Climate and Culture; and LOE 4: Victim Care and Support.

Affected Public: Individuals or households.

Frequency: Annually.

Respondent's Obligation: Voluntary.

DoD Clearance Officer: Mr. Reginald Lucas.

Dated: December 19, 2025.

Stephanie J. Bost,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2025-23790 Filed 12-23-25; 8:45 am]

BILLING CODE 6001-FR-P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD-2025-OS-0606]

Submission for OMB Review; Comment Request

AGENCY: Washington Headquarter Services, 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 January 28, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT: Reginald Lucas, (571) 372-7574, whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

SUPPLEMENTARY INFORMATION:

Title; associated form; and OMB number: Confirmation of Request for Reasonable Accommodation; Form A “Reasonable Accommodation Request, Form B “Medical Information and Restriction Assessment”; OMB Control Number 0704-0498.

Type of request: Revision.

Number of respondents: 720.

Responses per respondent: 1.

Annual responses: 720.
Average burden per response: 15 minutes.

Annual burden hours: 180.

Needs and uses: Request forms, serve as the formal documentation of an employee's accommodation request and guide the interactive process between the employee, supervisor, and Reasonable Accommodation Program Manager. They capture the employee's needs, initiate the evaluation process, and provide a record for compliance and accountability. Together, these forms help agencies plan accommodations: such as modified equipment, adjusted schedules, or workspace changes, while also safeguarding confidentiality and avoiding prohibited disclosures under the Genetic Information Nondiscrimination Act. Medical assessments are necessary in the Reasonable Accommodation process because they confirm whether an employee has a qualifying medical condition and identify the functional limitations that may affect their ability to perform essential job duties or access workplace benefits. These forms, completed by medical providers, outline restrictions, whether temporary or

permanent, and provide the foundation for determining what accommodations are appropriate. They ensure that decisions are based on verified medical need, protect the agency from legal risk, and align with requirements under the Rehabilitation Act and the Americans with Disabilities Act.

Affected public: Individuals and households.

Frequency: On Occasion.

Respondent's obligation: Required.

DOD clearance officer: Mr. Reginald Lucas.

Dated: December 19, 2025.

Stephanie J. Bost,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2025-23789 Filed 12-23-25; 8:45 am]

BILLING CODE 6001-FR-P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD-2025-OS-0837]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness (OUSD(P&R)), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995*, the Office of the Under Secretary of Defense for Personnel and Readiness announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by February 27, 2026.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

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

Mail: Department of Defense, Privacy, Civil Liberties, and Transparency Directorate, Office of the Director of Administration and Management, 4800 Mark Center Drive, Mailbox #24, Suite 05F16, Alexandria, VA 22350-1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at <http://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to ODASD(MC&FP), Mr. Trevor Dean, 1500 Defense Pentagon, Washington, DC 20301, (703) 571-2359.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Record of Emergency Data, DD Form 93; OMB Control Number 0704-0649.

Needs and Uses: The DD Form 93 is used by Service members to designate beneficiaries for certain benefits in the event of the Service member's death. It is also a guide for disposition of the member's pay and allowances if captured, missing or interned. It also shows the names and addresses of the person(s) the Service member desires to be notified in case of emergency or death, and designates the person authorized to direct disposition of the Service member's remains upon death. For civilian personnel, it is used to expedite the notification process in the event of an emergency and/or the death of the member. This requirement is identified in DoDI 1300.18, "Department of Defense Personnel Casualty Matters, Policies, and Procedures." The goal is to retain decisions by service members and deploying contractors relating to persons to be notified in the event of illness, injury, missing status, or death and to capture decisions as it relates to the provision of benefits and designation of a person authorized to direct disposition of their remains upon death. Support staff are able to direct benefits and decisional briefings to those designated as beneficiaries and decision makers as designated by the Service member or deploying contractor.

Affected Public: Individuals and households.

Annual Burden Hours: 144,918.
Number of Respondents: 1,739,012.
Responses per Respondent: 1.
Annual Responses: 1,739,012.
Average Burden per Response: 5 minutes.

Frequency: On Occasion.

Dated: December 19, 2025.

Stephanie J. Bost,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2025-23807 Filed 12-23-25; 8:45 am]

BILLING CODE 6001-FR-P

DEPARTMENT OF DEFENSE

Department of the Navy

[Docket ID: USN-2025-HQ-0169]

Submission for OMB Review; Comment Request

AGENCY: Department of the Navy, 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 January 28, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT:

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

SUPPLEMENTARY INFORMATION:

Title; associated form; and OMB number: Response to Marine Corps NAF Debt Collection Notice; NAVMC 11787; OMB Control Number 0712-0008.

Type of request: Revision.

Number of respondents: 1,975.

Responses per respondent: 1.

Annual responses: 1,975.

Average burden per response: 10 minutes.

Annual burden hours: 329.

Needs and uses: The information collection requirement is necessary to notify and account for vendors and patrons indebted to Marine Corps Non-Appropriated Fund Instrumentality (NAFI) businesses and services for the

purpose of repayment management or debt collection dependent on the response option elected by the respondent. Respondents are informed of their alleged debt and use the NAVMC Form 11787, "Response to Marine Corps NAF Debt Collection Notice," to elect to repay the debt in full, agree to a repayment plan, dispute the debt, or indicate that bankruptcy has been filed.

Affected public: Business or other for-profit; individuals or households.

Frequency: On occasion.

Respondent's obligation: Voluntary.

DoD clearance officer: Mr. Reginald Lucas.

Dated: December 19, 2025.

Stephanie J. Bost,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2025-23791 Filed 12-23-25; 8:45 am]

BILLING CODE 6001-FR-P

DEPARTMENT OF EDUCATION

[Docket No.: ED-2025-SCC-1241]

Agency Information Collection Activities; Comment Request; DCIA Aging and Compliance Data Requirements for Guaranty Agencies

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing an extension without change of a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before February 27, 2026.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use <http://www.regulations.gov> by searching the Docket ID number ED-2025-SCC-1241. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at <http://www.regulations.gov> by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the www.regulations.gov site is not available to the public for any reason, the Department will temporarily accept comments at ICDocketMgr@ed.gov. Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. Please note that comments submitted after the comment period will not be

accepted. Written requests for information or comments submitted by postal mail or delivery should be addressed to Carolyn Rose, U.S. Department of Education, Federal Student Aid, 400 Maryland Avenue SW, Washington, DC 20202-1200.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Carolyn Rose, 202-453-5967.

SUPPLEMENTARY INFORMATION: The Department, in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. The Department is soliciting comments on the proposed information collection request (ICR) that is described below. The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: DCIA Aging and Compliance Data Requirements for Guaranty Agencies.

OMB Control Number: 1845-0160.

Type of Review: An extension without change of a currently approved ICR.

Respondents/Affected Public: Private Sector; State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 275.

Total Estimated Number of Annual Burden Hours: 726.

Abstract: The Department of Education (the Department) is requesting OMB approval for an extension of the currently approved collection 1845-0160 DCIA Aging and Compliance Data Requirements for Guaranty Agencies (GAs).

The Department is required to report to the U.S. Department of the Treasury

(Treasury) the status and condition of its non-tax debt portfolio in accordance with the requirements of the Debt Collection Improvement Act of 1996 (DCIA) and the Digital Accountability and Transparency Act of 2014 (DATA Act). Receivable information is reported to Treasury via the Treasury Report on Receivables and Debt Collection Activities (previously called the TROR).

The Department is unable to prepare an accurate and compliant Treasury Report without additional data from its GAs. The continuing guidance requires the GAs to submit to the Department: age debt according to DCIA; report the eligibility of DCIA-aged debt for referral to the Treasury Offset Program (TOP); and report compliance with Form 1099-C reporting.

Neither the regulations or the data requirements have changed since the last extension of this ICR in 2023.

Ross Santy,

Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2025-23906 Filed 12-23-25; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

[Docket No.: ED-2025-SCC-1240]

Agency Information Collection Activities; Comment Request; Third Party Servicer Data Collection

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 February 27, 2026.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use <http://www.regulations.gov> by searching the Docket ID number ED-2025-SCC-1240. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at <http://www.regulations.gov> by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the www.regulations.gov site is not available to the public for any reason, the Department will temporarily accept comments at ICDocketMgr@ed.gov. Please include the docket ID number and the title of the information

collection request when requesting documents or submitting comments. Please note that comments submitted after the comment period will not be accepted. Written requests for information or comments submitted by postal mail or delivery should be addressed to Carolyn Rose, U.S. Department of Education, Federal Student Aid, 400 Maryland Avenue SW, Washington, DC 20202–1200.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Carolyn Rose, 202–453–5967.

SUPPLEMENTARY INFORMATION: The Department, in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. The Department is soliciting comments on the proposed information collection request (ICR) that is described below. The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Third Party Servicer Data Collection.

OMB Control Number: 1845–0130.

Type of Review: A revision of a currently approved ICR.

Respondents/Affected Public: Private Sector; Individuals and Households; State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 75.

Total Estimated Number of Annual Burden Hours: 48.

Abstract: The Department of Education (the Department) is seeking a revision of the OMB approval of the Third Party Servicer Data Form. This form collects information from third party servicers. The HEA allows

institutions of higher education to outsource aspects of their participation in Title IV programs. Any individual or entity that contracts with or performs work on behalf of an institution to administer any aspect of that institution's responsibilities required under the Title IV programs is defined as a third-party servicer. The Title IV regulations authorize the Department to provide oversight of third-party servicers, which are subject to the highest standard of care and diligence in their administration of Title IV programs. (34 CFR 668.2) The information collected through the Third-Party Servicer Data Inquiry form allows the Department to identify institutions of higher education that are failing to report or incorrectly reporting third-party servicer information; to monitor and enforce third-party servicer compliance with annual audit requirements; to identify other persons or organizations that contract with a third-party servicer to assist with any aspect of the administration of a Title IV program on behalf of the third-party servicer or its clients; and to effectively coordinate third-party servicer program review assessments.

Ross Santy,

Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2025–23907 Filed 12–23–25; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Northern New Mexico

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a virtual meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Northern New Mexico. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Wednesday, January 21, 2026, 11 a.m. to 2 p.m. MST.

ADDRESSES: This meeting will be held virtually. To receive the virtual access information, please contact Bridget Maestas, Northern New Mexico Citizens Advisory Board (NNMCAB) Executive Director, at the telephone number or email listed below at least two days prior to the meeting.

FOR FURTHER INFORMATION CONTACT: Bridget Maestas, NNMCAB Executive

Director, by Phone: 505–709–7466 or Email: bridget.maestas@em.doe.gov.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to provide advice and recommendations concerning the following EM site-specific issues: clean-up activities and environmental restoration; waste and nuclear materials management and disposition; excess facilities; future land use and long-term stewardship. The Board may also be asked to provide advice and recommendations on other EM program components. The Board also provides an avenue to fulfill public participation requirements outlined in the National Environmental Policy Act (NEPA), the Comprehensive Environmental Response, Compensation, and Liability Act (CERLA), the Resource Conservation and Recovery Act (RCRA), Federal Facility Agreements, Consent Orders, Consent Decrees and Settlement Agreements.

Tentative Agenda: (agenda topics are subject to change; please contact Bridget Maestas for the most current agenda).

- Presentations to the Board
- Agency Updates

Public Participation: The meeting is open to the public and public comment can be given orally or in writing. Fifteen minutes are allocated during the meeting for public comment and those wishing to make oral comment will be given a minimum of two minutes to speak. Written comments received at least two working days prior to the meeting will be provided to the members and included in the meeting minutes. Written comments received within two working days after the meeting will be included in the minutes. For additional information on public comment and to submit written comment, please contact Bridget Maestas. The EM SSAB, Northern New Mexico, welcomes the attendance of the public at its meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Bridget Maestas at least seven days in advance of the meeting.

Meeting Conduct: The Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Questioning of board members or presenters by the public is not permitted.

Minutes: Minutes will be available at the following website: <https://www.energy.gov/em/nnmcab/northern-new-mexico-citizens-advisory-board>.

Signing Authority: This document of the Department of Energy was signed on December 22, 2025, by David Borak, Committee Management Officer, 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 December 22, 2025.

Jennifer Hartzell,

*Alternate Federal Register Liaison Officer,
U.S. Department of Energy.*

[FR Doc. 2025–23900 Filed 12–23–25; 8:45 am]

BILLING CODE 6450–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1237; FR ID 323399]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information

collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before February 27, 2026. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email PRA@fcc.gov and to nicole.ongele@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele, (202) 418–2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1237.

Title: Workplace Discrimination Complaints.

Form Numbers: FCC Form–5621, FCC Form–5622.

Type of Review: Extension of a currently approved collection.

Respondents: Individuals or households; Federal Government.

Number of Respondents and Responses: 22 respondents; 22 responses.

Estimated Time per Response: 2.5–5 hours.

Frequency of Response: One-time reporting requirement.

Obligation to Respond: Voluntary. Statutory authority for these collections is contained in the Civil Rights Act of 1964 section 7, as amended, 42 U.S.C. 2000e; Age Discrimination in Employment Act of 1967 (ADEA), 29 U.S.C. 621–634; Americans with Disabilities Act of 1990 (ADA), as amended, 42 U.S.C. 12101–12213; Rehabilitation Act of 1973, as amended, 29 U.S.C. 501 *et seq.*

Total Annual Burden: 89 hours.

Total Annual Cost: \$26,000.

Needs and Uses: FCC employees and related individuals may seek a forum through the Office of Workplace Diversity to resolve, investigate, and issue Final Agency Decisions regarding allegations of discrimination and/or retribution or reprisals by completing FCC Form–5621 and/or FCC Form–5622.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2025–23871 Filed 12–23–25; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Savings and Loan Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Home Owners' Loan Act (12 U.S.C. 1461 *et seq.*) (HOLA), Regulation LL (12 CFR part 238), and Regulation MM (12 CFR part 239), and all other applicable statutes and regulations to become a savings and loan holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a savings association.

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 whether the proposed transaction complies with the standards enumerated in the HOLA (12 U.S.C. 1467a(e)).

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Benjamin W. McDonough, Deputy Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than January 28, 2026.

A. Federal Reserve Bank of Cleveland (Jenni M. Frazer, Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101–2566. Comments can also be sent electronically to Comments.applications@clev.frb.org:

1. *First Mutual Holding Co., Lakewood, Ohio*; to acquire First Federal Savings and Loan Association of Centerburg, Centerburg, Ohio.

Board of Governors of the Federal Reserve System.

Erin Cayce,

Assistant Secretary of the Board.

[FR Doc. 2025–23882 Filed 12–23–25; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Meeting of the Advisory Board on Radiation and Worker Health, Subcommittee for Procedure Reviews, National Institute for Occupational Safety and Health

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC) announces the following meeting for the Subcommittee on Procedures Reviews (SPR) of the Advisory Board on Radiation and Worker Health (ABRWH or the Advisory Board). This meeting is open to the public, but without a public comment period. The public is welcome to submit written comments in advance of the meeting, to the contact person below. The public is also welcome to listen to the meeting by joining the audio conference (information below). The audio conference line has 150 ports for callers.

DATES: The meeting will be held on January 28, 2026, from 11 a.m. to 4:30 p.m., EST.

Written comments must be received on or before January 21, 2026.

ADDRESSES: You may submit comments by mail to: Rashaun Roberts, Ph.D., Designated Federal Officer, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 1090 Tusculum Avenue, Mailstop C–24, Cincinnati, Ohio 45226. Email: ocas@cdc.gov.

Written comments received in advance of the meeting will be included in the official record of the meeting.

Meeting Information: Audio Conference Call via FTS Conferencing. The USA toll-free dial-in number is 1–866–659–0537; the passcode is 9933701.

FOR FURTHER INFORMATION CONTACT: Rashaun Roberts, Ph.D., Designated Federal Officer, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 1090 Tusculum Avenue, Mailstop C–24, Cincinnati, Ohio 45226, Telephone: (513) 533–6800, Email: ocas@cdc.gov.

SUPPLEMENTARY INFORMATION:

Background: The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines, which have been promulgated by the Department of Health and Human Services (HHS) as a final rule; advice on methods of dose reconstruction, which have also been promulgated by HHS as a final rule; advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program; and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC). In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC.

The charter was issued on August 3, 2001, renewed at appropriate intervals, and rechartered under Executive Order 14109 (September 29, 2023) on March 22, 2024. Unless continued by the President, the Advisory Board will terminate on September 30, 2027, consistent with Executive Order 14354 of September 29, 2025.

Purpose: The Advisory Board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advising the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class. The ABRWH Subcommittee on Procedure Reviews (SPR) is responsible for

overseeing, tracking, and participating in the reviews of all procedures used in the dose reconstruction process by the NIOSH Division of Compensation Analysis and Support (DCAS) and its dose reconstruction contractor (Oak Ridge Associated Universities—ORAU).

Matters to be Considered: The agenda will include discussions on the following:

1. Administrative items, including: a. SPR-approved documents for next Full Board meeting, b. discussion of professional judgement assessment of six PER–017 case reviews. c. list of documents awaiting NIOSH responses, including: i. Discussion of SPR priorities, and 2. Carry-over items from March 14, 2024, SPR Meeting including a. ORAUT–OTIB–0036, rev. 00 “Internal Dosimetry Coworker Data for Portsmouth Gaseous Diffusion Plant” b. ORAUT–OTIB–0040, rev. 00 PC–1 “External Coworker Dosimetry Data for the Portsmouth Gaseous Diffusion Plant.”; 3. NIOSH responses to Board questions and SC&A review including: a. ORAUT–OTIB–0052, rev. 00 “Parameters to Consider When Processing Claims for Construction Trade Workers,” b. ORAUT–RPRT–0071, rev. 00 “External Dose Coworker Methodology,” and c. “Internal Dosimetry Coworker Data for Portsmouth Gaseous Diffusion Plant”; 4. SC&A issued reviews: a. DCAS–PER–075, rev. 0 “Battelle Memorial Institute TBD revision,” b. DCAS–PER–040, rev. 0 “Mallinckrodt TBD Revisions,” c. DCAS–PER–051, rev. 0, ST4 “Weldon Spring Plant,” d. DCAS–PER–083, rev. 0, ST4 “Weldon Spring Plant,” e. DCAS–PER–079 rev. 0 “Pinellas TBD Revision,” f. DCAS–PER–034 rev. 0 “Harshaw Chemical Company TBD Revision,” g. DCAS–PER–036, rev. 0 “Blockson TBD Revision,” h. DCAS–PER–039, rev. 0 “Baker Perkins TBD Revision,” 5. Newly-Issued Guidance and Supplemental Topics. Agenda items are subject to change as priorities dictate. For additional information, please contact Toll Free 1(800) 232–4636.

The Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and

Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,
Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.
[FR Doc. 2025–23802 Filed 12–23–25; 8:45 am]
BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Office of Management and Budget #: 0970–0425]

Proposed Information Collection Activity; Children’s Justice Act Program Instruction

AGENCY: Children’s Bureau, Administration for Children and Families, U.S. Department of Health and Human Services.
ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF) is requesting a 3-year extension of the Children’s Justice Act (CJA) Program Instruction (Office of Management and Budget (OMB) #: 0970–0425, expiration March 31, 2026). There are no changes requested to the instructions.

DATES: *Comments due* February 27, 2026.
ADDRESSES: In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above. You can obtain copies of the proposed collection of information and submit comments by emailing infocollection@acf.hhs.gov. Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:
Description: The CJA Program Instruction, prepared in response to the enactment of the CJA Title I of Public Law 111–320, Child Abuse Prevention and Treatment Act Reauthorization of 2010, provides direction to the states and territories to accomplish the purposes of assisting states in developing, establishing, and operating programs designed to improve (1) the assessment and investigation of suspected child abuse and neglect cases, including cases of suspected child sexual abuse and exploitation, in a manner that limits additional trauma to the child and the child’s family; (2) the assessment and investigation of cases of suspected child abuse-related fatalities and suspected child neglect-related fatalities; (3) the investigation and prosecution of cases of child abuse and neglect, including child sexual abuse

and exploitation; and (4) the assessment and investigation of cases involving children with disabilities or serious health-related problems who are suspected victims of child abuse or neglect. This Program Instruction contains information collection requirements that are found in Public Law 111–320 at sections 107(b) and 107(d), and pursuant to receiving a grant award. The information being collected is required by statute to be submitted pursuant to receiving a grant award. The information submitted will be used by the agency to ensure compliance with the statute; to monitor, evaluate, and measure grantee achievements in addressing the investigation and prosecution of child abuse and neglect; and to report to Congress.
Respondents: State governments.

Annual Burden Estimates

The length of the CJA Program Instruction has been reduced by 18 percent from 17 pages to 14 pages. Edits have been made to remove requests for information not required by statute, reduce duplicative information, and simplify language. As a result of the reduction in the length of time needed to both read and respond to the Program Instruction, the estimated response burden has been lowered by 17 percent from 60 hours to 50 hours per response.

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Annual Report and Application	52	1	50	2,600

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 42 U.S.C. 5106c sec. 107 (b)4; and 42 U.S.C. 5106 sec. 107 (B)5.
Mary C. Jones,
ACF/OPRE Certifying Officer.
[FR Doc. 2025–23910 Filed 12–23–25; 8:45 am]
BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Office of Management and Budget #: 0970–0139]

Proposed Information Collection Activity; Administration for Children and Families Uniform Project Description

AGENCY: Office of Administration, Office of Grants Policy, Administration for Children and Families, U.S. Department of Health and Human Services.
ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF) is requesting revisions and a one-year

extension of the currently approved ACF Uniform Project Description (UPD) information collection (UPD; Office of Management and Budget (OMB) # 0970–0139, March 31, 2026 expiration date). This includes transitioning to use one simplified version of the UPD with edits to the language for clarification and plain language purposes. Two versions of the instructions remain in the proposed simplified version to accommodate two development methods. ACF is in the process of identifying more significant revisions to the UPD, which will be submitted through a future information collection request to OMB.

DATES: *Comments due* February 27, 2026.

ADDRESSES: In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above. You can obtain copies of the proposed collection of information and submit comments by emailing

infocollection@acf.hhs.gov. Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The UPD provides a uniform format for applicants to submit project information in response to ACF discretionary Notice of Funding Opportunities (NOFO). The UPD requires applicants to describe how program objectives will be achieved and provide a rationale for the project's budgeted costs. All ACF discretionary award programs are required to use the UPD.

Since 2023, there have been two versions of the UPD: the traditional version and the simplified version (SimplerNOFOs). SimplerNOFOs were implemented as a pilot, as approved by OMB. SimplerNOFOs streamline the process for applicants and has been well received by programs and applicants. ACF has expanded use of the simplified version as a result. At this time, ACF is proposing to transition completely to the SimplerNOFO UPD, but will retain

two sets of instructions for now due to the way NOFOs are currently developed. The distinction is made in the instructions with the labels “SimplerNOFO” v. “Traditional NOFO”.

ACF uses the information provided by applicants, along with other OMB-approved information collections (Standard Forms), to evaluate and rank applications. Use of the UPD protects the integrity of the ACF award selection process.

This current request would extend OMB approval for an additional year, with the following changes:

- Minor revisions for clarification and plain language purposes
- Updated burden estimates to only include the SimplerNOFOs UPD.

A larger revision effort is in process and will be submitted to OMB in the future. This future revision request will include two additional opportunities for public comment.

Respondents: Applicants responding to ACF Discretionary NOFOs.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total/annual burden hours
Streamlined UPD	2,672	1	57.9	154,709

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 2 CFR 200.204.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2025–23905 Filed 12–23–25; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB #: 0970–0589]

Proposed Information Collection Activity; Low Income Home Energy Assistance Program (LIHEAP) Quarterly Reports

AGENCY: The Office of Community Services, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF) is requesting a 3-year extension of the form Low Income Home Energy Assistance Program (LIHEAP) Quarterly Reports (Office of Management and Budget (OMB) #: 0970–0589, expiration October 31, 2025). Changes are proposed, which would reduce redundancy and administrative burden for respondents.

DATES: *Comments due* February 27, 2026.

ADDRESSES: In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above. You can obtain copies of the proposed collection of information and submit comments by emailing infocollection@acf.hhs.gov. Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The LIHEAP Quarterly Report assists the Office of Community Services in receiving data and information about LIHEAP during the federal fiscal year (FFY). This almost real time data ensures ACF can continue to:

1. Track key information, such as the number of households served, in “real time” versus in the new fiscal year.

2. Effectively address challenges in a timely manner, including supporting emerging training and technical assistance needs, addressing challenges with obligating funds, and addressing outreach and intake issues, such as reaching newly eligible households.

3. Ensure accountability and transparency by using the information

to regularly update public dashboards and keep key decision makers informed of grantee progress. All grant recipients, including states, tribes, and territories, will submit brief quarterly reports with critical information on the status of LIHEAP. The Quarterly Report forms will include questions on:

- Total households assisted,
- Performance management including the number of occurrences in which LIHEAP funding prevented the loss of or restored home energy services, and
- The estimated percentage of LIHEAP funds that have been obligated by funding component.

Grant recipients will also have an opportunity to highlight additional training/technical assistance needs/ suggestions, which the Office of

Community Services uses to inform support such as training and resources. ACF also proposes several small changes to the LIHEAP Quarterly Report beginning with the Quarter 4 report due October 31, 2025 and beyond. Those changes only affect Section III of the Quarter 3 (due July 31, 2026 and beyond) and Quarter 4 reports (due October 31, 2025 and beyond). The changes to Section III involve inclusion of the primary data elements from the separate LIHEAP Carryover and Reallotment Report (OMB #: 0970–0106), which ACF wishes to discontinue use of in favor of only obtaining such data through the LIHEAP Quarterly Report. Section III would more clearly distinguish “carryover” fund estimated (Quarter 3) and final amounts (Quarter 4) from “reallotment” fund estimated

and final amounts. The Quarter 3 and 4 Section III also includes a “remarks” field for grant recipients to complete only if they are indicating a request to carryover funds to obligate in the next FFY. The federal LIHEAP statute requires all grant recipients requesting carryover to explain why they wish to carryover and how they intend to use such carryover funds in the next year (42 U.S.C. 8626(b)(2)(A)).

Respondents: States and tribes.

Annual Burden Estimates

The estimated time per response for this report was increased from 12 to 16 hours to account for the proposed changes. These changes are expected to reduce effort overall, however, by eliminating the Carryover and Reallotment Report, as discussed above.

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
LIHEAP Quarterly Report	207	4	16	13,248

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: (42 U.S.C. 8626 and 8629) and federal regulations (45 CFR 96.92).

Mary C. Jones,
ACF/OPRE Certifying Officer.

[FR Doc. 2025–23909 Filed 12–23–25; 8:45 am]

BILLING CODE 4184–80–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Office of Management and Budget #: 0970–0490]

Proposed Information Collection Activity; Generic Program-Specific Performance Progress Report

AGENCY: Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: This notice describes the proposal to extend data collection under the Administration for Children and Families (ACF) Generic Program-Specific Performance Progress Report (PPR) (0970–0490). This overarching generic currently allows ACF program offices to collect performance and progress data from recipients and sub-recipients who receive funding from ACF under a grant or cooperative agreement. This generic mechanism provides the opportunity for ACF program offices to tailor requests for performance and progress data to specific funding recipients. There are no proposed changes to the overarching generic.

DATES: *Comments due* February 27, 2026.

ADDRESSES: In compliance with the requirements of the Paperwork

Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above. You can obtain copies of the proposed collection of information and submit comments by emailing infocollection@acf.hhs.gov. Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: ACF is primarily a grant-making agency that promotes the economic and social well-being of families, children, individuals and communities with partnerships, funding, guidance, training and technical assistance. Prior to the use of this umbrella generic for program-specific PPRs, all ACF discretionary grant and cooperative agreement awards used the standard ACF PPR (#0970–0406) for post award reporting. The standard ACF PPR form requires grantees to only respond to a common set of broad questions, which could result in receipt of only qualitative or incomplete information for some programs. This one-size-fits-all approach did not adequately collect the specific data needed for particular grant programs or allow program offices to assess continuous quality improvement. Different grant programs vary in purpose, target population, and activities. Therefore, a need for program offices to customize performance measurements was identified and the generic program-specific PPR was developed.

ACF program offices have benefited from the ability to create and use a program-specific PPR that is more effective and includes specific data elements that reflects a specific program's indicators, demographics, priorities and objectives.

A generic program-specific PPR that can be tailored for program-specific needs allows program offices to collect useful data in a uniform and systematic manner. The reporting format allows program offices to gather uniform program performance data from each grantee, allowing aggregation at the program level to calculate outputs and outcomes, providing a snapshot and allowing for longitudinal analysis.

Data from a tailored program-specific PPR that demonstrates a program's successes and challenges have been useful for accountability purposes, such as required reports to Congress. Moreover, it has been useful for program management and oversight, such as identifying grantees' technical assistance needs and ensuring compliance with federal and programmatic regulations and policies. To review currently approved PPRs under this generic, see: https://www.reginfo.gov/public/do/PRAICList?ref_nbr=202507-0970-011.

Respondents: ACF funding recipients.

Annual Burden Estimates

The following burden estimates include burden associated with currently approved individual requests that ACF expects will be extended through this extension request and an estimate of burden for potential new requests under this generic. Burden associated with currently approved individual requests has been updated to reflect current estimates for number of respondents, time per response, and reporting cadence. Note that new requests may be submitted during this comment period, which would be included with the extension request in 2026.

POTENTIAL NEW REQUESTS

Instrument	Number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Program Specific PPRs	900	3	6	16,200

ONGOING CURRENTLY APPROVED REQUESTS

Generic PPR title	Number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Administration for Native Americans (ANA) American Rescue Plan Emergency Language (ARP EL) Progress Report and Post Project Report.	30	2	0.75	45.
Community Economic Development—Planning (CED-P) Grant Recipient Performance Progress Report (PPR).	31	4	2	248.
Diaper Distribution Demonstration and Research Pilot Quarterly Reporting Requirements.	252	4	3.11	3,136.
Employer Engagement Program Performance Data	24	2	5	240.
Ethnic Community Self-Help (ECSH) Program Data Indicators	27	2	2	108.
Family Violence Prevention and Services: Grants to support Culturally Specific Domestic Violence and Sexual Assault (CSDVSA) Programs.	35	2	10	700.
Family Violence Prevention and Services: Grants to support Specialized Services for Abused Parents and Children (SSAPC).	55	2	10	1,100.
Family Violence Prevention and Services: Grants to the National Domestic Violence Hotline.	2	2	10	40.
Family Violence Prevention and Services: National, Special Issue, and Culturally Specific Resource Centers.	19	2	8	304.
Head Start Collaboration Office Annual Report	54	1	4	216.
Human Trafficking Youth Prevention Education (HTYPE) Demonstration Grant Program Performance Indicators.	8	1	6	48.
Instructions for the Office of Refugee Resettlement Unaccompanied Children Program Home Study and Post-Release Service Grant Recipient Program Indicators.	25	4	0.63	63.
Microenterprise Development (MED) Program Indicators	29	2	2	116.
Office of Refugee Resettlement Refugee Family Child Care Microenterprise (RFCCMED) Program Performance Data.	15	4	2	120.
Office of Refugee Resettlement Services to Afghan Survivors of Combat (SASIC) Program Performance Data Point Tool & User Guide.	24	1	5	120.
Preschool Development Grant Birth through Five (PDG B-5) Renewal Grant Annual Performance Progress Report—2025 Revision.	28	1	8	224.
Refugee Agricultural Partnership Program (RAPP) Indicators	20	2	2.3	92.
Refugee Individual Development Accounts (IDA) Program Indicators	9	4	6	624.
IDA Program Indicators—New Cohort	13	2	3	78.
Refugee Resettlement Refugee Career Pathways (RCP) Program Performance Data.	42	2	5	420.
Regional Partnership Grant Program Semi Annual ACF Performance Progress Report.	23	2	16.5	759.
Support for Trauma-Affected Refugees (STAR) Annual Program Data Points (PDP) Tool and User Guide.	28	1	3	84.
Wilson-Fish TANF Coordination Project Performance Report Part A and B	7	2	6	84
Total Respondents:	800.	Average # Annual Responses: 2.22.	Average Burden Hours per Response: 5.23.	Total Ongoing Annual Burden Hours: 8,969.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 45 CFR 75.342; 45 CFR 75.301, Pub L. 111–352, section 12.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2025–23908 Filed 12–23–25; 8:45 am]

BILLING CODE 4184–88–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–E–1293]

Determination of Regulatory Review Period for Purposes of Patent Extension; ZELSUVMI

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 ZELSUVMI 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 February 27, 2026. 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 June 29, 2026. 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 February 27, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2024–E–1293 for “Determination of Regulatory Review Period for Purposes of Patent Extension; ZELSUVMI.” 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: Jack Dan, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6200, Silver Spring, MD 20993, 240–402–6940.

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, ZELSUVMI (berdazimer sodium), indicated for the topical treatment of molluscum contagiosum (MC) in adults and pediatric patients 1 year of age and older. Subsequent to this approval, the USPTO received a patent term restoration application for ZELSUVMI (U.S. Patent No. 9,855,211) from LNHG, Inc. and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated June 27, 2025, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of ZELSUVMI 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 ZELSUVMI is 4,144 days. Of this time, 3,778 days occurred during the testing phase of the regulatory review period, while 366 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:* September 2, 2012. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on September 2, 2012.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* January 5, 2023. FDA has verified the applicant's claim that the new drug application (NDA) for ZELSUVMI (NDA 217424) was initially submitted on January 5, 2023.

3. *The date the application was approved:* January 5, 2024. FDA has verified the applicant's claim that NDA 217424 was approved on January 5, 2024.

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 application(s) for patent extension, this applicant seeks 1,280 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.

Brian Fahey,

Associate Commissioner for Legislation.

[FR Doc. 2025–23868 Filed 12–23–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–6971]

Authorization of Emergency Use for Two Animal Drugs for the Treatment of New World Screwworm; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the issuance of two Emergency Use Authorizations (EUA) (Authorization) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) for new animal drug products. FDA has issued one EUA for a new animal drug product as requested by Elanco US Inc. for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) (NWS) larvae (myiasis) in dogs and puppies and one EUA for a new animal drug product as requested by Elanco US Inc. for the treatment of infestations caused by NWS larvae (myiasis) in cats and kittens. The Authorizations contain, among other things, conditions on the emergency use of the authorized products. The Authorizations follow the August 18, 2025, determination by the Secretary of Health and Human Services (HHS) that there is a public health emergency, or a significant potential for a public health emergency, that affects or has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves NWS. On the basis of such determination, the Secretary of HHS declared on August 18, 2025, that circumstances exist justifying the authorization of emergency use of animal drugs to treat or prevent NWS myiasis in animals. The Authorizations, which include an explanation of the reasons for issuance, are reprinted in this document.

DATES: The Authorizations are effective on their dates of issuance: October 24, 2025, and November 21, 2025, respectively.

ADDRESSES: Submit written requests for single copies of the EUAs to the Policy and Regulations Staff, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorizations.

FOR FURTHER INFORMATION CONTACT:

Steven Fleischer, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740, 240-402-0809, Steven.Fleischer@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) allows FDA to strengthen public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives (among other criteria).

II. Criteria for EUA Authorization

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (A) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (B) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces, including personnel operating under the authority of title 10 or title 50, U.S. Code, of attack with (i) a biological, chemical, radiological, or nuclear agent or agents ("CBRN"); or (ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces;¹ (C) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national

security or the health and security of U.S. citizens living abroad, and that involves a CBRN agent or agents, or a disease or condition that may be attributable to such agent or agents; or (D) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F-2 of the Public Health Service (PHS) Act (42 U.S.C. 247d-6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Under section 564(h)(1) of the FD&C Act, revisions to an authorization shall be made available on FDA's website. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use in an actual or potential emergency when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), 512, or 515 of the FD&C Act (21 U.S.C. 355, 360(k), 360b, and 360e) or section 351 of the PHS Act (42 U.S.C. 262), or conditionally approved under section 571 of the FD&C Act (21 U.S.C. 360ccc).

Under section 564(c) of the FD&C Act, FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances), FDA² concludes: (1) that an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that: (A) the product may be effective in diagnosing, treating, or preventing (i) such disease

or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; (4) in the case of a determination described in section 564(b)(1)(B)(ii) of the FD&C Act, that the request for emergency use is made by the Secretary of Defense; and (5) that such other criteria as may be prescribed by regulation are satisfied. No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act.

III. The Authorizations

The Authorizations follow the August 18, 2025, determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad and that involves NWS. On the basis of such determination, the Secretary of HHS declared, on August 18, 2025, that circumstances exist justifying the authorization of emergency use of animal drugs to treat or prevent NWS myiasis in animals. Notice of the Secretary's determination and declaration was provided in the **Federal Register** on August 20, 2025 (90 FR 40609). Having concluded that the criteria for the issuance of the Authorizations under section 564(c) of the FD&C Act are met, FDA has issued two authorizations for the emergency use of animal drug products. On October 24, 2025, FDA issued an EUA to Elanco US Inc. for the animal drug product Credelio (lotilaner), subject to the terms of its Authorization. On November 21, 2025, FDA issued an EUA to Elanco US Inc. for the animal drug product Credelio CAT (lotilaner), subject to the terms of its Authorization.

The initial Authorizations, included below in their entirety after section IV of this document (not including the authorized versions of the fact sheets and other written materials), provide

¹ In the case of a determination by the Secretary of Defense, the Secretary of HHS shall determine, within 45 calendar days of such determination, whether to make a declaration under section 564(b)(1) of the FD&C Act, and, if appropriate, shall promptly make such a declaration (see section 564(b)(6) of the FD&C Act).

² The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

explanations of the reasons for issuance, as required by section 564(h)(1) of the FD&C Act. Any subsequent reissuance of the Authorizations can be found on FDA's web page at: <https://www.fda.gov/animal-veterinary/safety->

[health/animal-drugs-new-world-screwworm](https://www.fda.gov/animal-veterinary/safety-health/animal-drugs-new-world-screwworm).

IV. Electronic Access

An electronic version of this document and the full text of the Authorization is available on the

internet at: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

BILLING CODE 4164-01-P



October 24, 2025

Elanco US Inc
Attention: Brett McKusick, BA, DVM, MS, PhD
Senior Director, Global Regulatory Affairs
450 Elanco Circle
Indianapolis, IN 46221

Re: Emergency Use Authorization 006662

Dear Dr. McKusick:

This letter is in response to the request by Elanco US Inc. (Elanco) that the Food and Drug Administration (FDA or Agency) issue an Emergency Use Authorization (EUA) for the emergency use of Credelio (lotilaner) for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. §360bbb-3).

On August 18, 2025, pursuant to Section 564(b)(1)(C) of the FD&C Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves New World screwworm (*Cochliomyia hominivorax*) (hereinafter "NWS"). On the basis of such determination, the Secretary of HHS on August 18, 2025, declared that circumstances exist justifying the authorization of emergency use of animal drugs to treat or prevent NWS myiasis in animals, pursuant to section 564(b)(1) of the FD&C Act, subject to terms of any authorization issued under that section.¹

Credelio is an antiparasitic that kills adult fleas and is indicated under NADA 141-494 for the treatment and prevention of flea infestations (*Ctenocephalides felis*) and the treatment and control of tick infestations [*Amblyomma americanum* (lone star tick), *Dermacentor variabilis* (American dog tick), *Ixodes scapularis* (black-legged tick), *Rhipicephalus sanguineus* (brown dog tick), and *Haemaphysalis longicornis* (longhorned tick)] for one month in dogs and puppies 8 weeks of age and older, and weighing 4.4 pounds or greater. Credelio is indicated for the prevention of *Borrelia burgdorferi* infections as a direct result of killing *Ixodes scapularis* vector ticks; however, Credelio is not approved for the treatment of NWS myiasis.

Based on the scientific evidence available to the FDA, including data from published scientific literature, it is reasonable to believe that Credelio may be effective for the treatment of infestations caused by NWS larvae (myiasis) in dogs and puppies, as described in this authorization, and when used under the conditions described in this authorization, the known and potential benefits of Credelio outweigh the known and potential risks for dogs of all ages and weights because NWS is potentially fatal in dogs if left untreated, therefore justifying including dogs less than 8 weeks of age or less than 4.4 lbs in this authorization.

¹ <https://public-inspection.federalregister.gov/2025-15918.pdf>.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the FD&C Act are met, I am authorizing the emergency use of Credelio for the treatment of infestations caused by NWS larvae (myiasis) in dogs and puppies, as described in this authorization and subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of Credelio for the treatment of infestations caused by NWS larvae (myiasis) in dogs and puppies when administered as described in this authorization meets the criteria for issuance of an authorization under Section 564(c) of the FD&C Act, because:

1. NWS can cause a serious or life-threatening disease or condition to animals and humans;
2. Based on the scientific evidence available to FDA, it is reasonable to believe that Credelio may be effective in treating NWS myiasis, and that, when used under the conditions described in this authorization, the known and potential benefits of Credelio when used to treat NWS outweigh the known and potential risks of such product; and
3. There is no adequate, approved, and available alternative to the emergency use of Credelio for the treatment of infestations caused by NWS larvae (myiasis) in dogs and puppies.²

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the FD&C Act, that the scope of this authorization is limited as follows:

- The Credelio covered by this authorization will be used only for the treatment of infestations caused by NWS larvae (myiasis) in dogs and puppies as prescribed by a veterinarian; and
- The use of Credelio covered by this authorization should be in accordance with this authorized Fact Sheet.

Product Description

Credelio is an isoxazoline antiparasitic. The Credelio carton label is clearly marked for approved indications and "emergency use authorization", with a website address and QR code that links to the authorized Fact Sheet.

Store at 15-25°C (59-77°F), excursions permitted between 5 to 40°C (41 to 104°F).

² No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the FD&C Act.

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Credelio is authorized to be accompanied by the following product-specific information pertaining to emergency use, which is required to be made available to veterinarians:

- Fact Sheet for Veterinarians: Emergency Use Authorization of Credelio™ (lotilaner)

I have concluded, pursuant to Section 564(d)(2) of the FD&C Act, that it is reasonable to believe that the known and potential benefits of Credelio, when used for the treatment of infestations caused by NWS larvae (myiasis) in dogs and puppies and used in accordance with this authorization, outweigh its known and potential risks.

I have concluded, pursuant to Section 564(d)(3) of the FD&C Act, based on the scientific evidence available to FDA, that it is reasonable to believe that Credelio may be effective for the treatment of infestations caused by NWS larvae (myiasis) in dogs and puppies when used in accordance with this authorization, pursuant to Section 564(c)(2)(A) of the Act.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that Credelio (as described in this authorization) meets the criteria set forth in Section 564(c) of the FD&C Act concerning safety and potential effectiveness.

The emergency use of your product under an EUA must be consistent with, and may not exceed, the terms of the Authorization, including this authorization and the Conditions of Authorization (Section III). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the FD&C Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the FD&C Act, Credelio is authorized for the treatment of infestations caused by NWS larvae (myiasis) in dogs and puppies as described in this authorization under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

III. Conditions of Authorization

Pursuant to Section 564 of the FD&C Act, I am establishing the following conditions on this authorization:

- A. Elanco will ensure that the authorized Credelio, accompanied with the authorized Fact Sheet, is distributed to veterinarians consistent with the terms and conditions of this EUA.
- B. Elanco will ensure that if a sticker is used on the carton that the sticker contains a website address and QR code that link to the Fact Sheet and that the sticker is placed in a blank space or does not obscure any important use or safety information.
- C. Elanco and authorized distributor(s) will ensure that appropriate storage and cold chain is maintained until the product is delivered to the end user.

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- D. Elanco and authorized distributor(s) will ensure that the terms and conditions of this EUA are made available to all relevant stakeholders (e.g., U.S. government agencies, state and local government authorities, authorized distributors, veterinary clinics, veterinarians and dog owners) involved in distributing or receiving authorized Credelio. Elanco will provide to all relevant stakeholders a copy of this letter of authorization and communicate any subsequent amendments that might be made to this letter of authorization and its authorized accompanying materials (e.g., its authorized Fact Sheet).
- E. Elanco may request changes to this authorization, including to the authorized Fact Sheet for Credelio, and FDA may determine that such changes may be permitted without amendment of this EUA, upon concurrence of the Office of New Animal Product Evaluation.
- F. Reporting Adverse Drug Experiences and Product/Manufacturing Defects:
- Elanco will fully comply with the reporting requirements under 21 CFR 514.80. When collecting adverse event information, Elanco will attempt to ascertain whether the use of Credelio was related to the EUA and will put this categorization, as well as the reason for use, in the narrative description of the adverse event. Elanco will submit the reports electronically using either of the options that are described on FDA's Veterinary Adverse Event Reporting for Manufacturers webpage (www.fda.gov/IndustryReportAnimalAE).
- Submitted reports should state in the "Narrative of Adverse Event" field that: "use of Credelio was under an EUA". Contact the Pharmacovigilance Liaison in CVM's Division of Pharmacovigilance and Surveillance at CVMAESupport@fda.hhs.gov for any questions related to electronic reporting or for assistance with setting up a Safety Reporting Portal account.
- G. Through a process of inventory control, Elanco and authorized distributor(s) will maintain records regarding distribution of the authorized Credelio (i.e., lot numbers, quantity, receiving site, receipt date).
- H. Elanco and authorized distributor(s) will maintain records in connection with this EUA for at least two years following the termination or revocation of the EUA, or until notified by HHS or FDA, whichever is sooner, and will make such records available to FDA for inspection upon request.
- I. Elanco will comply with all other FD&C Act requirements applicable to the approved product, Credelio (including, but not limited to, requirements related to registration and listing, drug quality, manufacturing in accordance with the approved application, etc.) unless such requirement is specifically waived or modified in this authorization. Elanco should create a new drug listing that reflects the EUA, including submission of updated labeling, before commercial distribution of the EUA product begins.

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Veterinary Clinics and Other Similar Facilities to Whom the Authorized Credelio Is Distributed and Veterinarians Administering the Authorized Credelio

- J. Veterinary Clinics and veterinarians will ensure that the end user is aware of the terms and scope of this Letter of Authorization; that the authorized Fact Sheet is made available to veterinarians, through appropriate means; and that they adhere to the terms of the authorization as set forth in the letter of authorization.
- K. Veterinary Clinics and veterinarians receiving Credelio must track serious adverse events potentially attributable to Credelio use and must report these to FDA in accordance with the Fact Sheet for Veterinarians. Complete and submit a Form FDA 1932a available at FDA's "How to Report Animal Drug Side Effects" webpage (www.fda.gov/ReportAnimalAE). When completing the adverse event report form, begin the description in the "Adverse Event/Product Problem/Event Use Error (Long Narrative)" section with the statement: "Use of Credelio was under an EUA". This should be the first sentence of the narrative description, followed by a detailed account of the adverse event.
- L. Veterinary Clinics will maintain records regarding the dispensed authorized Credelio (i.e., lot numbers, quantity, receiving site, receipt date), product storage, and maintain use information (e.g., client name, age, disease manifestation, number of doses administered per patient, other drugs administered).
- M. Veterinary Clinics will ensure that any records associated with this EUA are maintained for at least two years following the termination or revocation of the EUA, or until notified by HHS, or FDA, whichever is sooner. Such records will be made available to Elanco, HHS, and FDA for inspection upon request.

Conditions Related to Advertisements and other Promotional Descriptive Printed Matter

- N. All advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter, relating to the authorized use of the Credelio, shall be consistent with the authorized Fact Sheet,³ as well as the terms set forth in this EUA, and comply with FD&C Act section(s) 502(a), 502(n), and 21 CFR Part 202. Additionally, the sponsor shall comply with any other applicable requirements in the FD&C Act and its implementing regulations regarding advertising and/or promotion.
- O. Elanco may not imply that Credelio is FDA approved for the authorized use by making statements such as "Credelio is safe and effective for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies." Elanco may disseminate advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter relating to the emergency use of Credelio that provide accurate descriptions of safety and effectiveness information summarized in the Fact Sheet. Such materials must include any limitations of the results and information as described in the authorized labeling.

³ If the authorized Fact Sheet references sections of a drug's FDA-approved labeling, the entirety of each section is considered part of the Fact Sheet, except as otherwise specified. Advertising and promotional materials may not use general references to approved labeling in lieu of summarizing or restating its contents when a summary or restatement is otherwise needed to comply with applicable requirements.

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P. All advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter, relating to the authorized use of the Credelio, shall be accompanied by the authorized Fact Sheet, and if applicable the approved labeling, and shall clearly and conspicuously state that:

- Credelio has not been approved for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies.
- Credelio has been authorized by FDA under an EUA for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies.
- Credelio is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of Credelio under Section 564(b)(1) of the FD&C Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is amended, terminated, or revoked sooner.

Q. All advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter must be submitted to the CVM OSC DER eSubmitter Program at the time of initial dissemination (publication or broadcast). Each submission of promotional labeling or advertisements must be accompanied by a completed Form FDA 2301.

If the FDA notifies Elanco that any descriptive materials, advertising, or promotional materials do not meet the terms set forth in Conditions N through Q of this EUA, Elanco must discontinue and/or cease distribution of such advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter in accordance with Agency's notification. Furthermore, as part of its notification, the Agency may also require Elanco to issue corrective communication(s).

IV. Duration of Authorization

This EUA will be effective as described herein until the declaration that circumstances exist justifying the authorization of the emergency use of animal drugs during the NWS public health emergency is terminated under Section 564(b)(2) of the FD&C Act or the EUA is revised or revoked under Section 564(g) of the FD&C Act.

Sincerely,

{see appended electronic signature page}
Timothy Schell, Ph.D.
Director
Center for Veterinary Medicine

Enclosures:
Freedom of Information Summary
Fact Sheet



November 21, 2025

Elanco US Inc
Attention: Brett McKusick, BA, DVM, MS, PhD
Senior Director, Global Regulatory Affairs
450 Elanco Circle
Indianapolis, IN 46221

Re: Emergency Use Authorization 006664

Dear Dr. McKusick:

This letter is in response to the request by Elanco US Inc. (Elanco) that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of Credelio CAT (lotilaner) for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in cats and kittens, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 360bbb-3).

On August 18, 2025, pursuant to Section 564(b)(1)(C) of the FD&C Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves New World screwworm (*Cochliomyia hominivorax*) (hereinafter "NWS"). On the basis of such determination, the Secretary of HHS on August 18, 2025, declared that circumstances exist justifying the authorization of emergency use of animal drugs to treat or prevent NWS myiasis in animals, pursuant to section 564(b)(1) of the FD&C Act, subject to terms of any authorization issued under that section.¹

Credelio CAT is an antiparasitic that kills adult fleas and is indicated under NADA 141-528 for the treatment and prevention of flea infestations (*Ctenocephalides felis*) for one month in cats and kittens 8 weeks of age and older, and weighing 2.0 pounds or greater. Credelio CAT is also indicated under NADA 141-528 for the treatment and control of *Ixodes scapularis* (black-legged tick) infestations for one month in cats and kittens 6 months of age and older, and weighing 2.0 pounds or greater. Credelio CAT is not approved or conditionally approved for the treatment of NWS myiasis.

Based on the scientific evidence available to the FDA, including data from published scientific literature, it is reasonable to believe that Credelio CAT may be effective for the treatment of infestations caused by NWS larvae (myiasis) in cats and kittens, as described in this authorization, and when used under the conditions described in this authorization, the known and potential benefits of Credelio CAT outweigh the known and potential risks for cats of all ages and weights because NWS is potentially fatal in cats if left untreated, therefore justifying including cats less than 8 weeks of age or less than 2.0 lbs in this authorization.

¹ <https://public-inspection.federalregister.gov/2025-15918.pdf>.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the FD&C Act are met, I am authorizing the emergency use of Credelio CAT for the treatment of infestations caused by NWS larvae (myiasis) in cats and kittens, as described in this authorization and subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of Credelio CAT for the treatment of infestations caused by NWS larvae (myiasis) in cats and kittens when administered as described in this authorization meets the criteria for issuance of an authorization under Section 564(c) of the FD&C Act, because:

1. NWS can cause a serious or life-threatening disease or condition to animals and humans;
2. Based on the scientific evidence available to FDA, it is reasonable to believe that Credelio CAT may be effective in treating NWS myiasis and that, when used under the conditions and within the scope described in this authorization, the known and potential benefits of Credelio CAT when used to treat NWS outweigh the known and potential risks of such product; and
3. There is no adequate, approved, and available alternative to the emergency use of Credelio CAT for the treatment of infestations caused by NWS larvae (myiasis) in cats and kittens.²

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the FD&C Act, that the scope of this authorization is limited as follows:

- The emergency use of Credelio CAT covered by this authorization will be used only for the treatment of infestations caused by NWS larvae (myiasis) in cats and kittens as prescribed by a veterinarian; and
- The emergency use of Credelio CAT covered by this authorization should be in accordance with the enclosed authorized Fact Sheet.

Product Description

Credelio CAT is an isoxazoline antiparasitic. The Credelio CAT carton label is clearly marked for approved indications and for NWS under "emergency use authorization", with a website address and QR code that links to the authorized Fact Sheet.

Store at 15-25°C (59-77°F), excursions permitted between 5 to 40°C (41 to 104°F).

² No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the FD&C Act.

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Credelio CAT is authorized to be accompanied by the following product-specific information pertaining to emergency use, which is required to be made available to veterinarians:

- Fact Sheet for Veterinarians: Emergency Use Authorization of Credelio™ CAT (lotilaner)

I have concluded, pursuant to Section 564(d)(2) of the FD&C Act, that it is reasonable to believe that the known and potential benefits of Credelio CAT, when used for the treatment of infestations caused by NWS larvae (myiasis) in cats and kittens and used in accordance with this authorization, outweigh its known and potential risks.

I have concluded, pursuant to Section 564(d)(3) of the FD&C Act, based on the scientific evidence available to FDA, that it is reasonable to believe that Credelio CAT may be effective for the treatment of infestations caused by NWS larvae (myiasis) in cats and kittens when used in accordance with this authorization, pursuant to Section 564(c)(2)(A) of the FD&C Act.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that Credelio CAT (as described in this authorization) meets the criteria set forth in Section 564(c) of the FD&C Act concerning safety and potential effectiveness.

The emergency use of this product under an EUA must be consistent with, and may not exceed, the terms of this authorization, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the FD&C Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the FD&C Act, Credelio CAT is authorized for the treatment of infestations caused by NWS larvae (myiasis) in cats and kittens as described in this authorization under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

III. Conditions of Authorization

Pursuant to Section 564 of the FD&C Act, I am establishing the following conditions on this authorization:

- Elanco will ensure that the authorized Credelio CAT, accompanied with the authorized Fact Sheet, is distributed to veterinary facilities³ and veterinarians consistent with the terms and conditions of this EUA.
- Elanco will ensure that if a sticker is used on the carton, that the sticker contains a website address and QR code that link to the authorized Fact Sheet and that the sticker is placed in a blank space or does not obscure any important use or safety information.
- Elanco and authorized distributor(s) will ensure that appropriate storage is maintained until the product is delivered to veterinary facilities and veterinarians.

³ Veterinary facilities include veterinary hospitals, veterinary clinics and other establishments providing veterinary care.

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- D. Elanco and authorized distributor(s) will ensure that the terms and conditions of this EUA are made available to all relevant stakeholders (e.g., U.S. government agencies, state and local government authorities, authorized distributors, veterinary facilities, and veterinarians) involved in distributing or receiving authorized Credelio CAT. Elanco will provide to all relevant stakeholders a copy of this Letter of Authorization and communicate any subsequent amendments that might be made to this Letter of Authorization and its authorized accompanying materials (e.g., its authorized Fact Sheet).
- E. Elanco may request changes to this authorization, including to the authorized Fact Sheet for Credelio CAT, and FDA may determine that such changes may be permitted without reissuing this Letter. Requests for changes should be submitted to the Office of New Animal Product Evaluation.
- F. Reporting Adverse Drug Experiences and Product/Manufacturing Defects:
- Elanco will fully comply with the reporting requirements under 21 CFR 514.80. When collecting adverse event information, Elanco will attempt to ascertain whether the use of Credelio CAT was related to the EUA and will put this categorization, as well as the reason for use, in the narrative description of the adverse event. Elanco will submit the reports electronically using either of the options that are described on FDA's Veterinary Adverse Event Reporting for Manufacturers webpage (www.fda.gov/IndustryReportAnimalAE).
- Submitted reports should state in the "Narrative of Adverse Event" field: "Credelio CAT use for NWS under an EUA". Contact the Pharmacovigilance Liaison in CVM's Division of Pharmacovigilance and Surveillance at CVMAESupport@fda.hhs.gov for any questions related to electronic reporting or for assistance with setting up a Safety Reporting Portal account.
- G. Through a process of inventory control, Elanco and authorized distributor(s) will maintain records regarding distribution of the authorized Credelio CAT (i.e., lot numbers, quantity, receiving site, receipt date).
- H. Elanco and authorized distributor(s) will maintain records in connection with this EUA for at least two years following the termination or revocation of the EUA, or until notified by HHS or FDA, whichever is sooner, and will make such records available to FDA for inspection upon request.
- I. Elanco will comply with all other FD&C Act requirements applicable to the approved product, Credelio CAT (including, but not limited to, requirements related to registration and listing, drug quality, and manufacturing in accordance with the approved application) unless such requirement is specifically waived or modified in this authorization. Elanco should update their drug listing to reflect the EUA, including submission of updated labeling, before commercial distribution of the EUA product begins.

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Conditions of Authorization for Veterinary Facilities and Veterinarians

- J. Veterinary facilities and veterinarians will ensure that they are aware of and adhere to the terms of this Letter of Authorization. Authorized Fact Sheets will be made available to veterinarians, and veterinary facilities and veterinarians will ensure that the client is aware that the drug is authorized for emergency use, but not approved, for the treatment of NWS myiasis and advise the client of the risks, benefits, and any alternatives.
- K. Veterinary facilities and veterinarians receiving Credelio CAT will track serious adverse events potentially related to Credelio CAT use under this EUA and must report these to FDA in accordance with the Fact Sheet for Veterinarians. Report by (1) contacting Elanco US at 1-888-545-5973, (2) downloading and submitting Form FDA 1932a available at <https://www.fda.gov/reportanimalae>, or (3) contacting FDA at 1-888-FDA-VETS to request this form. Include the statement "Credelio CAT use for the treatment of infestations of NWS under an EUA" under the "Describe Adverse Event/Product Problem/Event Use Error" heading, followed by a detailed account of the adverse event.
- L. Veterinary facilities will maintain health records for the authorized use in this Letter of Authorization that include the following information: client name, patient name, patient age, disease manifestation, number of doses prescribed or administered per patient, lot number prescribed or administered, and other drugs coadministered. The records shall be maintained in a manner that allows veterinary facilities to identify in a reasonable time which patients received drugs subject to this EUA.
- M. Veterinary facilities will maintain any health records for the authorized use in this Letter of Authorization for at least two years following the termination or revocation of this EUA, or until notified by HHS or FDA, whichever is sooner. Such records will be made available to Elanco, HHS, and FDA for inspection upon request.

Conditions of Authorization Related to Advertisements and other Promotional Descriptive Printed Matter

- N. All advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter, relating to the authorized use of Credelio CAT, shall be consistent with the authorized Fact Sheet,⁴ as well as the terms set forth in this EUA, and comply with FD&C Act section(s) 502(a) and 502(n), and 21 CFR Part 202. Additionally, the sponsor shall comply with any other applicable requirements in the FD&C Act and its implementing regulations regarding advertising and/or promotion.

⁴ If the authorized Fact Sheet references sections of a drug's FDA-approved labeling, the entirety of each section is considered part of the authorized Fact Sheet, except as otherwise specified. Advertising and promotional materials may not use general references to approved labeling in lieu of summarizing or restating its contents when a summary or restatement is otherwise needed to comply with applicable requirements.

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- O. Elanco may not imply that Credelio CAT is FDA approved or conditionally approved for the authorized use by making statements such as "Credelio CAT is safe and effective for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in cats and kittens." Elanco may disseminate advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter relating to the emergency use of Credelio CAT that provide accurate descriptions of safety and effectiveness information summarized in the authorized Fact Sheet. Such materials must include any limitations of the results and information as described in the authorized labeling.
- P. All advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter relating to the authorized use of Credelio CAT, shall be accompanied by the authorized Fact Sheet, and if applicable the approved labeling, and shall clearly and conspicuously state that:
- Credelio CAT has not been approved for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in cats and kittens;
 - Credelio CAT has been authorized by FDA under an EUA for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in cats and kittens;
 - Credelio CAT is authorized as described herein only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of Credelio CAT under Section 564(b)(1) of the FD&C Act, 21 U.S.C. § 360bbb-3(b)(1), unless this authorization is revised, terminated, or revoked sooner.
- Q. All advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter must be submitted to the CVM OSC DER eSubmitter Program at the time of initial dissemination (publication or broadcast). Each submission of promotional labeling or advertisements must be accompanied by a completed Form FDA 2301.

If the FDA notifies Elanco that any descriptive materials, advertising, or promotional materials do not meet the terms set forth in this EUA, Elanco must discontinue and/or cease distribution of such advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter in accordance with FDA's notification. Furthermore, as part of its notification, FDA may also require Elanco to issue corrective communication(s).

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IV. Duration of Authorization

This EUA will be effective as described herein until the declaration that circumstances exist justifying the authorization of the emergency use of animal drugs during the NWS public health emergency is terminated under Section 564(b)(2) of the FD&C Act or the EUA is revised or revoked under Section 564(g) of the FD&C Act.

Sincerely,

{see appended electronic signature page}
Timothy Schell, Ph.D.
Director
Center for Veterinary Medicine

Enclosures:
Freedom of Information Summary
Fact Sheet

Lowell M. Zeta,

Acting Deputy Commissioner for Policy,
Legislation, and International Affairs.

[FR Doc. 2025-23914 Filed 12-23-25; 8:45 am]

BILLING CODE 4164-01-C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-7022]

Roundtable on Premarket Tobacco Application Submissions for Electronic Nicotine Delivery Systems Products; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of roundtable discussion; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a roundtable discussion with small tobacco product manufacturers to solicit input on premarket tobacco product application (PMTA) submissions for electronic nicotine delivery systems (ENDS) products. The topics to be discussed will include certain components of PMTAs such as product characterization, manufacturing controls, pharmacological profile (e.g., pharmacokinetic studies), studies of adult benefit (e.g., longitudinal cohort/randomized controlled trial (RCT) studies), and toxicological profile (e.g., estimated lifetime cancer risk). The purpose of the roundtable is to provide manufacturers an opportunity to share their experience with, and other opinions about, the premarket application process. This notice provides information on meeting participation and selection. FDA is establishing a docket for public comments related to the roundtable meeting.

DATES: The roundtable meeting will be held on February 10, 2026, 9:00 a.m. to 5 p.m., Eastern Time. Electronic or written comments on the roundtable may be submitted beginning December 29, 2025. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The roundtable meeting will be held in the White Oak Great Room and virtually. Entrance for the roundtable panelists (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. Electronic comments must be submitted on or before February 3, 2026, to be considered for the roundtable discussion. All other electronic comments must be submitted on or before March 12, 2026. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 12, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before these dates.

The public can submit comments on the roundtable topics during the open comment period; the request for comments is not limited to small tobacco product manufacturers.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2025-N-7022 for "Roundtable on Premarket Tobacco Application Submissions for Electronic Nicotine Delivery Systems Products; Notice of Meeting; Establishment of a Public Docket; Request for Comments." Received, timely comments (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.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read 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:

Daniel Gittleston, Office of Regulations, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993-0002, 1-877-287-1373, email: CTPRegulations@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

Tobacco products that meet the definition of a “new tobacco product,” and that an applicant intends to market in the United States, including ENDS, are subject to the requirements for a PMTA set forth in section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). When reviewing PMTAs, the Agency evaluates, among other things, a tobacco product’s components, ingredients, additives, constituents, design, harmful and potentially harmful constituents (HPHCs), and health risks, as well as how the product is manufactured, packaged, and labeled. After reviewing a company’s PMTA, FDA determines if the application includes or lacks sufficient evidence to demonstrate that permitting the marketing of the products would be appropriate for the protection of the public health (APPH), which is the applicable legal standard required by the FD&C Act (see section 910(c) of the FD&C Act).

Through this notice, FDA announces a roundtable discussion to gather feedback from small tobacco product manufacturers (see 21 U.S.C. 387(16)) about their experience with, and other opinions about, the premarket application process. The topics to be discussed will include certain components of PMTAs such as product characterization, manufacturing controls, pharmacological profile (*e.g.*, pharmacokinetic studies), studies of adult benefit (*e.g.*, longitudinal cohort/randomized controlled trial (RCT) studies), and toxicological profile (*e.g.*, estimated lifetime cancer risk (ELCR)). FDA also is establishing a public docket to solicit comment on these topics.

II. Topics for Discussion at the Roundtable and for the Request for Comments

The purpose of the roundtable is to provide small ENDS manufacturers an opportunity to share their experience and other opinions about the premarket application process. Roundtable topics to be discussed include certain components of ENDS PMTAs, such as product characterization, manufacturing controls, pharmacological profile (*e.g.*, pharmacokinetic studies), studies of

adult benefit (*e.g.*, longitudinal cohort/RCT studies), and toxicological profile (*e.g.*, ELCR).

A. Product Characterization

The foundational information necessary to evaluate the quality and consistency of a new tobacco product is based on an understanding of the product as delivered to the user. One of the critical pieces of information is a complete product listing and description, including details of the product design. Also included in ENDS product characterization is the measurement of constituents in the aerosol, including HPHCs, which provide details of a user’s exposure to nicotine and other potentially harmful ingredients. This roundtable will discuss the types of information needed to fully characterize a product in an application and can cover topics including product formulation, validation of analytical measurements, and the assessment of leachables and extractables, where appropriate.

B. Manufacturing Controls

In addition to product characterization, a complete understanding of a manufacturer’s internal controls and practices is important for FDA to ensure that products delivered to a user will be sufficiently similar to the products that were tested and that form the basis of our scientific assessment of nicotine and potential toxic constituent exposure from the new product. This information includes standard operating procedures (SOPs); work instructions; certificates of analysis; the linkage between label claim and actual measured nicotine delivery; and stability of new products during storage, transport, and shelf life, and these are all topics which may be covered and discussed in the roundtable.

C. Pharmacological Profile (*e.g.*, Pharmacokinetic Studies)

One of the most important aspects of FDA’s evaluation of APPH for a new tobacco product focuses on the abuse liability of the new tobacco product including the delivery and uptake of nicotine by a user of the product. Nicotine exposure typically is evaluated through clinical studies that evaluate nicotine pharmacokinetics after use of the new tobacco product. Occasionally, it is possible to bridge the findings of one ENDS product to another, thus allowing a reduction in the number of studies needed to support a product. However, the proper designs of these clinical studies for ENDS products can be complex and need to be highly

developed before work is initiated. This roundtable will address criteria that could improve the quality of the clinical studies for ENDS products submitted by applicants and provide participants an opportunity to ask questions about design basics to inform their applications.

D. Studies of Adult Benefit (*e.g.*, Longitudinal Cohort/RCT Studies)

The understanding of the potential benefits that a new ENDS tobacco product may offer to users of combusted tobacco products by switching to the new ENDS tobacco product is critical to FDA’s APPH determination. Examples of population studies to assess switching include longitudinal cohort studies or randomized controlled trials of the new tobacco product with adult users. This roundtable will include a discussion of the critical considerations in the design and administration of these adult benefit studies.

E. Toxicological Profile (*e.g.*, ELCR)

The toxicological assessment of a new tobacco product application for APPH includes a careful evaluation of critical elements of potential and actual risk posed by the use of the product. These critical elements typically include, among other topics, the hazard identification and associated risk assessment of HPHCs found in the aerosol of ENDS products and the risks associated with constituents in a new product. This roundtable will discuss approaches that an applicant could use to evaluate their products for potential risks from a genotoxicity approach (ELCR), inhalation toxicity, and HPHC exposure.

III. Participating in the Roundtable and Selection of Participants

Registration for the roundtable is open to small tobacco product manufacturers as defined in section 900(16) of the FD&C Act. The term “small tobacco product manufacturer” means a tobacco product manufacturer that employs fewer than 350 employees. For purposes of determining the number of employees of a manufacturer under the preceding sentence, the employees of a manufacturer are deemed to include the employees of each entity that controls, is controlled by, or is under common control with such manufacturer. For example, if a parent company owns two subsidiaries, the total number of employees would include the employees in the parent company plus the number of employees in the two subsidiaries. Additionally, registration for participation in the roundtable will be limited to 30 participants

representing manufacturers who have previously submitted an ENDS PMTA, including those with a PMTA currently pending with FDA. Final eligibility for attendance will be determined by FDA. Participants should be at a sufficiently senior level with significant scientific and/or regulatory responsibility to be knowledgeable about their company's PMTA.

Registration: Registration is free. For information on how to register for the roundtable as a panelist, please visit the following website: <https://www.fda.gov/tobacco-products/ctp-newsroom/february-10-2026-roundtable-premarket-tobacco-application-submissions-electronic-nicotine-delivery>, by January 27, 2026, 11:59 p.m. Eastern Time. Registrants should include the following information for the attendee in their request to participate in the roundtable:

- Name of proposed attendee, job title, address, email, and telephone number
- Name of company and brief company description
- How many people the company employs (including subsidiaries)
- Indicate which of the 5 topics you wish to discuss as a panel member (you may select multiple topics):
 - A. Product Characterization
 - B. Manufacturing Controls
 - C. Pharmacological Profile
 - D. Studies of Adult Benefit
 - E. Toxicological Profile

Registration for panelists is on a rolling basis determined by space availability, with priority given to early registrants. FDA will evaluate registrations based on the submitted information until a maximum of 30 participants have been selected for the roundtable and will then inform applicants of selection decisions. Due to time and space constraints, there is a limit of one person to represent and speak on behalf of each company. Panel registrants will receive confirmation as to whether they have been accepted. If panelist registration closes prior to the submission deadline, we will update the website to reflect that change. For persons interested in viewing the roundtable virtually, information will be provided on our website: <https://www.fda.gov/tobacco-products/ctp-newsroom/february-10-2026-roundtable-premarket-tobacco-application-submissions-electronic-nicotine-delivery>.

If you need special accommodations due to a disability, please email: CTP-OS-ACS@fda.hhs.gov no later than February 3, 2026.

Virtual Participation and Live Streaming of the Roundtable: This roundtable will also be available for

virtual attendance. If you have been accepted to participate in the roundtable meeting as a panelist but will attend virtually, you will receive details prior to the roundtable. For non-panelist attendees interested in viewing the roundtable virtually, information will be provided on our website: <https://www.fda.gov/tobacco-products/ctp-newsroom/february-10-2026-roundtable-premarket-tobacco-application-submissions-electronic-nicotine-delivery>.

Transcripts: Please be advised that as soon as a transcript of the roundtable is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at <https://www.fda.gov/tobacco-products/ctp-newsroom/february-10-2026-roundtable-premarket-tobacco-application-submissions-electronic-nicotine-delivery>.

Notice of this meeting is given pursuant to 21 CFR 10.65.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025-23851 Filed 12-23-25; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-E-3236]

Determination of Regulatory Review Period for Purposes of Patent Extension; LEQEMBI

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 LEQEMBI 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 biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by February 27, 2026. 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 June 29, 2026. 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 February 27, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-

2023–E–3236 for “Determination of Regulatory Review Period for Purposes of Patent Extension; LEQEMBI.” 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: Jack Dan, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6200, Silver Spring, MD 20993, 240–402–6940.

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 biologic 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 biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological 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 biological 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 biologic product LEQEMBI (lecanemab- irmb). LEQEMBI is indicated for the treatment of Alzheimer’s disease. Subsequent to this approval, the USPTO received a patent term restoration application for LEQEMBI (U.S. Patent No. 8,025,878) from BioArctic AB, and the USPTO requested FDA’s assistance in determining this patent’s eligibility for patent term restoration. In a letter dated January 30, 2024, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of LEQEMBI 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 LEQEMBI is 4,546 days. Of this time, 4,300 days occurred during the testing phase of the regulatory review period, while 246 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 (21 U.S.C. 355(i)) became effective:* July 29, 2010. FDA has verified the applicant’s claim that the date the investigational new drug application became effective was on July 29, 2010.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* May 6, 2022. FDA has verified the applicant’s claim that the biologics license application (BLA) for LEQEMBI (BLA 761269) was initially submitted on May 6, 2022.

3. *The date the application was approved:* January 6, 2023. FDA has verified the applicant’s claim that BLA 761269 was approved on January 6, 2023.

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 application for patent extension, this applicant seeks 5 years 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.

Brian Fahey,

Associate Commissioner for Legislation.

[FR Doc. 2025–23865 Filed 12–23–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–6896]

Over-the-Counter Monograph Drug User Fee Amendments—OTC Monograph Order Request Fee Rates for Fiscal Year 2026

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Over-the-Counter Monograph Drug User Fee Amendments (herein referred to as “OMUFA II”), authorizes the Food and Drug Administration (FDA, the Agency, or we) to assess and collect user fees from qualifying manufacturers of over-the-counter (OTC) monograph drugs and submitters of OTC monograph order requests (OMOR)s for fiscal years 2026 through 2030. In this notice, FDA is announcing the OMOR fee rates for fiscal year (FY) 2026. FDA plans to announce the FY 2026 OMUFA facility fee rates, *i.e.*, monograph drug facility (MDF) and contract manufacturing organization (CMO) facility fee rates, in a subsequent **Federal Register** notice (and anticipates its issuance will generally align with the timing of the OMUFA facility fee rate publication for prior FYs).

DATES: These OMOR fees are effective on October 1, 2025, and will remain in effect through September 30, 2026.

FOR FURTHER INFORMATION CONTACT: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–4989; or the User Fees Support Staff at OO-OFBA-OFM-UFSS-Government@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 744M of the FD&C Act (21 U.S.C. 379j–72), as amended by OMUFA

II,¹ authorizes FDA to assess and collect, for each of fiscal years 2026 through 2030: (1) facility fees from qualifying owners of OTC MDFs and (2) fees from submitters of qualifying OTC OMORs. These fees are to support FDA’s OTC monograph drug activities, which are detailed in section 744L(6) of the FD&C Act (21 U.S.C. 379j–71(6)) and include specified FDA activities associated with regulating OTC monograph drugs.²

For OMUFA purposes, an OMOR is a request for an administrative order, with respect to an OTC monograph drug, which is submitted under section 505G(b)(5) of the FD&C Act (see section 744L(7) of the FD&C Act).

Under section 744M(a)(2)(A) of the FD&C Act, the Agency is authorized to assess and collect fees from submitters of OMORs, except for OMORs that request certain safety-related changes (as discussed below). There are two levels of OMOR fees, based on whether the OMOR at issue is a Tier 1 or Tier 2 OMOR.³

For FY 2026, the OMUFA fee rates for OMORs are: Tier 1 OMOR fees (\$587,529) and Tier 2 OMOR fees (\$117,505). These fees are effective for the period from October 1, 2025, through September 30, 2026. This document is issued pursuant to section 744M(a)(2) and (c)(5) of the FD&C Act and describes the calculations used to set the OMUFA OMOR fees for FY 2026 in accordance with the directives in the statute.

II. Determination of FY 2026 OMOR Fees

For FY 2026, the Tier 1 OMOR fee is \$587,529 and the Tier 2 OMOR fee is \$117,505, including an adjustment for inflation (see sections 744M(a)(2)(A)(i) and (ii) of the FD&C Act, respectively). OMOR fees are not included in the OMUFA target revenue calculation, which is based on the facility fees (see section 744M(b) of the FD&C Act).

An OMOR fee is generally assessed to each person who submits an OMOR (see section 744M(a)(2)(A) of the FD&C Act). OMOR fees are due on the date of the

submission of the OMOR (see section 744M(a)(2)(B) of the FD&C Act). The payor should submit the OMOR fee that applies to the type of OMOR they are submitting (*i.e.*, Tier 1 or Tier 2). FDA will determine whether the appropriate OMOR fee has been submitted following receipt of the OMOR and the fee.

An OMOR fee will not be assessed if the OMOR seeks to make certain safety changes with respect to an OTC monograph drug. Specifically, no fee will be assessed if FDA finds that the OMOR seeks to change the drug facts labeling of an OTC monograph drug in a way that would add to or strengthen: (1) a contraindication, warning, or precaution; (2) a statement about risk associated with misuse or abuse; or (3) an instruction about dosage and administration that is intended to increase the safe use of the OTC monograph drug (see section 744M(a)(2)(C) of the FD&C Act).

III. OMOR Fee Adjustment for Inflation

The dollar amount of the inflation adjustment to the fee for OMORs for FY 2026 is equal to the product of the applicable fee for FY 2025 and the inflation adjustment percentage.³ For FY 2026, the inflation adjustment percentage is equal to the sum of:

- The average annual percent change in the cost, per full-time equivalent (FTE) position at FDA, of all personnel compensation and benefits (PC&B) paid with respect to such positions for the first 3 years of the preceding 4 FYs, multiplied by the proportion of PC&B costs to total FDA costs of OTC monograph drug activities for the first 3 years of the preceding 4 FYs (see section 744M(c)(1)(C)(i) of the FD&C Act); and
- The average annual percent change that occurred in the Consumer Price Index (CPI) for urban consumers (Washington-Arlington-Alexandria, DC-VA-MD-WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than PC&B costs to total costs of OTC monograph drug activities for the first 3 years of the preceding 4 FYs (see section 744M(c)(1)(C)(ii) of the FD&C Act).

Table 1 summarizes the actual cost and FTE data for the specified FYs, provides the percent changes from the

¹ Over-the-Counter Monograph Drug User Fee Amendments, title V of Division F of the Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, 2026 (Pub. L. 119–37).

² For OMUFA purposes, an OTC monograph drug is a nonprescription drug without an approved new drug application that is governed by the provisions of section 505G of the FD&C Act (21 U.S.C. 355h) (see section 744L(5) of the FD&C Act).

³ Under OMUFA, a Tier 1 OMOR is defined as any OMOR that is not a Tier 2 OMOR (see section 744L(8) of the FD&C Act). Tier 2 OMORs are detailed in section 744L(9) of the FD&C Act.

³ See section 744M(c)(1)(B) of the FD&C Act.

previous FYs, and provides the average percent changes over the first 3 of the 4 FYs preceding FY 2026. The 3-year average is 5.4494 percent.

TABLE 1—FDA PERSONNEL COMPENSATION AND BENEFITS (PC&B) EACH YEAR AND PERCENT CHANGES

	2022	2023	2024	3-Year average
Total PC&B	\$3,165,477,000	\$3,436,513,000	\$3,791,729,000	
Total FTEs	18,474	18,729	19,687	
PC&B per FTE	\$171,348	\$183,486	192,601	
Percent Change from Previous Year	4.2967%	7.0838%	4.9677%	5.4494%

Under the statute, this 5.4494 percent is multiplied by the proportion of PC&B costs to the total FDA costs of OTC monograph drug activities for the first 3 years of the preceding 4 FYs (see section 744M(c)(1)(C)(i) of the FD&C Act). Table 2 shows the PC&B and the total obligations for OTC monograph drug activities for the first 3 of the preceding 4 FYs.

TABLE 2—PC&B AS A PERCENT OF TOTAL COST OF OTC MONOGRAPH DRUG ACTIVITIES

	2022	2023	2024	3-Year average
Total PC&B	\$25,415,237	\$39,133,075	\$41,579,890	
Total Costs	\$49,644,273	\$68,480,052	\$68,176,240	
PC&B Percent	51.1947%	57.1452%	60.9888%	56.4429%

The payroll adjustment is 5.4494 percent from table 1 multiplied by 56.4429 percent from table 2, resulting in 3.0758 percent. Table 3 provides the summary data for the percent changes in the specified CPI for the Washington-Arlington-Alexandria, DC-VA-MD-WV area.⁴

TABLE 3—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN CPI FOR WASHINGTON-ARLINGTON-ALEXANDRIA, DC-VA-MD-WV AREA

Year	2022	2023	2024	3-Year average
Annual CPI	296.12	305.32	315.19	
Annual Percent Change	6.6212%	3.1069%	3.2324%	4.3202%

The statute specifies that this 4.3202 percent be multiplied by the proportion of all costs other than PC&B to total costs of OTC monograph drug activities (see section 744M(c)(1)(C)(ii) of the FD&C Act). Because 56.4429 percent was obligated for PC&B (as shown in table 2), 43.5571 percent is the portion of costs other than PC&B (100 percent – 56.4429 percent = 43.5571 percent). The non-payroll adjustment is 4.3202 percent × 43.5571 percent, or 1.8818 percent.

Next, we add the payroll adjustment (3.0758 percent) to the non-payroll adjustment (1.8818 percent), for a total inflation adjustment of 4.9576 percent (rounded) for FY 2026.

IV. OMOR Fee Calculations

Under section 744M(a)(2)(A) of the FD&C Act, each person that submits a qualifying OMOR shall be subject to a fee for an OMOR. The amount of such fee shall be:

- (1) For a Tier 1 OMOR, \$500,000, adjusted for inflation for the FY (see section 744M(a)(2)(A)(i) of the FD&C Act); and
- (2) For a Tier 2 OMOR, \$100,000, adjusted for inflation for the FY (see section 744M(a)(2)(A)(ii) of the FD&C Act).
- In addition, under section 744M(c)(1)(B)(i) of the FD&C Act and for purposes of section 744M(a)(2) of the FD&C Act, the inflation adjustment for the FY 2026 OMOR fee shall be equal to the product of:
- (1) the fee for FY 2025 under section 744M(a)(2) of the FD&C (as in effect during OMFUFA I); and
- (2) the inflation adjustment percentage under subparagraph (C) of section 744M(c)(1) of the FD&C Act.
- Therefore, for FY 2026, the base of OMOR fees taken from the preceding FY (i.e., FY 2025) are: Tier 1: \$559,777 and Tier 2: \$111,955. The FY 2026 inflation adjustment percentage is: 4.9576 percent.

V. Fee Schedule for FY 2026

The fee rates for FY 2026 are displayed in Table 4.

TABLE 4—FEE SCHEDULE FOR FY 2026

Fee category	FY 2026 fee rates
OMOR:	
Tier 1	\$587,529
Tier 2	117,505

VI. Fee Payment Options and Procedures

The new OMOR fee rates are for the period from October 1, 2025, through September 30, 2026. To pay the OMOR fees, complete an OTC Monograph User Fee Cover Sheet, available at: https://userfees.fda.gov/OA_HTML/omufacAcidLogin.jsp, and generate a user fee identification (ID) number. Payment must be made in U.S. currency drawn on a U.S. bank by electronic

⁴ The data are published by the Bureau of Labor Statistics on its website: <https://data.bls.gov/pdq/>

[SurveyOutputServlet?data_tool=dropmap&series_id=CUURS35ASA0,CUUSS35ASA0.](#)

check or wire transfer, payable to the order of the Food and Drug Administration. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck). FDA has partnered with the U.S. Department of the Treasury to utilize *Pay.gov*, a web-based payment application, for online electronic payment. The *Pay.gov* feature is available on the FDA website after completing the OTC Monograph User Fee Cover Sheet and generating the user fee ID number.

Secure electronic payments can be submitted using the User Fees Payment Portal at <https://userfees.fda.gov/pay>. (Note: Only full payments are accepted; no partial payments can be made online). Once an invoice is located, "Pay Now" should be selected to be redirected to *Pay.gov*. Electronic payment options are based on the balance due.⁵

For payments made by wire transfer, include the unique user fee ID number to ensure that the payment is applied to the correct fee(s). Without the unique user fee ID number, the payment may not be applied, which could result in FDA not filing an OMOR request, or other consequences of nonpayment. The originating financial institution may charge a wire transfer fee. Include applicable wire transfer fees with payment to ensure fees are fully paid. Questions about wire transfer fees should be addressed to the financial institution. The following account information should be used to send payments by wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33. FDA's tax identification number is 53-0196965.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025-23852 Filed 12-23-25; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-E-0923]

Determination of Regulatory Review Period for Purposes of Patent Extension; ROMVIMZA

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 ROMVIMZA 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 February 27, 2026. 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 June 29, 2026. 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 February 27, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged.

Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information

that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2025-E-0923 for "Determination of Regulatory Review Period for Purposes of Patent Extension; ROMVIMZA." 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

⁵ Payment by credit card is available for balances that are less than \$25,000 (Discover, VISA, MasterCard, American Express). If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

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: Jack Dan, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6200, Silver Spring, MD 20993, 240–402–6940.

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, ROMVIMZA (vimseltinib), indicated for the treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause worsening functional limitation or severe morbidity. Subsequent to this approval, the USPTO received a patent term restoration application for ROMVIMZA (U.S. Patent No. 9,181,223) from Deciphera Pharmaceuticals, LLC and the USPTO requested FDA’s assistance in determining the patent’s eligibility for patent term restoration. In a letter dated June 27, 2025, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of ROMVIMZA 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 ROMVIMZA is 3,020 days. Of this time, 2,777 days occurred during the testing phase of the regulatory review period, while 243 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:* November 10, 2016. FDA has verified the applicant’s claim that the date the investigational new drug application became effective was on November 10, 2016.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* June 17, 2024. FDA has verified the applicant’s claim that the new drug application (NDA) for ROMVIMZA (NDA 219304) was initially submitted on June 17, 2024.

3. *The date the application was approved:* February 14, 2025. FDA has verified the applicant’s claim that NDA 219304 was approved on February 14, 2025.

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 application(s) for patent extension, this applicant seeks 1,632 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.

Brian Fahey,

Associate Commissioner for Legislation.

[FR Doc. 2025–23862 Filed 12–23–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–E–3865]

Determination of Regulatory Review Period for Purposes of Patent Extension; OJEMDA

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 OJEMDA 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 February 27, 2026. Furthermore, any interested person may petition FDA for a determination regarding whether the applicants for extension acted with due diligence during the regulatory review period by June 29, 2026. 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 February 27, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2024-E-3865 for “Determination of Regulatory Review Period for Purposes of Patent Extension; OJEMDA.” 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: Jack Dan, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6200, Silver Spring, MD 20993, 240-402-6940.

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 applicants 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, OJEMDA (tovorafenib), indicated for the treatment of patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma (LGG) harboring a BRAF fusion or rearrangement, or BRAF V600 mutation. Subsequent to this approval, the USPTO received a patent term restoration application for OJEMDA (U.S. Patent No. 8,293,752) from Day One Biopharmaceuticals, Inc. and Viracta

Therapeutics, Inc. and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated June 27, 2025, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of OJEMDA 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 OJEMDA is 4,942 days. Of this time, 4,705 days occurred during the testing phase of the regulatory review period, while 237 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:* October 14, 2010. FDA has verified the applicants' claim that the date the investigational new drug application became effective was on October 14, 2010.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* August 31, 2023. FDA has verified the applicants' claim that the new drug application (NDA) for OJEMDA (NDA 217700) was initially submitted on August 31, 2023.

3. *The date the application was approved:* April 23, 2024. FDA has verified the applicants' claim that NDA 217700 was approved on April 23, 2024.

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 application(s) for patent extension, the applicants seek 5 years 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 applicants 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 applicants. (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.

Brian Fahey,

Associate Commissioner for Legislation.

[FR Doc. 2025–23867 Filed 12–23–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–4684]

Egis Pharmaceuticals Limited, et.al.; Proposal To Withdraw Approval of Three Abbreviated New Drug Applications; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Drug Evaluation and Research (CDER) is proposing to withdraw approval of three abbreviated new drug applications (ANDAs) and is announcing an opportunity for the ANDA holders to request a hearing on this proposal. The basis for the proposal is that these ANDA holders have repeatedly failed to file required annual reports for those ANDAs.

DATES: The ANDA holder may submit a request for a hearing by January 28, 2026. Submit all data, information, and analyses upon which the request for a hearing relies February 27, 2026. Submit electronic or written comments by February 27, 2026.

ADDRESSES: The request for a hearing may be submitted by the ANDA holder by either of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the

instructions for submitting comments to submit your request for a hearing. Comments submitted electronically to <https://www.regulations.gov>, including any attachments to the request for a hearing, will be posted to the docket unchanged.

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.

- Because your request for a hearing will be made public, you are solely responsible for ensuring that your request 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. The request for a hearing must include the Docket No. FDA–2025–N–4684 for “Egis Pharmaceuticals Limited, *et al.*; Proposal to Withdraw Approval of Three Abbreviated New Drug Applications; Opportunity for a Hearing.” The request for a hearing will be placed in the docket and publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday. The ANDA holders may submit all data and analyses upon which the request for a hearing relies in the same manner as the request for a hearing except as follows:

- **Confidential Submissions—**To submit any data analyses with confidential information that you do not wish to be made publicly available, submit your data and analyses only as a written/paper submission. You should submit two copies total of all data and analyses. 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 any decisions on this matter. 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> or available at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday. Submit both copies to the Dockets Management Staff. Any information marked as “confidential” will not be disclosed

except in accordance with 21 CFR 10.20 and other applicable disclosure law.

Comments Submitted by Other Interested Parties: For all comments submitted by other interested parties, submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and

Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2025-N-4684 for "Egis Pharmaceuticals Limited, et.al.; Proposal to Withdraw Approval of Three Abbreviated New Drug Applications; Opportunity for a Hearing." 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.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993-0002, 301-796-3471, Martha.Nguyen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The holder of an approved ANDA to market a new drug for human use is required to submit annual reports to FDA concerning its approved ANDA under §§ 314.81 and 314.98 (21 CFR 314.81 and 21 CFR 314.98). The holders of the approved ANDAs listed in table 1 have repeatedly failed to submit the required annual reports and have not responded to the Agency's request for submission of the reports.

TABLE 1—APPROVED ANDAS FOR WHICH REQUIRED REPORTS HAVE NOT BEEN SUBMITTED

Application No.	Drug	Applicant
ANDA 060453	Bacitracin-neomycin sulfate-polymyxin B sulfate ointment with dipiperodon hydrochloride (HCl).	Ambix Laboratories, 55 West End Rd., Totowa, NJ 07512.
ANDA 074748	Captopril tablet, 12.5 mg, 25 mg, 50 mg, and 100 mg	Egis Pharmaceuticals Ltd., 1475 Budapest 10 Pf. 100 HUNGARY.
ANDA 074808	Piroxicam capsule, 10 mg and 20 mg	Do.

Therefore, under §§ 314.150(b)(1) and 314.200, notice is given to the holders of the approved ANDAs listed in table 1 and to all other interested persons that the Director of CDER proposes to issue an order, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)), withdrawing approval of the ANDAs and all amendments and supplements thereto on the grounds that the ANDA

holders have failed to submit reports required under § 314.81 and 314.98.

In accordance with section 505 of the FD&C Act and part 314 (21 CFR part 314), the ANDA holders are hereby provided an opportunity for a hearing to show why the approval of the ANDA listed previously should not be withdrawn and an opportunity to raise, for administrative determination, all

issues relating to the legal status of the drug products covered by these ANDAs.

An ANDA holder who decides to seek a hearing must file the following: (1) A written notice of participation and request for a hearing (see **DATES** and **ADDRESSES**) and (2) the data, information, and analyses relied on to demonstrate that there is a genuine and substantial issue of fact that requires a hearing (see **DATES** and **ADDRESSES**). Any

other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, notice of participation and request for a hearing, the information, and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in § 314.200 and in 21 CFR part 12.

The failure of an ANDA holder to file a timely written notice of participation and request for a hearing, as required by § 314.200, constitutes an election by that ANDA holder not to avail itself of the opportunity for a hearing concerning CDER's proposal to withdraw approval of the ANDAs and constitutes a waiver of any contentions concerning the legal status of the drug products. FDA will then withdraw approval of the ANDAs, and the drug products may not thereafter be lawfully introduced or delivered for introduction into interstate commerce. Any new drug product introduced or delivered for introduction into interstate commerce without an approved ANDA is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If a request for a hearing is not complete or is not supported, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions under this notice of opportunity for a hearing must be filed in two copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <https://www.regulations.gov>.

This notice is issued under section 505(e) of the FD&C Act and under authority delegated to the Director of CDER by the Commissioner of Food and Drugs.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025-23870 Filed 12-23-25; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-3656]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practices for Positron Emission Tomography Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by January 28, 2026.

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 0910-0667. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Current Good Manufacturing Practices for Positron Emission Tomography Drugs—21 CFR Part 212

OMB Control Number 0910-0667—Extension

This information collection implements statutory and regulatory requirements that govern positron emission tomography (PET) drugs. FDA has promulgated regulations in 21 CFR part 212 establishing current good manufacturing practice (CGMP)

intended to ensure that PET drugs meet the requirements of the Federal Food, Drug, and Cosmetic Act (the act) regarding safety, identity, strength, quality, and purity. While regulations in 21 CFR part 212, subpart A set forth general provisions, additional requirements are established in 21 CFR part 212 as follows:

Subpart B—Personnel and Resources—212.10
 Subpart C—Quality Assurance—212.20
 Subpart D—Facilities and Equipment—212.30
 Subpart E—Control of Components, Containers, and Closures—212.40
 Subpart F—Production and Process Controls—212.50
 Subpart G—Laboratory Controls—212.60–212.61
 Subpart H—Finished Drug Product Controls and Acceptance—212.70–212.71
 Subpart I—Packaging and Labeling—212.80
 Subpart J—Distribution—212.90
 Subpart K—Complaint Handling—212.100
 Subpart L—Records—212.110

Records must be maintained at the PET drug production facility or another location that is reasonably accessible to responsible officials of the production facility and to employees of FDA designated to perform inspections. All records, including those not stored at the inspected establishment, must be legible, stored to prevent deterioration or loss, and readily available for review and copying by FDA employees. All records and documentation referenced in this part must be maintained for a period of at least 1 year from the date of final release, including conditional final release, of a PET drug product.

The regulations contain what we believe are the minimum standards for quality production of PET drugs at all types of PET drug production facilities. These CGMP requirements are designed according to the unique characteristics of PET drugs, including their short half-lives and because most PET drugs are produced at locations close to the patients to whom the drugs are administered. We have also taken into account that time spent on recording procedures, processes, and specifications may be somewhat higher in the year in which records are first established and correspondingly lower in subsequent years, when only updates and revisions will be required.

We have also issued Agency guidance entitled, "PET Drugs—Current Good Manufacturing Practice (CGMP)," (December 2009), available for download from our website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/pet-drug-products-current-good-manufacturing-practice-cgmp>. The guidance document communicates

FDA's thinking concerning compliance with the CGMP regulations. The guidance document addresses resources, procedures, and documentation for all PET drug production facilities, academic and commercial. In some cases, the guidance provides practical examples of methods or procedures that

PET drug production facilities can use to comply with the CGMP requirements.

Respondents to the information collection include are PET production facilities, including academic or hospital facilities as well as commercial facilities.

In the **Federal Register** of September 25, 2025 (90 FR 46218), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of the collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

Required recordkeeping activity; 21 CFR 212	Number of recordkeepers	Records per recordkeeper	Total annual records	Average burden per record	Total hours
Academia, Small Firms, & High-Risk Component Manufacture Records.	76	~824.26	62,644	~.81 (50 minutes) ..	50,862
Corporate Firm Records	91	~1,447.10	131,686	~.35 (21 minutes) ..	45,728
External Control Testing Laboratory Records	23	145	3,335	~.67 (40 minutes) ..	2,243
Total			197,665		98,833

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL DISCLOSURE BURDEN

Notifications required under 21 CFR 212.70	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Sterility Testing Failures	11	3	33	2.5	83

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Totals have been rounded to the nearest whole number.

³ Two reports are sent to FDA per incident, and one notification is sent to the receiving site.

Our estimated burden for the information collection reflects an overall increase of 14,348 hours and a corresponding increase of 12,851 records. We attribute this adjustment to an increase in our estimate of the number of small firms due to new facilities.

Brian Fahey,

Associate Commissioner for Legislation.

[FR Doc. 2025-23859 Filed 12-23-25; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2024-E-1284; FDA-2024-E-1285; FDA-2024-E-1286; FDA-2024-E-1287; FDA-2024-E-1288]

Determination of Regulatory Review Period for Purposes of Patent Extension; ADZYNMA

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 ADZYNMA and is publishing this notice of that determination as required

by law. FDA has made the determination because of the submission of applications 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 biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by February 27, 2026. Furthermore, any interested person may petition FDA for a determination regarding whether the applicants for extension acted with due diligence during the regulatory review period by June 29, 2026. 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 February 27, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket Nos. FDA-2024-E-1284; FDA-2024-E-1285; FDA-2024-E-1286; FDA-2024-E-1287; and FDA-2024-E-1288 for

“Determination of Regulatory Review Period for Purposes of Patent Extension; ADZYNMA.” 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: Jack Dan, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6200, Silver Spring, MD 20993, 240-402-6940.

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 biologic 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 applicants may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological 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 biological 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 biologic product ADZYNMA (ADAMTS13, recombinant-krhn). ADZYNMA is indicated for prophylactic or on-demand enzyme replacement therapy (ERT) in adult and pediatric patients with congenital thrombotic thrombocytopenic purpura (cTTP). Subsequent to this approval, the

USPTO received patent term restoration applications for ADZYNMA (U.S. Patent Nos. 7,517,522; 8,623,352; 9,351,935; 9,572,778; 10,758,599) from Regents of the University of Michigan and Takeda Pharmaceutical Company Limited, and the USPTO requested FDA’s assistance in determining the patents’ eligibility for patent term restoration. In a letter dated June 27, 2025, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of ADZYNMA 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 ADZYNMA is 4,059 days. Of this time, 3,821 days occurred during the testing phase of the regulatory review period, while 238 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 (21 U.S.C. 355(i)) became effective:* September 30, 2012. Regents of the University of Michigan claims that September 28, 2012, is the date the investigational new drug application (IND) became effective. Takeda Pharmaceutical Company Limited claims that September 29, 2012, is the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was September 30, 2012, which was the first date after receipt of the IND that the investigational studies were allowed to proceed.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* March 17, 2023. FDA has verified the applicants’ claim that the biologics license application (BLA) for ADZYNMA (BLA 125795) was initially submitted on March 17, 2023.

3. *The date the application was approved:* November 9, 2023. FDA has verified the applicants’ claim that BLA 125795 was approved on November 9, 2023.

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 application for patent extension, the applicants seek 702, 1,346, 1,479,

1,916 days or 5 years 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 applicants 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 applicants. (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.

Brian Fahey,

Associate Commissioner for Legislation.

[FR Doc. 2025–23864 Filed 12–23–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–E–0917]

Determination of Regulatory Review Period for Purposes of Patent Extension; ALHEMO

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 ALHEMO 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 biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by February 27, 2026. 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 June 29, 2026. 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 February 27, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management

Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2025–E–0917 for “Determination of Regulatory Review Period for Purposes of Patent Extension; ALHEMO.” 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: Jack Dan, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6200, Silver Spring, MD 20993, 240-402-6940.

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 biologic 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 biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological 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 biological 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 biologic product ALHEMO (concizumab-mtci). ALHEMO is indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with:

- hemophilia A (congenital factor VIII deficiency) with FVIII inhibitors
- hemophilia B (congenital factor IX deficiency) with FIX inhibitors

Subsequent to this approval, the USPTO received a patent term restoration application for ALHEMO (U.S. Patent No. 8,361,469) from Novo Nordisk A/S, and the USPTO requested FDA's

assistance in determining this patent's eligibility for patent term restoration. In a letter dated June 27, 2025, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of ALHEMO 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 ALHEMO is 3,475 days. Of this time, 2,625 days occurred during the testing phase of the regulatory review period, while 850 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 (21 U.S.C. 355(i)) became effective:* June 18, 2015. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on June 18, 2015

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* August 24, 2022. FDA has verified the applicant's claim that the biologics license application (BLA) for ALHEMO (BLA 761315) was initially submitted on August 24, 2022.

3. *The date the application was approved:* December 20, 2024. FDA has verified the applicant's claim that BLA 761315 was approved on December 20, 2024.

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 application for patent extension, this applicant seeks 1,826 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.

Brian Fahey,

Associate Commissioner for Legislation.

[FR Doc. 2025-23863 Filed 12-23-25; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-P-5560]

Medical Devices; Exemption From Premarket Notification: Radiology Computer-Aided Detection and/or Diagnosis Devices and Computer-Aided Triage and Notification Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that it has received a petition requesting partial exemption from the premarket notification requirements for radiology computer-aided detection and/or diagnosis devices and computer-aided triage and notification devices. Specifically, the petition requests exemption from the premarket notification requirements for the following generic device types when certain conditions described in the petition are met: radiological computer-assisted diagnostic software for lesions suspicious of cancer; medical image analyzers; radiological computer aided triage and notification software; and radiological computer-assisted detection and diagnosis software. FDA is publishing this notice to obtain comments in accordance with procedures established by the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments on the notice by February 27, 2026.

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 February 27, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2025-P-5560 for "Medical Devices; Exemption from Premarket Notification: Radiology Computer-Aided Detection and/or Diagnosis Devices and Computer-Aided Triage and Notification Devices." 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: Gugandeep Kaur, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5504, Silver Spring, MD 20993-0002, 240-402-9534.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

The FD&C Act, as amended, 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)

establishes 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 (special controls), and class III (premarket approval).

Section 513(a)(1) of the FD&C Act defines the three classes of devices. Class I devices are those devices for which the general controls of the FD&C Act (controls authorized by or under section 501, 502, 510, 516, 518, 519, or 520 (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, or 360j) or any combination of such sections) are sufficient to provide reasonable assurance of safety and effectiveness of the device; or those devices for which insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of safety and effectiveness or to establish special controls to provide such assurance, but because the devices are not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and do not present a potential unreasonable risk of illness or injury, are to be regulated by general controls (section 513(a)(1)(A) of the FD&C Act).

Class II devices are those devices for which general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including the issuance of performance standards, post-market surveillance, patient registries, development and dissemination of guidelines, recommendations, and other appropriate actions FDA deems necessary to provide such assurance (section 513(a)(1)(B) of the FD&C Act).

Class III devices are those devices for which insufficient information exists to determine that general controls and special controls would provide a reasonable assurance of safety and effectiveness, and are purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury (section 513(a)(1)(C) of the FD&C Act).

Under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and FDA's implementing regulations in part 807 (21 CFR part 807), persons who propose to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use are required to

submit a premarket notification (510(k)) to FDA. The device may not be marketed until FDA finds it “substantially equivalent” within the meaning of section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a legally marketed device that does not require premarket approval.

The 21st Century Cures Act (Pub. L. 114–255) (Cures Act) was signed into law on December 13, 2016. Section 3054 of the Cures Act amended section 510(m) of the FD&C Act. As amended, section 510(m)(1) of the FD&C Act requires that within 90 days of the date of enactment of the Cures Act, and at least once every 5 years thereafter (as FDA determines appropriate), FDA publish in the **Federal Register** a notice containing a list of each type of class II device that FDA determines no longer requires a report under section 510(k) of the FD&C Act to provide reasonable assurance of safety and effectiveness. Additionally, section 510(m)(2) of the FD&C Act provides that FDA may exempt a class II device from the requirement to submit a report under section 510(k) of the FD&C Act, upon its own initiative or a petition of an interested person, if FDA determines that a report under section 510(k) is not necessary to assure the safety and effectiveness of the device. FDA must publish in the **Federal Register** notice of its intent to exempt the device, or of the petition, and provide a 60-calendar-day period for public comment. Within 120 days after the issuance of this notice, FDA must publish an order in the **Federal Register** that sets forth its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the **Federal Register** of January 21, 1998 (63 FR 3142) and subsequently in the guidance the Agency issued on February 19, 1998, entitled “Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff” (available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/procedures-class-ii-device-exemptions-premarket-notification-guidance-industry-and-cdrh-staff>).

Accordingly, FDA generally considers the following factors to determine

whether a report under section 510(k) is necessary or if an exemption would be appropriate for class II devices: (1) the device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device; (2) characteristics of the device necessary for its safe and effective performance are well established; (3) changes in the device that could affect safety and effectiveness will either (a) be readily detectable by users by visual examination or other means such as routine testing, before causing harm, or (b) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and (4) any changes to the device would not be likely to result in a change in the device’s classification. FDA may also consider that, even when exempting devices from the 510(k) requirements, these devices would still be subject to the general limitations on exemptions (see 21 CFR 892.9).

III. Proposed Class II Device Exemptions

FDA has received the following petition requesting partial exemption from the premarket notification requirements for certain class II devices: Nancy Stade, J.D., of Rubrum Advising, LLC, 404 Pembroke Rd., Bala Cynwyd, PA 19004, on behalf of Harrison.ai, for the following devices:

- Radiological computer-assisted diagnostic software for lesions suspicious of cancer, classified under § 892.2060 (21 CFR 892.2060), product code POK.
- Medical image analyzer, classified under § 892.2070 (21 CFR 892.2070), product code MYN.
- Radiological computer aided triage and notification software, classified under § 892.2080 (21 CFR 892.2080), product codes QAS and QFM.
- Radiological computer-assisted detection and diagnosis software, classified under § 892.2090 (21 CFR 892.2090), product codes QBS and QDQ.

The petition requests exemption from the premarket notification requirements for these devices when:

- The manufacturer has previously obtained a 510(k);
- For devices under § 892.2080, the manufacturer must have at least one clearance under the same classification regulation;
- For devices under § 892.2060, 892.2070, or 892.2090, the manufacturer must have at least one clearance under any of those same three classification regulations;
- The manufacturer must implement a robust post-market plan, transparency,

and training measures as described in the petition; and

- All existing special controls, quality systems, establishment registration, and device listing requirements will remain in force.

FDA seeks comment on the petition in accordance with section 510(m)(2) of the FD&C Act.

IV. Paperwork Reduction Act of 1995

While this notice contains no 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 (44 U.S.C. 3501–3521). The collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–23901 Filed 12–23–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health Disparities; Notice of Partially Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council on Minority Health and Health Disparities.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (<http://videocast.nih.gov/>).

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant

applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council on Minority Health and Health Disparities.

Date: February 6, 2026.

Open: 10:00 a.m. to 3:00 p.m.

Agenda: Opening Remarks, Administrative Matters, Director's Report, Presentations, and Other Business of the Council.

Closed: 3:30 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Meeting Format: Virtual Meeting.

Address: National Institutes of Health, 6707 Democracy Boulevard, Bethesda, MD 20892.

Contact Person: Paul Cotton, Ph.D., RDN, Director, Office of Extramural Research Activities, National Institute on Minority Health and Health Disparities, National Institutes of Health, 6707 Democracy Boulevard, Suite 800, Bethesda, MD 20892, 301-402-1366, paul.cotton@nih.gov.

The meeting identified below has been scheduled in the event the Council is unable to complete all agenda items identified for the February 6, 2026, meeting. Information on the agenda items and/or the necessity to hold the meeting listed below will be posted on the Institute/Center homepage (link identified below).

Name of Committee: National Advisory Council on Minority Health and Health Disparities.

Date: March 27, 2026.

Open: 10:00 a.m. to 3:00 p.m.

Agenda: Opening Remarks, Administrative Matters, Director's Report, Presentations, and Other Business of the Council not completed at the February meeting.

Closed: 3:30 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications not completed at the February meeting.

Meeting Format: Virtual Meeting.

Address: National Institutes of Health, 6707 Democracy Boulevard, Bethesda, MD 20892.

Contact Person: Paul Cotton, Ph.D., RDN, Director, Office of Extramural Research Activities, National Institute on Minority Health and Health Disparities, National Institutes of Health, 6707 Democracy Boulevard, Suite 800, Bethesda, MD 20892, 301-402-1366, paul.cotton@nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has procedures at <https://www.nih.gov/about-nih/visitor-information/campus-access-security> for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-

issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: NIMHD: <https://www.nimhd.nih.gov/about/advisory-council/>, where an agenda and any additional information for the meeting will be posted when available.

Zieta M. Charles,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-23889 Filed 12-23-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Partially Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Mental Health Council.

The meeting will be held as a virtual meeting and open to the public, as indicated below. Individuals who plan to view the virtual meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should submit a request using the following link: <https://www.nigms.nih.gov/Pages/ContactUs.aspx> at least 5 days prior to the event. The open session will also be videocast, closed captioned, and can be accessed from the NIH Videocasting and Podcasting website (<http://videocast.nih.gov>).

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.

The meeting identified below has been scheduled in the event the Council is unable to complete all agenda items identified for the February 5, 2026, meeting. Information on the agenda items and/or the necessity to hold the meeting listed below will be posted on the Institute/Center homepage (link identified below).

Name of Committee: National Advisory General Medical Sciences Council.

Date: March 18, 2026.

Open: 9:30 a.m. to 12:00 p.m.

Agenda: For the discussion of programs; opening remarks; report of the Director, NIGMS; and other business of the NAGMSC not completed at the February meeting.

Address: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892, Virtual Meeting.

Closed: 1:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications not completed at the February meeting.

Address: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892, Virtual Meeting.

Contact Person: Ariel Zane, Ph.D., Acting Director, Division of Extramural Activities, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 2AN24C, Bethesda, MD 20892, 301-594-3584, ariel.zane@nih.gov.

Registration is not required to attend the open portion of this meeting.

Any interested person may file written comments with the committee by forwarding the statement to *NIGMS DEA Mailbox@nigms.nih.gov* at least 3 days in advance of the meeting. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: <https://www.nigms.nih.gov/about/council/Pages/default>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program No. 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Zieta M. Charles,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-23835 Filed 12-23-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Cellular Signaling and Regulatory Mechanisms.

Date: January 22, 2026.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Jimok Kim, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 402-8559, jimok.kim@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Cancer Genetics, Initiation and Transcriptional Regulation.

Date: January 26, 2026.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Wing-hang Tong, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (302) 402-0360, tongw@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: NIGMS Predoctoral Research Training Program & NRSA Institutional Research Training Grant Review (T32, T35).

Date: January 30, 2026.

Time: 9:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: MIR AHAMED Hossain, Ph.D., Scientific Review Officer, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, (301) 496-9223, mirahamed.hossain@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: December 18, 2025.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-23833 Filed 12-23-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under the Office of Management and Budget (OMB) review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-0661.

Project: Extension to SAMHSA's 0930-0393 Fast Track Generic Clearance for the Collection of Qualitative Feedback on the Substance Abuse and Mental Health Services Administration (SAMHSA) Service Delivery

Executive Order 12862 directs Federal agencies to provide service to the public that matches or exceeds the best service available in the private sector. In order to work continuously to ensure that our programs are effective and meet our customers' needs, SAMHSA seeks to obtain the OMB approval of a generic clearance to collect qualitative feedback on our service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions but are not statistical surveys that yield quantitative results that can be generalized to the population of study.

This collection of information is necessary to enable SAMHSA to garner customer and stakeholder feedback in an efficient, timely manner, in accordance with our commitment to improving service delivery. The information collected from our customers and stakeholders will help ensure that users have an effective, efficient, and satisfying experience with SAMHSA's programs. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections

will allow for ongoing, collaborative and actionable communications between SAMHSA and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

This is an extension to the currently approved 0930-0393 Fast Track Generic Clearance for the Collection of Qualitative Feedback on SAMHSA Service Delivery which replaced multiple previously approved SAMHSA information collections including 0930-0197 Voluntary Customer Satisfaction Surveys to Implement Executive Order 12862 in SAMHSA, 0930-0196 Pretesting of Substance Abuse Prevention and Treatment and Mental Health Services Communications Messages, and 0930-0313 SAMHSA's Publications and Digital Products website Registration Survey. Changes were not made to this Information Collection Request from the previous approval. The information collections (ICs) under Generic collections 0930-0196 and 0930-0197 were transferred to the Fast Track Generic. After the IC transferred, the 0196 and 0197 Generic collections were discontinued. The 0930-0313 SAMHSA's Publications and Digital Products website Registration Survey consisted of customer satisfaction/feedback questions along with a SAMHSA website survey and a SAMHSA store survey developed utilizing the main pool of questions. The 0930-0313 information collection became an IC under the new Fast Track once it was approved and the 0313-information collection request (ICR) was discontinued. SAMHSA will continue due diligence to improve efficiency and lower burden by determining if other information collections are better served by becoming part of the Fast Track Generic.

A variety of instruments and platforms will be used to collect information from respondents. The annual burden hours requested (60,250) are based on the number of collections we expect to conduct over the requested period for this clearance. The burden estimates were calculated based on replacing previously approved burden hours for ICRs 0930-0197, 0930-0196 and 0930-0313 and internal assessments of projected IC submission over the next three years.

ESTIMATED ANNUAL REPORTING BURDEN

Type of collection	Number of respondents	Response per respondent	Hours per response	Total hours	Hourly wage rate (\$)	Total hour costs (\$)
In-person surveys, online surveys, telephone interviews/surveys, in-person observation/testing, interviews	75,000	1	0.37	27,750	\$27.00	\$749,250.00
Focus groups	10,000	1	2	20,000	27.00	540,000.00
Self-administered questionnaires, customer comment cards, interactive voice surveys	10,000	1	0.25	2,500	27.00	67,500.00
Unspecified collection formats	10,000	1	1	10,000	27.00	270,000.00
Totals	105,000			60,250		1,626,750.00

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.

Alicia Broadus,

Public Health Advisor.

[FR Doc. 2025–23777 Filed 12–23–25; 8:45 am]

BILLING CODE P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation of Altol Chemical and Environmental Laboratory (Ponce, PR) as a Commercial Laboratory

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

ACTION: Notice of accreditation of Altol Chemical and Environmental Laboratory (Ponce, PR), as a commercial laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Altol Chemical and Environmental Laboratory (Ponce, PR), has been accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of September 5, 2024.

DATES: Altol Chemical and Environmental Laboratory (Ponce, PR) was accredited as a commercial laboratory as of September 5, 2024. The

next triennial inspection date will be scheduled for September 2027.

FOR FURTHER INFORMATION CONTACT: Mr. Robert P. Munivez, Laboratories and Scientific Services, U.S. Customs and Border Protection, 4150 Interwood South Parkway, Houston, TX 77032, tel. 281–560–2937.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12, that Altol Chemical and Environmental Laboratory, 228 Sabanetas Industrial Park, Ponce, PR 00716, has been accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12.

Altol Chemical and Environmental Laboratory (Ponce, PR) is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–01	D287	Standard Test Method for API Gravity of Crude Petroleum and Petroleum Products (Hydrometer Method).
27–02	D1298	Standard Test Method for Density, Relative Density, or API Gravity of Crude Petroleum and Liquid Petroleum Products by Hydrometer Method.
27–11	D445	Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids (and Calculation of Dynamic Viscosity).
27–13	D4294	Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-ray Fluorescence Spectrometry.
27–48	D4052	Standard Test Method for Density, Relative Density, and API Gravity of Liquids by Digital Density Meter.

Anyone wishing to employ this entity to conduct laboratory analyses should request and receive written assurances from the entity that it is accredited by the U.S. Customs and Border Protection to conduct the specific test requested. Alternatively, inquiries regarding the specific test this entity is accredited to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to CBPGaugersLabs@cbp.dhs.gov. Please reference the website listed below for a complete listing of CBP approved gaugers and accredited laboratories. <http://>

www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories.

Aine M. Ramirez,

Laboratory Director, Houston, Laboratories and Scientific Services.

[FR Doc. 2025–23898 Filed 12–23–25; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF THE INTERIOR

Geological Survey

[Docket No. USGS–2025–0007; OMB Control Number 1028–0087; GX25GL00DT7ST00]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; National Geological and Geophysical Data Preservation Program (NGGDPP)

AGENCY: U.S. Geological Survey, Interior.

ACTION: Notice of Information Collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the U.S. Geological Survey (USGS) is proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before January 28, 2026.

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

■ *Internet:* <https://www.regulations.gov>.

Search for and submit comments on Docket No. USGS–2025–0007.

■ *U.S. Mail:* USGS, Information Collections Clearance Officer, 12201 Sunrise Valley Drive, MS 159, Reston, VA 20192.

FOR FURTHER INFORMATION CONTACT:

Michele Wolf by email at mwolf@usgs.gov, or by telephone at (720) 326–0284. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. You also may view the ICR at <http://www.reginfo.gov/public/do/PRAMain>.

SUPPLEMENTARY INFORMATION: In accordance with the PRA of 1995 (44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on July 23, 2025 (90 FR 34670). No comments were received.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again soliciting comments from the public and other Federal agencies on the proposed ICR that is described below. We are especially interested in public comments addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How the agency might 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, *e.g.*, permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personally identifiable information (PII) in your comment, you should be aware that your entire comment—including your PII—may be made publicly available at any time. While you can ask us in your comment to withhold your PII from public review, we cannot guarantee that we will be able to do so.

Abstract: This notice concerns the collection of information that is sufficient and relevant to evaluate and select proposals for funding under the NGGDPP. We will accept proposals from state geological surveys requesting funds to inventory and assess the condition of current collections and data preservation needs. Financial assistance will be awarded annually on a competitive basis following the evaluation and ranking of state proposals by a review panel composed of representatives from the U.S. Department of the Interior, state geological surveys, and academic institutions. To submit a proposal, respondents must complete a project narrative and submit the application via <http://www.grants.gov>. Grant recipients must complete a final technical report at the end of the project period. Narrative and report guidance is available at the NGGDPP website (NGGDPP Grants | U.S. Geological Survey) or <https://www.grants.gov> and <https://home.grantsolutions.gov>.

Annual data preservation priorities are provided in the Program Announcement as guidance for applicants to consider when submitting proposals. Since its inception in 2007, NGGDPP has awarded 46 states with \$32 million, which, when matched or exceeded by the states, amounts to over \$64 million invested in the rescue and preservation efforts. We will protect information from respondents considered proprietary under the Freedom of Information Act (5 U.S.C.

552) and implementing regulations (43 CFR part 2), and under regulations at 30 CFR 250.197, “Data and information to be made available to the public or for limited inspection.” Responses are voluntary. No questions of a “sensitive” nature are asked. We intend to release the project abstracts and identify states for awarded/funded projects only.

Title of Collection: National Geological and Geophysical Data Preservation Program (NGGDPP).

OMB Control Number: 1028–0087.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: All state geological surveys may apply for NGGDPP grants.

Total Estimated Number of Annual Respondents: 35.

Total Estimated Number of Annual Responses: 70 (35 applications, 35 final technical report submissions).

Estimated Completion Time per Response: Grant application time estimate is 80 hours; final technical report completion time estimate is 10 hours.

Total Estimated Number of Annual Burden Hours: 3,150.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: Annually.

Total Estimated Annual Nonhour Burden Cost: None.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the PRA of 1995 (44 U.S.C. 3501 *et seq.*).

Michele Wolf,

NGGDPP Science Advisor (acting).

[FR Doc. 2025–23888 Filed 12–23–25; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[267A2100DD/AAKC001030/
A0A501010.000000]

Receipt of Request for Authorization To Re-Petition for Federal Acknowledgment as an American Indian Tribe

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: The Department of the Interior (Department) announces that the group known as the Burt Lake Band of Ottawa and Chippewa Indians (BLB)

has submitted a request for authorization to re-petition for Federal acknowledgment as an American Indian Tribe to the Office of Federal Acknowledgment (OFA) under 25 CFR part 83, subpart D. The Department invites public comment and evidence concerning the request.

DATES: Comments and evidence must be postmarked by April 28, 2026.

ADDRESSES: The narrative portion of the re-petition request, submitted by BLB (with any redactions in accordance with 25 CFR 83.50(b)), is available at the OFA website: www.bia.gov/as-ia/ofa.

Comments and evidence may be submitted to: Department of the Interior, Office of the Assistant Secretary—Indian Affairs, Attention: Office of Federal Acknowledgment, Mail Stop 4071 MIB, 1849 C Street NW, Washington, DC 20240, or by email to: Ofa_Info@bia.gov.

FOR FURTHER INFORMATION CONTACT: Ms. Nikki Bass, OFA Director, Office of the Assistant Secretary—Indian Affairs, Department of the Interior, by phone: (202) 513-7650; or by email: Ofa_Info@bia.gov.

SUPPLEMENTARY INFORMATION: On March 21, 2025, the Department revised the Federal acknowledgment regulations in 25 CFR part 83 to establish a conditional and time-limited opportunity for petitioners denied Federal acknowledgment to request authorization to re-petition.

On August 22, 2025, OFA received a request for authorization to re-petition from BLB, in accordance with 25 CFR 83.50. This group has been assigned Petition Number R002.

The contact information for BLB is Bart T. Stupak, 600 Massachusetts Avenue NW, Washington, DC 20004.

Under 25 CFR 83.51(b)(1), OFA publishes on its website the following:

- i. The narrative portion of the request for authorization to re-petition, as submitted by the petitioner (with any redactions appropriate under 25 CFR 83.50(b));
- ii. The name, location, and mailing address of the petitioner and other information to identify the entity;
- iii. The date of receipt;
- iv. The opportunity for individuals and entities to submit comments and evidence supporting or opposing the petitioner's request for acknowledgment within 120 days of this notice of the request; and
- v. The opportunity for individuals and entities to request to be kept informed of general actions regarding the petitioner.

Authority

The Department publishes this notice and request for comment in the exercise

of authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by Department Manual part 209, chapter 8.

William Henry Kirkland III,

Assistant Secretary—Indian Affairs.

[FR Doc. 2025-23904 Filed 12-23-25; 8:45 am]

BILLING CODE 4337-15-P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[267A2100DD/AAKC001030/
A0A51010.000000]

Request for Nominations for Bureau of Indian Education Advisory Board for Exceptional Children

AGENCY: Bureau of Indian Affairs, Interior

ACTION: Notice of request for nominations.

SUMMARY: The Bureau of Indian Affairs is seeking nominations for individuals to be considered for appointment to the Advisory Board for Exceptional Children (Advisory Board). There will be five positions available to serve specifically in the areas of: Indian persons with disabilities; Teachers of children with disabilities; State education officials; Local Education Officials; State Interagency Coordinating Councils under Section 641 of the Act in States having Indian reservations; and Tribal representatives or tribal organization representatives. Advisory Board members shall serve a staggered term of two years or three years from the date of their appointment. The BIE will consider nominations received in response to this request for nominations, as well as other sources.

The **SUPPLEMENTARY INFORMATION** section of this notice provides committee and membership criteria.

DATES: Please submit nominations by February 27, 2026.

ADDRESSES: Please submit nominations to Ms. Jennifer Davis, Designated Federal Officer (DFO), Bureau of Indian Education, Division of Performance and Accountability, 2600 N Central Ave., Suite 800, Phoenix, AZ 85004, or Fax to (602) 265-0293 or email to jennifer.davis@bie.edu.

FOR FURTHER INFORMATION CONTACT: Jennifer Davis, DFO, at Telephone (202) 860-7845; or email jennifer.davis@bie.edu.

SUPPLEMENTARY INFORMATION: The Advisory Board was established in accordance with the Federal Advisory Committee Act, 5 U.S.C. Ch. 10. The

following provides information about the Committee, the membership, and the nomination process.

1. Objective and Duties

(a) Members of the Advisory Board will provide guidance, advice and recommendations with respect to special education and related services for children with disabilities in BIE funded schools in accordance with the requirements of IDEA.

(b) The Advisory Board will: (1) Provide advice and recommendations for the coordination of services within the BIE and with other local, State and Federal agencies; (2) Provide advice and recommendations on a broad range of policy issues dealing with the provision of educational services to American Indian children with disabilities; (3) Serve as advocates for American Indian students with special education needs by providing advice and recommendations regarding best practices, effective program coordination strategies, and recommendations for improved educational programming; (4) Provide advice and recommendations for the preparation of information required to be submitted to the Secretary of Education under 20 U.S.C. 1411 (h)(2); (5) Provide advice and recommend policies concerning effective inter/intra agency collaboration, including modifications to regulations, and the elimination of barriers to inter- and intra-agency programs and activities; and (6) Will report and direct all correspondence to the Assistant Secretary—Indian Affairs through the Director, BIE with a courtesy copy to the Designated Federal Officer (DFO).

2. Membership

(a) Pursuant to 20 U.S.C. 1411(h)(6), the Advisory Board will be composed of up to fifteen individuals involved in or concerned with the education and provision of services to American Indian infants, toddlers, children, and youth with disabilities. The Advisory Board composition will reflect a broad range of viewpoints and will include at least one member representing each of the following interests: American Indians with disabilities; teachers of children with disabilities; American Indian parents or guardians of children with disabilities; service providers; state education officials; local education officials; state interagency coordinating councils (for states having Indian reservations); tribal representatives or tribal organization representatives; and other members representing the various divisions and entities of the BIE.

(b) The Assistant Secretary—Indian Affairs may provide the Secretary of the Interior recommendations for the chairperson; however, the chairperson and other Advisory Board members will be appointed by the Secretary of the Interior. Advisory Board members shall serve staggered terms of two years or three years from the date of their appointment.

3. Miscellaneous

(a) Members of the Advisory Board will not receive compensation, but will be reimbursed for travel, including subsistence, and other necessary expenses incurred in the performance of their duties in the same manner as persons employed intermittently in Government Service under 5 U.S.C. 5703.

(b) The Advisory Board meets at least three or four times a year, budget permitting, but additional meetings may be held as deemed necessary by the Assistant Secretary—Indian Affairs or the DFO.

(c) All Advisory Board meetings are open to the public.

4. Nomination Information

(a) Nominations are requested from individuals, organizations, and federally recognized tribes, as well as from State Directors of Special Education (within the 23 states in which BIE-funded schools are located) concerned with the education of Indian children with disabilities as described above.

(b) Nominees should have expertise and knowledge of the issues and/or needs of American Indian children with disabilities. Such knowledge and expertise are needed to provide advice and recommendations to the BIE regarding the needs of American Indian children with disabilities.

(c) A summary of the candidates' qualifications (resume or curriculum vitae) must be included with a completed nomination application form, which is located on the Bureau of Indian Education website. Nominees must have the ability to attend Advisory Board meetings, carry out Advisory Board assignments, participate in teleconference calls, and work in groups.

5. Basis for Nominations

If you wish to nominate someone for appointment to the Advisory Board, please do not make the nomination until the person has agreed to have his or her name submitted to the BIE for this purpose. A person can also self-nominate.

6. Nomination Application

Please submit a complete application form and a copy of the nominee's resume or curriculum vitae to the DFO by February 27, 2026. The nomination application form can be found on the BIE website at <https://www.bie.edu/landing-page/special-education>

7. Information Collection

This collection of information is authorized by OMB Control Number 1076-0179, "Solicitation of Nominations for the Advisory Board for Exceptional Children" Dated: 11/30/2027.

Authority: 5 U.S.C. Ch. 10; 20 U.S.C. 1400 *et seq.*

William Henry Kirkland III,

Assistant Secretary—Indian Affairs.

[FR Doc. 2025-23831 Filed 12-23-25; 8:45 am]

BILLING CODE 4337-15-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-NERO-CEBE-39906; PPNECEBE00, PPMSPD1Z.Y00000]

Request for Nominations for the Cedar Creek and Belle Grove National Historical Park Advisory Commission

AGENCY: National Park Service, Interior.

ACTION: Request for nominations.

SUMMARY: The National Park Service (NPS), U.S. Department of the Interior, is requesting nominations for qualified persons to serve as members on the Cedar Creek and Belle Grove National Historical Park Advisory Commission (Commission).

DATES: Written nominations must be received by January 28, 2026.

ADDRESSES: Nominations or requests for further information should be sent to Karen Beck-Herzog, Site Manager, Cedar Creek and Belle Grove National Historical Park, P.O. Box 700, Middletown, Virginia 22645, or via email karen_beck-herzog@nps.gov.

FOR FURTHER INFORMATION CONTACT: Karen Beck-Herzog, via telephone (540) 868-0938.

SUPPLEMENTARY INFORMATION: The Commission was established in accordance with the Cedar Creek and Belle Grove National Historical Park Act of 2002 (16 U.S.C. 410iii-7). The Commission was designated by Congress to provide advice to the Secretary of the Interior on the preparation and implementation of the park's general management plan and in the identification of sites of significance outside the park boundary.

The Commission consists of 15 members appointed by the Secretary, as follows:

(a) 1 representative from the Commonwealth of Virginia; (b) 1 representative each from the local governments of Strasburg, Middletown, Frederick County, Shenandoah County, and Warren County; (c) 2 representatives of private landowners within the Park; (d) 1 representative from a citizen interest group; (e) 1 representative from the Cedar Creek Battlefield Foundation; (f) 1 representative from the Belle Grove, Incorporated; (g) 1 representative from the National Trust for Historic Preservation; (h) 1 representative from the Shenandoah Valley Battlefields Foundation; (i) 1 ex-officio representative from the National Park Service; and (j) 1 ex-officio representative from the United States Forest Service. Alternate members may be appointed to the Commission.

We are currently seeking primary and alternate members to represent Belle Grove, Inc., the Cedar Creek Battlefield Foundation, the Shenandoah Valley Battlefields Foundation, the National Trust for Historic Preservation, the Town of Strasburg, the Town of Middletown, Shenandoah County, Frederick County, Warren County, and private landowners within the Park.

Each member shall be appointed for a term of three years and may be reappointed for not more than two successive terms. A member may serve after the expiration of that member's term until a successor has been appointed. The Chairperson of the Commission shall be elected by the members to serve a term of one-year renewable for one additional year.

Nominations should be typed and should include a resume providing an adequate description of the nominee's qualifications, including information that would enable the Department of the Interior to make an informed decision regarding meeting the membership requirements of the Commission and permit the Department to contact a potential member. All documentation, including letters of recommendation, must be compiled and submitted in one complete package. All those interested in membership must follow the nomination process.

Members of the Commission serve without compensation. However, while away from their homes or regular places of business in the performance of services for the Commission as approved by the NPS, members may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as persons employed

intermittently in Government service are allowed such expenses under 5 U.S.C. 5703.

Authority: 5 U.S.C. Ch. 10.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2025–23878 Filed 12–23–25; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

[RR02054000, 26XR0680A1, RX021489457000000]

Central Valley Project Improvement Act 2026 Criteria for Evaluating Water Management Plans (Standard Criteria)

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of availability.

SUMMARY: The Bureau of Reclamation (Reclamation) has made available the draft 2026 Criteria for Evaluating Water Management Plans (Standard Criteria) for public review and comment.

DATES: Interested persons are invited to submit comments on the draft 2026 Standard Criteria on or before March 30, 2026.

ADDRESSES: Send written comments to Mr. Thomas Hawes, Bureau of Reclamation, Attention: CBG–400, 2800 Cottage Way, Sacramento, CA 95825; or via email at thawes@usbr.gov. To view a copy of the draft 2026 Standard Criteria, go to <https://www.usbr.gov/mp/watershare>.

FOR FURTHER INFORMATION CONTACT: Mr. Thomas Hawes at (916) 978–5271, or via email at thawes@usbr.gov, regarding the Standard Criteria or to be placed on a mailing list for any subsequent information.

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: Section 3405(e) of the Central Valley Project Improvement Act (Pub. L. 102–575, title 34) requires the Secretary of the Interior to, among other things, “develop criteria for evaluating the adequacy of all water conservation plans” developed by certain contractors. According to section 3405(e)(1), these criteria must promote “the highest level of water use efficiency reasonably achievable by

project contractors using best available cost-effective technology and best management practices.” In accordance with this legislative mandate, Reclamation developed and published the Standard Criteria, which is updated every 3 years.

Public Disclosure. We invite the public to comment on our preliminary (i.e., draft) 2026 Standard Criteria. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Scott Springer,

Acting Regional Resources Manager, Division of Resources Management, California-Great Basin—Interior Region 10.

[FR Doc. 2025–23911 Filed 12–23–25; 8:45 am]

BILLING CODE 4332–90–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–512 and 731–TA–1248 (Second Review)]

Carbon and Certain Alloy Steel Wire Rod From China; Determinations

On the basis of the record¹ developed in the subject five-year reviews, the United States International Trade Commission (“Commission”) determines, pursuant to the Tariff Act of 1930 (“the Act”), that revocation of the countervailing and antidumping duty orders on carbon and certain alloy steel wire rod from China would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

Background

The Commission instituted these reviews on May 1, 2025 (90 FR 18704) and determined on August 4, 2025, that it would conduct expedited reviews (90 FR 45958, September 24, 2025).

The Commission made these determinations pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)). It completed and filed its determinations in these reviews on December 22, 2025. The views of the Commission are contained in USITC Publication 5692

¹ The record is defined in § 207.2(f) of the Commission’s Rules of Practice and Procedure (19 CFR 207.2(f)).

(December 2025), entitled *Carbon and Certain Alloy Steel Wire Rod from China: Investigation Nos. 701–TA–512 and 731–TA–1248 (Second Review)*.

By order of the Commission.

Issued: December 22, 2025.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2025–23913 Filed 12–23–25; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–919 (Fourth Review)]

Certain Welded Large Diameter Line Pipe from Japan

Determination

On the basis of the record¹ developed in the subject five-year review, the United States International Trade Commission (“Commission”) determines, pursuant to the Tariff Act of 1930 (“the Act”), that revocation of the antidumping duty order on Certain Welded Large Diameter Line Pipe from Japan would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

Background

The Commission instituted this review on September 3, 2024 (89 FR 71417) and determined on December 9, 2024, that it would conduct a full review (90 FR 6010, January 17, 2025). Notice of the scheduling of the Commission’s review and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** on March 13 (90 FR 11995).² The Commission conducted its hearing on September 11, 2025. All persons who requested the opportunity were permitted to participate.

The Commission made this determination pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)). It completed and filed its determination in this review on December 19, 2025. The views of the Commission are contained

¹ The record is defined in § 207.2(f) of the Commission’s Rules of Practice and Procedure (19 CFR 207.2(f)).

² Due to the lapse in appropriations and ensuing cessation of Commission operations, the Commission tolled its schedule for this proceeding. The schedule was revised in a subsequent notice published in the **Federal Register** on November 21, 2025 (90 FR 52696).

in USITC Publication 5689 (December 2025), entitled *Certain Welded Large Diameter Line Pipe from Japan: Investigation No. 731-TA-919 (Fourth Review): Certain Welded Large Diameter Line Pipe from Japan*.

By order of the Commission.

Issued: December 19, 2025.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2025-23803 Filed 12-23-25; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1471]

Certain Clear Aligners and Components Thereof; 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 September 23, 2025, under section 337 of the Tariff Act of 1930, as amended, on behalf of Align Technology, Inc. of Tempe, Arizona. A letter supplementing the complaint was filed on November 20, 2025. 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 clear aligners and components thereof by reason of the infringement of certain claims of U.S. Patent No. 11,766,313 (“the ‘313 patent”); U.S. Patent No. 11,766,314 (“the ‘314 patent”); U.S. Patent No. 8,899,977 (“the ‘977 patent”); U.S. Patent No. 12,059,321 (“the ‘321 patent”); U.S. Patent No. 10,980,616 (“the ‘616 patent”); and U.S. Patent No. 11,490,996 (“the ‘996 patent”). The complaint further alleges that an industry in the United States exists as required by the applicable Federal Statute.

The complainant requests that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and 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: Susan Orndoff, The Office of Docket Services, U.S. International Trade Commission, telephone (202) 205–1802.

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 (2025).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on December 19, 2025, *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 and 16 of the ‘313 patent; claims 1, 11, and 21 of the ‘314 patent; claims 1 and 9 of the ‘977 patent; claim 1 of the ‘321 patent; claims 1, 12, and 20 of the ‘616 patent; and claims 1, 17, and 21 of the ‘996 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 “clear plastic aligners used to treat misaligned teeth and bites, and components of those aligners including the tri-layer material used to construct the aligner”;

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is:

Align Technology, Inc., 410 North Scottsdale Road, Suite 1300, Tempe, Arizona 85288

(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:

Angelalign Technology Inc., 6/F–7/F, Building No. 7, KIC Business Center, No. 500 Zhengli Road, Yangpu District, Shanghai, China

Wuxi EA Medical Instruments, Technologies Co., Ltd., No.1619, Huishan Avenue, Huishan Economic Development Zone, Wuxi, Jiangsu 214174, China

Wuxi EA Bio-Tech Co., Ltd., No. 36 Guanshan Road, Xinwu District, Wuxi, Jiangsu 214000, China

Shanghai EA Medical Instruments Co., Ltd., Room 601–603, No. 500 Zhengli Road, Yangpu District, Shanghai 200433, China

USA Angelalign Technology Corp., 300 Creek View Rd Ste 209, Newark, DE 19711–8548

(3) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

The Office of Unfair Import Investigations will not participate as a party in this investigation.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission’s Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: December 19, 2025.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2025–23801 Filed 12–23–25; 8:45 am]

BILLING CODE 7020-02-P

**INTERNATIONAL TRADE
COMMISSION**

[Investigation Nos. 731–TA–986–987 (Fourth Review)]

**Ferrovandium From China and South
Africa; 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 ferrovandium from China and South Africa would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time.

DATES: November 24, 2025.

FOR FURTHER INFORMATION CONTACT: Alec Resch (202–708–1448), 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 November 24, 2025, the Commission determined that the domestic interested party group response to its notice of institution (90 FR 28774, July 1, 2025) 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)).

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 January 30, 2026. 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,² 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 February 4, 2026 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 February 4, 2026. 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 Tariff Act of 1930; this notice is published pursuant to § 207.62 of the Commission’s rules.

By order of the Commission.

Issued: December 22, 2025.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2025–23874 Filed 12–23–25; 8:45 am]

BILLING CODE 7020–02–P

**INTERNATIONAL TRADE
COMMISSION****Notice of Receipt of Complaint;
Solicitation of Comments Relating to
the Public Interest**

AGENCY: U.S. International Trade
Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Processed Slabs and Methods for Making Same, DN 3870*; the Commission is soliciting comments on any public interest issues raised by the complaint or complainant’s filing pursuant to the Commission’s Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission’s Electronic Document Information System (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email EDIS3Help@usitc.gov.

General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at <https://www.usitc.gov>. The public record for this investigation may be viewed on the Commission’s Electronic Document Information System (EDIS) at <https://edis.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission’s TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint

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 The Commission has found the joint response submitted on behalf of the Vanadium Producers and Reclaimers Association, AMG Vanadium LLC, and U.S. Vanadium, LLC to be individually adequate. Comments from other interested parties will not be accepted (see 19 CFR 207.62(d)(2)).

and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf Cambria Company LLC on December 19, 2025. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain processed slabs and methods for making same. The complaint names as respondents: Surface Warehouse, L.P. d/b/a US Surfaces and d/b/a Vadara Quartz Surfaces of Austin, TX; MSI International Inc. d/b/a MSI of Orange, CA; Arizona Tile, LLC of Tempe, AZ; OHM International Inc. of Monroe Twp, NJ; Architectural Surfaces Group LLC of Spicewood, TX; Caesarstone Ltd. of Israel; Caesarstone USA, Inc. of Charlotte, NC; LX Hausys, Ltd. of South Korea; LX Hausys America, Inc. of Alpharetta, GA; Mohawk Industries, Inc. of Calhoun, GA; and Dal-Tile, LLC of Dallas, TX. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders, and impose a bond upon respondents' alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j). Proposed respondents, other interested parties, members of the public, and interested government agencies are invited to file comments on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and

desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due, notwithstanding § 201.14(a) of the Commission's Rules of Practice and Procedure. No other submissions will be accepted, unless requested by the Commission. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments. Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number ("Docket No. 3870") in a prominent place on the cover page and/or the first page. (See Handbook for Electronic Filing Procedures, Electronic Filing Procedures).¹ Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, <https://edis.usitc.gov>). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding filing should contact the Secretary at EDIS3Help@usitc.gov.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. See 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly

sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,² solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.³

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: December 19, 2025.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2025-23806 Filed 12-23-25; 8:45 am]

BILLING CODE 7020-02-P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA-2025-0002]

CBNA/Halmar Joint Venture; Potomac River Tunnel Project; Grant of Permanent Variance

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: In this notice, OSHA grants a permanent variance to CBNA/Halmar Joint Venture (CBNA/Halmar) related to work in compressed air environments.

DATES: The permanent variance specified by this notice becomes effective on December 29, 2025 and shall remain in effect until the completion of the Potomac River Tunnel Project or until modified or revoked by OSHA.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of

² All contract personnel will sign appropriate nondisclosure agreements.

³ Electronic Document Information System (EDIS): <https://edis.usitc.gov>.

¹ Handbook for Electronic Filing Procedures: https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.

Labor; telephone: (202) 693–1999; email: meilinger.francis2@dol.gov.

General and technical information: Contact Mr. Kevin Robinson, Director, Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor; telephone: (202) 693–1911; email: robinson.kevin@dol.gov.

SUPPLEMENTARY INFORMATION: *Copies of this Federal Register notice.*

Electronic copies of this **Federal Register** notice are available at <http://www.regulations.gov>. This **Federal Register** notice, as well as news releases and other relevant information, also are available at OSHA's web page at <http://www.osha.gov>.

I. Overview

On April 1, 2024, CBNA/Halmar Joint Venture (CBNA/Halmar or the applicant), submitted under Section 6(d) of the Occupational Safety and Health Act of 1970 (the Act), 29 U.S.C. 655, and 29 CFR 1905.11 (Variances and other relief under Section 6(d)) an application for a permanent variance from several provisions of the OSHA standard that regulates work in compressed air, 1926.803 of 1926 Subpart S—Underground Construction, Caissons, Cofferdams, and Compressed Air, and an interim order allowing it to proceed while OSHA considers the request for a permanent variance (OSHA–2025–0002–0002). This notice addresses CBNA/Halmar's application for a permanent variance and interim order for construction of the Potomac River Tunnel Project in Washington, DC only and is not applicable to future CBNA/Halmar Joint Venture tunneling projects.

This notice addresses CBNA/Halmar's application for a permanent variance and interim order from the provisions of the standard that: (1) require the use of the decompression values specified in decompression tables in Appendix A of subpart S (29 CFR 1926.803(f)(1)); and (2) require the use of automated operational controls and a special decompression chamber (29 CFR 1926.803(g)(1)(iii) and (xvii), respectively).

OSHA reviewed CBNA/Halmar's application for the variance and interim order and determined that they were appropriately submitted in compliance with the applicable variance procedures in Section 6(d) of the Occupational Safety and Health Act of 1970 (OSH Act; 29 U.S.C. 655) and OSHA's regulations at 29 CFR 1905.11 (Variances and other relief under section 6(d)), including the requirement that the applicant inform workers and their representatives of

their rights to petition the Assistant Secretary of Labor for Occupational Safety and Health for a hearing on the variance application.

OSHA reviewed the alternative procedures in CBNA/Halmar's application and preliminarily determined that the applicant's proposed alternatives, on the whole, subject to the conditions in the request and imposed by the interim order, provide measures that are as safe and healthful as those required by the cited OSHA standards. On July 24, 2025, OSHA published a **Federal Register** notice announcing CBNA/Halmar's application for permanent variance, stating the preliminary determination along with the basis of that determination, and granting the interim order (90 FR 34902). OSHA requested comments on each.

OSHA did not receive any comments or other information disputing the preliminary determination that the alternatives were at least as safe as OSHA's standard, nor any objections to OSHA granting a permanent variance. Accordingly, through this notice OSHA grants a permanent variance, subject to the conditions set out in this document.

A. Background

The information that follows about CBNA/Halmar, its methods, and the Potomac River Tunnel Project comes from the CBNA/Halmar variance application.

CBNA/Halmar is a contractor for the Potomac River Tunnel Project (the project), that works on complex tunnel projects using innovations in tunnel-excavation methods. The applicant's workers engage in the construction of tunnels using advanced shielded mechanical excavation techniques in conjunction with an earth pressure balanced micro-tunnel boring machine (TBM). Using shielded mechanical excavation techniques, in conjunction with precast concrete tunnel liners and backfill grout, TBMs provide methods to achieve the face pressures required to maintain a stabilized tunnel face through various geologies and isolate that pressure to the forward section (the working chamber) of the TBM.

CBNA/Halmar asserts that it bores tunnels using a TBM at levels below the water table through soft soils consisting of clay, silt, and sand. TBMs are capable of maintaining pressure at the tunnel face, and stabilizing existing geological conditions, through the controlled use of a mechanically driven cutter head, bulkheads within the shield, ground-treatment foam, and a screw conveyor that moves excavated material from the working chamber. The forward-most

portion of the TBM is the working chamber, and this chamber is the only pressurized segment of the TBM. Within the shield, the working chamber consists of two sections: the forward working chamber and the staging chamber. The forward working chamber is immediately behind the cutter head and tunnel face. The staging chamber is behind the forward working chamber and between the man-lock door and the entry door to the forward working chamber.

The TBM has twin man-locks located between the pressurized working chamber and the non-pressurized portion of the machine. Each man-lock has two compartments. This configuration allows workers to access the man-locks for compression and decompression, and medical personnel to access the man-locks if required in an emergency.

CBNA/Halmar's Hyperbaric Operations Manual (HOM) for the Potomac River Tunnel Project indicates that the maximum pressure to which it is likely to expose workers during project interventions for the tunnel drives is 49.5 pounds per square inch gauge (p.s.i.g.). The applicant will pressurize the working chamber to the level required to maintain a stable tunnel face, which for this project CBNA/Halmar estimates will be up to a pressure not exceeding 49.5 p.s.i.g., which does not exceed the maximum pressure specified by the OSHA standard at 29 CFR 1926.803(e)(5).¹ CBNA/Halmar is not seeking a variance from this provision of the compressed-air standard.

CBNA/Halmar employs specially trained personnel for the construction of the tunnel. To keep the machinery working effectively, CBNA/Halmar asserts that these workers must periodically enter the excavation working chamber of the TBM to perform hyperbaric interventions during which workers would be exposed to air pressures up to 49.5 p.s.i.g. which does not exceed the maximum pressure specified by the existing OSHA standard at 29 CFR 1926.803(e)(5). These interventions consist of conducting inspections or maintenance work on the cutter-head structure and cutting tools of the TBM, such as changing replaceable cutting tools and disposable wear bars, and, in rare cases, repairing structural damage to the cutter head.

¹ The decompression tables in Appendix A of subpart S express the working pressures as pounds per square inch gauge (p.s.i.g.). Therefore, throughout this notice, OSHA expresses the p.s.i. value specified by 29 CFR 1926.803(e)(5) as p.s.i.g., consistent with the terminology in Appendix A, Table 1 of subpart S.

These interventions are the only time that workers are exposed to compressed air. Interventions in the excavation working chamber (the pressurized portion of the TBM) take place only after halting tunnel excavation and preparing the machine and crew for an intervention.

During interventions, workers enter the working chamber through one of the twin man-locks that open into the staging chamber. To reach the forward part of the working chamber, workers pass through a door in a bulkhead that separates the staging chamber from the forward working chamber. The man-locks and the working chamber are designed to accommodate three people, which is the maximum crew size allowed under the permanent variance. When the required decompression times are greater than work times, the twin man-locks allow for crew rotation. During crew rotation, one crew can be compressing or decompressing while the second crew is working. Therefore, the working crew always has an unoccupied man-lock at its disposal.

CBNA/Halmar asserts that these innovations in tunnel excavation have greatly reduced worker exposure to hazards of pressurized air work because they have eliminated the need to pressurize the entire tunnel for the project and thereby reduce the number of workers exposed, as well as the total duration of exposure, to hyperbaric pressure during tunnel construction. These advances in technology have substantially modified the methods used by the construction industry to excavate subaqueous tunnels compared to the caisson work regulated by the current OSHA compressed-air standard for construction at 29 CFR 1926.803.

In addition to the reduced exposures resulting from the innovations in tunnel-excavation methods, CBNA/Halmar asserts that innovations in hyperbaric medicine and technology improve the safety of decompression from hyperbaric exposures. These procedures, however, deviate from the decompression process that OSHA requires for construction in 29 CFR 1926.803(f)(1) and the decompression tables in Appendix A of 29 CFR 1926, subpart S. Nevertheless, according to CBNA/Halmar, their use of decompression protocols incorporating oxygen is more efficient, effective, and safer for tunnel workers than compliance with the decompression tables specified by the existing OSHA standard.

CBNA/Halmar contends that the alternative safety measures included in the application provide CBNA/Halmar's workers with a place of employment

that is at least as safe as they would be under OSHA's compressed-air standard for construction. CBNA also provided OSHA a project-specific HOM (OSHA–2025–0002–0003) for the Potomac River Tunnel Project that requires specialized medical support and hyperbaric supervision to provide assistance to a team of specially trained man-lock attendants and hyperbaric or compressed-air workers to support their assertions of equivalency in worker protection.

OSHA included all of the above information in the **Federal Register** notice announcing CBNA/Halmar's variance application and did not receive any comments disputing any of that information, including the safety assertions made by CBNA/Halmar in the variance application.

II. The Variance Application

Pursuant to the requirements of OSHA's variance regulations (29 CFR 1905.11), the applicant has certified that it notified its affected workers² of the variance application and request for interim order by posting, at prominent locations where it normally posts workplace notices, a summary of the application and information specifying where the workers can examine a copy of the application. In addition, the applicant has certified that it informed its workers of their right to petition the Assistant Secretary of Labor for Occupational Safety and Health for a hearing on the variance application.

III. OSHA History of Approval of Nearly Identical Variance Requests

OSHA has previously approved several nearly identical variances involving the same types of tunneling equipment used for similar projects (tunnel construction variances). OSHA notes that it granted several subaqueous tunnel construction permanent variances from the same provisions of OSHA's compressed-air standard (29 CFR 1926.803(e)(5), (f)(1), (g)(1)(iii), and (g)(1)(xvii)) that are the subject of the present application: (1) Impregilo, Healy, Parsons, Joint Venture (IHP JV) for the Anacostia River Tunnel in Washington, DC (80 FR 50652, August 20, 2015); (2) Traylor JV for the Blue Plains Tunnel in Washington, DC (80 FR 16440, March 27, 2015); (3) Tully/OHL USA Joint Venture for the New York Economic Development Corporation's New York Siphon Tunnel project (79 FR 29809, May 23, 2014); (4) Salini-Impregilo/Healy Joint Venture for the Northeast Boundary Tunnel in

Washington, DC (85 FR 27767, May 11, 2020); (5) McNally/Kiewit SST for the Shoreline Storage Tunnel in Cleveland, Ohio (88 FR 15080, March 10, 2023); (6) Traylor Shea Joint Venture for the Alexandria RiverRenew Tunnel Project in Alexandria, Virginia and Washington, DC (88 FR 15090, March 10, 2023); (7) Traylor-Sundt Joint Venture, for the Integrated Pipeline Tunnel Project in Dallas, Texas (88 FR 83152, November 28, 2023); (8) Ballard Marine Construction for the Bay Park Conveyance Tunnel Project in Nassau County, New York (89 FR 8442, February 7, 2024); and (9) Ballard Marine Construction for the Lower Olentangy Tunnel Project in Columbus, Ohio (89 FR 78906, September 26, 2024). OSHA also granted an interim order to Ballard Marine Construction for the Suffolk County, New York Outfall Tunnel Project (86 FR 5253, January 19, 2021), as well as an interim order to McNally/ASI Marine for the Southerly Tunnel and Consolidation Project in Cleveland, Ohio (90 FR 34887, July 24, 2025) in addition to the interim order granted for this project. The proposed alternate conditions in this notice are nearly identical to the alternate conditions of the previous permanent variances.³ OSHA is not aware of any injuries or other safety issues that arose from work performed under these conditions in accordance with the previous variances.

IV. Applicable OSHA Standard and the Relevant Variance

A. Variance From Paragraph (f)(1) of 29 CFR 1926.803, Requirement To Use OSHA Decompression Tables

OSHA's compressed-air standard for construction requires decompression in accordance with the decompression tables in Appendix A of 29 CFR 1926, subpart S (see 29 CFR 1926.803(f)(1)). As an alternative to the OSHA decompression tables, the applicant proposes to use newer decompression schedules (the 1992 French Decompression Tables) that rely on staged decompression and supplement breathing air used during decompression with air or oxygen (as appropriate).⁴ The applicant asserts

³ The previous tunnel construction variances allowed further deviation from OSHA standards by permitting employee exposures above 50 p.s.i.g., based on the composition of the soil and the amount of water that will be above the tunnel for various sections of this project. The current permanent variance includes substantively the same safeguards as the variances that OSHA granted previously even though employees will not be exposed to pressures higher than 49.5 p.s.i.g.

⁴ In 1992, the French Ministry of Labour replaced the 1974 French Decompression Tables with the

² See the definition of "Affected employee or worker" in section VII.C of this Notice.

decompression protocols using the 1992 French Decompression Tables for air or oxygen as specified by the Integrated Pipeline Tunnel Project-specific HOM are safer for tunnel workers than the decompression protocols specified in Appendix A of 29 CFR 1926 Subpart S. Accordingly, the applicant commits to following the decompression procedures described in that HOM, which requires CBNA/Halmar to follow the 1992 French Decompression Tables to decompress compressed air workers (CAWs) after they exit the hyperbaric conditions in the working chamber.

Depending on the maximum working pressure and exposure times, the 1992 French Decompression Tables provide for air decompression with or without oxygen. CBNA/Halmar asserts that oxygen decompression has many benefits, including (1) keeping the partial pressure of nitrogen in the lungs as low as possible; (2) keeping external pressure as low as possible to reduce the formation of gas bubbles in the blood; (3) removing nitrogen from the lungs and arterial blood and increasing the rate of nitrogen elimination; (4) improving the quality of breathing during decompression stops so that workers are less tired and to prevent bone necrosis; (5) reducing decompression time by approximately 33 percent as compared to air decompression; and (6) reducing inflammation.

In addition, the project-specific HOM requires a physician, certified in hyperbaric medicine, to manage the medical condition of CAWs during hyperbaric exposures and decompression. A trained and experienced man-lock attendant is also required to be present during hyperbaric exposures and decompression. This man-lock attendant is to operate the hyperbaric system to ensure compliance with the specified decompression table. A hyperbaric supervisor, who is trained in hyperbaric operations, procedures, and safety, directly oversees all hyperbaric interventions, and ensures that staff follow the procedures delineated in the HOM or by the attending physician.

B. Variance From Paragraph (g)(1)(iii) of 29 CFR 1926.803, Automatically Regulated Continuous Decompression

CBNA/Halmar seeks a permanent variance from the OSHA standard at 29 CFR 1926.803(g)(1)(iii), which requires automatic controls to regulate decompression. As noted above, the applicant is conducting the staged decompression according to the 1992 French Decompression Tables under the direct control of the trained man-lock attendant and under the oversight of the hyperbaric supervisor.

Breathing air under hyperbaric conditions increases the amount of nitrogen gas dissolved in a CAW's tissues. The greater the hyperbaric pressure under these conditions and the more time spent under the increased pressure, the greater the amount of nitrogen gas is dissolved in the tissues. When the pressure decreases during decompression, tissues release the dissolved nitrogen gas into the blood system, which then carries the nitrogen gas to the lungs for elimination through exhalation. Releasing hyperbaric pressure too rapidly during decompression can increase the size of the bubbles formed by nitrogen gas in the blood system, resulting in decompression illness (DCI), commonly referred to as "the bends." This description of the etiology of DCI is consistent with current scientific theory and research on the issue.

The 1992 French Decompression Tables, proposed for use by the applicant, provide for stops during worker decompression (*i.e.*, staged decompression) to control the release of nitrogen gas from tissues into the blood system. Studies show that staged decompression, in combination with other features of the 1992 French Decompression Tables such as the use of oxygen, result in a lower incidence of DCI than the use of automatically regulated continuous decompression.⁵

⁵ See, *e.g.*, Dr. Eric Kindwall, EP (1997), Compressed air tunneling and caisson work decompression procedures: development, problems, and solutions. *Undersea and Hyperbaric Medicine*, 24(4), pp. 337–345. This article reported 60 treated cases of DCI among 4,168 exposures between 19 and 31 p.s.i.g. over a 51-week contract period, for a DCI incidence of 1.44% for the decompression tables specified by the OSHA standard. Dr. Kindwall notes that the use of automatically regulated continuous decompression in the Washington State safety standards for compressed-air work (from which OSHA derived its decompression tables) was at the insistence of contractors and the union, and against the advice of the expert who calculated the decompression table and recommended using staged decompression. Dr. Kindwall then states, "Continuous decompression is inefficient and wasteful. For example, if the last stage from 4 p.s.i.g. . . . to the surface took 1h, at least half the

In addition, the applicant asserts that staged decompression administered in accordance with its HOM is at least as effective as an automatic controller in regulating the decompression process because the HOM requires a hyperbaric supervisor who directly supervises all hyperbaric interventions and ensures that the man-lock attendant, who is a competent person in the manual control of hyperbaric systems, follows the schedule specified in the decompression tables, including stops.

C. Variance From Paragraph (g)(1)(xvii) of 29 CFR 1926.803, Requirement of Special Decompression Chamber

The OSHA compressed-air standard for construction requires employers to use a special decompression chamber of sufficient size to accommodate all CAWs being decompressed at the end of the shift when total decompression time exceeds 75 minutes (see 29 CFR 1926.803(g)(1)(xvii)). Use of the special decompression chamber enables CAWs to move about and flex their joints to prevent neuromuscular problems during decompression.

Space limitations in the TBM do not allow for the installation and use of an additional special decompression lock or chamber. The applicant proposes that it be permitted to rely on the man-locks and staging chamber in lieu of adding a separate, special decompression chamber. Because only a few workers out of the entire crew are exposed to hyperbaric pressure, the man-locks (which, as noted earlier, connect directly to the working chamber) and the staging chamber are of sufficient size to accommodate all of the exposed workers during decompression. The applicant uses the existing man-locks, each of which adequately accommodates a three-member crew for this purpose when decompression lasts up to 75 minutes. When decompression exceeds 75 minutes, crews can open the door connecting the two compartments in each man-lock (during decompression stops) or exit the man-lock and move into the staging chamber where additional space is available. The applicant asserts that this alternative arrangement is as effective as a special decompression chamber in that it has sufficient space for all the CAWs at the

time is spent at pressures less than 2 p.s.i.g. . . . which provides less and less meaningful bubble suppression" In addition, Dr. Kindwall addresses the continuous-decompression protocol in the OSHA compressed-air standard for construction, noting that "[a]side from the tables for saturation diving to deep depths, no other widely used or officially approved diving decompression tables use straight line, continuous decompressions at varying rates. Stage decompression is usually the rule, since it is simpler to control."

1992 French Decompression Tables, which differ from OSHA's decompression tables in Appendix A by using: (1) staged decompression as opposed to continuous (linear) decompression; (2) decompression tables based on air or both air and pure oxygen; and (3) emergency tables when unexpected exposure times occur (up to 30 minutes above the maximum allowed working time).

end of a shift and enables the CAWs to move about and flex their joints to prevent neuromuscular problems.

V. Decision

After reviewing the proposed alternatives, OSHA has determined that the applicant's proposed alternatives, on the whole, subject to the conditions in the request and imposed by this permanent variance, provide measures that are as safe and healthful as those required by the cited OSHA standards addressed in section IV of this notice.

In addition, OSHA has determined that each of the following alternatives are at least as effective as the specified OSHA requirements:

A. 29 CFR 1926.803(f)(1)

The applicant has proposed to implement equally effective alternative measures to the requirement in 29 CFR 1926.803(f)(1) for compliance with OSHA's decompression tables. The HOM specifies the procedures and personnel qualifications for performing work safely during the compression and decompression phases of interventions. The HOM also specifies the decompression tables the applicant proposes to use (the 1992 French Decompression Tables). Depending on the maximum working pressure and exposure times during the interventions, the tables provide for decompression using air, pure oxygen, or a combination of air and oxygen. The decompression tables also include delays or stops for various time intervals at different pressure levels during the transition to atmospheric pressure (*i.e.*, staged decompression). In all cases, a physician certified in hyperbaric medicine will manage the medical condition of CAWs during decompression. In addition, a trained and experienced man-lock attendant, experienced in recognizing decompression sickness or illnesses and injuries, will be present. Of key importance, a hyperbaric supervisor, trained in hyperbaric operations, procedures, and safety, will directly supervise all hyperbaric operations to ensure compliance with the procedures delineated in the project-specific HOM or by the attending physician.

Prior to granting the previous permanent variances to Traylor JV, IHP JV, Tully/OHL JV, Salini-Impregilo/Healy JV, McNally/Kiewit SST JV, Traylor Shea JV, McNally/ASI Marine and Ballard Marine Bay Park Tunnel New York, OSHA conducted a review of the scientific literature and concluded that the alternative decompression method (*i.e.*, the 1992 French Decompression Tables) CBNA/Halmar

proposed would be at least as safe as the decompression tables specified by OSHA when applied by trained medical personnel under the conditions imposed by the permanent variance.

Some of the literature indicates that the alternative decompression method may be safer, concluding that decompression performed in accordance with these tables resulted in a lower occurrence of DCI than decompression conducted in accordance with the decompression tables specified by the standard. For example, H.L. Andersen studied the occurrence of DCI at maximum hyperbaric pressures ranging from 4 p.s.i.g. to 43 p.s.i.g. during construction of the Great Belt Tunnel in Denmark (1992–1996).⁶ This project used the 1992 French Decompression Tables to decompress the workers during part of the construction. Andersen observed 6 DCI cases out of 7,220 decompression events and reported that switching to the 1992 French Decompression tables reduced the DCI incidence to 0.08% compared to a previous incidence rate of 0.14%. The DCI incidence in the study by H.L. Andersen is substantially less than the DCI incidence reported for the decompression tables specified in Appendix A.

OSHA found no studies in which the DCI incidence reported for the 1992 French Decompression Tables were higher than the DCI incidence reported for the OSHA decompression tables.⁷

OSHA's experience with the previous seven variances, which all incorporated nearly identical decompression plans and did not result in safety issues, also provides evidence that the alternative procedure as a whole is at least as effective for this type of tunneling project as compliance with OSHA's decompression tables. The experience of State Plans⁸ that granted variances (Nevada, Oregon and Washington)⁹ for

⁶ Andersen HL (2002). Decompression sickness during construction of the Great Belt tunnel, Denmark. *Undersea and Hyperbaric Medicine*, 29(3), pp. 172–188.

⁷ Le Péchon JC, Barre P, Baud JP, Ollivier F (September 1996). Compressed air work—French Tables 1992—operational results. *JCLP Hyperbarie Paris, Centre Medical Subaquatique Interentreprise, Marseille: Communication a l'EUBS*, pp. 1–5 (see Ex. OSHA–2012–0036–0005).

⁸ Section 18 of the OSH Act, Congress expressly provides that States and U.S. territories may adopt, with Federal approval, a plan for the development and enforcement of occupational safety and health standards. OSHA refers to States and territories which have developed and are operating their own job safety and health programs as “States with OSHA-approved State Plans.” Their programs must be at least as effective in providing safe and healthful employment and places of employment as the Federal standards (29 U.S.C. 667).

⁹ These state variances are available in the docket for the 2015 Traylor JV variance: Exs. OSHA–2012–

hyperbaric exposures occurring during similar subaqueous tunnel-construction work provide additional evidence of the effectiveness of this alternative procedure.

B. 29 CFR 1926.803(g)(1)(iii)

The applicant developed, and proposed to implement, an equally effective alternative to 29 CFR 1926.803(g)(1)(iii), which requires the use of automatic controllers that continuously decrease pressure to achieve decompression in accordance with the tables specified by the standard. The applicant's alternative includes using the 1992 French Decompression Tables for guiding staged decompression to achieve lower occurrences of DCI, using a trained and competent attendant for implementing appropriate hyperbaric entry and exit procedures, and providing a competent hyperbaric supervisor and attending physician certified in hyperbaric medicine to oversee all hyperbaric operations.

In reaching this conclusion, OSHA again notes the experience of previous nearly identical tunneling variances, the experiences of States with OSHA-approved State Plans, and a review of the literature and other information noted earlier.

C. 29 CFR 1926.803(g)(1)(xvii)

The applicant developed, and proposed to implement, an effective alternative to the use of the special decompression chamber required by 29 CFR 1926.803(g)(1)(xvii). The TBM's man-lock and working chamber appear to satisfy all of the conditions of the special decompression chamber, including that they provide sufficient space for the maximum crew of three CAWs to stand up and move around, and safely accommodate decompression times up to 360 minutes. Therefore, again noting OSHA's previous experience with nearly identical variances including the same alternative, OSHA preliminarily determined that the TBM's man-lock and working chamber function as effectively as the special decompression chamber required by the standard.

Based on a review of available evidence, the experience of State Plans that granted variances (Nevada, Oregon, and Washington)¹⁰ or promulgated a

0035–0006 (Nevada), OSHA–2012–0035–0005 (Oregon), and OSHA–2012–0035–0004 (Washington).

¹⁰ These state variances are available in the docket: Exs. OSHA–2012–0035–0006 (Nevada), OSHA–2012–0035–0007 (Oregon), and OSHA–2012–0035–0008 (Washington).

new standard (California)¹¹ for hyperbaric exposures occurring during similar subaqueous tunnel-construction work, and the information provided in the applicant's variance application, OSHA is granting the permanent variance.

Pursuant to Section 6(d) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655(d)), and based on the record discussed above, the agency finds that when CBNA/Halmar complies with the conditions of the following order, the working conditions of the workers are at least as safe and healthful as if it complied with the working conditions specified by paragraphs (f)(1), (g)(1)(iii), and (g)(1)(xvii) of 29 CFR 1926.803. Therefore, CBNA/Halmar must: (1) comply with the conditions listed below under "Conditions Specified for the Permanent Variance" for the period between the date of this notice and completion of the Potomac River Tunnel Project; (2) comply fully with all other applicable provisions of 29 CFR part 1926; and (3) provide a copy of this **Federal Register** notice to all employees affected by the conditions, including the affected employees of other employers, using the same means it used to inform these employees of the application for a permanent variance. Additionally, this order will remain in effect until one of the following conditions occurs: (1) completion of the Potomac River Tunnel Project; or (2) OSHA modifies or revokes this final order in accordance with 29 CFR 1905.13.

VI. Description of the Specified Conditions for the Permanent Variance

The conditions for the variance are set out in the Order at the end of this document. This section provides additional detail regarding the conditions in the Order.

Condition A: Scope

The scope of the permanent variance limits coverage to the work situations specified. Clearly defining the scope of the permanent variance provides CBNA/Halmar, their employees, potential future applicants, other stakeholders, the public, and OSHA with necessary information regarding the work situations in which the permanent variance applies. To the extent that CBNA/Halmar exceeds the defined scope of this variance, it will be required to comply with OSHA's standards. This permanent variance applies only to the applicant, CBNA/

Halmar, and only to the remainder of construction work on the Potomac River Tunnel Project.

Condition B: List of Abbreviations

Condition B defines abbreviations used in the permanent variance. OSHA believes that defining these abbreviations serves to clarify and standardize their usage, thereby enhancing the applicant's and its employees' understanding of the conditions specified by the permanent variance.

Condition C: Definitions

The condition defines a series of terms, mostly technical terms, used in the permanent variance to standardize and clarify their meaning. OSHA believes that defining these terms serves to enhance the applicant's and its employees' understanding of the conditions specified by the permanent variance.

Condition D: Safety and Health Practices

This condition requires the applicant to develop and submit to OSHA a HOM specific to the Potomac River Tunnel Project at least six months before using the TBM for tunneling operations. The applicant must also submit, at least six months before using the TBM, proof that the TBM's hyperbaric chambers have been designed, fabricated, inspected, tested, marked, and stamped in accordance with the requirements of the most recent edition of ASME PVHO-1 (*Safety Standards for Pressure Vessels for Human Occupancy*). These requirements ensure that the applicant develops hyperbaric safety and health procedures suitable for the project.

The submission of the HOM enables OSHA to determine whether the safety and health instructions and measures it specifies are appropriate to the field conditions of the tunnel (including expected geological conditions), conform to the conditions of the variance, and adequately protect the safety and health of the CAWs. It also facilitates OSHA's ability to ensure that the applicant is complying with these instructions and measures. The requirement for proof of compliance with ASME PVHO-1 is intended to ensure that the equipment is structurally sound and capable of performing to protect the safety of the employees exposed to hyperbaric pressure. The applicant has submitted the HOM and proof of compliance with the most recent edition of ASME PVHO-1.

Additionally, the condition includes a series of related hazard prevention and

control requirements and methods (*e.g.*, decompression tables, job hazard analyses (JHA), operations and inspections checklists, incident investigation, and recording and notification to OSHA of recordable hyperbaric injuries and illnesses) designed to ensure the continued effective functioning of the hyperbaric equipment and operating system.

Condition E: Communication

This condition requires the applicant to develop and implement an effective system of information sharing and communication. Effective information sharing and communication are intended to ensure that affected workers receive updated information regarding any safety-related hazards and incidents, and corrective actions taken, prior to the start of each shift. The condition also requires the applicant to ensure that reliable means of emergency communications are available and maintained for affected workers and support personnel during hyperbaric operations. Availability of such reliable means of communications enables affected workers and support personnel to respond quickly and effectively to hazardous conditions or emergencies that may develop during TBM operations.

Condition F: Worker Qualification and Training

This condition requires the applicant to develop and implement an effective qualification and training program for affected workers. The condition specifies the factors that an affected worker must know to perform safely during hyperbaric operations, including how to enter, work in, and exit from hyperbaric conditions under both normal and emergency conditions. Having well-trained and qualified workers performing hyperbaric intervention work is intended to ensure that they recognize, and respond appropriately to, hyperbaric safety and health hazards. These qualification and training requirements enable affected workers to cope effectively with emergencies, as well as the discomfort and physiological effects of hyperbaric exposure, thereby preventing worker injury, illness, and fatalities.

Paragraph (2)(e) of this condition requires the applicant to provide affected workers with information they can use to contact the appropriate healthcare professionals if the workers believe they are developing hyperbaric-related health effects. This requirement provides for early intervention and treatment of DCI and other health effects resulting from hyperbaric exposure,

¹¹ See California Code of Regulations, Title 8, Subchapter 7, Group 26, Article 154, available at <http://www.dir.ca.gov/title8/sb7g26a154.html>.

thereby reducing the potential severity of these effects.

Condition G: Inspections, Tests, and Accident Prevention

Condition G requires the applicant to develop, implement, and operate a program of frequent and regular inspections of the TBM's hyperbaric equipment and support systems, and associated work areas. This condition helps to ensure the safe operation and physical integrity of the equipment and work areas necessary to conduct hyperbaric operations. The condition also enhances worker safety by reducing the risk of hyperbaric-related emergencies.

Paragraph (3) of this condition requires the applicant to document tests, inspections, corrective actions, and repairs involving the TBM, and maintain these documents at the jobsite for the duration of the job. This requirement provides the applicant with information needed to schedule tests and inspections to ensure the continued safe operation of the equipment and systems, and to determine that the actions taken to correct defects in hyperbaric equipment and systems were appropriate, prior to returning them to service.

Condition H: Compression and Decompression

This condition requires the applicant to consult with the designated medical advisor regarding special compression or decompression procedures appropriate for any unacclimated CAW and then implement the procedures recommended by the medical advisor. This proposed provision ensures that the applicant consults with the medical advisor, and involves the medical advisor in the evaluation, development, and implementation of compression or decompression protocols appropriate for any CAW requiring acclimation to the hyperbaric conditions encountered during TBM operations. Accordingly, CAWs requiring acclimation have an opportunity to acclimate prior to exposure to these hyperbaric conditions. OSHA believes this condition will prevent or reduce adverse reactions among CAWs to the effects of compression or decompression associated with the intervention work they perform in the TBM.

Condition I: Recordkeeping

Under OSHA's recordkeeping requirements in 29 CFR part 1904 regarding Recording and Reporting Occupational Injuries and Illnesses, the employer must maintain a record of any recordable injury, illness, or fatality (as

defined by 29 CFR part 1904) resulting from exposure of an employee to hyperbaric conditions, or any other work condition, by completing the OSHA Form 301 Incident Report and OSHA Form 300 Log of Work-Related Injuries and Illnesses. The applicant did not seek a variance from this standard and therefore CBNA/Halmar must comply fully with those requirements.

Examples of important information to include on the OSHA Form 301 Injury and Illness Incident Report (along with the corresponding questions on the form) are:

Q14

- the task performed;
- the composition of the gas mixture (e.g., air or oxygen);
- an estimate of the CAW's workload;
- the maximum working pressure;
- temperature in the work and decompression environments;
- unusual occurrences, if any, during the task or decompression

Q15

- time of symptom onset;
- duration between decompression and onset of symptoms

Q16

- type and duration of symptoms;
- a medical summary of the illness or injury.

Q17

- duration of the hyperbaric intervention;
- possible contributing factors;
- the number of prior interventions completed by the injured or ill CAW; and the pressure to which the CAW was exposed during those interventions.¹²

Condition I adds additional reporting responsibilities, beyond those already required by the OSHA standard. The applicant is required to maintain records of specific factors associated with each hyperbaric intervention. The information gathered and recorded under Condition I, in concert with the information provided under Condition J (using OSHA Form 301 Injury and Illness Incident Report to investigate and record hyperbaric recordable injuries as defined by 29 CFR 1904.4, 1904.7, and 1904.8–.12), enables the applicant and OSHA to assess the effectiveness of the permanent variance in preventing DCI and other hyperbaric-related effects.

Condition J: Notifications

Under the notifications condition, the applicant is required, within specified periods of time, to notify OSHA of: (1) any recordable injury, illness, in-patient hospitalization, amputation, loss of an eye, or fatality that occurs as a result of hyperbaric exposures during TBM operations; and in-patient hospitalization, amputation, loss of an eye or fatality that occurs during other operations must also be reported pursuant to 29 CFR 1910.39(a); (2) provide OSHA a copy of the hyperbaric exposures incident investigation report (using OSHA Form 301 Injury and Illness Incident Report) of these events within 24 hours of the incident; (3) include on OSHA Form 301 Injury and Illness Incident Report information on the hyperbaric conditions associated with the recordable injury or illness, the root-cause determination, and preventive and corrective actions identified and implemented; (4) provide the certification that affected workers were informed of the incident and the results of the incident investigation; (5) notify OSHA's Office of Technical Programs and Coordination Activities (OTPCA) and the Baltimore/Washington OSHA Area Office within 15 working days should the applicant need to revise the HOM to accommodate changes in its compressed-air operations that affect CBNA/Halmar's ability to comply with the conditions of the permanent variance; and (6) provide OTPCA and the Baltimore/Washington OSHA Area Office at the end of the project, with a report evaluating the effectiveness of the decompression tables.

It should be noted that the requirement for completing and submitting the hyperbaric exposure-related (recordable) incident investigation report (OSHA 301 Injury and Illness Incident Report) is more restrictive than the current recordkeeping requirement of completing OSHA Form 301 Injury and Illness Incident Report within 7 calendar days of the incident (1904.29(b)(3)). This modified, more stringent incident investigation and reporting requirement is restricted to intervention-related hyperbaric (recordable) incidents only. Providing rapid notification to OSHA is essential because time is a critical element in OSHA's ability to determine the continued effectiveness of the variance conditions in preventing hyperbaric incidents, and the applicant's identification and implementation of appropriate corrective and preventive actions.

¹² See 29 CFR 1904 Recording and Reporting Occupational Injuries and Illnesses (http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9631); recordkeeping forms and instructions <https://www.osha.gov/recordkeeping/forms>.

Further, these notification requirements also enable the applicant, its employees, and OSHA to assess the effectiveness of the permanent variance in providing the requisite level of safety to the applicant's workers and based on this assessment, whether to revise or revoke the conditions of the permanent variance. Timely notification permits OSHA to take whatever action may be necessary and appropriate to prevent possible further injuries and illnesses. Providing notification to employees informs them of the precautions taken by the applicant to prevent similar incidents in the future.

Additionally, this condition requires the applicant to notify OSHA if it ceases to do business, has a new address or location for the main office, or transfers the operations covered by the permanent variance to a successor company. In addition, the condition specifies that the transfer of the permanent variance to a successor company must be approved by OSHA. These requirements allow OSHA to communicate effectively with the applicant regarding the status of the permanent variance and expedite the agency's administration and enforcement of the permanent variance. Stipulating that the applicant is required to have OSHA's approval to transfer a variance to a successor company provides assurance that the successor company has knowledge of, and will comply with, the conditions specified by the permanent variance, thereby ensuring the safety of workers involved in performing the operations covered by the permanent variance.

VII. Order

As of the effective date of this final order, OSHA is revoking the interim order granted to the employer on July 24, 2024 (90 FR 34902) and replacing it with a permanent variance order. Note that there are not any substantive changes in the conditions between the interim order and this final order.

OSHA issues this final order authorizing CBNA/Halmar to comply with the following conditions instead of complying with the requirements of 29 CFR 1926.803 (f)(1), (g)(1)(iii), and (g)(1)(xvii). These conditions are:

A. Scope

The permanent variance applies only when CBNA/Halmar stops the tunnel-boring work, pressurizes the working chamber, and the CAWs either enter the working chamber to perform an intervention (*i.e.*, inspect, maintain, or repair the mechanical-excavation components), or exit the working chamber after performing interventions.

The permanent variance applies only to work:

1. That occurs in conjunction with construction of the Potomac River Tunnel Project, a tunnel constructed using advanced shielded mechanical-excavation techniques and involving operation of a TBM;
 2. In the TBM's forward section (the working chamber) and associated hyperbaric chambers used to pressurize and decompress employees entering and exiting the working chamber; and
 3. Performed in compliance with all applicable provisions of 29 CFR part 1926 except for the requirements specified by 29 CFR 1926.803 (f)(1), (g)(1)(iii), and (g)(1)(xvii).
4. This order will remain in effect until one of the following conditions occurs: (1) completion of the Potomac River Tunnel Project; or (2) OSHA modifies or revokes this final order in accordance with 29 CFR 1905.13.

B. List of Abbreviations

Abbreviations used throughout this permanent variance include the following:

1. CAW—Compressed-air worker
2. CFR—Code of Federal Regulations
3. DCI—Decompression Illness
4. DMT—Diver Medical Technician
5. TBM—Earth Pressure Balanced Micro-Tunnel Boring Machine
6. HOM—Hyperbaric Operations Manual
7. JHA—Job hazard analysis
8. OSHA—Occupational Safety and Health Administration
9. OTPCA—Office of Technical Programs and Coordination Activities

C. Definitions

The following definitions apply to this permanent variance, CBNA/Halmar's project-specific HOM, and all work carried out under the conditions of this permanent variance.

1. *Affected employee or worker*—an employee or worker who is affected by the conditions of this permanent variance, or any one of his or her authorized representatives. The term "employee" has the meaning defined and used under the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 *et seq.*).

2. *Atmospheric pressure*—the pressure of air at sea level, generally 14.7 pounds per square inch absolute (p.s.i.a.), 1 atmosphere absolute, or 0 pounds per square inch gauge (p.s.i.g.).

3. *Compressed-air worker*—an individual who is specially trained and medically qualified to perform work in a pressurized environment while breathing air at pressures not exceeding 49.5 p.s.i.g.

4. *Competent person*—an individual who is capable of identifying existing and predictable hazards in the surroundings or working conditions that are unsanitary, hazardous, or dangerous to employees, and who has authorization to take prompt corrective measures to eliminate them.¹³

5. *Decompression illness*—an illness (also called decompression sickness or "the bends") caused by gas bubbles appearing in body compartments due to a reduction in ambient pressure. Examples of symptoms of decompression illness include, but are not limited to: joint pain (also known as the "bends" for agonizing pain or the "niggles" for slight pain); areas of bone destruction (termed dysbaric osteonecrosis); skin disorders (such as cutis marmorata, which causes a pink marbling of the skin, or in people with darker skin tones, the rash will appear as a marbled or lacy dark brown or purplish color); spinal cord and brain disorders (such as stroke, paralysis, paresthesia, and bladder dysfunction); cardiopulmonary disorders, such as shortness of breath; and arterial gas embolism (gas bubbles in the arteries that block blood flow).¹⁴

Note: Health effects associated with hyperbaric intervention, but not considered symptoms of DCI, can include: barotrauma (direct damage to air-containing cavities in the body such as ears, sinuses, and lungs); nitrogen narcosis (reversible alteration in consciousness that may occur in hyperbaric environments and is caused by the anesthetic effect of certain gases at high pressure); and oxygen toxicity (a central nervous system condition resulting from the harmful effects of breathing molecular oxygen (O₂) at elevated partial pressures).

6. *Diver Medical Technician*—Member of the dive team who is experienced in first aid.

7. *Earth Pressure Balanced Tunnel Boring Machine*—the machinery used to excavate a tunnel.

8. *Hot work*—any activity performed in a hazardous location that may introduce an ignition source into a potentially flammable atmosphere.¹⁵

9. *Hyperbaric*—at a higher pressure than atmospheric pressure.

10. *Hyperbaric intervention*—a term that describes the process of stopping the TBM and preparing and executing work under hyperbaric pressure in the working chamber for the purpose of

¹³ Adapted from 29 CFR 1926.32(f).

¹⁴ See Appendix 10 of "A Guide to the Work in Compressed-Air Regulations 1996," published by the United Kingdom Health and Safety Executive available from NIOSH at <http://www.cdc.gov/niosh/docket/archive/pdfs/NIOSH-254/compReg1996.pdf>.

¹⁵ Also see 29 CFR 1926.1202 for examples of hot work.

inspecting, replacing, or repairing cutting tools and/or the cutterhead structure.

11. *Hyperbaric Operations Manual*—a detailed, project-specific health and safety plan developed and implemented by CBNA/Halmar for working in compressed air during the Potomac River Tunnel Project.

12. *Job hazard analysis*—an evaluation of tasks or operations to identify potential hazards and to determine the necessary controls.

13. *Man-lock*—an enclosed space capable of pressurization, and used for compressing or decompressing any employee or material when either is passing into, or out of, a working chamber.

14. *Medical Advisor*—medical professional experienced in the physical requirements of compressed air work and the treatment of decompression illness.

15. *Pressure*—a force acting on a unit area. Usually expressed as pounds per square inch (p.s.i.).

16. *p.s.i.*—pounds per square inch, a common unit of measurement of pressure; a pressure given in p.s.i. corresponds to absolute pressure.

17. *p.s.i.a.*—pounds per square inch absolute, or absolute pressure, is the sum of the atmospheric pressure and gauge pressure. At sea-level, atmospheric pressure is approximately 14.7 p.s.i.a. Adding 14.7 to a pressure expressed in units of p.s.i.g. will yield the absolute pressure, expressed as p.s.i.a.

18. *p.s.i.g.*—pounds per square inch gauge, a common unit of pressure; pressure expressed as p.s.i.g. corresponds to pressure relative to atmospheric pressure. At sea-level, atmospheric pressure is approximately 14.7 p.s.i.a. Subtracting 14.7 from a pressure expressed in units of p.s.i.a. yields the gauge pressure, expressed as p.s.i.g. At sea level the gauge pressure is 0 p.s.i.g.

19. *Qualified person*—an individual who, by possession of a recognized degree, certificate, or professional standing, or who, by extensive knowledge, training, and experience, successfully demonstrates an ability to solve or resolve problems relating to the subject matter, the work, or the project.¹⁶

20. *Working chamber*—an enclosed space in the TBM in which CAWs perform interventions, and which is accessible only through a man-lock.

D. Safety and Health Practices

1. CBNA/Halmar must implement the project-specific HOM submitted to OSHA as part of the application (see OSHA–2025–0002–0003). The HOM provides the minimum requirements regarding expected safety and health hazards (including anticipated geological conditions) and hyperbaric exposures during the tunnel-construction project.

2. CBNA/Halmar must demonstrate that the TBM on the project is designed, fabricated, inspected, tested, marked, and stamped in accordance with the most recent requirements of ASME PVHO–1 (*Safety Standards for Pressure Vessels for Human Occupancy*) for the TBM's hyperbaric chambers.

3. CBNA/Halmar must implement the safety and health instructions included in the manufacturer's operations manuals for the TBM, and the safety and health instructions provided by the manufacturer for the operation of decompression equipment.

4. CBNA/Halmar must ensure that there are no exposures to pressures greater than 49.5 p.s.i.g.

5. CBNA/Halmar must ensure that air or oxygen is the only breathing gas in the working chamber.

6. CBNA/Halmar must follow the 1992 French Decompression Tables for air or oxygen decompression as specified in the HOM; specifically, the extracted portions of the 1992 French Decompression tables titled, "French Regulation Air Standard Tables."

7. CBNA/Halmar must equip man-locks used by employees with an air or oxygen delivery system, as specified by the HOM for the project. CBNA/Halmar is prohibited from storing in the tunnel any oxygen or other compressed gases used in conjunction with hyperbaric work.

8. Workers performing hot work under hyperbaric conditions must use flame-retardant personal protective equipment and clothing.

9. In hyperbaric work areas, CBNA/Halmar must maintain an adequate fire-suppression system approved for hyperbaric work areas.

10. CBNA/Halmar must develop and implement one or more job hazard analysis (JHA) for work in the hyperbaric work areas, and review, periodically and as necessary (*e.g.*, after making changes to a planned intervention that affects its operation), the contents of the JHAs with affected employees. The JHAs must include all the job functions that the risk

assessment¹⁷ indicates are essential to prevent injury or illness.

11. CBNA/Halmar must develop a set of checklists to guide compressed-air work and ensure that employees follow the procedures required by the permanent variance (including all procedures required by the HOM approved by OSHA for the project, which this permanent variance incorporates by reference). The checklists must include all steps and equipment functions that the risk assessment indicates are essential to prevent injury or illness during compressed-air work.

12. CBNA/Halmar must ensure that the safety and health provisions of this project-specific HOM adequately protect the workers of all contractors and subcontractors involved in hyperbaric operations for the project to which the HOM applies.¹⁸

E. Communication

1. Prior to beginning a shift, CBNA/Halmar must implement a system that informs workers exposed to hyperbaric conditions of any hazardous occurrences or conditions that might affect their safety, including hyperbaric incidents, gas releases, equipment failures, earth or rockslides, cave-ins, flooding, fires, or explosions.

2. CBNA/Halmar must provide a power-assisted means of communication among affected workers and support personnel in hyperbaric conditions where unassisted voice communication is inadequate.

(a) CBNA/Halmar must use an independent power supply for powered communication systems, and these systems have to operate such that use or disruption of any one phone or signal location will not disrupt the operation of the system from any other location.

(b) CBNA/Halmar must test communication systems at the start of each shift and as necessary thereafter to ensure proper operation.

F. Worker Qualifications and Training

CBNA/Halmar must:

1. Ensure that each affected worker receives effective training on how to safely enter, work in, exit from, and undertake emergency evacuation or rescue from, hyperbaric conditions, and document this training.

2. Provide effective instruction on hyperbaric conditions, before beginning

¹⁷ See ANSI/AIHA Z10–2012, American National Standard for Occupational Health and Safety Management Systems, for reference.

¹⁸ See ANSI/ASSE A10.33–2011, American National Standard for Construction and Demolition Operations—Safety and Health Program Requirements for Multi-Employer Projects, for reference.

¹⁶ Adapted from 29 CFR 1926.32(m).

hyperbaric operations, to each worker who performs work, or controls the exposure of others, and document this instruction. The instruction must include:

- (a) The physics and physiology of hyperbaric work;
- (b) Recognition of pressure-related injuries;
- (c) Information on the causes and recognition of the signs and symptoms associated with decompression illness, and other hyperbaric intervention-related health effects (e.g., barotrauma, nitrogen narcosis, and oxygen toxicity);
- (d) How to avoid discomfort during compression and decompression;
- (e) Information the workers can use to contact the appropriate healthcare professionals should the workers have concerns that they may be experiencing adverse health effects from hyperbaric exposure; and
- (f) Procedures and requirements applicable to the employee in the project-specific HOM.

3. Repeat the instruction specified in paragraph (G) of this condition periodically and as necessary (e.g., after making changes to its hyperbaric operations).

4. When conducting training for its hyperbaric workers, make this training available to OSHA personnel and notify the OTPCA at OSHA's national office and OSHA's Baltimore/Washington Area Office before the training takes place.

G. Inspections, Tests, and Accident Prevention

1. CBNA/Halmar must initiate and maintain a program of frequent and regular inspections of the TBM's hyperbaric equipment and support systems (such as temperature control, illumination, ventilation, and fire-prevention and fire-suppression systems), and hyperbaric work areas, as required under 29 CFR 1926.20(b)(2), including:

(a) Developing a set of checklists to be used by a competent person in conducting weekly inspections of hyperbaric equipment and work areas; and

(b) Ensuring that a competent person conducts daily visual checks and weekly inspections of the TBM.

2. CBNA/Halmar must remove any equipment that is found to constitute a safety hazard until CBNA/Halmar corrects the hazardous condition and has the correction approved by a qualified person.

3. CBNA/Halmar must maintain records of all tests and inspections of the TBM, as well as associated corrective actions and repairs, at the job

site for the duration of the tunneling project and for 90 days after the final project report is submitted to OSHA.

H. Compression and Decompression

CBNA/Halmar must consult with its attending physician concerning the need for special compression or decompression exposures appropriate for CAWs not acclimated to hyperbaric exposure.

I. Recordkeeping

In addition to completing OSHA Form 301 Injury and Illness Incident Report and OSHA Form 300 Log of Work-Related Injuries and Illnesses, CBNA/Halmar must maintain records of:

- 1. The date, times (e.g., time compression started, time spent compressing, time performing intervention, time spent decompressing), and pressure for each hyperbaric intervention.
- 2. The names of all supervisors and DMTs involved for each intervention.
- 3. The name of each individual worker exposed to hyperbaric pressure and the decompression protocols and results for each worker.
- 4. The total number of interventions and the amount of hyperbaric work time at each pressure.
- 5. The results of the post-intervention physical assessment of each CAW for signs and symptoms of decompression illness, barotrauma, nitrogen narcosis, oxygen toxicity or other health effects associated with work in compressed air for each hyperbaric intervention.

J. Notifications

1. To assist OSHA in administering the conditions specified herein, CBNA/Halmar must:

(a) Notify the OTPCA and the Baltimore/Washington OSHA Area Office at www.osha.gov/contactus/byoffice of any recordable injury, illness, or fatality (by submitting the completed OSHA Form 301 Injury and Illness Incident Report)¹⁹ resulting from exposure of an employee to hyperbaric conditions, including those that do not require recompression treatment (e.g., nitrogen narcosis, oxygen toxicity, barotrauma), but still meet the recordable injury or illness criteria of 29 CFR 1904. The notification must be made within 8 hours of the incident or 8 hours after becoming aware of a recordable injury, illness, or fatality; a copy of the incident investigation

(OSHA Form 301 Injuries and Illness Incident Report) must be submitted to OSHA within 24 hours of the incident or 24 hours after becoming aware of a recordable injury, illness, or fatality. In addition to the information required by OSHA Form 301 Injuries and Illness Incident Report, the incident-investigation report must include a root-cause determination, and the preventive and corrective actions identified and implemented.

(b) Provide certification to OTPCA and the Baltimore/Washington OSHA Area Office within 15 working days of the incident that CBNA/Halmar informed affected workers of the incident and the results of the incident investigation (including the root-cause determination and preventive and corrective actions identified and implemented).

(c) Notify the OTPCA and the Baltimore/Washington OSHA Area Office within 15 working days and in writing, of any change in the compressed-air operations that affects CBNA/Halmar's ability to comply with the conditions specified herein.

(d) Upon completion of the Potomac River Tunnel Project, evaluate the effectiveness of the decompression tables used throughout the project, and provide a written report of this evaluation to the OTPCA and the Baltimore/Washington OSHA Area Office.

Note: The evaluation report must contain summaries of: (1) The number, dates, durations, and pressures of the hyperbaric interventions completed; (2) decompression protocols implemented (including composition of gas mixtures (air and/or oxygen), and the results achieved; (3) the total number of interventions and the number of hyperbaric incidents (decompression illnesses and/or health effects associated with hyperbaric interventions as recorded on OSHA Form 301 Injuries and Illness Incident Report and OSHA Form 300 Log of Work-Related Injuries and Illnesses, and relevant medical diagnoses, and treating physicians' opinions); and (4) root causes of any hyperbaric incidents, and preventive and corrective actions identified and implemented.

(e) To assist OSHA in administering the conditions specified herein, inform the OTPCA and the Baltimore/Washington OSHA Area Office as soon as possible, but no later than seven (7) days, after it has knowledge that it will:

- (i) Cease doing business;
- (ii) Change the location and address of the main office for managing the tunneling operations specified herein; or
- (iii) Transfer the operations specified herein to a successor company.

¹⁹ See 29 CFR 1904 (Recording and Reporting Occupational Injuries and Illnesses) (http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9631); recordkeeping forms and instructions <http://www.osha.gov/recordkeeping/forms>.

(f) Notify all affected employees of this permanent variance by the same means required to inform them of its application for a permanent variance.

2. This permanent variance cannot be transferred to a successor company without OSHA approval.

OSHA hereby grants a permanent variance to CBNA/Halmar Joint Venture for the completion of the Potomac River Tunnel Project in Washington, DC.

VIII. Authority and Signature

David Keeling, Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue NW, Washington, DC 20210, authorized the preparation of this notice. Accordingly, the agency is issuing this notice pursuant to 29 U.S.C. 655(d), Secretary of Labor's Order No. 7–2025 (90 FR 27878, June 30, 2025), and 29 CFR 1905.11.

Signed at Washington, DC, on December 19, 2025.

David Keeling,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2025–23805 Filed 12–23–25; 8:45 am]

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DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2025–0004]

McNally Tunneling Corp./ASI Marine Southerly Tunnel and Consolidation Project: Grant of Permanent Variance

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: In this notice, OSHA grants a permanent variance to McNally Tunneling Corp./ASI Marine (McNally/ASI Marine) related to work in compressed-air environments.

DATES: The permanent variance specified by this notice becomes effective on December 29, 2025 and shall remain in effect until the completion of the Southerly Tunnel and Consolidation project or until modified or revoked by OSHA.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, phone: (202) 693–1999; email: meilinger.francis2@dol.gov.

General and Technical Information: Contact Kevin Robinson, Director, Office of Technical Programs and

Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor; phone: (202) 693–1911 or email: robinson.kevin@dol.gov.

SUPPLEMENTARY INFORMATION:

Copies of this Federal Register notice: Electronic copies of this **Federal Register** notice are available at <http://www.regulations.gov>. This **Federal Register** notice and other relevant information are also available at OSHA's web page at <http://www.osha.gov>.

I. Overview

On July 16, 2024, OSHA received a variance application submitted by letter from McNally Tunneling Corp./ASI (McNally/ASI Marine or the applicant) submitted under Section 6(d) of the Occupational Safety and Health Act of 1970 (the Act), 29 U.S.C. 655, and 29 CFR 1905.11 (Variances and other relief under Section 6(d)) an application for a permanent variance from several provisions of the OSHA standard that regulates work in compressed air, 1926.803 of 1926 Subpart S—Underground Construction, Caissons, Cofferdams, and Compressed Air, and an interim order allowing it to proceed while OSHA considers the request for a permanent variance. This notice addresses McNally/ASI Marine's application for a permanent variance and interim order for construction of Southerly Tunnel and Consolidation Project in Cleveland, Ohio, only and is not applicable to future McNally/ASI Marine tunneling projects.

Specifically, McNally/ASI Marine sought a variance from the provisions of the standard that: (1) prohibit compressed-air worker exposure to pressures exceeding 50 pounds per square inch (p.s.i.) except in an emergency (29 CFR 1926.803(e)(5));¹ (2) require the use of the decompression values specified in decompression tables in Appendix A of the compressed-air standard for construction (29 CFR 1926.803(f)(1)); and (3) require the use of automated operational controls and a special decompression chamber (29 CFR 1926.803(g)(1)(iii) and .803(g)(1)(xvii), respectively). McNally/ASI Marine also requested an interim order pending OSHA's decision on the application for

¹ The decompression tables in Appendix A of subpart S express the maximum working pressures as pounds per square inch gauge (p.s.i.g.), with a maximum working pressure of 50 p.s.i.g. Therefore, throughout this notice, OSHA expresses the 50 p.s.i. value specified by 29 CFR 1926.803(e)(5) as 50 p.s.i.g., consistent with the terminology in Appendix A, Table 1 of subpart S.

a variance (Document ID No. OSHA–2025–0004–0002).

OSHA reviewed McNally/ASI Marine's application for a permanent variance and interim order and determined that it was appropriately submitted in compliance with the applicable variance procedures in Section 6(d) of the Occupational Safety and Health Act of 1970 (OSH Act; 29 U.S.C. 655) and OSHA's regulations at 29 CFR 1905.11 (variances and other relief under section 6(d)).

OSHA reviewed the alternative procedures in McNally/ASI Marine's application and preliminarily determined that the applicant's proposed alternatives on the whole, subject to the conditions in the request and imposed by the interim order, provide measures that are as safe and healthful as those required by the cited OSHA standards. On July 24, 2025, OSHA published a **Federal Register** notice announcing McNally/ASI Marine's application for permanent variance, stating the preliminary determination along with the basis of that determination, and granting the interim order (90 FR 34887). OSHA requested comments on each.

OSHA did not receive any comments or other information disputing the preliminary determination that the alternatives were at least as safe as OSHA's standard, nor any objections to OSHA granting a permanent variance. Accordingly, through this notice OSHA grants a permanent variance, subject to the conditions set out in this document.

A. Background

The information that follows about McNally/ASI Marine, its methods, and its project comes from McNally/ASI Marine's variance application.

McNally/ASI Marine is a contractor for the Southerly Tunnel and Consolidation Project (the project), that works on complex tunnel projects using innovations in tunnel-excavation methods. The applicant's workers engage in the construction of tunnels using advanced shielded mechanical excavation techniques in conjunction with an earth pressure balanced micro-tunnel boring machine (TBM). Using shielded mechanical excavation techniques, in conjunction with precast concrete tunnel liners and backfill grout, TBMs provide methods to achieve the face pressures required to maintain a stabilized tunnel face through various geologies and isolate that pressure to the forward section (the working chamber) of the TBM.

McNally/ASI Marine asserts that it bores tunnels using a TBM at levels below the water table through soft soils

consisting of clay, silt, and sand. TBMs are capable of maintaining pressure at the tunnel face, and stabilizing existing geological conditions, through the controlled use of a mechanically driven cutter head, bulkheads within the shield, ground-treatment foam, and a screw conveyor that moves excavated material from the working chamber. The forward-most portion of the TBM is the working chamber, and this chamber is the only pressurized segment of the TBM. Within the shield, the working chamber consists of two sections: the forward working chamber and the staging chamber. The forward working chamber is immediately behind the cutter head and tunnel face. The staging chamber is behind the forward working chamber and between the man-lock door and the entry door to the forward working chamber.

The TBM has twin man-locks located between the pressurized working chamber and the non-pressurized portion of the machine. Each man-lock has two compartments. This configuration allows workers to access the man-locks for compression and decompression, and medical personnel to access the man-locks if required in an emergency.

McNally/ASI Marine's Hyperbaric Operations Manual (HOM) for the Southerly Tunnel and Consolidation Project indicates that the maximum pressure to which it is likely to expose workers during project interventions for the Southerly Tunnel and Consolidation Project is 58 p.s.i. Therefore, to work effectively, McNally/ASI Marine must perform hyperbaric interventions in compressed air at pressures nearly 20% higher than the maximum pressure specified by the existing OSHA standard, 29 CFR 1926.803(e)(5), which states: "No employee shall be subjected to pressure exceeding 50 p.s.i. except in emergency" (see footnote 1).

McNally/ASI Marine employs specially trained personnel for the construction of the tunnel. To keep the machinery working effectively, McNally/ASI Marine asserts that these workers must periodically enter the excavation working chamber of the TBM to perform hyperbaric interventions during which workers would be exposed to air pressures up to 58 p.s.i., which exceeds the maximum pressure specified by the existing OSHA standard at 29 CFR 1926.803(e)(5). These interventions consist of conducting inspections or maintenance work on the cutter-head structure and cutting tools of the TBM, such as changing replaceable cutting tools and disposable wear bars, and, in rare cases, repairing structural damage to the cutter head.

These interventions are the only time that workers are exposed to compressed air. Interventions in the working chamber (the pressurized portion of the TBM) take place only after halting tunnel excavation and preparing the machine and crew for an intervention.

During interventions, workers enter the working chamber through one of the twin man-locks that open into the staging chamber. To reach the forward part of the working chamber, workers pass through a door in a bulkhead that separates the staging chamber from the forward working chamber. The man-locks and the working chamber are designed to accommodate three people, which is the maximum crew size allowed under the permanent variance. When the required decompression times are greater than work times, the twin man-locks allow for crew rotation. During crew rotation, one crew can be compressing or decompressing while the second crew is working. Therefore, the working crew always has an unoccupied man-lock at its disposal.

McNally/ASI Marine asserts that these innovations in tunnel excavation have greatly reduced worker exposure to hazards of pressurized air work because they have eliminated the need to pressurize the entire tunnel for the project and would thereby reduce the number of workers exposed, as well as the total duration of exposure, to hyperbaric pressure during tunnel construction. These advances in technology substantially modified the methods used by the construction industry to excavate subaqueous tunnels compared to the caisson work regulated by the current OSHA compressed-air standard for construction at 29 CFR 1926.803.

In addition to the reduced exposures resulting from the innovations in tunnel-excavation methods, McNally/ASI Marine asserts that innovations in hyperbaric medicine and technology improve the safety of decompression from hyperbaric exposures. These procedures, however, would deviate from the decompression process that OSHA requires for construction in 29 CFR 1926.803(e)(5) and (f)(1) and the decompression tables in Appendix A of 29 CFR 1926, subpart S. Nevertheless, according to McNally/ASI Marine, their use of decompression protocols incorporating oxygen is more efficient, effective, and safer for tunnel workers than compliance with the decompression tables specified by the existing OSHA standard.

McNally/ASI Marine contends that the alternative safety measures included in the application provide McNally/ASI Maine's workers with a place of

employment that is at least as safe under its proposed alternatives as they would be under OSHA's compressed-air standard for construction. McNally/ASI Marine also provided OSHA a project-specific HOM, (OSHA-2025-0004-0003) that requires specialized medical support and hyperbaric supervision to provide assistance to a team of specially trained man-lock attendants and hyperbaric or compressed-air workers to support their assertions of equivalency in worker protection.

OSHA included all of the above information in the **Federal Register** notice regarding McNally/ASI Marine's variance application and did not receive any comments disputing any of that information, including the safety assertions made by McNally/ASI Marine in the variance application.

II. The Variance Application

Pursuant to the requirements of OSHA's variance regulations (29 CFR 1905.11), the applicant has certified that it notified its workers² of the variance application and request for interim order by posting, at prominent locations where it normally posts workplace notices, a summary of the application and information specifying where the workers can examine a copy of the application. In addition, the applicant has certified that it informed its workers of their right to petition the Assistant Secretary of Labor for Occupational Safety and Health for a hearing on the variance modification application.

III. OSHA History of Approval of Nearly Identical Variance Requests

OSHA has previously approved several nearly identical variances involving the same types of tunneling equipment used for similar projects (tunnel construction variances). OSHA notes that it granted several subaqueous tunnel construction permanent variances from the same provisions of OSHA's compressed-air standard (29 CFR 1926.803(e)(5), (f)(1), (g)(1)(iii), and (g)(1)(xvii)) that are the subject of the present application: (1) Impregilo, Healy, Parsons, Joint Venture (IHP JV) for the Anacostia River Tunnel in Washington, DC (80 FR 50652, August 20, 2015); (2) Traylor JV for the Blue Plains Tunnel in Washington, DC (80 FR 16440, March 27, 2015); (3) Tully/OHL USA Joint Venture for the New York Economic Development Corporation's New York Siphon Tunnel project (79 FR 29809, May 23, 2014); (4) Salini-Impregilo/Healy Joint Venture for the Northeast Boundary Tunnel in

² See the definition of "Affected employee or worker" in section VII.C. of this Notice.

Washington, DC (85 FR 27767, May 11, 2020); (5) McNally/Kiewit SST for the Shoreline Storage Tunnel in Cleveland, Ohio (88 FR 15080, March 10, 2023); (6) Traylor Shea Joint Venture for the Alexandria RiverRenew Tunnel Project in Alexandria, Virginia and Washington, DC (88 FR 15090, March 10, 2023); (7) Traylor-Sundt Joint Venture, for the Integrated Pipeline Tunnel Project in Dallas, Texas (88 FR 83152, November 28, 2023); (8) Ballard Marine Construction for the Bay Park Conveyance Tunnel Project in Nassau County, New York (89 FR 8442, February 7, 2024); and (9) Ballard Marine Construction for the Lower Olentangy Tunnel Project in Columbus, Ohio (89 FR 78906, September 26, 2024). OSHA also granted interim orders to Ballard Marine Construction for the Suffolk County, New York Outfall Tunnel Project (86 FR 5253, January 19, 2021) and CBNA/Halmar Joint Venture (90 FR 34902, July 24, 2025) in addition to the interim order granted for this project. The proposed alternate conditions in this notice are nearly identical to the alternate conditions of the previous permanent variances. OSHA is not aware of any injuries or other safety issues that arose from work performed under these conditions in accordance with the previous variances.

IV. Applicable OSHA Standard and the Relevant Variance

A. Variance From Paragraph (e)(5) of 29 CFR 1926.803, Prohibition of Exposure to Pressure Greater Than 50 p.s.i.g. (see footnote 1)

The applicant states that it may perform hyperbaric interventions at pressures up to 58 p.s.i.g. in the working chamber of the TBM; this pressure exceeds the pressure limit of 50 p.s.i. specified for nonemergency purposes by 29 CFR 1926.803(e)(5). The TBM has twin man-locks, with each man-lock having two compartments. This configuration allows workers to access the man-locks for compression and decompression, and medical personnel to access the man-locks if required in an emergency.

TBMs are capable of maintaining pressure at the tunnel face, and stabilizing existing geological conditions, through the controlled use of a mechanically driven cutter head, bulkheads within the shield, ground-treatment foam, and a screw conveyor that moves excavated material from the working chamber. As noted earlier, the forward-most portion of the TBM is the working chamber, and this chamber is the only pressurized segment of the

TBM. Within the shield, the working chamber consists of two sections: the staging chamber and the forward working chamber. The staging chamber is the section of the working chamber between the man-lock door and the entry door to the forward working chamber. The forward working chamber is immediately behind the cutter head and tunnel face.

McNally/ASI Marine will pressurize the working chamber to the level required to maintain a stable tunnel face. Pressure in the staging chamber ranges from atmospheric (no increased pressure) to a maximum pressure equal to the pressure in the working chamber. The applicant asserts that they may have to perform interventions at pressures up to 58 p.s.i.

During interventions, workers enter the working chamber through one of the twin man-locks that open into the staging chamber. To reach the forward part of the working chamber, workers pass through a door in a bulkhead that separates the staging chamber from the forward working chamber. The maximum crew size allowed in the forward working chamber is three. At certain hyperbaric pressures (*i.e.*, when decompression times are greater than work times), the twin man-locks allow for crew rotation. During crew rotation, one crew can be compressing or decompressing while the second crew is working. Therefore, the working crew always has an unoccupied man-lock at its disposal.

Further, McNally/ASI Marine has developed a project-specific HOM (OSHA–2025–0004–0003) that describes in detail the hyperbaric procedures, the required medical examination used during the tunnel-construction project, the standard operating procedures and the emergency and contingency procedures. The procedures include using experienced and knowledgeable man-lock attendants who have the training and experience necessary to recognize and treat decompression illnesses and injuries. The attendants are under the direct supervision of the hyperbaric supervisor (a competent person experienced and trained in hyperbaric operations, procedures and safety) and attending physician. In addition, procedures include medical screening and review of prospective compressed-air workers (CAWs). The purpose of this screening procedure is to vet prospective CAWs with medical conditions (*e.g.*, deep vein thrombosis, poor vascular circulation, and muscle cramping) that could be aggravated by sitting in a cramped space (*e.g.*, a man-lock) for extended periods, or by exposure to elevated pressures and

compressed gas mixtures. A transportable recompression chamber (shuttle) is available to extract workers from the hyperbaric working chamber for emergency evacuation and medical treatment; the shuttle attaches to the topside medical lock, which is a large recompression chamber. The applicant believes that the procedures included in the HOM provide safe work conditions when interventions are necessary, including interventions above 50 p.s.i. or 50 p.s.i.g.

OSHA comprehensively reviewed the project-specific HOM and determined that the safety and health instructions and measures it specifies are appropriate, conform with the conditions in the variance, and adequately protect the safety and health of the CAWs.

B. Variance From Paragraph (f)(1) of 29 CFR 1926.803, Requirement To Use OSHA Decompression Tables

OSHA's compressed-air standard for construction requires decompression in accordance with the decompression tables in Appendix A of 29 CFR 1926, subpart S (29 CFR 1926.803(f)(1)). As an alternative to the OSHA decompression tables, the applicant proposes to use newer decompression schedules (the 1992 French Decompression Tables) that rely on staged decompression and supplement breathing air used during decompression with air or oxygen (as appropriate).³ The applicant asserts decompression protocols using the 1992 French Decompression Tables for air or oxygen as specified by the Southerly Tunnel and Consolidation Project-specific Hyperbaric Operations Manual (HOM) are safer for tunnel workers than the decompression protocols specified in Appendix A of 29 CFR 1926, subpart S. Accordingly, the applicant commits to following the decompression procedures described in that HOM, which would require it to follow the 1992 French Decompression Tables to decompress CAWs after they exit the hyperbaric conditions in the working chamber.

Depending on the maximum working pressure and exposure times, the 1992 French Decompression Tables provide for air decompression with or without oxygen. McNally/ASI Marine asserts that oxygen decompression has many

³ In 1992, the French Ministry of Labour replaced the 1974 French Decompression Tables with the 1992 French Decompression Tables, which differ from OSHA's decompression tables in Appendix A by using: (1) staged decompression as opposed to continuous (linear) decompression; (2) decompression tables based on air or both air and pure oxygen; and (3) emergency tables when unexpected exposure times occur (up to 30 minutes above the maximum allowed working time).

benefits, including (1) keeping the partial pressure of nitrogen in the lungs as low as possible; (2) keeping external pressure as low as possible to reduce the formation of bubbles in the blood; (3) removing nitrogen from the lungs and arterial blood and increasing the rate of nitrogen elimination; (4) improving the quality of breathing during decompression stops so that workers are less tired and to prevent bone necrosis; (5) reducing decompression time by about 33 percent as compared to air decompression; and (6) reducing inflammation.

In addition, the project-specific HOM requires a physician, certified in hyperbaric medicine, to manage the medical condition of CAWs during hyperbaric exposures and decompression. A trained and experienced man-lock attendant also will be present during hyperbaric exposures and decompression. This man-lock attendant will operate the hyperbaric system to ensure compliance with the specified decompression table. A hyperbaric supervisor, trained in hyperbaric operations, procedures, and safety, directly oversees all hyperbaric interventions, and ensures that staff follow the procedures delineated in the HOM or by the attending physician.

C. Variance From Paragraph (g)(1)(iii) of 29 CFR 1926.803, Automatically Regulated Continuous Decompression

McNally/ASI Marine seeks a permanent variance from the OSHA standard at 29 CFR 1926.803(g)(1)(iii), which requires automatic controls to regulate decompression. As noted above, the applicant is committed to conducting the staged decompression according to the 1992 French Decompression Tables under the direct control of the trained man-lock attendant and under the oversight of the hyperbaric supervisor.

Breathing air under hyperbaric conditions increases the amount of nitrogen gas dissolves in a CAW's tissues. The greater the hyperbaric pressure under these conditions and the more time spent under the increased pressure, the greater the amount of nitrogen gas dissolved in the tissues. When the pressure decreases during decompression, tissues release the dissolved nitrogen gas into the blood system, which then carries the nitrogen gas to the lungs for elimination through exhalation. Releasing hyperbaric pressure too rapidly during decompression can increase the size of the bubbles formed by nitrogen gas in the blood system, resulting in decompression illness (DCI), commonly referred to as "the bends." This

description of the etiology of DCI is consistent with current scientific theory and research on the issue (see footnote 16 in this notice discussing a 1985 NIOSH report on DCI).

The 1992 French Decompression Tables proposed for use by the applicant provide for stops during worker decompression (*i.e.*, staged decompression) to control the release of nitrogen gas from tissues into the blood system. Studies show that staged decompression, in combination with other features of the 1992 French Decompression Tables such as the use of oxygen, result in a lower incidence of DCI than the use of automatically regulated continuous decompression.⁴ In addition, the applicant asserts that staged decompression administered in accordance with its HOM is at least as effective as an automatic controller in regulating the decompression process because the HOM includes a hyperbaric supervisor who directly supervises all hyperbaric interventions and ensures that the man-lock attendant, who is a competent person in the manual control of hyperbaric systems, follows the schedule specified in the decompression tables, including stops.

D. Variance From Paragraph (g)(1)(xvii) of 29 CFR 1926.803, Requirement of Special Decompression Chamber

The OSHA compressed-air standard for construction requires employers to use a special decompression chamber of sufficient size to accommodate all CAWs being decompressed at the end of the shift when total decompression time exceeds 75 minutes (see 29 CFR 1926.803(g)(1)(xvii)). Use of the special decompression chamber enables CAWs

to move about and flex their joints to prevent neuromuscular problems during decompression.

Space limitations in the TBM do not allow for the installation and use of an additional special decompression lock or chamber. The applicant proposes that it be permitted to rely on the man-locks and staging chamber in lieu of adding a separate, special decompression chamber. Because only a few workers out of the entire crew are exposed to hyperbaric pressure, the man-locks (which, as noted earlier, connect directly to the working chamber) and the staging chamber are of sufficient size to accommodate all exposed workers during decompression. The applicant uses the existing man-locks, each of which adequately accommodates a three-member crew for this purpose when decompression lasts up to 75 minutes. When decompression exceeds 75 minutes, crews can open the door connecting the two compartments in each man-lock (during decompression stops) or exit the man-lock and move into the staging chamber where additional space is available. The applicant asserts that this alternative arrangement is as effective as a special decompression chamber in that it has sufficient space for all the CAWs at the end of a shift and enables the CAWs to move about and flex their joints to prevent neuromuscular problems.

V. Decision

After reviewing the proposed alternatives, OSHA has determined that the applicant's proposed alternatives on the whole, subject to the conditions in the variance request and imposed by this permanent variance, provide measures that are as safe and healthful as those required by the cited OSHA standards addressed in section IV of this notice.

In addition, OSHA has determined that each of the following alternatives are at least as effective as the specified OSHA requirements:

A. 29 CFR 1926.803(e)(5)

McNally/ASI Marine has developed, and proposed to implement, effective alternative measures to the prohibition of using compressed air under hyperbaric conditions exceeding 50 p.s.i. The alternative measures include use of engineering and administrative controls of the hazards associated with work performed in compressed-air conditions exceeding 50 p.s.i. while engaged in the construction of a subaqueous tunnel using advance shielded mechanical-excavation techniques in conjunction with the TBM. Prior to conducting interventions

⁴ See, *e.g.*, Dr. Eric Kindwall, EP (1997), Compressed air tunneling and caisson work decompression procedures: development, problems, and solutions. *Undersea and Hyperbaric Medicine*, 24(4), pp. 337-345. This article reported 60 treated cases of DCI among 4,168 exposures between 19 and 31 p.s.i.g. over a 51-week contract period, for a DCI incidence of 1.44% for the decompression tables specified by the OSHA standard. Dr. Kindwall notes that the use of automatically regulated continuous decompression for compressed-air work was in some cases at the insistence of contractors and the union, and against the advice of the expert who calculated the decompression table and recommended using staged decompression. Dr. Kindwall then states, "Continuous decompression is inefficient and wasteful. For example, if the last stage from 4 p.s.i.g. . . . to the surface took 1h, at least half the time is spent at pressures less than 2 p.s.i.g. . . . , which provides less and less meaningful bubble suppression. . . ." In addition, Dr. Kindwall addresses the continuous-decompression protocol in the OSHA compressed-air standard for construction, noting that "[a]side from the tables for saturation diving to deep depths, no other widely used or officially approved diving decompression tables use straight line, continuous decompressions at varying rates. Stage decompression is usually the rule, since it is simpler to control."

in the TBM's pressurized working chamber, McNally/ASI Marine halts tunnel excavation and prepares the machine and crew to conduct the interventions. Interventions involve inspection, maintenance, or repair of the mechanical-excavation components located in the working chamber.

B. 29 CFR 1926.803(f)(1)

The applicant has proposed to implement equally effective alternative measures to the requirement in 29 CFR 1926.803(f)(1) for compliance with OSHA's decompression tables. The HOM specifies the procedures and personnel qualifications for performing work safely during the compression and decompression phases of interventions. The HOM also specifies the decompression tables the applicant proposes to use (the 1992 French Decompression Tables). Depending on the maximum working pressure and exposure times during the interventions, the tables provide for decompression using air, pure oxygen, or a combination of air and oxygen. The decompression tables also include delays or stops for various time intervals at different pressure levels during the transition to atmospheric pressure (*i.e.*, staged decompression). In all cases, a physician certified in hyperbaric medicine will manage the medical condition of CAWs during decompression. In addition, a trained and experienced man-lock attendant, experienced in recognizing decompression sickness or illnesses and injuries, will be present. Of key importance, a hyperbaric supervisor, trained in hyperbaric operations, procedures, and safety, will directly supervise all hyperbaric operations to ensure compliance with the procedures delineated in the project-specific HOM or by the attending physician.

Prior to granting the previous permanent variances to IHP JV, Traylor JV, Tully JV, Salini-Impregilo Joint Venture, McNally/Kiewit, Traylor-Shea, Traylor-Sundt and Ballard, OSHA conducted a review of the scientific literature and concluded that the alternative decompression method (*i.e.*, the 1992 French Decompression Tables) McNally/ASI Marine proposed would be at least as safe as the decompression tables specified by OSHA when applied by trained medical personnel under the conditions outlined in this variance application.

Some of the literature indicates that the alternative decompression method may be safer, concluding that decompression performed in accordance with these tables resulted in a lower occurrence of DCI than decompression

conducted in accordance with the decompression tables specified by the standard. For example, H. L. Andersen studied the occurrence of DCI at maximum hyperbaric pressures ranging from 4 p.s.i.g. to 43 p.s.i.g. during construction of the Great Belt Tunnel in Denmark (1992–1996).⁵ This project used the 1992 French Decompression Tables to decompress the workers during part of the construction. Andersen observed 6 DCI cases out of 7,220 decompression events and reported that switching to the 1992 French Decompression tables reduced the DCI incidence to 0.08% compared to a previous incidence rate of 0.14%. The DCI incidence in the study by H. L. Andersen is substantially less than the DCI incidence reported for the decompression tables specified in Appendix A.

OSHA found no studies in which the DCI incidence reported for the 1992 French Decompression Tables were higher than the DCI incidence reported for the OSHA decompression tables.⁶

OSHA's experience with the previous variances, which all incorporated nearly identical decompression plans and did not result in safety issues, also provides evidence that the alternative procedure as a whole is at least as effective for this type of tunneling project as compliance with OSHA's decompression tables. The experience of State Plans⁷ that either granted variances (Nevada, Oregon and Washington)⁸ or promulgated a new standard (California)⁹ for hyperbaric exposures occurring during similar subaqueous tunnel-construction work, provide additional evidence of the effectiveness of this alternative procedure.

⁵ Anderson HL (2002). Decompression sickness during construction of the Great Belt tunnel, Denmark.

⁶ Le Péchon JC, Barre P, Baud JP, Ollivier F (September 1996). Compressed air work—French Tables 1992—operational results. *JCLP Hyperbarie Paris, Centre Medical Subaquatique Interentreprise, Marseille: Communication a l'EUBS*, pp. 1–5 (see Ex. OSHA–2012–0036–0005).

⁷ Section 18 of the OSH Act. Congress expressly provides that States and U.S. territories may adopt, with Federal approval, a plan for the development and enforcement of occupational safety and health standards. OSHA refers to such States and territories as "State Plans." Occupational safety and health standards developed by State Plans must be at least as effective in providing safe and healthful employment and places of employment as the Federal standards (29 U.S.C. 667).

⁸ These state variances are available in the docket for the 2015 Traylor JV variance: Exs. OSHA–2012–0035–0006 (Nevada), OSHA–2012–0035–0005 (Oregon), and OSHA–2012–0035–0004 (Washington).

⁹ See California Code of Regulations, Title 8, Subchapter 7, Group 26, Article 154, available at <http://www.dir.ca.gov/title8/sb7g26a154.html>.

C. 29 CFR 1926.803(g)(1)(iii)

The applicant developed, and proposed to implement, an equally effective alternative to 29 CFR 1926.803(g)(1)(iii), which requires the use of automatic controllers that continuously decrease pressure to achieve decompression in accordance with the tables specified by the standard. The applicant's alternative includes using the 1992 French Decompression Tables for guiding staged decompression to achieve lower occurrences of DCI, using a trained and competent attendant for implementing appropriate hyperbaric entry and exit procedures, and providing a competent hyperbaric supervisor and attending physician certified in hyperbaric medicine to oversee all hyperbaric operations.

In reaching this preliminary conclusion, OSHA again notes the experience of previous nearly identical tunneling variances, the experiences of State Plan States, and a review of the literature and other information noted earlier.

D. 29 CFR 1926.803(g)(1)(xvii)

The applicant developed, and proposed to implement, an effective alternative to the use of the special decompression chamber required by 29 CFR 1926.803(g)(1)(xvii). The TBM's man-lock and working chamber appear to satisfy all of the conditions of the special decompression chamber, including that they provide sufficient space for the maximum crew of three CAWs to stand up and move around, and safely accommodate decompression times exceeding 75 minutes. Therefore, again noting OSHA's previous experience with nearly identical variances including the same alternative, OSHA preliminarily determined that the TBM's man-lock and working chamber function as effectively as the special decompression chamber required by the standard.

Based on a review of available evidence, the experience of State Plans that either granted variances (Nevada, Oregon, and Washington)¹⁰ or promulgated a new standard (California)¹¹ for hyperbaric exposures occurring during similar subaqueous tunnel-construction work, and the information provided in the applicant's

¹⁰ These state variances are available in the docket: Exs. OSHA–2012–0035–0006 (Nevada), OSHA–2012–0035–0007 (Oregon), and OSHA–2012–0035–0008 (Washington).

¹¹ See California Code of Regulations, Title 8, Subchapter 7, Group 26, Article 154, available at <http://www.dir.ca.gov/title8/sb7g26a154.html>.

variance application, OSHA is granting the permanent variance.

Pursuant to Section 6(d) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655), and based on the record discussed above, the agency finds that when the McNally/ASI Marine complies with the conditions of the following order, the working conditions of the McNally/ASI Marine's workers are at least as safe and healthful as if it complied with the working conditions specified by paragraphs (e)(5), (f)(1), (g)(1)(iii), and (g)(1)(xvii) of 29 CFR 1926.803. Therefore, McNally/ASI Marine must: (1) comply with the conditions listed below under "Conditions Specified for the Permanent Variance" for the period between the date of this notice and completion of the Southerly Tunnel and Consolidation Project; (2) comply fully with all other applicable provisions of 29 CFR part 1926; and (3) provide a copy of this **Federal Register** notice to all employees affected by the conditions, including the affected employees of other employers, using the same means it used to inform these employees of the application for a permanent variance. Additionally, this order will remain in effect until one of the following conditions occurs: (1) completion of the Southerly Tunnel and Consolidation Project; or (2) OSHA modifies or revokes this final order in accordance with 29 CFR 1905.13.

VI. Description of the Conditions Specified for the Permanent Variance

The conditions for the variance are set out in the Order at the end of this document. This section provides additional detail regarding the conditions in the Order.

Condition A: Scope

The scope of the permanent variance limits coverage to the work situations specified under this condition. Clearly defining the scope of the permanent variance provides McNally/ASI Marine, their employees, potential future applicants, other stakeholders, the public and OSHA with necessary information regarding the work situations in which the permanent variance applies. To the extent that McNally/ASI Marine exceeds the defined scope of this variance, it will be required to comply with OSHA's standards. This permanent variance applies only to McNally/ASI Marine, and only to the remainder of construction work on the Southerly Tunnel and Consolidation Project.

Condition B: List of Abbreviations

Condition B defines a number of abbreviations used in the permanent variance. OSHA believes that defining these abbreviations serves to clarify and standardize their usage, thereby enhancing the applicant's and their employees' understanding of the conditions specified by the permanent variance.

Condition C: Definitions

Condition C defines a series of terms, mostly technical terms, used in the permanent variance to standardize and clarify their meaning. Defining these terms serves to enhance the applicant's and their employees' understanding of the conditions specified by the permanent variance.

Condition D: Safety and Health Practices

This condition requires the applicant to develop and submit to OSHA an HOM specific to the Southerly Tunnel and Consolidation Project at least six months before using the TBM for tunneling operations. The applicant must also submit, at least six months before using the TBM, proof that the TBM's hyperbaric chambers have been designed, fabricated, inspected, tested marked, and stamped in accordance with the requirements of the most recent edition of ASME PVHO-1—*Safety Standards for Pressure Vessels for Human Occupancy*). These requirements ensure that the applicant develops hyperbaric safety and health procedures suitable for the project.

The submission of the HOM to OSHA enables OSHA to determine that the specific safety and health instructions and measures it specifies are appropriate to the field conditions of the tunnel (including expected geological conditions), conform to the conditions of the variance, and adequately protect the safety and health of the CAWs. It also facilitates OSHA's ability to ensure that the applicant is complying with these instructions and measures. The requirement for proof of compliance with ASME PVHO-1 is intended to ensure that the equipment is structurally sound and capable of performing to protect the safety of the employees exposed to hyperbaric pressure. The applicant has submitted the HOM and proof of compliance with the most recent edition of ASME PVHO-1.

Additionally, the condition includes a series of related hazard prevention and control requirements and methods (e.g., decompression tables, job hazard analysis (JHA), operations and

inspections checklists, incident investigation, and recording and notification to OSHA of recordable hyperbaric injuries and illnesses) designed to ensure the continued effective functioning of the hyperbaric equipment and operating system.

Condition E: Communication

Condition E requires the applicant to develop and implement an effective system of information sharing and communication. Effective information sharing and communication ensures that affected workers receive updated information regarding any safety-related hazards and incidents, and corrective actions taken, prior to the start of each shift. The condition also requires McNally/ASI Marine to ensure that reliable means of emergency communications are available and maintained for affected workers and support personnel during hyperbaric operations. Availability of such reliable means of communications enables affected workers and support personnel to respond quickly and effectively to hazardous conditions or emergencies that may develop during TBM operations.

Condition F: Worker Qualification and Training

This condition requires the applicant to develop and implement an effective qualification and training program for affected workers. The condition specifies the factors that an affected worker must know to perform safely during hyperbaric operations, including how to enter, work in, and exit from hyperbaric conditions under both normal and emergency conditions. Having well-trained and qualified workers performing hyperbaric intervention work ensures that they recognize, and respond appropriately to, hyperbaric safety and health hazards. These qualification and training requirements enable affected workers to cope effectively with emergencies, as well as the discomfort and physiological effects of hyperbaric exposure, thereby preventing worker injury, illness, and fatalities.

Paragraph (2)(e) of this condition also requires the applicant to provide affected workers with information they can use to contact the appropriate healthcare professionals if they believe they are developing hyperbaric-related health effects. This requirement provides for early intervention and treatment of DCI and other health effects resulting from hyperbaric exposure, thereby reducing the potential severity of these effects.

Condition G: Inspections, Tests, and Accident Prevention

Condition G requires the applicant to develop, implement, and operate a program of frequent and regular inspections of the TBM's hyperbaric equipment and support systems, and associated work areas. This condition helps to ensure the safe operation and physical integrity of the equipment and work areas necessary to conduct hyperbaric operations. The condition also enhances worker safety by reducing the risk of hyperbaric-related emergencies.

Paragraph (3) of this condition requires the applicant to document tests, inspections, corrective actions, and repairs involving the TBM, and maintain these documents at the job site for the duration of the job. This requirement provides the applicant with information needed to schedule tests and inspections to ensure the continued safe operation of the equipment and systems, and to determine that the actions taken to correct defects in hyperbaric equipment and systems were appropriate, prior to returning them to service.

Condition H: Compression and Decompression

This condition requires the applicant to consult with a designated medical advisor regarding special compression or decompression procedures appropriate for any unacclimated CAW and then implement the procedures recommended by the medical advisor. This provision ensures that the applicant consults with the medical advisor, and involves the medical advisor in the evaluation, development, and implementation of compression or decompression protocols appropriate for any CAW requiring acclimation to the hyperbaric conditions encountered during TBM operations. Accordingly, CAWs requiring acclimation have an opportunity to acclimate prior to exposure to these hyperbaric conditions. OSHA believes this condition will prevent or reduce adverse reactions among CAWs to the effects of compression or decompression associated with the intervention work they perform in the TBM.

Condition I: Recordkeeping

Under OSHA's existing recordkeeping requirements in 29 CFR part 1904 regarding Recording and Reporting Occupational Injuries and Illnesses, the employer must maintain a record of any recordable injury, illness, or fatality (as defined by 29 CFR part 1904) resulting from exposure of an employee to

hyperbaric conditions by completing the OSHA Form 301 Incident Report and OSHA Form 300 Log of Work-Related Injuries and Illnesses. The applicant did not seek a variance from this standard and therefore McNally/ASI Marine must comply fully with those requirements.

Examples of important information to include on the OSHA Form 301 Injury and Illness Incident Report (along with the corresponding question on the form) are:

Q14

- the task performed;
- the composition of the gas mixture (e.g., air or oxygen);
- an estimate of the CAW's workload;
- the maximum working pressure;
- temperature in the work and decompression environments;
- unusual occurrences, if any, during the task or decompression

Q15

- time of symptom onset;
- duration between decompression and onset of symptoms

Q16

- type and duration of symptoms;
- a medical summary of the illness or injury

Q17

- duration of the hyperbaric intervention;
- possible contributing factors;
- the number of prior interventions completed by the injured or ill CAW; and the pressure to which the CAW was exposed during those interventions.¹²

Condition I adds additional reporting responsibilities, beyond those already required by the OSHA rule. McNally/ASI Marine is required to maintain records of specific factors associated with each hyperbaric intervention. The information gathered and recorded under this provision, in concert with the information provided under Condition J (using OSHA's Form 301 Injury and Illness Incident Report to investigate and record hyperbaric recordable injuries as defined by 29 CFR 1904.4, 1904.7, and 1904.8–.12), enables McNally/ASI Marine and OSHA to assess the effectiveness of the permanent variance in preventing DCI and other hyperbaric-related effects.

Condition J: Notifications

Under the notification condition, the applicant is required, within specified

periods of time, to notify OSHA of: (1) any recordable injury, illness, in-patient hospitalization, amputation, loss of an eye, or fatality that occurs as a result of hyperbaric exposures during TBM operations; (2) provide OSHA a copy of the hyperbaric exposures incident investigation report (using OSHA Form 301 Injury and Illness Incident Report) of these events within 24 hours of the incident; (3) include on OSHA Form 301 Injury and Illness Incident Report information on the hyperbaric conditions associated with the recordable injury or illness, the root-cause determination, and preventive and corrective actions identified and implemented; (4) provide the certification that affected workers were informed of the incident and the results of the incident investigation; (5) notify OSHA's Office of Technical Programs and Coordination Activities (OTPCA) and the Cleveland Ohio OSHA Area Office within 15 working days should the applicant need to revise the HOM to accommodate changes in its compressed-air operations that affect McNally/ASI Marine's ability to comply with the conditions of the modified permanent variance; and (6) provide OTPCA and the Cleveland Ohio OSHA Area Office, at the end of the project, with a report evaluating the effectiveness of the decompression tables.

It should be noted that the requirement for completing and submitting the hyperbaric exposure-related (recordable) incident investigation report (OSHA 301 Injury and Illness Incident Report) is more restrictive than the current recordkeeping requirement of completing OSHA Form 301 Injury and Illness Incident Report within 7 calendar days of the incident (1904.29(b)(3)). This modified, more stringent incident investigation and reporting requirement is restricted to intervention-related hyperbaric (recordable) incidents only. Providing rapid notification to OSHA is essential because time is a critical element in OSHA's ability to determine the continued effectiveness of the variance conditions in preventing hyperbaric incidents, and the applicant's identification and implementation of appropriate corrective and preventive actions.

Further, these notification requirements also enable the applicant, their employees, and OSHA to assess the effectiveness of the modified permanent variance in providing the requisite level of safety to the applicant's workers and based on this assessment, whether to revise or revoke

¹² See 29 CFR 1904 Recording and Reporting Occupational Injuries and Illnesses (http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9631); recordkeeping forms and instructions <https://www.osha.gov/recordkeeping/forms>.

the conditions of the modified permanent variance. Timely notification permits OSHA to take whatever action may be necessary and appropriate to prevent possible further injuries and illnesses. Providing notification to employees informs them of the precautions taken by the applicant to prevent similar incidents in the future.

Additionally, this condition requires the applicant to notify OSHA if it ceases to do business, has a new address or location for the main office, or transfers the operations covered by the modified permanent variance to a successor company. In addition, the condition specifies that the transfer of the modified permanent variance to a successor company must be approved by OSHA. These requirements allow OSHA to communicate effectively with the applicant regarding the status of the modified permanent variance and expedite the agency's administration and enforcement of the modified permanent variance. Stipulating that an applicant is required to have OSHA's approval to transfer a variance to a successor company provides assurance that the successor company has knowledge of, and will comply with, the conditions specified by modified permanent variance, thereby ensuring the safety of workers involved in performing the operations covered by the modified permanent variance.

VII. Order

As of the effective date of this final order, OSHA is revoking the interim order granted to the applicant on July 24, 2025 (90 FR 34887) and replacing it with a permanent variance order. Note that there are not any substantive changes in the conditions between the interim order and this final order.

OSHA issues this final order authorizing McNally/ASI Marine to comply with the following conditions instead of complying with the requirements of 29 CFR 1926.803(e)(5), (f)(1), (g)(1)(iii), and (g)(1)(xvii). These conditions are:

A. Scope

The permanent variance applies only when McNally/ASI Marine stops the tunnel-boring work, pressurizes the working chamber, and the CAWs either enter the working chamber to perform an intervention (*i.e.*, inspection, maintain, or repair the mechanical-excavation components), or exit the working chamber after performing interventions.

The permanent variance applies only to work:

1. That occurs in conjunction with construction of the Southerly Tunnel

and Consolidation Project in Cleveland, Ohio, a subaqueous tunnel constructed using advanced shielded mechanical-excavation techniques and involving operation of a TBM;

2. In the TBM's forward section (the working chamber) and associated hyperbaric chambers used to pressurize and decompress employees entering and exiting the working chamber; and

3. Performed in compliance with all applicable provisions of 29 CFR 1926 except for the requirement specified by 29 CFR 1926.803(e)(5), (f)(1), (g)(1)(iii), and (g)(1)(xvii).

4. This order will remain in effect until one of the following conditions occurs: (1) completion of the Southerly Tunnel and Consolidation Project; or (2) OSHA modifies or revokes this final order in accordance with 29 CFR 1905.13.

B. List of Abbreviations

Abbreviations used throughout this permanent variance include the following:

1. CAW—Compressed-air worker
2. CFR—Code of Federal Regulations
3. DCI—Decompression Illness
4. DMT—Diver Medical Technician
5. TBM—Earth Pressure Balanced Micro-Tunnel Boring Machine
6. HOM—Hyperbaric Operations and Safety Manual
7. JHA—Job hazard analysis
8. OSHA—Occupational Safety and Health Administration
9. OTPCA—Office of Technical Programs and Coordination Activities

C. Definitions

The following definitions apply to this permanent variance, McNally/ASI Marine's project-specific HOM, and all work carried out under the conditions of this permanent variance.

1. *Affected employee or worker*—an employee or worker who is affected by the conditions of this permanent variance, or any one of his or her authorized representatives. The term "employee" has the meaning defined and used under the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 *et seq.*)

2. *Atmospheric pressure*—the pressure of air at sea level, generally 14.7 p.s.i.a., 1 atmosphere absolute, or 0 pounds per square inch gauge (p.s.i.g.).

3. *Compressed-air worker*—an individual who is specially trained and medically qualified to perform work in a pressurized environment while breathing air at pressures not exceeding 58 p.s.i.g.

4. *Competent person*—an individual who is capable of identifying existing

and predictable hazards in the surroundings or working conditions that are unsanitary, hazardous, or dangerous to employees, and who has authorization to take prompt corrective measures to eliminate them.¹³

5. *Decompression illness (also called decompression sickness or the bends)*—an illness caused by gas bubbles appearing in body compartments due to a reduction in ambient pressure.

Examples of symptoms of decompression illness include (but are not limited to): joint pain (also known as the "bends" for agonizing pain or the "niggles" for slight pain); areas of bone destruction (termed "dysbaric osteonecrosis"); skin disorders (such as cutis marmorata, which causes a pink marbling of the skin); spinal cord and brain disorders (such as stroke, paralysis, paresthesia, and bladder dysfunction); cardiopulmonary disorders, such as shortness of breath; and arterial gas embolism (gas bubbles in the arteries that block blood flow).¹⁴

Note: Health effects associated with hyperbaric intervention, but not considered symptoms of DCI, can include: barotrauma (direct damage to air-containing cavities in the body such as ears, sinuses, and lungs); nitrogen narcosis (reversible alteration in consciousness that may occur in hyperbaric environments and caused by the anesthetic effect of certain gases at high pressure); and oxygen toxicity (a central nervous system condition resulting from the harmful effects of breathing molecular oxygen (O₂) at elevated partial pressures).

6. *Diver Medical Technician*—Member of the dive team who is experienced in first aid.

7. *Earth Pressure Balanced Micro-Tunnel Boring Machine*—the machinery used to excavate the tunnel.

8. *Hot work*—any activity performed in a hazardous location that may introduce an ignition source into a potentially flammable atmosphere.¹⁵

9. *Hyperbaric*—at a higher pressure than atmospheric pressure.

10. *Hyperbaric intervention*—a term that describes the process of stopping the TBM and preparing and executing work under hyperbaric pressure in the working chamber for the purpose of inspecting, replacing, or repairing cutting tools and/or the cutterhead structure.

11. *Hyperbaric Operations Manual*—a detailed, project-specific health and

¹³ Adapted from 29 CFR 1926.32(f).

¹⁴ See Appendix 10 of "A Guide to the Work in Compressed Air Regulations 1996," published by the United Kingdom Health and Safety Executive and available from NIOSH at <http://www.cdc.gov/niosh/docket/archive/pdfs/NIOSH-254/compReg1996.pdf>.

¹⁵ Also see 29 CFR 1926.1202 for examples of hot work.

safety plan developed and implemented by the McNally/ASI Marine for working in compressed air during the Southerly Tunnel and Consolidation Project.

12. *Job hazard analysis*—an evaluation of tasks or operations to identify potential hazards and to determine the necessary controls.

13. *Man lock*—an enclosed space capable of pressurization, and used for compressing or decompressing any employee or material when either is passing into or out of a working chamber.

14. *Medical Advisor*—medical professional experienced in the physical requirements of compressed air work and the treatment of decompression illness.

15. *Pressure*—a force acting on a unit area; usually expressed as pounds per square inch (p.s.i.).

16. *p.s.i.*—pounds per square inch, a common unit of measurement of pressure; a pressure given in p.s.i. corresponds to absolute pressure.

17. *p.s.i.a.*—pounds per square inch absolute, or absolute pressure, is the sum of the atmospheric pressure and gauge pressure. At sea level, atmospheric pressure is approximately 14.7 p.s.i. Adding 14.7 to a pressure expressed in units of p.s.i.g. will yield the absolute pressure, expressed as p.s.i.a.

18. *p.s.i.g.*—pounds per square inch gauge, a common unit of pressure; pressure expressed as p.s.i.g. corresponds to pressure relative to atmospheric pressure. At sea level, atmospheric pressure is approximately 14.7 p.s.i. Subtracting 14.7 from a pressure expressed in units of p.s.i.a. yields the gauge pressure, expressed as p.s.i.g.

19. *Qualified person*—an individual who, by possession of a recognized degree, certificate, or professional standing, or who, by extensive knowledge, training, and experience, successfully demonstrates an ability to solve or resolve problems relating to the subject matter, the work, or the project.¹⁶

20. *Working chamber*—an enclosed space in the TBM in which CAWs perform interventions, and which is accessible only through a man-lock.

D. Safety and Health Practices

1. McNally/ASI Marine must implement the project-specific HOM submitted to OSHA as part of the variance application (see OSHA–2025–0004–0003). The HOM provides the minimum requirements regarding expected safety and health hazards

(including anticipated geological conditions) and hyperbaric exposures during the tunnel-construction project.

2. McNally/ASI Marine must demonstrate that the TBM on the project is designed, fabricated, inspected, tested, marked and stamped in accordance with the requirements of the most recent edition of ASME PVHO–1 (*Safety Standards for Pressure Vessels for Human Occupancy*) for the TBM's hyperbaric chambers.

3. McNally/ASI Marine must implement the safety and health instructions included in the manufacturer's operations manuals for the TBM, and the safety and health instructions provided by the manufacturer for the operation of decompression equipment.

4. McNally/ASI Marine must ensure that there are no exposures to pressures greater than 58 p.s.i.g.

5. McNally/ASI Marine must ensure that air or oxygen is the only breathing gas in the working chamber.

6. McNally/ASI Marine must follow the 1992 French Decompression Tables for air or oxygen decompression as specified in the HOM, specifically the tables titled "French Regulation Air Standard Tables."

7. McNally/ASI Marine must equip man-locks used by their employees with an oxygen-delivery system as specified by the HOM. McNally/ASI Marine is prohibited from storing in the tunnel any oxygen or other compressed gases used in conjunction with hyperbaric work.

8. Workers performing hot work under hyperbaric conditions must use flame-retardant personal protective equipment and clothing.

9. In hyperbaric work areas, McNally/ASI Marine must maintain an adequate fire-suppression system approved for hyperbaric work areas.

10. McNally/ASI Marine must develop and implement one or more job hazard analysis (JHA) for work in the hyperbaric work areas, and review, periodically and as necessary (*e.g.*, after making changes to a planned intervention that affects their operation), the contents of the JHAs with affected employees. The JHAs must include all the job functions that the risk assessment¹⁷ indicates are essential to prevent injury or illness.

11. McNally/ASI Marine must develop a set of checklists to guide compressed-air work and ensure that employees follow the procedures required by this permanent variance

(including all procedures required by the HOM, which this permanent variance incorporates by reference). The checklists must include all steps and equipment functions that the risk assessment indicates are essential to prevent injury or illness during compressed-air work.

12. McNally/ASI Marine must ensure that the safety and health provisions of this project-specific HOM adequately protect the workers of all contractors and subcontractors involved in hyperbaric operations for the project to which the HOM applies.¹⁸

E. Communication

1. Prior to beginning a shift, McNally/ASI Marine must implement a system that informs workers exposed to hyperbaric conditions of any hazardous occurrences or conditions that might affect their safety, including hyperbaric incidents, gas releases, equipment failures, earth or rockslides, cave-ins, flooding, fires, or explosions.

2. McNally/ASI Marine must provide a power-assisted means of communication among affected workers and support personnel in hyperbaric conditions where unassisted voice communication is inadequate.

(a) McNally/ASI Marine must use an independent power supply for powered communication systems, and these systems must operate such that use or disruption of any one phone or signal location will not disrupt the operation of the system from any other location.

(b) McNally/ASI Marine must test communication systems at the start of each shift and as necessary thereafter to ensure proper operation.

F. Worker Qualifications and Training

McNally/ASI Marine must:

1. Ensure that each affected worker receives effective training on how to safely enter, work in, exit from, and undertake emergency evacuation or rescue from, hyperbaric conditions, and document this training.

2. Provide effective instruction, before beginning hyperbaric operations, to each worker who performs work, or controls the exposure of others, in hyperbaric conditions, and document this instruction. The instruction must include:

(a) The physics and physiology of hyperbaric work;

(b) Recognition of pressure-related injuries;

¹⁷ See ANSI/AIHA Z10–2012, American National Standard for Occupational Health and Safety Management Systems, for reference.

¹⁶ Adapted from 29 CFR 1926.32(m).

¹⁸ See ANSI/ASSE A10.33–2011, American National Standard for Construction and Demolition Operations—Safety and Health Program Requirements for Multi-Employer Projects, for reference.

(c) Information on the causes and recognition of the signs and symptoms associated with decompression illness, and other hyperbaric intervention-related health effects (e.g., barotrauma, nitrogen narcosis, and oxygen toxicity);

(d) How to avoid discomfort during compression and decompression;

(e) Information the workers can use to contact the appropriate healthcare professionals should the workers have concerns that they may be experiencing adverse health effects from hyperbaric exposure; and

(f) Procedures and requirements applicable to the employee in the project-specific HOM.

3. Repeat the instruction specified in paragraph (2) of this condition periodically and as necessary (e.g., after making changes to their hyperbaric operations).

4. When conducting training for their hyperbaric workers, make this training available to OSHA personnel and notify OTPCA at OSHA's national office and the Cleveland, Ohio OSHA Area Office before the training takes place.

G. Inspections, Tests, and Accident Prevention

1. McNally/ASI Marine must initiate and maintain a program of frequent and regular inspections of the TBM's hyperbaric equipment and support systems (such as temperature control, illumination, ventilation, and fire-prevention and fire-suppression systems), and hyperbaric work areas, as required under 29 CFR 1926.20(b)(2), including:

(a) Developing a set of checklists to be used by a competent person in conducting weekly inspections of hyperbaric equipment and work areas; and

(b) Ensuring that a competent person conducts daily visual checks, as well as weekly inspections of the TBM.

2. McNally/ASI Marine must remove from service any equipment that constitutes a safety hazard until it corrects the hazardous condition and has the correction approved by a qualified person.

3. McNally/ASI Marine must maintain records of all tests and inspections of the TBM, as well as associated corrective actions and repairs, at the job site for the duration of the tunneling project and for 90 days after the final project report is submitted to OSHA.

H. Compression and Decompression

McNally/ASI Marine must consult with their attending physician concerning the need for special compression or decompression

exposures appropriate for CAWs not acclimated to hyperbaric exposure.

I. Recordkeeping

In addition to completing OSHA Form 301 Injury and Illness Incident Report and OSHA Form 300 Log of Work-Related Injuries and Illnesses, McNally/ASI Marine must maintain records of:

1. The date, times (e.g., time compression started, time spent compressing, time performing intervention, time spent decompressing), and pressure for each hyperbaric intervention.

2. The names of all supervisors and DMTs involved for each intervention.

3. The name of each individual worker exposed to hyperbaric pressure and the decompression protocols and results for each worker.

4. The total number of interventions and the amount of hyperbaric work time at each pressure.

5. The results of the post-intervention physical assessment of each CAW for signs and symptoms of decompression illness, barotrauma, nitrogen narcosis, oxygen toxicity or other health effects associated with work in compressed air for each hyperbaric intervention.

J. Notifications

1. To assist OSHA in administering the conditions specified herein, McNally/ASI Marine must:

(a) Notify the OTPCA and the Cleveland Ohio OSHA Area Office of any recordable injury, illness, or fatality (by submitting the completed OSHA's Form 301 Injury and Illness Incident Report form)¹⁹ resulting from exposure of an employee to hyperbaric conditions, including those exposures that do not require recompression treatment (e.g., nitrogen narcosis, oxygen toxicity, barotrauma), but still meet the recordable injury or illness criteria of 29 CFR 1904. The notification must be made within 8 hours of the incident or 8 hours after becoming aware of a recordable injury, illness, or fatality, and submit a copy of the incident investigation (OSHA's Form 301 Injury and Illness Injury Reporting Form) within 24 hours of the incident or 24 hours after becoming aware of a recordable injury, illness, or fatality. In addition to the information required by the OSHA's Form 301 Injury and Illness Injury Reporting Form, the incident-investigation report must include a root-cause determination, and the preventive

and corrective actions identified and implemented.

(b) Provide certification within 15 days of the incident that the employer informed affected workers of the incident and the results of the incident investigation (including the root-cause determination and preventive and corrective actions identified and implemented).

(c) Notify the OTPCA and the Cleveland Ohio OSHA Area Office within 15 working days in writing of any change in the compressed-air operations that affects the employer's ability to comply with the conditions specified herein.

(d) Upon completion of the Southerly Tunnel and Consolidation Project, evaluate the effectiveness of the decompression tables used throughout the project, and provide a written report of this evaluation to the OTPCA and the Cleveland Ohio OSHA Area Office.

Note: The evaluation report is to contain summaries of: (1) the number, dates, durations, and pressures of the hyperbaric interventions completed; (2) decompression protocols implemented (including composition of gas mixtures (air and/or oxygen), and the results achieved; (3) the total number of interventions and the number of hyperbaric incidents (decompression illnesses and/or health effects associated with hyperbaric interventions as recorded on OSHA's Form 301 Injury and Illness Incident Report and OSHA's Form 300 Log of Work-Related Injuries and Illnesses, and relevant medical diagnoses and treating physicians' opinions); and (4) root causes of any hyperbaric incidents, and preventive and corrective actions identified and implemented.

(e) To assist OSHA in administering the conditions specified herein, inform the OTPCA and the Cleveland Ohio OSHA Area Office as soon as possible, but no later than seven (7) days, after it has knowledge that it will:

i. Cease to do business;

ii. Change the location and address of the main office for managing the tunneling operations specified herein; or

iii. Transfer the operations specified herein to a successor company.

(f) Notify all affected employees of this permanent variance by the same means required to inform them of the application for a variance.

(g) This permanent variance cannot be transferred to a successor company without OSHA approval.

OSHA hereby grants a permanent variance to McNally/ASI Marine to the provisions of 29 CFR 1926.803 outlined in this notice for the completion of the Southerly Tunnel and Consolidation Project in Cleveland, Ohio.

¹⁹ See 29 CFR 1904 (Recording and Reporting Occupational Injuries and Illnesses) (http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9631); recordkeeping forms and instructions <https://www.osha.gov/recordkeeping/forms>.

VIII. Authority and Signature

David Keeling, Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue NW, Washington, DC 20210, authorized the preparation of this notice. Accordingly, the agency is issuing this notice pursuant to 29 U.S.C. 655(d), Secretary of Labor's Order No. 7–2025 (90 FR 27878, June 30, 2025), and 29 CFR 1905.11.

Signed at Washington, DC, on December 19, 2025.

David Keeling,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2025–23804 Filed 12–23–25; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL COUNCIL ON DISABILITY

Sunshine Act Meetings

TIME AND DATE: The Members of the National Council on Disability (NCD) will hold a two-day in-person Council meeting on Thursday, January 22, 2026, 9:00 a.m.–3:25 p.m. Eastern Standard Time (EST) and Friday, January 23, 2026, 9:00–12:00 p.m.

PLACE: This meeting will take place at the Rosen Shingle Creek Orlando, 9939 Universal Blvd., Orlando, Florida 32819. The event will also be streamed live via Zoom videoconference for those not able to attend in person. Details are available on NCD's event page at <https://www.ncd.gov/meeting/2026-01-22-jan-22-23-2026-council-meeting/>.

MATTERS TO BE CONSIDERED:

Day 1—Following welcome remarks by Vice Chair/Acting Chair, Shawn Kennemer, and introductions, the Council will receive a policy update, followed by a panel discussion on institutionalization of youth in nursing homes and a public comment period for input, in person and by Zoom, on youth in nursing homes. After a break, there will be a panel of Floridians with disabilities describing their experience; lastly, there will be a presentation on NCD's disability competency curriculum project for medical professionals, followed by a Council discussion.

es during and safter recent natural disasters, followed by a public comment period for Floridians to provide their experiences in person and by Zoom. After a lunch break, the meeting will resume with a panel discussion on barriers and innovations in accessible transportation in Florida followed by a Council discussion.

Day 2—Following welcoming remarks, the Council will receive the

Chairman's report; Council member's individual reports; an Executive Committee report; and a legislative and media update; a presentation on NCD's disability competency curriculum project for medical professionals, followed by a Council discussion; a presentation on a study of HCBS denials in Florida, followed by a Council question. We conclude the meeting with an award presentation for NCD Council Member/Former Chair Neil Romano.

Agenda: The times provided below are approximations (all Eastern Standard Time):

Thursday, January 22, 2026

9:00–9:15 a.m.—Welcome Greetings, Roll Call, Acceptance of Agenda
9:15–9:30 a.m.—Policy Update
9:30–10:40 a.m.—Panel on Institutionalization of Youth in Nursing Homes
10:40–11:05 a.m.—Public Comment on Youth in Nursing Homes
11:05V11:20 a.m.—Break
11:20–12:25 p.m.—Panel on Experiences of Disabled Floridians During/After Recent Natural Disasters
12:25–12:50 p.m.—Public Comment on Experiences in Natural Disasters
12:50–;2:10 p.m.—Lunch Break
2:10–3:10 p.m.—Panel on Accessible Transportation in Florida: Barriers and Innovations
3:10–3:35 p.m.—Public Comment on Accessible Transportation in Florida
3:35 p.m.—Adjourn until January 23 at 9:00 a.m.

Friday, January 23, 2026

9:00–9:10 a.m.—Welcome and Call to Order
9:10–9:20 a.m.—Chairman's Report
9:20–9:40 a.m.—Council Member Reports
9:40–9:55 a.m.—Executive Committee Report
9:55–10:10 a.m.—Legislative and Media Updates
10:10–10:25 a.m.—Break
10:25–10:50 a.m.—Description of Disability Competency Curriculum Project, RFI Responses to Date, and Potential NCD Recommendations
10:50–11:00 p.m.—Council Question and Answer on Project
11:00–11:30—Presentation: A Study of Denials of Florida HCBS Waiver Eligibility
11:30–11:40 a.m.—Council Questions and Answers on Study
11:40–12:00 p.m.—Public Service Award for NCD Council Member Neil Romano
12:00 p.m.—Adjourn the Quarterly Meeting

Public Comment: Public participation during the public comment period provides an opportunity for us to hear from individuals, businesses, providers, educators, parents and advocates. Your comments are important in bringing to the Council's attention the issues and priorities of the disability community.

For the January 22 Council meeting, NCD will have two public comment periods of 25 minutes each. The first on youth institutionalized in nursing homes, and the second on experiences of disabled Floridians in recent natural disasters. Additional information on specifics of the topic is available on NCD's public comment page at <https://ncd.gov/public-comment>.

The Council will receive comments from in-person commenters first, and time allowing, from Florida residents who attend via Zoom for Government livestream. Comments are also always accepted via email.

To provide public comment during an NCD Council Meeting, NCD requires advanced registration by either signing up to present while registering for the meeting or sending an email to PublicComment@ncd.gov with the subject line "Public Comment" and your name, organization (if applicable), state, and topic of comment in the body of your email.

Deadline for public comment registration is January 20, 2026, 8:00 p.m. EST. Please indicate if you are providing the comment in-person or only submitting via email. All individuals desiring to make public comments are encouraged to read NCD's guidelines for public comment in advance of the meeting at: <https://ncd.gov/public-comment>.

Comments during this meeting must be specific to youth in nursing homes and experiences in recent natural disasters.

To provide comments by email, please send personal experiences, and/or articles, data, and other research on the following topics to PublicComment@ncd.gov. Your contributions will help strengthen our investigations and provide for a more comprehensive view for federal policymakers.

I. Youth and Younger Adults With Disabilities in Nursing Homes

This project seeks to uncover the drivers of the growing population of youth and younger adults with disabilities living in nursing homes and explore policy solutions that seek to keep youth and younger adults with disabilities in their communities where they can live, learn, and seek

employment. Responses to any of the following questions are helpful.

1. What number of people with disabilities ages 21–40 are receiving LTSS in nursing homes? How large is the subset of those under age 21? What are the numbers by state? What are the demographics? What is the average length of stay? What placements were made out of state?

2. What data gaps exist on these questions and how could the Centers for Medicare and Medicaid Services (CMS) improve them? What reporting could HHS or HUD require of federal fund recipients to obtain data on people with disabilities age 40 and under in nursing homes?

3. How many people are estimated to be on waiting lists to transfer out of nursing facilities are ages 21–40 and under 21? What federal and state policies assist in gathering this information and what are the federal and state barriers?

4. Are there existing federal and state policies that have the effect of routing younger people with disabilities into nursing homes? (Please note that NCD is not seeking information on what keeps people with disabilities from leaving nursing facilities as we have well-established research on that topic).

5. What impact has Money Follows the Person had on nursing home diversion for younger people with disabilities? Please provide specific examples to the degree possible. What other programs are successful at diversion of younger people with disabilities from nursing homes?

6. What opportunities are available to younger people with disabilities who reside in nursing homes, for free appropriate public education (FAPE), recreation, community participation? What are the results of unavailability/restricted availability of the activities?

7. How could policymakers specifically address the needs of younger people with disabilities in LTSS and housing policy?

II. Improving the Outcome of People With Disabilities During and After Disasters

This project focuses on how state and local governments execute their emergency management plans; identifies promising practices; and provides resources and recommendations. Comments on any of the following questions are helpful.

1. What elements are lacking in state and local disaster preparation plans that would mitigate the adverse impact of disaster recovery and response on people with disabilities?

2. How do states encourage local emergency management operators to be inclusive of people with disabilities before, during and after disasters?

3. What is FEMA's role and responsibility to ensure people with disabilities needs are included in disaster preparation at the local level?

4. What states have an infrastructure that promotes the inclusivity of people with disabilities?

CONTACT PERSON FOR MORE INFORMATION: Nicholas Sabula, Public Affairs Specialist, NCD, 1331 F Street NW, Suite 850, Washington, DC 20004; 202–272–2004 (V), or nsabula@ncd.gov.

Accommodations: ASL Interpreters will be provided in-room and included during the live streamed meeting, and CART has been arranged for this meeting and will be embedded into the Zoom platform as well as available via streamtext link. The web link to access CART Streamtext: <https://www.streamtext.net/player?event=NCD>.

If you require additional accommodations, please notify Stacey Brown by sending an email to sbrown@ncd.gov as soon as possible and no later than 48 hours prior to the meeting.

Due to last-minute confirmations or cancellations, NCD may substitute items without advance public notice.

Dated: December 22, 2025.

Nicholas Sabula,

Public Affairs Specialist.

[FR Doc. 2025–23952 Filed 12–22–25; 4:15 pm]

BILLING CODE 8421–02–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 52–009; NRC–2025–1864]

System Energy Resources Inc.; Grand Gulf Site Early Site Permit; Early Site Permit Renewal Application

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice; receipt.

SUMMARY: On September 24, 2025, Entergy Operations, Inc. (Entergy), on behalf of System Energy Resources Inc. (SERI), a subsidiary of Entergy Corporation, filed an application with the U.S. Nuclear Regulatory Commission (NRC), to renew the early site permit (ESP) ESP–002 for the Grand Gulf ESP Site for an additional 20 years beyond the period specified in the current license. The application also includes a request for an exemption from the requirement that the application for renewal must contain all information necessary to bring up to date the information and data contained

in the previous application. The current ESP license for the Grand Gulf ESP Site expires on April 5, 2027.

DATES: The ESP renewal application was available as of October 2, 2025.

ADDRESSES: Please refer to Docket ID NRC–2025–1864 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- **Federal Rulemaking Website:** Go to <https://regulations.gov> and search for Docket ID NRC–2025–1864. Address questions about Docket IDs in *Regulations.gov* to Bridget Curran; telephone: 301–415–1003; email: Bridget.Curran@nrc.gov. For technical questions, contact the individual(s) listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “Begin ADAMS Public Search.” For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to PDR.Resource@nrc.gov. For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the “Availability of Documents” section.

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

FOR FURTHER INFORMATION CONTACT: Carolyn Lauron, telephone 301–415–2736; email: Carolyn.Lauron@nrc.gov, or Mahmoud Jardaneh, telephone: 301–415–4126; email: Mahmoud.Jardaneh@nrc.gov. Both are staff of the Office of Nuclear Reactor Regulation at the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Introduction

Pursuant to Section 103 of the Atomic Energy Act, as amended, and part 52 of title 10 of the *Code of Federal Regulations* (10 CFR), “Licenses, Certifications, and Approvals for Nuclear Power Plants,” the applicant, System Energy Resources Inc., a

subsidiary of Entergy Operations, Inc., filed an application to request the NRC renew its ESP for the Grand Gulf ESP Site for an additional 20 years beyond the period specified in the current license. The current ESP expires on April 7, 2027.

In accordance with Subpart A of 10 CFR part 52, an applicant may seek an ESP separate from the filing of an application for a construction permit (CP) or combined license (COL) for a nuclear power facility. The ESP process allows resolution of issues relating to siting, and if an application for a CP or COL references an early site permit, the Commission shall treat as resolved those matters resolved in the proceeding on the application for issuance or renewal of the early site permit, except as

provided for in paragraphs (b), (c), and (d) of 10 CFR 52.39.

The Grand Gulf ESP renewal application references and proposes to pilot the alternate ESP renewal method described in Appendix A to NEI 25–06, Rev 0. The NRC is reviewing NEI 25–06, Rev 0 and has not made a final determination on the acceptability of the proposed guidance. The application includes a request for an exemption from the requirement of 10 CFR 52.29 that the application for renewal must contain all information necessary to bring up to date the information and data contained in the previous application.

II. Further Information

The NRC will publish subsequent **Federal Register** notices addressing the

acceptability of the tendered ESP renewal application for docketing and, if the application is acceptable for docketing, provisions for public participation in the ESP renewal application review process, including an opportunity to request a hearing. The NRC will post publicly available materials related to this application in ADAMS and on the NRC’s public website.

III. Availability of Documents

The following table indicates the ADAMS accession number where the renewal application and related documents are available to interested persons.

Document title	Adams accession No.
Grand Gulf ESP Site, Resubmittal of Request for Exemption from 10 CFR 52.29(a) and Renewal of Early Site Permit ESP–002, dated September 24, 2025	ML25267A217
NEI Guidance for Implementing the Requirements of 10 CFR part 52 for Early Site Permit Renewal, dated June 9, 2025	ML25171A132

Dated: December 22, 2025.
For the Nuclear Regulatory Commission.
Mahmoud Jardaneh,
Chief, Licensing and Regulatory Infrastructure Branch, Division of New and Renewed Licenses, Office of Nuclear Reactor Regulation.
[FR Doc. 2025–23843 Filed 12–23–25; 8:45 am]
BILLING CODE 7590–01–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage Negotiated Service Agreements

AGENCY: Postal Service.
ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to

the list of Negotiated Service Agreements in the Mail Classification Schedule’s Competitive Products List.

DATES: *Date of required notice:* December 29, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), it filed with the Postal Regulatory Commission the following requests:

Date filed with Postal Regulatory Commission	Negotiated service agreement product category and number	MC docket number	K docket number
12/15/25	PME–PM–GA 1469	MC2026–136	K2026–136
12/17/25	PM 951	MC2026–140	K2026–140
12/17/25	PME–PM–GA 1470	MC2026–141	K2026–141
12/19/25	PME–PM–GA 1471	MC2026–142	K2026–142
12/19/25	PS 36	MC2026–143	K2026–143

Documents are available at www.prc.gov.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2025–23800 Filed 12–23–25; 8:45 am]
BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–104476; File No. SR–CboeBZX–2025–141]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To List and Trade Shares of the GraniteShares 4x Long Russell 1000 Daily ETF and the GraniteShares 4x Short Russell 1000 Daily ETF Under Rule 14.11(f)(4) (Trust Issued Receipts)

December 19, 2025.

On September 30, 2025, Cboe BZX Exchange, Inc. (“BZX” or “Exchange”) filed with the Securities and Exchange Commission (“Commission”), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”) ¹ and Rule 19b–4 thereunder, ² a proposed rule change to list and trade shares of the GraniteShares 4x Long Russell 1000 Daily ETF (“4x Long Fund”) and the GraniteShares 4x Short Russell 1000 Daily ETF (“4x Short Fund,” and together with the 4x Long Fund, the “Funds”), each a series of GraniteShares ETP Trust, under BZX Rule 14.11(f)(4). The proposed rule change was published for comment in the **Federal Register** on October 3, 2025.³

On November 3, 2025, pursuant to Section 19(b)(2) of the Act,⁴ the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.⁵

The Commission is publishing this order to solicit comments on the proposed rule change from interested persons and to institute proceedings under Section 19(b)(2)(B) of the Act ⁶ to determine whether to approve or disapprove the proposed rule change.

I. Summary of the Proposal

As described in more detail in the Notice,⁷ the Exchange proposes to list and trade Shares of the Funds under Rule 14.11(f)(4), which governs the

listing and trading of Trust Issued Receipts on the Exchange.⁸ The Funds seek to provide daily investment results (before fees and expenses) that correspond to the performance of a benchmark that seeks to offer either short or long exposure to the benchmark for the Funds.⁹ The benchmark for the Funds is the Russell 1000 Index (“Index”). The Funds are “leveraged,” which means that each Fund has an investment objective to seek daily investment results, before fees and expenses, that correspond either to a multiple (4x) or an inverse multiple (–4x) of the daily performance of the Index on a given day.¹⁰

The Funds may invest in over-the-counter swaps referencing the Index (“Russell Swap Agreements”), forward contracts, options contracts, futures contracts (“Russell Futures Contracts”), and other Financial Instruments ¹¹ based on the Index.¹² The amount of exposure each Fund has to a specific combination of Financial Instruments differs with each Fund and should be expected to change from time to time at the discretion of GraniteShares Advisors LLC based on market conditions and other factors.¹³ The Funds may also invest in money market instruments (*i.e.*, “Cash and Cash Equivalents”) ¹⁴ as part of their core investment strategy or to meet collateral and margin requirements for their Russell Futures Contract positions, Russell Swap Agreements, and Russell Option Contracts (collectively, “Russell Derivative Products”).¹⁵ The Exchange represents that the Funds seek to remain fully invested at all times in Russell Derivative Products (and Cash and Cash Equivalents as collateral) that provide exposure to the Index consistent with each Fund’s investment objective.¹⁶

⁸ BZX Rule 14.11(f)(4) applies to Trust Issued Receipts that invest in “Financial Instruments.” The term “Financial Instruments,” as defined in BZX Rule 14.11(f)(4)(A)(iv), means any combination of investments, including cash; securities; options on securities and indices; futures contracts; options on futures contracts; forward contracts; equity caps, collars and floors; and swap agreements.

⁹ See Notice, *supra* note 3, 90 FR at 48107.

¹⁰ See Notice, *supra* note 3, 90 FR at 48108–09.

¹¹ See note 8, *supra*.

¹² See Notice, *supra* note 3, 90 FR at 48107–08.

¹³ See Notice, *supra* note 3, 90 FR at 48108.

¹⁴ For purposes of this proposal, the term “Cash and Cash Equivalents” shall have the definition provided in BZX Rule 14.11(i)(4)(C)(iii), applicable to Managed Fund Shares.

¹⁵ See Notice, *supra* note 3, 90 FR at 48108.

¹⁶ See *id.*

II. Proceedings To Determine Whether To Approve or Disapprove SR–CboeBZX–2025–141 and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act ¹⁷ to determine whether the proposed rule change should be approved or disapproved. Institution of such proceedings is appropriate at this time in view of the legal and policy issues raised by the proposed rule change. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, as described below, the Commission seeks and encourages interested persons to provide comments on the proposed rule change.

Pursuant to Section 19(b)(2)(B) of the Act,¹⁸ the Commission is providing notice of the grounds for disapproval under consideration. The Commission is instituting proceedings to allow for additional analysis of the proposal’s consistency with Section 6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchange be “designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade,” and “to protect investors and the public interest.” ¹⁹

The Commission asks that commenters address the sufficiency of the Exchange’s statements in support of the proposal, which are set forth in the Notice, in addition to any other comments they may wish to submit about the proposed rule change. In particular, the Commission seeks comment on whether the proposal to list and trade Shares of the Funds, which seek to provide daily investment results that correspond to either 400% or –400% of the daily performance of the Index, is designed to prevent fraudulent and manipulative acts and practices and to protect investors and the public interest, or raises any new or novel concerns not previously contemplated by the Commission.

III. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their data, views, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposal. In particular, the Commission

¹⁷ 15 U.S.C. 78s(b)(2)(B).

¹⁸ *Id.*

¹⁹ 15 U.S.C. 78f(b)(5).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ See Securities Exchange Act Release No. 104161 (Sept. 30, 2025), 90 FR 48107 (“Notice”). The Commission has not received any comments regarding the proposed rule change.

⁴ 15 U.S.C. 78s(b)(2).

⁵ See Securities Exchange Act Release No. 104173, 90 FR 51424 (Nov. 17, 2025) (designating January 1, 2026, as the date by which the Commission shall either approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change).

⁶ 15 U.S.C. 78s(b)(2)(B).

⁷ See Notice, *supra* note 3.

invites the written views of interested persons concerning whether the proposed rule change is consistent with Section 6(b)(5) of the Act²⁰ or any other provision of the Act, or the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of data, views, and arguments, the Commission will consider, pursuant to Rule 19b-4 under the Act,²¹ any request for an opportunity to make an oral presentation.²²

Interested persons are invited to submit written data, views, and arguments regarding whether the proposed rule change should be approved or disapproved by January 20, 2026. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by February 2, 2026. The Commission asks that commenters address the sufficiency of the Exchange's statements in support of the proposal, in addition to any other comments they may wish to submit about the proposed rule change. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-CboeBZX-2025-141 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090. All submissions should refer to file number SR-CboeBZX-2025-141. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable

information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-CboeBZX-2025-141 and should be submitted on or before January 20, 2026. Rebuttal comments should be submitted by February 2, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²³

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025-23820 Filed 12-23-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-104486; File No. SR-FICC-2025-801]

Self-Regulatory Organizations; Fixed Income Clearing Corporation; Notice of Filing and Extension of Review Period of Advance Notice To Amend and Restate the Second Amended and Restated Cross-Margining Agreement Between FICC and CME and Amend Related GSD Rules

December 22, 2025.

Pursuant to Section 806(e)(1) of Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act entitled the Payment, Clearing, and Settlement Supervision Act of 2010 ("Clearing Supervision Act")¹ and Rule 19b-4(n)(1)(i) under the Securities Exchange Act of 1934 ("Exchange Act"),² notice is hereby given that on December 12, 2025, Fixed Income Clearing Corporation ("FICC") filed with the Securities and Exchange Commission ("Commission") the advance notice SR-FICC-2025-801 ("Advance Notice") as described in Items I, II and III below, which Items have been prepared by the clearing agency.³ On December 19, 2025, FICC filed Partial Amendment No. 1 to the Advance Notice to make certain changes to the narrative description of the filing

and exhibits provided by FICC.⁴ The Commission is publishing this notice to solicit comments on the Advance Notice, as modified by Partial Amendment No. 1 (hereafter "Advance Notice"), from interested persons and to extend the review period of the advance notice.

I. Clearing Agency's Statement of the Terms of Substance of the Advance Notice

This Advance Notice consists of proposed rule changes related its cross-margining arrangement (the "Cross-Margining Arrangement") with the Chicago Mercantile Exchange Inc. ("CME", and collectively with FICC, the "Clearing Organizations" or "Parties"). The proposed rule changes consist of (i) a proposed Third Amended and Restated Cross-Margining Agreement (the "Third A&R Agreement") between FICC and CME, which would replace the Second Amended and Restated Cross-Margining Agreement between the Parties (the "Second A&R Agreement") in its entirety and would be incorporated into the FICC Government Securities Division ("GSD") Rulebook ("GSD Rules" or "Rules"), and (ii) a number of related rule changes to the GSD Rules. Together, the proposed changes would extend the availability of the Cross-Margining Arrangement to positions cleared and carried for customers by a dually registered broker-dealer ("BD") and futures commission merchant ("FCM") that is a common member of FICC and CME (an "Eligible BD-FCM").⁵

⁴ Partial Amendment No. 1 makes clarifications and corrections to the narrative description of the Advance Notice and Exhibit 5A of the filing. Specifically, the Amendment corrects the narrative description of a proposed change to the GSD Rules to accurately reflect the change, as it appears in Exhibit 5A. The Amendment also modifies Exhibit 5A to correct to correct a typographical error and mismarked rule text as compared to the currently effective GSD Rules. These clarifications and corrections have been incorporated, as appropriate, into the description of the Advance Notice in Item II below.

⁵ The Commission recently approved FICC's proposed rule change to enter into the Second Amended and Restated Cross-Margining Agreement between FICC and CME. See Self-Regulatory Organizations; Fixed Income Clearing Corporation; Order Approving Proposed Rule Change to Amend and Restate the Cross-Margining Agreement between FICC and CME, 90 FR 31043 (July 11, 2025). The Second A&R Agreement has thus been incorporated in the GSD Rules available at www.dtcc.com/legal/rules-and-procedures. Unless otherwise specified, capitalized terms not defined herein shall have the meanings ascribed to them in the GSD Rules.

²⁰ 15 U.S.C. 78f(b)(5).

²¹ 17 CFR 240.19b-4.

²² Section 19(b)(2) of the Act, as amended by the Securities Acts Amendments of 1975, Public Law 94-29 (June 4, 1975), grants to the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. See Securities Acts Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

²³ 17 CFR 200.30-3(a)(57).

¹ 12 U.S.C. 5465(e)(1).

² 17 CFR 240.19b-4(n)(1)(i).

³ On December 12, 2025, FICC filed this Advance Notice as a proposed rule change (SR-FICC-2025-025) with the Commission pursuant to Section 19(b)(1) of the Exchange Act, 15 U.S.C. 78s(b)(1), and Rule 19b-4 thereunder, 17 CFR 240.19b-4. A copy of the proposed rule change is available at www.dtcc.com/legal/sec-rule-filings.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Advance Notice

In its filing with the Commission, the clearing agency included statements concerning the purpose of and basis for the Advance Notice and discussed any comments it received on the Advance Notice. The text of these statements may be examined at the places specified in Item IV below. The clearing agency has prepared summaries, set forth in sections A and B below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement on Comments on the Advance Notice Received From Members, Participants, or Others

FICC has not received or solicited any written comments relating to this proposal. If any written comments are received, they will be publicly filed as an Exhibit 2 to this filing, as required by Form 19b-4 and the General Instructions thereto.

Persons submitting comments are cautioned that, according to Section IV (Solicitation of Comments) of the Exhibit 1A in the General Instructions to Form 19b-4, the Commission does not edit personal identifying information from comment submissions. Commenters should submit only information that they wish to make available publicly, including their name, email address, and any other identifying information.

All prospective commenters should follow the Commission's instructions on how to submit comments, available at www.sec.gov/rules-regulations/how-submit-comment. General questions regarding the rule filing process or logistical questions regarding this filing should be directed to the Main Office of the Commission's Division of Trading and Markets at tradingandmarkets@sec.gov or 202-551-5777.

FICC reserves the right not to respond to any comments received.

(B) Advance Notice Filed Pursuant to Section 806(e) of the Clearing Supervision Act

Currently, the Cross-Margining Arrangement allows FICC and CME to recognize for margin purposes the offsetting risk of certain positions in futures on U.S. Treasury securities and other interest rate futures and Treasury market transactions ("Eligible Positions") maintained by a member of both Clearing Organizations (a "Joint Clearing Member") for itself or certain eligible affiliates (an "Eligible Affiliate"), or by affiliated members of CME and FICC (each, a "Cross-

Margining Affiliate," and each Joint Clearing Member and each Cross-Margining Affiliate, a "Cross-Margining Participant"), at the two Clearing Organizations in circumstances when the Clearing Organizations can look to all of those positions (and all associated margin) for performance of the Joint Clearing Member's or a pair of Cross-Margining Affiliates' obligations (the "Proprietary Cross-Margining Arrangement"). In particular, the Proprietary Cross-Margining Arrangement allows the Clearing Organizations to consider the net risk of a Joint Clearing Member's and its Eligible Affiliates' Eligible Positions or a pair of Cross-Margining Affiliates' Eligible Positions at FICC and CME when setting margin requirements for such positions.⁶ Any resulting margin reductions create capital efficiencies for the Cross-Margining Participants and their Eligible Affiliates and incentivize them to maintain or carry portfolios that present lower overall risk.

FICC and CME have submitted to the Securities and Exchange Commission (the "Commission") and the Commodity Futures Trading Commission (the "CFTC") petitions for exemptive relief from certain provisions of the Commodity Exchange Act ("CEA") and Exchange Act that would enable FICC and CME to make cross-margining available to customers (other than an Eligible Affiliate) of an Eligible BD-FCM ("Cross-Margining Customers").⁷ The proposed rule changes aim to set forth a customer cross-margining arrangement that is consistent with the descriptions in the Petitions and the requirements of the Proposed Orders (the "Customer Cross-Margining Arrangement"). The Customer Cross-Margining Arrangement would allow Cross-Margining Customers to benefit from the margin reductions that are currently only available to Cross-Margining Participants and their Eligible Affiliates under the Proprietary Cross-Margining Arrangement. As a result, it would facilitate access to clearing for indirect participants, promote the maintenance of more balanced portfolios that present lower risk, and enhance liquidity in,

⁶ See Section 4 of the Second A&R Agreement, *supra* note 3.

⁷ See Letter from the Fixed Income Clearing Corporation and Chicago Mercantile Exchange Inc. to Vanessa Countryman dated as of December 11, 2025 and filed as Confidential Exhibit 3B (the "SEC Petition") and Letter from the Fixed Income Clearing Corporation and Chicago Mercantile Exchange Inc. to Christopher J. Kirkpatrick dated as of May 14, 2025, and filed as Confidential Exhibit 3C (the "CFTC Petition", and collective with the SEC Petition, the "Petitions", and the proposed Commission and CFTC orders as described in the Petitions, the "Proposed Orders").

and otherwise promote the resilience and robustness of, the Treasury market.

The Third A&R Agreement would effectuate the Customer Cross-Margining Arrangement via the following features:

- *Eligibility Criteria and Participation Requirements.* The Third A&R Agreement would set out the eligibility criteria for a Joint Clearing Member and its Cross-Margining Customer to participate in the Customer Cross-Margining Arrangement, as well as the requirements that would apply to such a Joint Clearing Member and its Cross-Margining Customer. These include the requirements that:

- A Joint Clearing Member be an Eligible BD-FCM;
- Each Cross-Margining Customer be a "futures customer" within the meaning of CFTC Regulation 1.3 and a "Sponsored Member" or "Eligible Firm Customer" as defined under the GSD Rules;
- The Joint Clearing Member enter into a participant agreement with the Clearing Organizations; and
- The Joint Clearing Member enter into an agreement with each Cross-Margining Customer containing certain terms, including that the Cross-Margining Customer agrees to subordinate its claims under the Securities Investor Protection Act of 1970 ("SIPA") and subchapter III of Chapter 7 of the U.S. Bankruptcy Code in relation to its cross-margined positions and associated margin (the "Subordination Agreement").

As discussed in greater detail below, these criteria and requirements for participation are designed to ensure that each participating Cross-Margining Customer and its Joint Clearing Member satisfy certain conditions set forth in the Proposed Orders.

- *Customer Cross-Margining Accounts.* The Third A&R Agreement would include provisions to enable Eligible BD-FCMs to establish "Customer Cross-Margining Accounts" for purposes of recording Eligible Positions at the Clearing Organizations (such Eligible Positions in a Customer Cross-Margining Account, "Customer Positions") and set forth a definition of "Proprietary Cross-Margining Accounts" to refer to the accounts established by Eligible BD-FCMs at the Clearing Organizations for the purposes of recording positions subject to the Proprietary Cross-Margining Arrangement ("Proprietary Positions").

- *Margin Methodology.* The Third A&R Agreement would include provisions describing the methodology for calculating potential reductions to the margin requirements for Customer Positions. As discussed in greater detail

below, FICC is proposing to apply the same margin reduction methodology to Customer Positions as it applies to Proprietary Positions, with margin reductions calculated on a customer-by-customer basis for each Cross-Margining Customer.

- **Default Management.** The Third A&R Agreement would include provisions to address how the Clearing Organizations would manage a default of a Cross-Margining Participant (a “Defaulting Member”) carrying positions for Cross-Margining Customers. Under the Third A&R Agreement, the Clearing Organizations would follow substantially the same approach to handling Customer Positions carried by a Defaulting Member as applies to Proprietary Positions. However, Customer Positions and Proprietary Positions and associated margin would form part of separate “Liquidation Portfolios” and therefore would not be netted against one another in calculating Net Gain or Net Loss (or VM Net Gain or VM Net Loss) under the Cross-Margining Agreement. By virtue of these changes, the Clearing Organizations would not be able to apply Customer Positions or associated margin to the obligations arising under a Defaulting Member’s Proprietary Positions. The Third A&R Agreement would also include edits clarifying that the Clearing Organizations may “port” Customer Positions to another clearing member in a default scenario.

In addition to replacing the Second A&R Agreement with the Third A&R Agreement, FICC proposes the following changes to the GSD Rules to effectuate the Customer Cross-Margining Arrangement:

- **Account Structure.** FICC proposes to create a new Account type, the “Cross-Margining Customer Account,” for purposes of recording FICC-cleared Customer Positions.

- **Margin Methodology and Treatment.** As discussed in greater detail below, under the proposed changes, FICC would collect and hold Cross-Margining Customer Margin in a substantially similar manner to how it collects and holds “Segregated Customer Margin” (as defined under the GSD Rules), with certain adjustments to ensure consistency with the requirements of the Proposed Orders and the general requirements and conventions applicable to futures. Consistent with how it treats Segregated Customer Margin, FICC would credit all Cross-Margining Customer Margin collected from an Eligible BD–FCM to a securities account on its books and records in the name of the Eligible BD–FCM for the benefit of its customers (a

“Cross-Margining Customer Margin Custody Account”). FICC would also agree to treat all assets credited to the Cross-Margining Customer Margin Custody Account as “financial assets” credited to a “securities account” for which FICC is the “securities intermediary,” as such terms are used in Article 8 of the Uniform Commercial Code as in effect in the State of New York (“NYUCC”). This treatment is designed to ensure that Cross-Margining Customer Margin does not form part of FICC’s bankruptcy estate and is not exposed to the claims of FICC’s general creditors, and is instead reserved for Eligible BD–FCMs claiming on behalf of their Cross-Margining Customers. Consistent with how it holds Segregated Customer Margin, FICC would hold Cross-Margining Customer Margin in a segregated account at a bank insured by the Federal Deposit Insurance Corporation and at the Federal Reserve Bank of New York (the “FRBNY”). In accordance with the Proposed Orders, any such account (other than one at the FRBNY) would need to be subject to a written notice consistent with the Proposed Orders.

- **Conforming and Clarifying Changes.** FICC proposes to make a number of clarifying and conforming edits to the GSD Rules, including (i) adding references to Cross-Margining Customer, Cross-Margining Customer Margin, Cross-Margining Customer Account, and Cross-Margining Customer Margin Requirements to relevant provisions that refer to indirect participants, initial margin collected by FICC, position accounts maintained by FICC, and FICC’s initial margin requirements; (ii) removing the existing prohibition under Section 10(e) of Rule 3A on Sponsored Members from participating in the Cross-Margining Arrangement; (iii) expanding Rule 43, which sets forth certain terms related to the Proprietary Cross-Margining Arrangement, to encompass the Customer Cross-Margining Arrangement; and (iv) removing references to the Market Professionals cross-margining arrangement, which is no longer offered by FICC.

The Third A&R Agreement would also include a number of clarifying and conforming edits, including to make clear that, with respect to both the Proprietary Cross-Margining Arrangement and Customer Cross-Margining Arrangement, FICC and CME would only manage a default of a Joint Clearing Member independently of one another if a joint management or buy-out by one of the Clearing Organizations were not legally permissible or possible

or would result in substantially greater losses to each Clearing Organization.

In addition, the Second A&R Agreement is supplemented by a Service Level Agreement (“SLA”) between FICC and CME. FICC and CME will make edits to the SLA as necessary to ensure conformance with the proposed Third A&R Agreement.⁸

Description of Proposed Changes

(i) The Proposed Third A&R Agreement

As noted above, FICC proposes to enter into the Third A&R Agreement with CME. The proposed changes to the Second A&R Agreement contained in the Third A&R Agreement are designed to make cross-margining available to Cross-Margining Customers consistently with the framework set out in the Proposed Orders. FICC believes that such amendments would promote the maintenance of more balanced portfolios that present lower risk and facilitate the access of indirect participants to central clearing in accordance with Rule 17ad–22 under the Exchange Act.

A. Eligibility Criteria and Participation Requirements

a. Eligibility Criteria for Joint Clearing Members

The Third A&R Agreement would set forth the eligibility criteria for a Cross-Margining Participant to participate in the Customer Cross-Margining Arrangement. To facilitate compliance with the conditions and limitations of the Proposed Orders, Section 2(a) of the Third A&R Agreement would provide that, to become a Cross-Margining Participant for the Customer Cross-Margining Arrangement and establish a Customer Cross-Margining Account, a Clearing Member would need to be a Joint Clearing Member that is both a BD registered with the Commission and an FCM registered with the CFTC (*i.e.*, an Eligible BD–FCM).⁹ Section 3(a) of the Third A&R Agreement would further require that the Eligible BD–FCM hold the Cross-Margining Customer’s Customer Positions at FICC and associated money, securities and property together with such customer’s Customer Positions at CME and the associated “futures customer funds,” as defined in CFTC Regulation 1.3, held by the Eligible BD–FCM, in a “futures account,” as defined in CFTC Regulation 1.3, “in accordance with any conditions set forth in the regulatory approvals of [the Third A&R Agreement]

⁸ The SLA is provided as confidential Exhibit 3 to this proposed rule change.

⁹ See Section 2(a) of the proposed Third A&R Agreement.

issued by [the Commission] and CFTC and applicable law.”¹⁰

In addition, the Eligible BD-FCM would be required to enter into a participant agreement with FICC and CME in the form of Appendix C to the Third A&R Agreement (the “Customer Cross-Margining Clearing Member Agreement”), which is further described below.¹¹ The definition of “Clearing Member Agreement” would correspondingly be amended to refer, with respect to the Proprietary Cross-Margining Arrangement, to the existing participant agreement currently in Appendix A or Appendix B of the Second A&R Agreement (the “Proprietary Clearing Member Agreement”), as applicable, and with respect to the Customer Cross-Margining Arrangement, to the Customer Cross-Margining Clearing Member Agreement.¹²

As a conforming change, Sections 2(a) and (c) and the first sentence of Section 2(a) of the Third A&R Agreement would also be amended to provide that the pre-existing language therein applies to a Cross-Margining Participant for the Proprietary Cross-Margining Arrangement.¹³

b. Definition of Customer and Non-Customer

The Customer Cross-Margining Arrangement would only be available for the positions carried by an Eligible BD-FCM for “Customers.” To ensure compliance with the limitations under the Proposed Orders of the types of persons eligible to be Cross-Margining Customers, the Third A&R Agreement would define “Customer” as an indirect clearing participant that meets the definition of futures customer set out in CFTC Regulation 1.3 and is a “Sponsored Member” or “Executing Firm Customer” as defined under the GSD Rules.¹⁴ CFTC Regulation 1.3 defines “futures customer” to mean any person who uses an FCM as an agent in connection with trading in any futures contract, but excludes persons whose futures positions are held in a

“proprietary account.”¹⁵ Any Customer wishing to participate in the Customer Cross-Margining Arrangement would need to enter into an agreement with its Eligible BD-FCM that includes certain terms described in greater detail below (the “Customer Agreement”).¹⁶ Because affiliates of the Eligible BD-FCM would generally have their CME-cleared futures positions held in a proprietary account of the Eligible BD-FCM, such affiliates would not constitute “futures customers” under CFTC Regulation 1.3. However, Eligible Affiliates would continue to be able to access cross-margining under the Proprietary Cross-Margining Arrangement so long as they constitute “Non-Customers.”¹⁷ The Third A&R Agreement would revise the definition of “Non-Customer” to mean any affiliate of the Eligible BD-FCM or any person that is an officer, director, partner or other related person of the Eligible BD-FCM (i) that is not a “customer” of the Eligible BD-FCM within the meaning of SIPA, Subchapter III of Chapter VII of the U.S. Bankruptcy Code, or Exchange Act Rule 15c3-3 and (ii) whose CME-cleared positions are carried in a proprietary account of the Eligible BD-FCM.¹⁸

¹⁵ See CFTC Regulation 1.3, definition of “futures customer” (defining “futures customer” as “any person who uses a futures commission merchant, introducing broker, commodity trading advisor, or commodity pool operator as an agent in connection with trading in any contract for the purchase or sale of a commodity for future delivery or any option on such contract; Provided, however, an owner or holder of a proprietary account as defined in this section shall not be deemed to be a futures customer within the meaning of sections 4d(a) and 4d(b) of the [CEA], the regulations in this chapter that implement sections 4d and 4f of the [CEA] and [CFTC Regulation] § 1.35, and such an owner or holder of such a proprietary account shall otherwise be deemed to be a futures customer within the meaning of the [CEA] and [CFTC Regulations] §§ 1.37 and 1.46 and all other sections of these rules, regulations, and orders which do not implement sections 4d and 4f of the [CEA].”); CFTC Regulation 1.3, definition of “proprietary account” (defining “proprietary account” as “futures, commodity option, or swap trading account carried on the books and records of” a person or entity for such person or entity itself or certain affiliates, as well as such account “of which ten percent or more is owned by . . . or an aggregate of ten percent or more of which is owned by more than one” such persons, entities, or affiliates).

¹⁶ See *infra* Part 10(i)(H) “Customer Agreement.”

¹⁷ See Section 3(b) of the proposed Third A&R Agreement (allowing the transactions, positions and margin that are maintained by an “Eligible Affiliate” to be maintained in a Cross-Margining Account provided that certain conditions, which are not proposed to be modified in the Third A&R Agreement, are satisfied); Self-Regulatory Organizations; Fixed Income Clearing Corporation; Order Approving Proposed Rule Change to Amend and Restate the Cross-Margining Agreement between FICC and CME, 90 FR 31043 (July 11, 2025).

¹⁸ See Section 1 of the proposed Third A&R Agreement.

c. Relationship Between the Clearing Organizations and Cross-Margining Customers

Because a Cross-Margining Customer’s participation in the Customer Cross-Margining Arrangement would be intermediated through the Eligible BD-FCM, Section 2(a) of the Third A&R Agreement would specify that the Clearing Organizations would have no obligation to deal directly with a Cross-Margining Customer, and that a Cross-Margining Customer would have no right to assert a claim against a Clearing Organization with respect to, nor would a Clearing Organization be liable to a Cross-Margining Customer for, any obligations of a Clearing Organization in connection with the Cross-Margining Customer’s participation in the Customer Cross-Margining Arrangement pursuant to the Third A&R Agreement.¹⁹ These terms are consistent with those applicable to Eligible Firm Customers under the GSD Rules, as well as those applicable to customers under CME’s rules.²⁰

B. Customer Cross-Margining Account

To effectuate the Customer Cross-Margining Arrangement, the Third A&R Agreement would include changes to enable an Eligible BD-FCM to establish a “Customer Cross-Margining Account” separate from any of its “Proprietary Cross-Margining Accounts.”

A Customer Cross-Margining Account would be defined as, with respect to FICC, an Indirect Participants Account (as defined in the GSD Rules) at FICC maintained for Cross-Margining Customers and identified in FICC’s books and records as being subject to the Third A&R Agreement (which, as discussed below, would be the “Cross-Margining Customer Account” under the GSD Rules) and with respect to CME, an account carried on the books and records of CME for an Eligible BD-FCM, which contains only the positions, transactions, and margin of that Eligible BD-FCM’s Cross-Margining Customers.²¹ A Proprietary Cross-Margining Account would be defined as, with respect to FICC, a Proprietary Account at FICC (as defined in the GSD Rules) or an Indirect Participants Account at FICC that is maintained for Non-Customers and identified in FICC’s books and records as being subject to the Third A&R Agreement, and, with respect to CME, an account carried on the books and records of CME for an

¹⁹ See Section 2(a) of the proposed Third A&R Agreement.

²⁰ See GSD Rules, Rule 2, Section 4; Rule 8, Section 6(c)-(e); CME Rulebook, Rule 803.

²¹ See *id.*

¹⁰ See Section 3(a) of the proposed Third A&R Agreement.

¹¹ See *infra* Part 10(i)(G) “Customer Cross-Margining Clearing Member Agreement”; Section 2(d) of the proposed Third A&R Agreement; Appendix C “Fixed Income Clearing Corporation/Chicago Mercantile Exchange Inc. Cross-Margining Participant Agreement (Common Member) [Customer Cross-Margining Program]” of the proposed Third A&R Agreement.

¹² See Section 1 of the proposed Third A&R Agreement.

¹³ See Sections 2(a), (c) of the proposed Third A&R Agreement.

¹⁴ See Section 1 of the proposed Third A&R Agreement.

Eligible BD–FCM, which contains only the positions, transactions, and margin of the “proprietary accounts” (as defined in CFTC Regulation 1.3) of the Eligible BD–FCM.²²

The Third A&R Agreement would also define “Cross-Margining Account” to mean either a Proprietary Cross-Margining Account or a Customer Cross-Margining Account.²³ An Eligible BD–FCM would be required to designate each Cross-Margining Account it opens at the Clearing Organizations as either a Customer Cross-Margining Account or a Proprietary Cross-Margining Account.²⁴

C. Margin Methodology

The Third A&R Agreement would also specify how potential margin reductions would be calculated for Customer Positions carried in a Customer Cross-Margining Account. As with Proprietary Positions, each Clearing Organization would calculate the margin savings that would result from viewing the “Combined Portfolio” of CME-cleared Customer Positions and FICC-cleared Customer Positions as a single portfolio rather than as separate standalone portfolios. The Clearing Organizations would then compare the respective margin reduction percentages, and each would then reduce the margin required for the Combined Portfolio by the lower percentage (subject to a cap of 80%). For Customer Positions, this process would occur on a Cross-Margining Customer-by-Cross-Margining Customer basis. In other words, each Cross-Margining Customer’s Customer Positions would form part of a separate Combined Portfolio. This customer-by-customer approach is consistent both with how futures contracts are required to be margined under the rules of the CFTC, as well as how FICC margins Segregated Indirect Participant positions.²⁵

To implement this margin reduction methodology, the Third A&R Agreement would redefine “Combined Portfolio” to mean, in the case of a Pair of Cross-Margining Accounts consisting of Proprietary Cross-Margining Accounts, all Eligible Positions in such Cross-Margining Accounts, and in the case of a Pair of Cross-Margining Accounts consisting of Customer Cross-Margining Accounts, all Eligible Positions of a single Customer in such Cross-Margining Accounts.²⁶ The term “Pair

of Cross-Margining Accounts”, in turn, would be defined to mean a Customer Cross-Margining Account at CME and a Customer Cross-Margining Account at FICC or a Proprietary Cross-Margining Account at CME and a Proprietary Cross-Margining Account at FICC.²⁷ The Third A&R Agreement would clarify that an Eligible BD–FCM would only be able to establish one Pair of Cross-Margining Accounts for each type of Indirect Participants Account offered at FICC under the GSD Rules and that the Customer Positions of the same Cross-Margining Customer may not be maintained in multiple Pairs of Cross-Margining Accounts of the same Eligible BD–FCM.²⁸ This limitation is aimed at ensuring that, as is the case with futures contracts, an Eligible BD–FCM would not be permitted to establish a separate account at the Clearing Organization for a particular customer or group of customers.

In addition to these changes, the Third A&R Agreement would include conforming changes in Section 4 to make clear that the margin calculations are performed on the Combined Portfolio and to provide that Sections 4(c) and 4(e), concerning the ability of the Clearing Organizations to require margin equal to or in excess of the Standalone Margin Requirement, would apply in relation to each Cross-Margining Account.²⁹ The Third A&R Agreement would also make conforming changes to a number of defined terms by:

- Revising the definition of “Cross-Margin Requirement” to refer to the joint amount of Margin required by FICC and CME in connection with a Combined Portfolio as provided for in Section 4(a) of the Third A&R Agreement;
- Revising definitions of “Margin Reduction” and “Variation Margin” to clarify that these terms apply separately with respect to Proprietary Cross-Margining Accounts and Customer Cross-Margining Accounts;
- Further revising the “Variation Margin” definition to reflect that amounts may be owed by or to a Cross-Margining Customer in relation to positions recorded in a Customer Cross-Margining Account;
- Revising the definition of “Stand-Alone Margin Requirement” to provide that it is determined with respect to a particular Cross-Margining Account, and that with regard to a Stand-Alone

Margin Requirement of FICC, such requirement is calculated without regard to any netting across positions of multiple Executing Firm Customers in the same Agent Clearing Member Omnibus Account (as such terms are defined in the GSD Rules);

- Revising the definition of “Margin” to include Cross-Margining Customer Margin securing the obligations of a Cross-Margining Customer and to contemplate a Joint Clearing Member having multiple Cross-Margining Accounts; and

- Removing the definition of “Cross-Margin Positions”, which would no longer be used.³⁰

Section 6(b) of the Third A&R Agreement would be revised to require FICC and CME to notify each other in the event a material problem arises with respect to a Cross-Margining Customer in the same manner as they are currently required to do with respect to Cross-Margining Participants.³¹

D. Default Management

The Third A&R Agreement would include certain adjustments to the default management provisions to describe how the Clearing Organizations would address a default of an Eligible BD–FCM that is carrying Customer Positions for Cross-Margining Customers, elaborate on the steps the Clearing Organizations may take in a joint liquidation, and clarify when the Clearing Organizations may manage the default of a Cross-Margining Participant independently of one another.

The Third A&R Agreement would subject Customer Positions to substantially the same default management process as Proprietary Positions. In particular, under Section 7(b) of the Third A&R Agreement, the Clearing Organizations would attempt in good faith to jointly transfer, liquidate, or close-out the Proprietary Positions or Customer Positions, which may include a joint liquidating auction so that hedged positions can be closed-out simultaneously or, in the case of a transfer of Customer Positions, so that the positions of each Cross-Margining Customer in a Combined Portfolio can, if feasible, be transferred to the same clearing firm. Section 7(b) would further provide that if one Clearing Organization determines that such joint action is not feasible or advisable for any Liquidation Portfolio, then either Clearing Organization could buy-out the Proprietary Positions or Customer

²² See *id.*

²³ See Section 1 of the proposed Third A&R Agreement.

²⁴ See Section 2(a) of the proposed Third A&R Agreement.

²⁵ 17 CFR 39.13(g)(8)(i); GSD Rules, Rule 4, Section 1b(b).

²⁶ See Section 1 of the proposed Third A&R Agreement.

²⁷ See *id.*

²⁸ See Section 2(d) of the proposed Third A&R Agreement.

²⁹ See Sections 4(a), (c), and (e) of the proposed Third A&R Agreement.

³⁰ See Section 1 of the proposed Third A&R Agreement.

³¹ See Section 6(b) of the proposed Third A&R Agreement.

Positions in such Liquidation Portfolio at the other Clearing Organization in accordance with the existing terms of the Third A&R agreement related to buy-outs. Lastly, Section 7(b) would provide that if one Clearing Organization determines that neither the joint transfer, liquidation, or close-out option nor the buy-out option is legally permissible or possible as to a particular Liquidation Portfolio, or if such methods would result in substantially greater losses to each Clearing Organization than in the case of a separate liquidation by each Clearing Organization, the Clearing Organizations could conduct separate liquidations in accordance with the existing terms related to such separate liquidations.³² The Clearing Organizations do not foresee particular circumstances that could lead to separate liquidations being applicable. To the contrary, the Clearing Organizations believe it is highly unlikely that they would engage in separate liquidations. However, the Clearing Organizations believe it is prudent to have a separate liquidation option so that there is a clear methodology in the very unlikely event that some unforeseen circumstance causes it not to be possible or legally permissible to conduct a joint liquidation or buy-out or for such methods to result in substantially greater costs.

The Third A&R Agreement would also include provisions designed to ensure that Customer Positions and associated margin are not used by either Clearing Organization to satisfy obligations arising from Proprietary Positions. The principal mechanism to achieve this would be a new concept of a "Liquidation Portfolio," which would be defined as, with respect to a Defaulting Member, all such Defaulting Member's Proprietary Cross-Margining Account(s) or all such Defaulting Member's Customer Cross-Margining Account(s).³³ The definitions of "Collateral on Hand", "Net Gain", "Net Loss", "Cross-Margin VM Gain", "Cross-Margin VM Loss", "Other VM Gain", "Liquidation Cost", and "Share of the Cross-Margining Requirement", in turn, would be revised so that they are separately determined by reference to each Liquidation Portfolio, rather than to a Defaulting Member or Cross-Margining Account.³⁴ The Third A&R Agreement would also provide for the

concept of a "Related GSD Account", which would be defined as, with respect to a Liquidation Portfolio of a Defaulting Member consisting of Proprietary Cross-Margining Accounts, the "Proprietary Accounts" (as defined in the GSD Rules) of the Defaulting Member at FICC, and with respect to a Liquidation Portfolio of a Defaulting Member consisting of Customer Cross-Margining Accounts, the Indirect Participant Account(s) of the Defaulting Member at FICC.³⁵

In addition, the Third A&R Agreement would revise Sections 7(b) through (g) to clarify that the provisions thereof would apply separately to each Liquidation Portfolio. These changes include replacing certain references to "Cross-Margining Account" with "Liquidation Portfolio,"³⁶ additional language specifying that provisions apply with respect to each Liquidation Portfolio,³⁷ and deletions of language providing for liquidation actions or calculations to be performed with respect to a Defaulting Member.³⁸ In addition, as mentioned above, the definition of "Combined Portfolio" would be revised to mean, in the case of a Pair of Cross-Margining Accounts consisting of Proprietary Cross-Margining Accounts, all Eligible Positions in such Cross-Margining Accounts, and in the case of a Pair of Cross-Margining Accounts consisting of Customer Cross-Margining Accounts, all Eligible Positions of a single Customer in such Cross-Margining Accounts.³⁹

By virtue of these changes, upon a default of a Joint Clearing Member, the Proprietary Positions and associated margin of the Joint Clearing Member would be closed-out and netted into a single Net Gain or Net Loss, and the Customer Positions and associated margin would be separately close-out and netted into a separate Net Gain or Net Loss. As a result of these separate calculations, Customer Positions and associated margin could not be used to satisfy obligations arising under any Proprietary Positions. Similarly, variation margin gains in respect of Customer Positions would not be available to address losses on Proprietary Positions. However, the definition of "Other VM Gains" would be modified to make clear that, if there were Cross-Margin VM Gains in relation to Proprietary Positions at a time when the Clearing Organization with those

Cross-Margin VM Gains also had losses on account of Customer Positions, the VM Gains may first be applied to satisfy the losses on the Customer Positions before being remitted to the other Clearing Organization.⁴⁰

Although the Clearing Organizations would generally close-out and net the Liquidation Portfolios of a Defaulting Member separately, Section 7(a) of the Third A&R Agreement would provide that the decision as to whether to commence the liquidation process with respect to a Joint Clearing Member would be made based on the Joint Clearing Member itself, rather than a particular Liquidation Portfolio. In accordance with this framework, Section 7(a) of the Third A&R Agreement would provide that if one Clearing Organization decides not to take default action against a Defaulting Member following a Default Event (the "Non-Liquidating CO"), the Non-Liquidating CO shall immediately require the Defaulting Member to pay the Non-Liquidating CO in immediately available funds the sum of (x) its Margin Reduction at the other Clearing Organization for all Combined Portfolios of the Defaulting Member, and (y) its Margin Reduction at the Non-Liquidating CO for all Combined Portfolios of the Defaulting Member, within one hour of demand.⁴¹

E. Conforming Changes

The Third A&R Agreement would also include a number of conforming changes in light of the addition of the Customer Cross-Margining Arrangement. These would include new recitals which describe the purpose of the Third A&R Agreement as to establish the Customer Cross-Margining Arrangement, introduce defined terms for the "Proprietary Cross-Margining Arrangement" and "Customer Cross-Margining Arrangement", and define the prior versions of the agreement as the "Original Agreement", the "First A&R Agreement", and the "Second A&R Agreement." They would also include non-substantive revisions and movements of defined terms as shown in Exhibit 5 to conform to the addition of the Customer Cross-Margining Arrangement and the provisions described above.⁴²

⁴⁰ See *id.*

⁴¹ See Section 7(a) of the proposed Third A&R Agreement.

⁴² See Section 1 of the proposed Third A&R Agreement; see, e.g., Section 3(c) of the proposed Third A&R Agreement (updating references to "Cross-Margining Account(s)" to refer to "Proprietary Cross-Margining Account(s)"); Section 7(a) of the proposed Third A&R Agreement

³² See Section 7(b) of the proposed Third A&R Agreement.

³³ See Section 1 of the proposed Third A&R Agreement.

³⁴ *Id.*

³⁵ *Id.*

³⁶ See Sections 7(c), (d), and (e) of the proposed Third A&R Agreement.

³⁷ See Sections 7(b), (c), (e), (f), and (g) of the proposed Third A&R Agreement.

³⁸ See Section 7(c) of the proposed Third A&R Agreement.

³⁹ See Section 1 of the proposed Third A&R Agreement.

The Third A&R Agreement would also revise Section 3(b), which sets out certain requirements applicable to positions of Eligible Affiliates, to provide that it does not apply to Proprietary Positions of a Joint Clearing Member or to Customer Positions.⁴³

In addition, the Third A&R Agreement would revise Section 7(i) to clarify that the requirement for a Defaulting Member to reimburse a Clearing Organization in the event that the Clearing Organization is obligated to make a guaranty payment to the other Clearing Organization in respect of an obligation of such Defaulting Member applies in respect of the obligations of any Cross-Margining Customer.⁴⁴

F. Clarifying Edits

The Third A&R Agreement would also include a number of clarifying edits not specifically related to the Customer Cross-Margining Arrangement. Specifically, Section 2(f) of the Third A&R Agreement would specify that FICC or CME may terminate the participation of a particular Cross-Margining Participant with respect to some or all Cross-Margining Accounts of the Cross-Margining Participant upon two business days' prior written notice to the other Clearing Organization, provided that no such termination would be effective with respect to any reimbursement obligation or guaranty with respect to such Cross-Margining Participant that was incurred prior to such termination, or with respect to Section 7 of the Third A&R Agreement until the Stand-Alone Margin Requirement with respect to each Cross-Margining Account subject to such termination has been fully satisfied.⁴⁵

The Third A&R Agreement would also include a new Section 5 to make clear that, as is currently the case, the collateral acceptable to satisfy the Cross-Margin Requirement must meet the respective eligibility requirements of the Clearing Organization to which the collateral is posted.⁴⁶

In addition, the titles of the Proprietary Cross-Margining Agreements in Appendix A and Appendix B of the Third A&R Agreement would be amended to specify that they are for use in

connection with the Proprietary Cross-Margining Arrangement.⁴⁷

G. Customer Cross-Margining Clearing Member Agreement

As described above, an Eligible BD-FCM would be required to enter into the Customer Cross-Margining Clearing Member Agreement in order to participate in the Customer Cross-Margining Arrangement. The Customer Cross-Margining Clearing Member Agreement would be set forth in Appendix C to the Third A&R Agreement.⁴⁸

The Customer Cross-Margining Clearing Member Agreement would be modeled on the Proprietary Clearing Member Agreement in Appendix A of the Second A&R Agreement (the "Existing Joint Clearing Member Proprietary Clearing Member Agreement"), with changes designed to facilitate compliance with the conditions in the Proposed Orders and to clarify the rights and obligations of the Clearing Organizations, the Eligible BD-FCM, and the Cross-Margining Customers.⁴⁹

The first three paragraphs of the Customer Cross-Margining Clearing Member Agreement would be substantially identical to those of the Existing Joint Clearing Member Proprietary Clearing Member Agreement, except that the first paragraph would note that the Eligible BD-FCM is electing to become a Cross-Margining Participant for purposes of the Customer Cross-Margining Arrangement, rather than the Cross-Margining Arrangement generally, and the third paragraph (concerning the Eligible BD-FCM's payment obligations) would reference the payment obligations arising in respect of Customer Cross-Margining Accounts.

The Customer Cross-Margining Clearing Member Agreement would provide that the Eligible BD-FCM makes application to the Clearing Organizations to establish a Customer Cross-Margining Account at CME and one or more Customer Cross-Margining Accounts at FICC in the name of the

Eligible BD-FCM, and clarify that each such account would be in addition to any Proprietary Cross-Margining Account of the Eligible BD-FCM established pursuant to the Third A&R Agreement. The Customer Cross-Margining Clearing Member Agreement would provide that each Customer Cross-Margining Account shall be limited to transactions and positions carried by the Eligible BD-FCM for Cross-Margining Customers who have signed a Customer Agreement. The Eligible BD-FCM would be required to agree that it shall not commence clearing transactions through or carrying positions in a Customer Cross-Margining Account for any Cross-Margining Customer until such Cross-Margining Customer has executed a Customer Agreement.

The Eligible BD-FCM would be required under the Customer Cross-Margining Clearing Member Agreement to indemnify and hold harmless the Clearing Organizations, their respective directors, officers and employees and each person, if any, who controls either of the Clearing Organizations against any claims, losses, liabilities and expenses, including, without limitation, reasonable legal fees and expenses and amounts paid or payable in settlement of any action, proceeding or investigation arising from any claim by any party resulting from the carrying of positions in a Customer Cross-Margining Account that belong to any person other than a Cross-Margining Customer for whom a Customer Agreement is in effect.

The Customer Cross-Margining Clearing Member Agreement would provide that the Eligible BD-FCM, as agent for each of its Cross-Margining Customers, (i) unconditionally promises immediate payment of any payment or reimbursement obligations to a Clearing Organization arising under the Third A&R Agreement or the GSD Rules or rules of CME in respect of a Cross-Margining Customer's positions in a Customer Cross-Margining Account, and (ii) agrees that each Cross-Margining Customer is bound by the GSD Rules and the rules of CME as applicable to them and by the provisions of the Customer Cross-Margining Clearing Member Agreement and the Third A&R Agreement. The Eligible BD-FCM would also be required to represent and warrant to the Clearing Organizations that it has full power and authority to bind each of its Cross-Margining Customers to the terms in the foregoing sentence.

The Customer Cross-Margining Clearing Member Agreement would also provide for the Eligible BD-FCM to

(updating a reference to "Eligible Affiliates" to refer to "Eligible Affiliates or Customers").

⁴³ See Section 3(b) of the proposed Third A&R Agreement.

⁴⁴ See Section 7(i) of the proposed Third A&R Agreement.

⁴⁵ See Section 2(f) of the proposed Third A&R Agreement.

⁴⁶ See Recitals, Section 1, and Section 5 of the proposed Third A&R Agreement.

⁴⁷ See Appendix A "Fixed Income Clearing Corporation/Chicago Mercantile Exchange Inc. Cross-Margining Participant Agreement (Common Member) [Proprietary Cross-Margining Program]" of the proposed Third A&R Agreement; Appendix B "Fixed Income Clearing Corporation/Chicago Mercantile Exchange Inc. Cross-Margining Participant Agreement (Common Member) [Proprietary Cross-Margining Program]" of the proposed Third A&R Agreement.

⁴⁸ See Appendix C "Fixed Income Clearing Corporation/Chicago Mercantile Exchange Inc. Cross-Margining Participant Agreement (Common Member) [Customer Cross-Margining Program]" of the proposed Third A&R Agreement.

⁴⁹ See *id.*

pledge, as security for its and its Cross-Margining Customers' present and future payment and reimbursement obligations to FICC and CME arising from its Customer Cross-Margining Accounts or otherwise under the Customer Cross-Margining Clearing Member Agreement on behalf of itself and each Cross-Margining Customer, and grant to each Clearing Organization a first priority continuing security interest in, lien on and right of set-off against all of the positions, margin deposits or other property held by or subject to the control of or owing from either Clearing Organization including any and all Net Gains in respect of the Eligible BD-FCM's Customer Cross-Margining Accounts and the proceeds in respect thereof.

The Eligible BD-FCM would also provide for the Eligible BD-FCM to agree that (i) the rights of each Clearing Organization set forth in the preceding paragraph are in addition to any other rights arising out of the NYUCC or other statute, common law, or governmental regulation, or under their respective rules, (ii) the Eligible BD-FCM will execute, deliver, file and record any financing statement, specific assignment or other document and take any other action necessary or desirable and reasonably requested by FICC or CME to create, preserve, perfect or validate the security interest or lien granted in this paragraph, to enable such Clearing Organization to exercise or enforce its rights, (iii) the Eligible BD-FCM will promptly give notice to the Clearing Organizations of, and defend against, any suit, action, proceeding or lien that involves or could adversely affect the security interest and lien granted by the Eligible BD-FCM, and (iv) the Eligible BD-FCM authorizes FICC to comply with CME's entitlement orders with respect to any Cross-Margining Customer Margin pursuant to the Third A&R Agreement without further consent of the Eligible BD-FCM or Cross-Margining Customer for whom such Cross-Margining Customer Margin is held. Clauses (i) through (iii) broadly align with the Existing Joint Clearing Member Proprietary Clearing Member Agreement, while clause (iv) would be designed to facilitate the perfection of CME's security interest in the Cross-Margining Customer Margin and help ensure that Cross-Margining Customer Margin is treated as "customer property" under Part 190 of the CFTC's regulations, as described in the Petitions.

The Customer Cross-Margining Clearing Member Agreement would contain the same provision regarding the disclosure of Clearing Data as in the

Existing Joint Clearing Member Proprietary Clearing Member Agreement. Consistently with the Existing Joint Clearing Member Proprietary Clearing Member Agreement, it would also provide that neither FICC nor CME guarantees to the Eligible BD-FCM that the calculation of the margin reduction for a Combined Portfolio pursuant to the Third A&R Agreement will yield any, or the highest possible, margin reduction for the Combined Portfolio. The Customer Cross-Margining Clearing Member Agreement would also, as in the Existing Joint Clearing Member Proprietary Clearing Member Agreement, provide that, without limiting any provision of the GSD Rules, the rules of CME or any other agreement between the Eligible BD-FCM and FICC or CME, any transfer by the Eligible BD-FCM or any Cross-Margining Customer of any rights it may have in the Net Gain (or any component thereof) shall be null and void and, in any event, subject to the prior payment in full of all payment and reimbursement obligations under the Third A&R Agreement. The Customer Cross-Margining Clearing Member Agreement would contain the same representations as the Existing Joint Clearing Member Proprietary Clearing Member Agreement, except those concerning the proprietary nature of the positions and Eligible Affiliates.

The Customer Cross-Margining Clearing Member Agreement would specify that the Eligible BD-FCM may terminate the Customer Cross-Margining Clearing Member Agreement upon two business day's written notice to FICC and CME, and that such termination shall be effective upon written acknowledgement by both FICC and CME provided that (i) all positions in the Customer Cross-Margining Accounts have been closed-out or transferred to other accounts in accordance with the GSD Rules or the rules of CME, and (ii) all Stand-alone Margin Requirement in respect of any such transferred positions and all obligations of the Eligible BD-FCM to the Clearing Organizations in respect of the Customer Cross-Margining Accounts have been fully satisfied.

The Customer Cross-Margining Clearing Member Agreement would also specify that either Clearing Organization may terminate the Eligible BD-FCM's participation with respect to any Customer Cross-Margining Account (defined as an "Affected Customer Cross-Margining Account") of the Eligible BD-FCM at any time upon written notice to the other Clearing Organization pursuant to the Third A&R Agreement and to the Eligible BD-FCM. In connection with such termination,

the Clearing Organizations would be permitted to require the Eligible BD-FCM to close-out or transfer all positions in the Affected Customer Cross-Margining Accounts in accordance with the GSD Rules or the rules of CME, and the Customer Cross-Margining Clearing Member Agreement would thereupon terminate with respect to Affected Customer Cross-Margining Accounts, provided that the Stand-alone Margin Requirement in respect of the transferred positions and all obligations of the Eligible BD-FCM to the Clearing Organizations in respect of the Affected Customer Cross-Margining Accounts have been fully satisfied.

The Customer Cross-Margining Clearing Member Agreement would also include the same governing law, choice-of-jurisdiction, and execution in counterparts provisions as the Existing Joint Clearing Member Proprietary Clearing Member Agreement. The Customer Cross-Margining Clearing Member Agreement would also provide that it would become effective upon the later of execution of the Customer Cross-Margining Clearing Member Agreement, or on the receipt of all necessary regulatory approvals from the Commission and the CFTC.

H. Customer Agreement

The Customer Agreement would include the terms of the Subordination Agreement and acknowledgements corresponding to the disclosures required by the Proposed Orders.⁵⁰ In particular, the Customer Agreement would require the Cross-Margining Customer to acknowledge and agree that:

- it agrees to the terms of the Subordination Agreement, under which the Cross-Margining Customer agrees that all of its Customer Positions and Customer Property (including any margin at FICC) (i) will not receive customer treatment under the Exchange Act or SIPA or be treated as "customer property" as defined in 11 U.S.C. 741 in a liquidation of Clearing Member, and (ii) will be subject to any applicable protections under Subchapter IV of Chapter 7 of the U.S. Bankruptcy Code and rules and regulations thereunder including Part 190 of the CFTC's Regulations ("Part 190"), and that the Cross-Margining Customer's claims to "customer property" as defined in SIPA or 11 U.S.C. 741 against the Eligible BD-FCM with respect to its Customer Positions and Customer Property (including any margin held at FICC) will

⁵⁰ See Appendix C, Exhibit I "Customer Required Terms Annex or Agreement" of the proposed Third A&R Agreement.

be subordinated to the claims of all other customers, as the term “customer” is defined in 11 U.S.C. 741 or SIPA;⁵¹

- all money, securities and property deposited with the Eligible BD–FCM by the Cross-Margining Customer to margin, guarantee or secure Customer Positions (the “Customer Property”) will be held in a “futures account” as defined in CFTC Regulation 1.3 and subject to CEA Section 4d(a) and (b);⁵²

- its Customer Positions and associated margin may be commingled with the positions and property of other customers of the Eligible BD–FCM and may be used by the Eligible BD–FCM to purchase, margin, secure, settle, or otherwise carry positions on behalf of the Cross-Margining Customer or other futures customers of the Eligible BD–FCM;⁵³

- property held in connection with Customer Positions will be treated in a manner consistent with the CFTC Order and that such property held on the Cross-Margining Customer’s behalf by the Eligible BD–FCM will be customer property received by an FCM to be accounted for, treated and dealt with by such FCM in a manner consistent with Section 4d of the CEA;⁵⁴

- in the event a Clearing Organization suspends or ceases to act for Clearing Member, it shall be within the sole discretion of the Clearing Organizations to determine whether to transfer, liquidate, or settle Customer Positions in the relevant Customer Cross-Margining Account;⁵⁵

- its participation in the Customer Cross-Margining Arrangement is subject to the terms of (i) the Third A&R Agreement, (ii) the Customer Cross-Margining Clearing Member Agreement, and (iii) the GSD Rules and the rules of CME;⁵⁶ and

- if CME determines at any time that any Eligible Positions of the Cross-Margining Customer cleared through the Customer Cross-Margining Account at CME are non-risk reducing, CME may either restrict the Cross-Margining Customer from adding positions or require the Cross-Margining Customer to move or liquidate Eligible Positions in the Customer Cross-Margining Account at CME;⁵⁷

The Customer Agreement would also require the Cross-Margining Customer to pledge, as security for the Cross-Margining Customer’s present and

future payment and delivery obligations in respect of its Customer Positions (including, without limitation, any obligation of the Cross-Margining Customer to reimburse the Eligible BD–FCM as a result of the Eligible BD–FCM’s performance of such obligations), and grant to the Eligible BD–FCM a continuing security interest in, lien on and right of set-off against its right, entitlement, and interest in all of positions in each Customer Cross-Margining Account, all margin posted by the Cross-Margining Customer in connection with such positions, and the proceeds in respect thereof.⁵⁸ The Customer Agreement would also require the Cross-Margining Customer to agree that the Eligible BD–FCM may enter into agreements with the Clearing Organizations on the Cross-Margining Customer’s behalf as set forth in the Customer Cross-Margining Clearing Member Agreement.⁵⁹

(ii) Other Proposed Changes to the GSD Rules

A. Overview

FICC is proposing to make a number of changes to the GSD Rules to effectuate the Customer Cross-Margining Arrangement.

First, FICC proposes to create a new position Account type, the “Cross-Margining Customer Account,” in which Customer Positions would be recorded. The Cross-Margining Customer Account would constitute an “Indirect Participants Account.” A Netting Member that is an Eligible BD–FCM and approved participant in the Customer Cross-Margining Arrangement would be permitted to designate an Indirect Participants Account (other than a Segregated Indirect Participants Account) as a Cross-Margining Customer Account.⁶⁰ Any such designation would constitute a representation to FICC by the Netting Member that the Netting Member has complied with all regulatory requirements applicable to it in connection with its participation in the Customer Cross-Margining Arrangement, including the conditions in the Proposed Orders, and this representation would be deemed repeated each time the Netting Member

deposits Cross-Margining Customer Margin.

Second, FICC proposes to adopt rule changes to set forth how FICC would calculate, collect, and hold margin for positions recorded in a Cross-Margining Customer Account. As noted above, FICC proposes to collect and hold Cross-Margining Customer Margin pursuant to substantially similar provisions as apply to Segregated Customer Margin, with certain modifications to satisfy the requirements of the Proposed Orders and align with the treatment of futures margin. Specifically:

- Consistent with Segregated Customer Margin and in accordance with the Proposed Orders, FICC would credit all Cross-Margining Customer Margin deposited by a Netting Member to a “securities account”, as defined in the NYUCC,⁶¹ on its books and records maintained for that Netting Member for the benefit of its Cross-Margining Customers (*i.e.*, a Cross-Margining Customer Margin Custody Account). The GSD Rules would further provide that all cash and securities credited to the Cross-Margining Customer Margin Custody Account shall be treated as “financial assets” within the meaning of Article 8 of the NYUCC, New York shall be the “securities intermediary’s jurisdiction” for purposes of the NYUCC and New York law shall govern all issues specified in Article 2(1) of the Hague Securities Convention.⁶² Such provisions are designed to ensure the Cross-Margining Customer Margin would not form part of FICC’s estate in the event FICC became subject to insolvency proceedings. They would also facilitate the ability of CME to perfect its security interest in the Cross-Margining Customer Margin. Such perfection would serve to protect CME, and in turn both the Cross-Margining Customers and the non-participating futures customers in the event of a Cross-Margining Participant default. It would also aim to ensure that the Cross-Margining Customer Margin is treated as “customer property” under Part 190 in the event of an Eligible BD–FCM’s insolvency, by helping to establish that the Cross-Margining Customer Margin is held to secure the futures positions of customers.

- In accordance with the Proposed Orders, FICC would hold Cross-Margining Customer Margin in (i) an account of FICC at a bank insured by the Federal Deposit Insurance Corporation

⁵¹ See *id.*, Section 2(b).

⁵² See *id.*, Section 2(a).

⁵³ See *id.*, Section 2(c).

⁵⁴ See *id.*

⁵⁵ See *id.*, Section 2(d).

⁵⁶ See *id.*, Section 3.

⁵⁷ See *id.*

⁵⁸ See *id.*, Section 4.

⁵⁹ See *id.*, Section 5.

⁶⁰ As mentioned above, the Third A&R Agreement would provide that a Netting Member may only designate one Sponsoring Member Omnibus Account and one Agent Clearing Member Omnibus Account as a Cross-Margining Customer Account. See Section 2(d) of the proposed Third A&R Agreement.

⁶¹ NYUCC § 8–501(a).

⁶² NYUCC § 8–102(9); NYUCC § 8–110(e); The Convention on the Law Applicable to Certain Rights in Respect of Securities Held with an Intermediary, July 5, 2006, 17 U.S.T. 401, 46 I.L.M. 649 (entered into force April 1, 2017).

("FDIC") that is segregated from any other account of FICC and used exclusively to hold Cross-Margining Customer Margin, and (ii) an account at the FRBNY that is segregated from any other account of FICC and used exclusively to hold Segregated Customer Margin and Cross-Margining Customer Margin. The GSD Rules would provide that any such account (other than one at the FRBNY) would need to be subject to a written notice consistent with the Proposed Orders.

- The same requirements applicable to Segregated Customer Margin with respect to the form and composition of eligible collateral, the minimum amounts of cash and Eligible Clearing Fund Treasury Securities, substitution and withdrawal, and treatment of excess margin would be applicable to Cross-Margining Customer Margin, except that (i) a Netting Member's rights or FICC's obligation with respect to any excess Cross-Margining Customer Margin would be subject to the Third A&R Agreement and the Customer Cross-Margining Clearing Member Agreement, and (ii) FICC would be permitted to retain the excess Cross-Margining Customer Margin deposited by a Netting Member with respect to a Cross-Margining Customer when the Netting Member has any outstanding payment or margin obligation arising from any Customer Positions, including those of another Cross-Margining Customer.

With regard to calculation, FICC proposes that, as with Segregated Customer Margin and in accordance with the requirements of the Proposed Orders, FICC would calculate the margin requirement in respect of each Cross-Margining Customer Account (the "Cross-Margining Customer Margin Requirement") on a gross (*i.e.*, Cross-Margining Customer-by-Cross-Margining Customer) basis, as though each Cross-Margining Customer were a separate Netting Member. However, such margin requirement would be subject to any margin reduction pursuant to the Third A&R Agreement (which, as discussed above, would be determined using the same margin reduction methodology under Proprietary Cross-Margining Arrangement).

Third, FICC proposes to provide that Cross-Margining Customer Margin would be pledged to FICC to secure all obligations of the Netting Member and its Cross-Margining Customers arising under Customer Positions.⁶³

Fourth, FICC proposes to remove the existing Section 10(e) of Rule 3A, which currently prohibits Sponsored Members from participating in the Cross-Margining Arrangement.

Fifth, FICC proposes to make conforming changes to Rule 43, which sets out the terms related to Cross-Margining Arrangements, so that the Rule encompasses the Customer Cross-Margining Arrangement. In particular, FICC proposes to specify in Rule 43 that a Netting Member that is an Eligible BD-FCM may become a Cross-Margining Participant in connection with the Customer Cross-Margining Arrangement with the consent of FICC and CME. An Eligible BD-FCM would become such a Cross-Margining Participant and be permitted to establish a Cross-Margining Customer Account upon acceptance by FICC and CME of an executed Customer Cross-Margining Clearing Member Agreement. FICC further proposes to make clear that if FICC becomes obligated to make a payment to CME pursuant to the cross-guaranty under the Third A&R Agreement in relation to the obligations of a Cross-Margining Customer, both the Cross-Margining Customer and the relevant Eligible BD-FCM would be responsible for the reimbursement obligation that is owed to FICC as a result. If FICC receives a payment from CME pursuant to the Third A&R Agreement in connection with the Customer Cross-Margining Arrangement, FICC would not be permitted to apply such payment to any obligation other than the obligations of Cross-Margining Customers (whether or not arising in connection with any Eligible Positions).

Lastly, FICC proposes to remove provisions relating to "Market Professional" and "Market Professional Agreement for Cross-Margining" from the GSD Rules. Those provisions were adopted in connection with a "market professional" cross-margining program between FICC and New York Portfolio Clearing, LLC.⁶⁴ That program—which permitted certain "market professional" customers of Netting Members to participant in cross-margining—is no

recorded in the same Cross-margining Customer Account, even if such Customer Positions are not the particular ones of the individual Cross-Margining Customer that posted such margin. This treatment would be consistent with how futures customer margin is generally treated.

⁶⁴ See Self-Regulatory Organizations; Fixed Income Clearing Corporation; Order Approving Proposed Rule Change To Expand the One-Pot Cross-Margining Program With New York Portfolio Clearing, LLC to Certain "Market Professionals", 77 FR 30032 (May 21, 2012).

longer active as New York Portfolio Clearing, LLC has since become defunct.

B. Summary of Proposed Rule Changes

To effectuate the proposed changes described above, FICC proposes to make the following amendments to its Rules.

New Defined Terms. FICC would revise Rule 1 to add the following new defined terms: (1) "Cross-Margining Customer", (2) "Cross-Margining Customer Account", (3) "Cross-Margining Customer Margin Custody Account", (4) "Cross-Margining Customer Margin", (5) "Cross-Margining Customer Margin Requirement", and (6) "Customer Cross-Margining Arrangement."

The term "Cross-Margining Customer" would mean a Sponsored Member or Executing Firm Customer whose Transactions are recorded in a Cross-Margining Customer Account.

The term "Cross-Margining Customer Account" would mean an Indirect Participants Account maintained by FICC for a Sponsoring Member or an Agent Clearing Member that has been designated pursuant to Rule 2B for purposes of recording Transactions of Cross-Margining Customers.

The term "Cross-Margining Customer Margin Custody Account" would mean a securities account within the meaning of the NYUCC maintained by FICC, in its capacity as securities intermediary as such term is used in the NYUCC, for an Agent Clearing Member or Sponsoring Member for the benefit of such Member's Cross-Margining Customers.

The term "Cross-Margining Customer Margin" would mean all securities and funds deposited by a Sponsoring Member or an Agent Clearing Member with FICC to satisfy its Cross-Margining Customer Margin Requirement.

The term "Cross-Margining Customer Margin Requirement" would mean the amount of cash or Eligible Clearing Fund Securities that an Agent Clearing Member or Sponsoring Member is required to deposit with FICC to support the obligations arising from Transactions recorded in its Cross-Margining Customer Accounts. Specifically, a Netting Member's Cross-Margining Customer Margin Requirement would be the amount of the item listed in Section 2(a)(vii) of Rule 4 (as described below). This definition would specify that references to the Cross-Margining Customer Margin Requirement "for" or "with respect to" a particular Cross-Margining Customer Account or Cross-Margining Customer (or similar language) would mean the portion of a Netting Member's Cross-Margining Customer Margin

⁶³ We note that in this regard, unlike Segregated Customer Margin, FICC would be able to use all Cross-Margining Customer Margin to satisfy the obligations arising from all Customer Positions

Requirement arising from such Account or Cross-Margining Customer.

The term “Customer Cross-Margining Arrangement” would mean a Cross-Margining Arrangement pursuant to which a Cross-Margining Participant, at the discretion of FICC and in accordance with the provisions of Rule 43, may elect to have any of its Cross-Margining Customers’ margin requirement in respect of Eligible Positions at FICC and such Cross-Margining Customer’s margin requirements in respect of Eligible Positions at a clearing organization for a board of trade designated as a contract market under Section 5 of the CEA that has entered into a Cross-Margining Agreement with FICC (an “FCO”) calculated by taking into consideration the net risk of such Eligible Positions at each of the clearing organizations.

Revisions to Defined Terms. In addition, FICC would make conforming revisions to the following defined terms in Rule 1: (1) “Cross-Margining Affiliate,” (2) “Cross-Margining Agreement,” (3) “Current Net Settlement Positions,” (4) “Indirect Participants Account,” and (5) “Type of Account” and “Type.”

FICC proposes to amend the definition to “Cross-Margining Affiliate” to remove existing prong (ii), which relates to the “market professional” cross-margining program.

FICC proposes to amend the definition to “Cross-Margining Agreement” to encompass the Customer Cross-Margining Arrangement by specifying that the applicable Cross-Margining Participant may have any of its Cross-Margining Customers’ margin requirement in respect of Eligible Positions at FICC and such Cross-Margining Customer’s margin requirements in respect of Eligible Positions at a relevant FCO calculated by taking into consideration the net risk of such Eligible Positions at each of the clearing organizations. FICC also proposes to remove the last sentence of this definition, which relates to the “market professional” cross-margining program.

FICC proposes to make conforming edits to the definition of “Current Net Settlement Positions” to add references to “Cross-Margining Customer,” “Cross-Margining Customer Account,” and “Cross-Margining Customer Margin Requirement” after each reference to “Segregated Indirect Participant,” “Segregated Indirect Participants Account,” and “Segregated Customer Margin Requirement,” respectively.

FICC proposes to amend the definitions of “Indirect Participants Account,” “Type of Account” and

“Type” to include a Cross-Margining Customer Account.

Removal of defined terms. FICC proposes to remove the following defined terms from Rule 1: (1) “Market Professional” and (2) “Market Professional Agreement for Cross-Margining.”

Establishment of Cross-Margining Customer Accounts. FICC proposes to amend Section 3 of Rule 2B to provide that a Cross-Margining Customer Account may not be designated as a Segregated Indirect Participants Account.

In addition, FICC proposes to add a new Section 3a of Rule 2B to provide that (i) a Netting Member that is an Eligible BD-FCM and has been approved to become a Cross-Margining Participant in a Customer Cross-Margining Arrangement pursuant to a Cross-Margining Agreement may designate any of its Indirect Participants Accounts (other than a Segregated Indirect Participants Account) as a Cross-Margining Customer Account; (ii) any such designation of an Account shall constitute a representation to FICC by the Netting Member that the Netting Member has complied with all regulatory requirements applicable to it in connection with its participation in the Customer Cross-Margining Arrangement, including the conditions in the Proposed Orders; and (iii) the Netting Member shall be deemed to repeat this representation each time it deposits Cross-Margining Customer Margin.

Treatment of Cross-Margining Customer Margin. FICC proposes to make the following changes in relation to FICC’s calculation, collection, and holding of Cross-Margining Customer Margin:

FICC proposes to amend Section 1a of Rule 4 to make clear that FICC’s account at the FRBNY that is currently used to hold Segregated Customer Margin would also hold Cross-Margining Customer Margin.

FICC proposes to renumber current Section 1b of Rule 4 to Section 1c and add a new Section 1b. The new Section 1b would provide that:

- Each Netting Member shall deposit Cross-Margining Customer Margin with FICC in an amount equal to its Cross-Margining Customer Margin Requirement, which requirement shall be determined in accordance with Rule 4 and the Margin Component Schedule. The timing of the satisfaction of the Cross-Margining Customer Margin Requirement shall be determined in accordance with the provisions of Section 9 of Rule 4.

- FICC shall establish and maintain on its books and records a Cross-Margining Customer Margin Custody Account to which all Cross-Margining Customer Margin deposited with FICC shall be credited. The Cross-Margining Customer Margin credited to a Cross-Margining Customer Margin Custody Account shall be used exclusively to secure the present and future payment and reimbursement obligations of the Netting Member and its Cross-Margining Customers in relation to Eligible Positions of the Netting Member’s Cross-Margining Customers at FICC and CME.

- All assets credited to each Cross-Margining Customer Margin Custody Account shall be treated as “financial assets” within the meaning of Article 8 of the NYUCC. New York is the “securities intermediary’s jurisdiction” for purposes of the NYUCC and New York law shall govern all issues specified in Article 2(1) of the Hague Securities Convention.

- FICC shall hold all Cross-Margining Customer Margin in an account of FICC at an FDIC-insured bank within the meaning of the Exchange Act that is a qualified custodian under the Investment Company Act of 1940, as amended, or at the FRBNY. Any account at an FDIC-insured bank shall be segregated from any other account of FICC and shall be used exclusively to hold Cross-Margining Customer Margin, and shall be subject to a written notice of the bank provided to and retained by FICC consistent with the Proposed Orders. The account at the FRBNY shall be segregated from any other account of FICC and shall be used exclusively to hold Cross-Margining Customer Margin and Segregated Customer Margin (the account at the FRBNY would not be subject to a written notice).

FICC proposes to amend current Section 1b (to be renumbered as Section 1c) of Rule 4 to (i) add references to “Cross-Margining Customer Accounts” after references to “Segregated Indirect Participants Accounts” in current Section 1b(a), and (ii) add a new sentence at the end of current Section 1b(b) to provide that FICC would calculate the Cross-Margining Customer Margin Requirement for a Cross-Margining Customer Account as the sum of the requirements applicable to each Cross-Margining Customer whose Transactions are recorded in such Account, as though each such Cross-Margining Customer were a separate Netting Member with a single Margin Portfolio consisting of such Transactions, in accordance with the Margin Component Schedule.

FICC proposes to amend Section 2 of Rule 4 by (i) adding references to

“Cross-Margining Customer Margin Requirement” after references to “Segregated Customer Margin Requirement” in the title of Section 2 and Section 2(a), and (ii) adding a new clause (vii) of Section 2(a) to specify that the Cross-Margining Customer Margin Requirement would be an amount calculated with respect to the Netting Member’s Cross-Margining Customer Accounts.

FICC proposes to add a new Section 2c of Rule 4 entitled “Cross-Margining Customer Margin Requirement” to provide that (i) each Netting Member shall deposit any Cross-Margining Customer Margin with FICC by the Required Fund Deposit Deadline through a separate Deposit ID established by the Netting Member for each Cross-Margining Customer Account, and (ii) FICC shall report the Cross-Margining Customer Margin Requirements to each Netting Member twice daily in a Report which shall specify the Cross-Margining Customer Margin Requirement for each Cross-Margining Customer Account.

FICC proposes to add a new Section 3(d) of Rule 4 and insert it before the last sentence of Section 3. The new Section 3(d) would provide that each Cross-Margining Customer Margin Requirement for a particular Cross-Margining Customer Account would be subject to the requirements that (i) a minimum of 40 percent of the Cross-Margining Customer Margin Requirement for such Account shall be satisfied with cash and/or Eligible Clearing Fund Treasury Securities, and (ii) a minimum of the product of \$1 million and the number of Cross-Margining Customers whose Transactions are recorded in such Cross-Margining Account must be made and maintained in cash. In addition, FICC proposes to amend the last sentence of Section 3 by adding a reference to “Cross-Margining Customer Margin Requirement” after the reference to “Segregated Indirect Participants Requirement.”

FICC proposes to amend Section 3a of Rule 4 to add a reference to “Cross-Margining Customers” after the reference to “Segregated Indirect Participants.” FICC also proposes to amend Section 3b of Rule 4 to add a reference to “Cross-Margining Customer Margin Custody Account” after the reference to “Segregated Customer Margin Custody Account.”

FICC proposes to amend Sections 3a, 3b, and 9 of Rule 4 to add references to “Cross-Margining Customer Margin,” after each reference to “Segregated Customer Margin.” FICC also proposes to amend Sections 3b and 9 of Rule 4

to add references to “Cross-Margining Customer Margin Requirement,” after each reference to “Segregated Customer Margin Requirement.”

FICC proposes to add a new Section 4(c) of Rule 4 to provide that (i) as security for any and all obligations and liabilities of a Netting Member and any of its Cross-Margining Customers to FICC arising out of or in connection with any Cross-Margining Customer Accounts of such Netting Member or Transactions recorded therein, each such Netting Member on behalf of itself and its Cross-Margining Customers grants to FICC a first priority perfected security interest in its right, title and interest in and to all Cross-Margining Customer Margin, each Cross-Margining Customer Margin Custody Account, and all distributions thereon and proceeds thereof, and (ii) FICC shall be entitled to exercise the rights of a pledgee under common law and a secured party under Articles 8 and 9 of the NYUCC with respect to such assets.

FICC proposes to amend Section 5 of Rule 4 by (i) adding a reference to “Cross-Margining Customer Margin” after the reference to “Segregated Customer Margin” in the title of Section 5, and (ii) adding a new paragraph at the end of Section 5 to provide that FICC shall only use Cross-Margining Customer Margin deposited by a Netting Member to (A) secure the Transactions of Cross-Margining Customers of such Netting Member recorded in any Cross-Margining Customer Account and satisfy payment and delivery obligations owing to FICC (including liquidating or otherwise using such Cross-Margining Customer Margin to obtain relevant cash or securities) in connection with a default in respect of such Transactions; and (B) for investment in U.S. Treasury securities with a maturity of one year or less.

FICC proposes to amend Section 10 of Rule 4 by (i) adding a reference to “Cross-Margining Customer Margin” after the reference to “Segregated Customer Margin” in the title of Section 10, (ii) amending the first paragraph of Section 10 to require FICC to separately determine whether the amount of Cross-Margining Customer Margin supporting a Cross-Margining Customer’s Transactions is in excess of the Cross-Margining Customer Margin Requirement for such Cross-Margining Customer (“Excess Cross-Margining Customer Margin”), and (iii) adding a new Section 10(c) to provide that upon a Member’s request, and in accordance with such procedures as FICC may set forth from time to time, the Corporation shall return to the Member its Excess Cross-Margining Customer Margin,

subject to the minimum amount of cash or Eligible Clearing Fund Securities required to be maintained pursuant to the GSD Rules (valued at their collateral value on the day of such withdrawal) and the terms of the Third A&R Agreement and Customer Cross-Margining Clearing Member Agreement, as the Member requests, provided that, subject to the Third A&R Agreement and the Customer Cross-Margining Clearing Member Agreement, and except to the extent required by applicable law or authorized by the Commission, FICC shall not retain Excess Cross-Margining Customer Margin due to any obligations of the Member unrelated to a Cross-Margining Customer Account of such Member. Section 10(c) of Rule 4 would further provide that FICC may, at its discretion, retain some or all of the Excess Cross-Margining Customer Margin if the Member has an outstanding payment or margin obligation to the Corporation with respect to the Transactions of any Cross-Margining Customer.

FICC proposes to amend the Margin Component Schedule to set out how Cross-Margining Customer Margin Requirements would be determined. Specifically, FICC proposes to insert a new paragraph at the end of Section 1 to provide that (i) on each Business Day, each Netting Member for which FICC maintains a Cross-Margining Customer Account shall be required to deposit with FICC Cross-Margining Customer Margin equal to the sum of all Cross-Margining Customer Margin Requirements for all such Accounts, (ii) each Cross-Margining Customer Margin Requirement shall equal the sum of the amounts calculated pursuant to Section 3a of the Margin Component Schedule for each Cross-Margining Customer whose Transactions are recorded in the relevant Cross-Margining Customer Account, and (iii) each such calculation shall be performed twice daily or on a more frequent basis if FICC deems it appropriate pursuant to the Margin Component Schedule and subject to the provisions of Rule 4. Further, FICC proposes to add a new Section 3a to the Margin Component Schedule titled “Cross-Margining Customer Margin Requirement Calculations” to set out how specifically such requirement would be calculated, which would be substantially identical to how Segregated Customer Margin Requirement is calculated as set out in Section 3 of the Margin Component Schedule. Finally, FICC proposes to amend Section 5 to add references to “Cross-Margining Customer,” “Cross-Margining Customer Account,” and

“Cross-Margining Customer Margin Requirement” after each reference to “Segregated Indirect Participant,” “Segregated Indirect Participants Account,” and “Segregated Customer Margin Requirement,” respectively.

Description of the Customer Cross-Margining Arrangement. FICC proposes to amend Rule 43 to explicitly describe the Customer Cross-Margining Arrangement as follows:

FICC proposes to add a new Section 2(c) of Rule 43 to provide that (i) a Netting Member that is an Eligible BD-FCM may become a Cross-Margining Participant in connection with the Customer Cross-Margining Arrangement with the consent of FICC and CME, and (ii) an Eligible BD-FCM that would become such a Cross-Margining Participant shall be permitted to establish a Cross-Margining Customer Account upon acceptance by FICC and CME of an executed Customer Cross-Margining Clearing MSD Member Agreement.

FICC proposes to amend Section 3 of Rule 43 to provide that, if FICC becomes obligated to make a payment to CME pursuant to the cross-guaranty under the Third A&R Agreement in relation to the obligations of a Cross-Margining Participant, its Cross-Margining Affiliate, or its Cross-Margining Customer, the Cross-Margining Participant (and, if FICC becomes obligated to make such a payment in respect of the obligations of a Cross-Margining Customer, the Cross-Margining Customer) shall thereupon immediately be obligated, whether or not FICC has then made payment to CME, to pay to FICC the amount of the reimbursement obligation that is owed to FICC as a result.

FICC proposes to add a new sentence at the end of Section 5 of Rule 43 to provide that, if FICC receives a payment from CME pursuant to the Third A&R Agreement in connection with the Customer Cross-Margining Arrangement, FICC would not be permitted to apply such payment to any obligation other than the obligations of Cross-Margining Customers (whether or not arising in connection with any Eligible Positions).

Conforming and clarifying Changes. FICC proposes to make the following conforming or clarifying changes:

FICC proposes to amend Section 4(b)(i) of Rule 2A to make clear that an applicant to become a Netting Member must have sufficient financial ability to make anticipated required deposits to not only Clearing Fund and Segregated Customer Margin, but also any Cross-Margining Customer Margin.

FICC proposes to remove Section 10(e) of Rule 3A to remove the current prohibition of Sponsored Members from participating in any Cross-Margining Arrangements, and accordingly renumber current Section 10(f) of Rule 3A to Section 10(e).

FICC proposes to remove (i) the language in parentheses in the first sentence of Section 1 of Rule 13, (ii) the second sentence in Section 2(b) of Rule 22A, and (iii) the portions of Sections 2(a) and 2(b) of Rule 43 that are crossed out in Exhibit 5, because those provisions relate to the “market professional” cross-margining program, which is no longer active and would not be used if the Customer Cross-Margining Arrangement becomes available.

Implementation Timeframe

The proposed Third A&R Agreement would not become effective and replace the Second A&R Agreement until the latest of (i) the date on which all necessary regulatory approvals of the proposed Third A&R Agreement have been received by FICC and CME and (ii) a date agreed by FICC and CME.⁶⁵ FICC would issue an important notice to GSD Members providing the specific operative date at least two weeks prior to such date.

Expected Effect on Management of Risk

FICC believes that the proposed rule changes to extend the availability of the Cross-Margining Arrangement to positions cleared and carried for Cross-Margining Customers by an Eligible BD-FCM would enhance FICC’s and its Netting Members’ risk management.

First, the Customer Cross-Margining Arrangement would produce margin levels commensurate with the risks and particular attributes of the Eligible Positions. This is because FICC would first calculate initial margin requirements for Customer Positions using the same methodology as applies to Segregated Indirect Participant positions and then determine possible margin reductions using the same methodology as is used under the Proprietary Cross-Margining Arrangement, with each Cross-Margining Customer treated effectively as an independent Netting Member. The Commission recently approved each of these methodologies in connection with other FICC rule filings, confirming in particular that they satisfied the requirements of Rule 17ad-22(e)(6) under the Exchange Act.⁶⁶ As with the

margin methodology applicable to Segregated Indirect Participants, FICC would calculate margin requirements on a gross (*i.e.*, Cross-Margining Customer-by-Cross-Margining Customer) basis and would not net Eligible Positions across separate Cross-Margining Customers. With respect to such gross calculation methodology in the context of Segregated Indirect Participants, the Commission noted in the approval order covering that rule filing that it would “better isolate the risk profiles of individual indirect participants from Netting Members, which should help FICC better understand and monitor each individual participant’s risk exposures.”⁶⁷

Second, by applying the same margin reduction methodology that is utilized under the Proprietary Cross-Margining Arrangement, FICC would continue to recognize risk offsets that arise from Eligible Positions cleared at CME. This would help ensure that the margin requirements are not overstated or understated and are calibrated based on the particular risk the Cross-Margining Customer’s portfolio presents to FICC and CME. This would provide FICC with robust protection against a default, and incentivize Cross-Margining Customers to maintain portfolios that present lower risk. Such lower risk portfolios would, in turn, reduce the risk of a default in the first place.

Third, the proposed changes would require Eligible BD-FCMs to collect from Cross-Margining Customers the initial margin calculated for the Customer Positions. The collateral posted by the Cross-Margining Customers would serve to reduce the exposure of an Eligible BD-FCM to its Cross-Margining Customers and thus reduce the risk of a default by the Eligible BD-FCM to FICC.

Finally, the proposed rule changes would require an Eligible BD-FCM to enter into a Customer Cross-Margining Clearing Member Agreement with FICC and CME, under which the Eligible BD-FCM would pledge to FICC, on behalf of itself and each Cross-Margining Customer, the positions and margin subject to the Customer Cross-Margining Arrangement at both FICC and CME. This pledge, coupled with the cross-guaranty between FICC and CME set forth in the Third A&R Agreement, would help to ensure that FICC is able to look to the full portfolio of Customer Positions and associated margin at FICC

(SR-FICC-2023-010); and 101695 (Nov. 21, 2024), 89 FR 93763, 93776 (Nov. 27, 2024) (SR-FICC-2024-007).

⁶⁷ See Securities Exchange Act Release No. 101695 (Nov. 21, 2024), 89 FR 93763, 93776 (Nov. 27, 2024) (SR-FICC-2024-007).

⁶⁵ See Section 18(j) of the proposed Third A&R Agreement.

⁶⁶ See Securities Exchange Act Release Nos. 98327 (Sept. 8, 2023), 88 FR 63185 (Sept. 14, 2023)

and CME in order to satisfy any obligations arising under the Customer Positions.

Consistency With Section 805 of the Clearing Supervision Act

FICC believes the proposed rule changes are consistent with Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act entitled the Payment, Clearing Supervision Act.⁶⁸ Specifically, FICC believes the proposed rule changes are consistent with the risk management objectives and principles of Section 805 of the Clearing Supervision Act.⁶⁹

(i) Consistency With Section 805(b) of the Clearing Supervision Act

Section 805(b) of the Clearing Supervision Act provides that “[t]he objectives and principles for the risk management standards prescribed under subsection (a) shall be to (1) promote robust risk management; (2) promote safety and soundness; (3) reduce systemic risks; and (4) support the stability of the broader financial system.”⁷⁰ The proposed rule changes would do this by providing that FICC would calculate the margin requirement applicable to Customer Positions on a gross Cross-Margining Customer-by-Cross-Margining Customer basis, with margin reductions for Eligible Positions in futures at CME that present offsetting risk. This would ensure that margin requirements are calibrated based on the risk of each Cross-Margining Customer’s portfolio, which in turn would promote robust risk management by Cross-Margining Customers and reduce the risk of a default of a Cross-Margining Customer or its Eligible BD-FCM.

The reduced margin requirements which would result from the proposed rule changes would also incentivize Cross-Margining Customers to post initial margin in respect of their Eligible Positions, rather than rely on their Eligible BD-FCM to do so. Currently, FICC understands that it is common practice for Sponsoring Members and Agent Clearing Members to use their own assets to satisfy the FICC initial margin requirements associated with FICC-cleared positions that Eligible BD-FCMs carry for their customers. This increases the costs to Sponsoring Members and Agent Clearing Members of offering customer clearing services and limits their capacity to do so. As a result of the proposed rule changes, a Cross-Margining Customer’s Eligible Positions at FICC would be eligible for

a possible margin reduction with respect to offsetting futures positions at CME if the Cross-Margining Customer posts the initial margin instead of its Eligible BD-FCM doing so. It would thus incentivize indirect participants to post margin, which would likely result in an associated cost reduction from their Eligible BD-FCMs. Such posting would, in turn, serve to reduce Eligible BD-FCMs’ risk to their Cross-Margining Customers.

The reduced costs to Eligible BD-FCMs would also enhance their ability to provide access to FICC’s clearance and settlement services to a greater number of indirect participants, and thereby increase the diversity and scope of market participants able to utilize FICC’s U.S. Treasury clearing services. These services can reduce systemic risk through FICC’s multilateral netting, support the stability of the financial system through FICC’s trade guaranty and centralized default management, and promote safety and soundness through FICC’s counterparty risk management.⁷¹

The proposed rule changes would also allow Cross-Margining Customers to benefit from the margin offsets that are currently only available to Cross-Margining Participants and their Eligible Affiliates under the Proprietary Cross-Margining Arrangement, thereby facilitating increased access to clearing for indirect participants and promoting the maintenance of more balanced portfolios that present lower risk. The proposed rule changes would consequently serve to enhance liquidity in, and otherwise promote the resilience and robustness of, the U.S. Treasury market.

As a result, FICC believes the proposed rule changes will advance Section 805(b)’s objectives and principles of promoting robust risk management, promoting safety and soundness, reducing systemic risks, and supporting the stability of the broader financial system.

(ii) Consistency with Section 805(a)(2) of the Clearing Supervision Act

Section 805(a)(2) of the Clearing Supervision Act authorizes the Commission to prescribe risk management standards for the payment, clearing, and settlement activities of designated clearing entities, like FICC.⁷² Accordingly, the Commission has adopted risk management standards

under this section and under Section 17A of the Exchange Act.⁷³ These standards require registered clearing agencies to establish, implement, maintain, and enforce written policies and procedures that are reasonably designed to meet certain minimum requirements for their operations and risk management practices on an ongoing basis.⁷⁴ FICC believes that the proposed rule changes are consistent with Rules 17ad-22(e)(4)(i), (e)(6)(i), and (e)(18)(iv)(C), each promulgated under the Exchange Act.⁷⁵

Rule 17ad-22(e)(4)(i) under the Exchange Act requires that a covered clearing agency establish, implement, maintain, and enforce written policies and procedures reasonably designed to effectively identify, measure, monitor, and manage its credit exposures to participants and those arising from its payment, clearing, and settlement processes by maintaining sufficient financial resources to cover its credit exposure to each participant fully with a high degree of confidence.⁷⁶ FICC believes that the proposed rule changes would ensure that FICC continues to effectively measure and manage its credit exposure to participants by maintaining sufficient financial resources to cover its exposure thereto with a high degree of confidence. This is because, under the Customer Cross-Margining Arrangement, FICC would calculate the margin requirement applicable to Customer Positions on a gross Cross-Margining Customer-by-Cross-Margining Customer basis, with margin reductions for offsetting futures positions at CME calculated using a cross-margin methodology that the Commission recently approved.⁷⁷ As described above, the Commission found that similar customer-by-customer gross margining arrangements adopted by FICC for Segregated Indirect Participants would help FICC to better understand and monitor the risk exposures of individual participants.⁷⁸

In addition, the proposed rule changes would require each Eligible BD-FCM for whom FICC maintains one or more Cross-Margining Customer Account(s) to deposit to FICC cash or eligible securities to meet the Cross-Margining Customer Margin

⁷³ See 17 CFR 240.17ad-22(e).

⁷⁴ *Id.*

⁷⁵ 17 CFR 240.17ad-22(e)(4)(i), (e)(6)(i), and (e)(18)(iv)(C).

⁷⁶ 17 CFR 240.17ad-22(e)(4)(i).

⁷⁷ See Securities Exchange Act Release No. 98327 (Sept. 8, 2023), 88 FR 63185 (Sept. 14, 2023) (SR-FICC-2023-010).

⁷⁸ See Securities Exchange Act Release No. 101695 (Nov. 21, 2024), 89 FR 93763, 93776 (Nov. 27, 2024) (SR-FICC-2024-007).

⁶⁸ 12 U.S.C. 5461 *et seq.*

⁶⁹ 12 U.S.C. 5464.

⁷⁰ 12 U.S.C. 5464(b).

⁷¹ See Securities Exchange Act Release Nos. 99817 (Mar. 21, 2024), 89 FR 21362, 21375-76 (Mar. 27, 2024) (SR-FICC-2024-005); and 99844 (Mar. 22, 2024), 89 FR 21603, 21615 (Mar. 28, 2024) (SR-FICC-2024-007).

⁷² 12 U.S.C. 5464(a)(2).

Requirement that is calibrated to the risks of each Cross-Margining Customer's portfolio. Such Eligible BD-FCM would also be required to enter into a Customer Cross-Margining Clearing Member Agreement with FICC and CME, pursuant to which the Eligible BD-FCM would pledge to FICC, on behalf of itself and each Cross-Margining Customer, the positions and margin subject to the Customer Cross-Margining Arrangement at both FICC and CME. This pledge, along with the cross-guaranty between FICC and CME set forth in the Third A&R Agreement, would allow FICC and CME to look to the full portfolio of Customer Positions and associated margin at FICC and CME in order to satisfy any obligations arising under Customer Positions. Accordingly, the proposed rule changes would ensure that FICC will have sufficient resources to rely on to cover cross-margining exposures under the Customer Cross-Margining Arrangement, and would ensure compliance with Rule 17ad-22(e)(4)(i).

Rule 17ad-22(e)(6)(i) under the Exchange Act requires that a covered clearing agency establish, implement, maintain, and enforce written policies and procedures reasonably designed to cover its credit exposures to its participants by establishing a risk-based margin system that, at a minimum, considers, and produces margin levels commensurate with, the risks and particular attributes of each relevant product, portfolio, and market, and, if the covered clearing agency provides central counterparty services for U.S. Treasury securities, calculates, collects, and holds margin amounts from a direct participant for its proprietary positions in Treasury securities separately and independently from margin calculated and collected from that direct participant in connection with U.S. Treasury securities transactions by an indirect participant that relies on the services provided by the direct participant to access the covered clearing agency's payment, clearing, or settlement facilities.⁷⁹

FICC believes that the proposed rule changes would satisfy these requirements. The Customer Cross-Margining Arrangement would produce margin levels commensurate with the risks and particular attributes of the Eligible Positions, as FICC would calculate initial margin requirements for each Cross-Margining Customer using the same methodology that FICC applies to Segregated Indirect Participants, with potential margin offsets for Customer Positions calculated using the same

methodology as is used under the Proprietary Cross-Margining Arrangement. The Commission recently confirmed that such methodologies satisfied the requirements of Rule 17ad-22(e)(6) in connection with other FICC rule filings.⁸⁰

In addition, the proposed rule changes would provide that margin applicable to Customer Positions would be calculated separately and independently of the margin for any positions recorded in any Proprietary Account of a Cross-Margining Participant. The proposed rule changes would also provide for Cross-Margining Customer Margin to be collected and held in substantially a similar manner to Segregated Customer Margin. The Commission recently approved FICC's arrangements for Segregated Customer Margin, finding in particular that they "should ensure that a Netting Member's proprietary transactions are not netted with indirect participant transactions for margin calculations and that margin for indirect participant transactions is collected and held separately and independently from margin for a Netting Member's proprietary transactions."⁸¹ Accordingly, the proposed rule changes would ensure compliance with Rule 17ad-22(e)(6)(i).

Rule 17ad-22(e)(18)(iv)(C) under the Exchange Act requires, among other things, that a covered clearing agency that provides central counterparty services for transactions in U.S. Treasury securities ensure that it has appropriate means to facilitate access to clearance and settlement services of all eligible secondary market transactions in U.S. Treasury securities, including those of indirect participants.⁸² The proposed rule changes would expand the Cross-Margining Arrangement, which currently is available for proprietary positions of Cross-Margining Participants and those of their Eligible Affiliates, to Customer Positions. This expansion would serve to facilitate greater access to clearing for indirect participants of FICC by more effectively aligning the margin requirements applicable to such participants' positions with the overall risk those positions present.

Furthermore, by creating an incentive for Cross-Margining Customers to post margin for their positions, the proposed rule changes would serve to reduce the need for Eligible BD-FCMs to use their own liquidity resources to cover such

margin obligations. As a result, it would reduce the costs and increase the capacity of Eligible BD-FCMs to provide clearing services, which would in turn allow Eligible BD-FCMs to increase the volume of transactions they submit to FICC for clearing. Moreover, by creating significant cost savings and efficiencies for Cross-Margining Customers that maintain offsetting futures positions at CME, the proposed rule changes would create an incentive for Eligible BD-FCMs to offer done-away clearing services. For Eligible BD-FCMs, clearing U.S. Treasury securities positions entered into by a customer with other trading counterparties would provide a potential opportunity to reduce overall financial risk without the cost of funding the customer's margin obligations at FICC. Therefore, the proposed rule changes would facilitate enhanced access to clearance and settlement services of all eligible secondary market transactions in U.S. Treasury securities, including those of indirect participants.⁸³

III. Date of Effectiveness of the Advance Notice

The proposed change may be implemented if the Commission does not object to the proposed change within 60 days of the later of (i) the date that the proposed change was filed with the Commission or (ii) the date that any additional information requested by the Commission is received. The clearing agency shall not implement the proposed change if the Commission has any objection to the proposed change.

The Commission may extend the period for review by an additional 60 days if the proposed change raises novel or complex issues, subject to the Commission providing the clearing agency with prompt written notice of the extension. A proposed change may be implemented in less than 60 days from the date the advance notice is filed, or the date further information requested by the Commission is received, if the Commission notifies the clearing agency in writing that it does not object to the proposed change and authorizes the clearing agency to implement the proposed change on an earlier date, subject to any conditions imposed by the Commission.

The clearing agency shall post notice on its website of proposed changes that are implemented.

The proposal shall not take effect until all regulatory actions required with respect to the proposal are completed.

⁸⁰ *Supra* note 62.

⁸¹ See Securities Exchange Act Release No. 101695 (Nov. 21, 2024), 89 FR 93763, 93776 (Nov. 27, 2024) (SR-FICC-2024-007).

⁸² 17 CFR 240.17ad-22(e)(18)(iv)(C).

⁸³ *Id.*

⁷⁹ 17 CFR 240.17ad-22(e)(6)(i).

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the Advance Notice is consistent with the Clearing Supervision 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-FICC-2025-801 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to file number SR-FICC-2025-801. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of FICC and on DTCC's website (www.dtcc.com/legal/sec-rule-filings). 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-FICC-2025-801 and should be submitted on or before January 20, 2026.

V. Date of Timing for Commission Action

Section 806(e)(1)(G) of the Clearing Supervision Act provides that FICC may implement the changes if it has not received an objection to the proposed changes within 60 days of the later of (i) the date that the Commission receives the Advance Notice or (ii) the date that any additional information requested by the Commission is received,⁸⁴ unless extended as described below.

Pursuant to Section 806(e)(1)(H) of the Clearing Supervision Act, the Commission may extend the review period of an advance notice for an additional 60 days, if the changes

proposed in the advance notice raise novel or complex issues, subject to the Commission providing the clearing agency with prompt written notice of the extension.⁸⁵

Here, as the Commission has not requested any additional information, the date that is 60 days after FICC filed the Advance Notice with the Commission is February 10, 2026. However, the Commission finds that the changes proposed in the Advance Notice raise novel and complex issues. The Commission finds the issues novel because FICC proposes to extend the availability of its Cross-Margining Arrangement with CME to customers of an Eligible BD-FCM to allow Cross-Margining Customers to benefit from the margin reductions that are currently only available to Cross-Margining Participants and their Eligible Affiliates. The Commission also finds the issues raised by the Advance Notice complex because the proposed changes to the Cross-Margining Agreement between FICC and CME and the GSD Rules entail new provisions including criteria and requirements for participation in the Customer Cross-Margining Arrangement, as well as consistency with the Petitions. Therefore, the Commission finds it appropriate to extend the review period of the Advance Notice for an additional 60 days under Section 806(e)(1)(H) of the Clearing Supervision Act.⁸⁶

Accordingly, the Commission, pursuant to Section 806(e)(1)(H) of the Clearing Supervision Act,⁸⁷ extends the review period for an additional 60 days so that the Commission shall have until April 11, 2026, to issue an objection or non-objection to Advance Notice SR-FICC-2025-801.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁸⁸

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025-23886 Filed 12-23-25; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-104473; File No. SR-Phlx-2025-76]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Options 7, Section 9, B, Port Fees

December 19, 2025.

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 December 18, 2025, Nasdaq PHLX LLC ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Phlx's Pricing Schedule at Options 7, Section 9, B, Port Fees.³

While the changes proposed herein are effective upon filing, the Exchange has designated the amendments become operative on January 1, 2026.

The text of the proposed rule change is available on the Exchange's website at <https://listingcenter.nasdaq.com/rulebook/phlx/rulefilings>, and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ On December 11, 2025 the Exchange filed SR-Phlx-2025-71. On December 18, 2025, the Exchange withdrew SR-Phlx-2025-71 and filed this proposal.

⁸⁴ 12 U.S.C. 5465(e)(1)(G).

⁸⁵ 12 U.S.C. 5465(e)(1)(H).

⁸⁶ *Id.*

⁸⁷ *Id.*

⁸⁸ 17 CFR 200.30-3(a)(91).

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Phlx recently completed a technology migration to a new platform on December 8, 2025. As part of the technology migration, Phlx members and member organizations acquired new ports to connect to the new technology platform to accommodate the symbol migration plan. Specifically, members and member organizations utilized both existing or “legacy”⁴ ports and “new”⁵ ports during the technology migration rollout which occurred over a 5 week period on a symbol-by-symbol basis. During the transition to the new platform, Phlx did not assess the SQF Port,⁶ SQF Purge Port,⁷ and CTI Port⁸ fees in Options 7, Section 9, B for any new SQF Ports, SQF Purge Ports, and CTI Ports, which were duplicative of legacy SQF Ports, SQF Purge Ports, and CTI Ports, acquired as part of the migration from November 1, 2025 through December 31, 2025 (“Transition

Period”).⁹ Phlx did assess the SQF Port, SQF Purge Port, and CTI Port fees in Options 7, Section 9, B for legacy SQF Ports, SQF Purge Ports, and CTI Ports during the Transition Period, including new SQF Ports, SQF Purge Ports, and CTI Ports. The prior Phlx rule change¹⁰ provided that, as of January 1, 2026, Phlx will assess the SQF Port, SQF Purge Port, and CTI Port fees in Options 7, Section 9, B for all new and legacy SQF Ports, SQF Purge Ports, and CTI Ports to which they subscribe. Phlx members and member organizations may return legacy SQF Ports, SQF Purge Ports, and CTI Ports in December 2025 to avoid any fees. Legacy SQF Ports, SQF Purge Ports, and CTI Ports are no longer necessary since the Phlx migration is complete and all trading is currently on the new platform.

SR–Phlx–2025–32 also discussed fees for FIX Ports during the Transition Period¹¹ as well as new OTTO¹² Port

⁹ The duplicate new SQF Ports, SQF Purge Ports, and CTI Ports and duplicate mnemonics were offered at no cost will allow members and member organizations time to test ports to the new environment as well as provide continuous connection to the Exchange's match engine during the migration. During the Transition Period, members and member organizations will be required to utilize their new ports on the new platform for symbols that have migrated to the new platform, while continuing to leverage legacy ports for symbols that have not yet migrated to the new platform. The technology migration does not require Phlx members and member organizations to acquire additional ports or any new ports that are being offered, rather the technology migration requires a new port to connect to the new environment. Phlx assessed port fees for December 2025 as of December 1, 2025.

¹⁰ See Securities Exchange Act Release No. 103593 (July 30, 2025), 90 FR 36479 (August 4, 2025) (SR–Phlx–2025–32) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Options 7, Section 9, B, Port Fees).

¹¹ As of January 1, 2026, the Exchange will assess a FIX Port Fee based on each mnemonic associated with new and legacy FIX Ports.

¹² As proposed, “OTTO” is an interface that allows member organizations and their Sponsored Customers to connect, send, and receive messages related to orders, auction orders, and auction responses to the Exchange. Features include the following: (1) options symbol directory messages (e.g., underlying and complex instruments); (2) system event messages (e.g., start of trading hours messages and start of opening); (3) trading action messages (e.g., halts and resumes); (4) execution messages; (5) order messages; (6) risk protection triggers and cancel notifications; (7) auction notifications; (8) auction responses; and (9) post trade allocation messages. OTTO will be located in the Exchange's revised rules at Supplementary Material .03 of Options 3, Section 7. The Exchange will assess an OTTO Port fee of \$400 per port, per month, per mnemonic, subject to a monthly cap of \$4,000. See Securities Exchange Act Release No. 102337 (February 4, 2025), 90 FR 9267 (February 10, 2025) (SR–Phlx–2025–05) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Adopt a New OTTO Protocol),

and new FIX Drop¹³ Port Fees.¹⁴ Finally, Phlx provided that it planned to sunset legacy FIX Ports, SQF Ports, SQF Purge Ports, and CTI Ports on February 27, 2026, after which time these ports will no longer be available.

Proposal

At this time, the Exchange proposes to expedite the sunset date for SQF Ports, SQF Purge Ports, and CTI Ports from February 27, 2026 to January 1, 2026. The Phlx migration was complete on December 8, 2025. The Exchange believes that Phlx market participants have enough time to return their SQF Ports, SQF Purge Ports, and CTI Ports in December 2025 to allow the Exchange to sunset these ports.

This proposal does not impact FIX Ports which would sunset on February 27, 2026. As of January 1, 2026, Phlx will assess a FIX Port Fee based on each mnemonic associated with new and legacy FIX Ports. Phlx members and member organizations may return legacy FIX Ports in December 2025 to avoid any fees or opt to return them any time prior to February 27, 2026.

The Exchange notes that legacy FIX Ports currently provide data from the new platform while legacy SQF Ports, SQF Purge Ports, and CTI Ports do not currently provide any data.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,¹⁵ in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,¹⁶ in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

Phlx's proposal to expedite the sunset date for SQF Ports, SQF Purge Ports,

¹³ FIX DROP is a real-time order and execution update message that is sent to a member after an order has been received/modified or an execution has occurred and contains trade details specific to that member. The information includes, among other things, the following: (i) executions; (ii) cancellations; (iii) modifications to an existing order; and (iv) busts or post-trade corrections. FIX Drop will be located in the Exchange's rules at Options 3, Section 23(b)(3). The Exchange will assess a FIX Drop Fee of \$500 per port, per month, per account number. See Securities Exchange Act Release No. 90 FR 8818 (February 3, 2025) (SR–Phlx–2025–04) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Adopt a FIX Drop Port and Related Fees).

¹⁴ On November 1, 2025, Phlx began assessing OTTO Port Fees and FIX Drop Port Fees to any member or member organization that subscribed to these new ports.

¹⁵ See 15 U.S.C. 78f(b).

¹⁶ See 15 U.S.C. 78f(b)(4) and (5).

⁴ A “legacy” port refers to a port that was subscribed to by a Phlx member or member organization prior to the technology migration and connects to the existing technology platform.

⁵ A “new” port refers to a port acquired for the Phlx technology migration and would connect to the new technology migration.

⁶ “Specialized Quote Feed” or “SQF” is an interface that allows Lead Market Makers, Streaming Quote Traders (“SQTs”) and Remote Streaming Quote Traders (“RSQTs”) to connect, send, and receive messages related to quotes, Immediate-or-Cancel Orders, and auction responses into and from the Exchange. Features include the following: (1) options symbol directory messages (e.g., underlying and complex instruments); (2) system event messages (e.g., start of trading hours messages and start of opening); (3) trading action messages (e.g., halts and resumes); (4) execution messages; (5) quote messages; (6) Immediate-or-Cancel Order messages; (7) risk protection triggers and purge notifications; (8) opening imbalance messages; (9) auction notifications; and (10) auction responses. The SQF Purge Interface only receives and notifies of purge requests from the Lead Market Maker, SQT or RSQT. Lead Market Makers, SQTs and RSQTs may only enter interest into SQF in their assigned options series. Immediate-or-Cancel Orders entered into SQF are not subject to the Order Price Protection, the Market Order Spread Protection, or Size Limitation in Options 3, Section 15(a)(1), (a)(2) and (b)(2), respectively. See Options 3, Section 7(a)(i)(B).

⁷ An SQF Purge Interface only receives and notifies of purge request from the Market Maker.

⁸ Clearing Trade Interface (“CTI”) is a real-time clearing trade update message that is sent to a member after an execution has occurred and contains trade details specific to that member. The information includes, among other things, the following: (i) The Clearing Member Trade Agreement or “CMTA” or “OCC” number; (ii) Exchange badge or house number; (iii) the Exchange internal firm identifier; (iv) an indicator which will distinguish electronic and non-electronically delivered orders; (v) liquidity indicators and transaction type for billing purposes; and (vi) capacity. See Options 3, Section 23(b)(1).

and CTI Ports from February 27, 2026 to January 1, 2026 is reasonable because the Phlx migration was complete on December 8, 2025 and the SQF Ports, SQF Purge Ports, and CTI Ports are not functional at this time. Also, the Exchange believes that Phlx market participants have enough time to return these ports in December 2025 to allow the Exchange to sunset these ports. This proposal does not impact FIX Ports which would sunset on February 27, 2026. Unlike legacy SQF Ports, SQF Purge Ports, and CTI Ports, legacy FIX Ports provide data from the new platform and are still functional. As of January 1, 2026, Phlx will assess a FIX Port Fee based on each mnemonic associated with new and legacy FIX Ports. Phlx members and member organizations may return legacy FIX Ports in December 2025 to avoid any fees. The Exchange notes that Market Makers acquire SQF Ports and SQF Purge Ports to quote on the Exchange. In contrast, all market participants utilize FIX Ports to enter orders and may utilize CTI Ports for clearing information. The Exchange believes that all members and member organizations would be able to return all legacy ports prior to December 31, 2025.

Phlx's proposal to expedite the sunset date for SQF Ports, SQF Purge Ports, and CTI Ports from February 27, 2026 to January 1, 2026 is equitable and not unfairly discriminatory because no Phlx member or member organization is able to utilize SQF Ports, SQF Purge Ports, and CTI Ports today because they are not connected to a platform that is active. Also, no Phlx member or member organization would be able to log into their SQF Ports, SQF Purge Ports or CTI Ports after the sunset date.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Intermarket Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Intermarket Competition

The Exchange believes its proposal remains competitive with other options markets, and will offer market participants with another choice of venue to transact options. The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

Intramarket Competition

Phlx's proposal to expedite the sunset date for SQF Ports, SQF Purge Ports, and CTI Ports from February 27, 2026 to January 1, 2026 does not impose an undue burden on competition because no Phlx member or member organization is able to utilize SQF Ports, SQF Purge Ports or CTI Ports today because they are not connected to a platform that is active. Also, no Phlx member or member organization would be able to log into their SQF Ports, SQF Purge Ports or CTI Ports after the sunset date.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.¹⁷

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in

furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-Phlx-2025-76 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-Phlx-2025-76. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-Phlx-2025-76 and should be submitted on or before January 20, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁸

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025-23817 Filed 12-23-25; 8:45 am]

BILLING CODE 8011-01-P

¹⁷ 15 U.S.C. 78s(b)(3)(A)(ii).

¹⁸ 17 CFR 200.30-3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–104470; File No. SR–CboeEDGX–2025–072]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To Modify Rule 11.21 To Adopt a Retail Price Improvement Program and Modify Rule 11.6(e)(2) and Rule 11.10(a)(4)(C)–(D) in Order To Describe the Behavior of Orders Containing a Non-Displayed Instruction

December 19, 2025.

I. Introduction

On September 30, 2025, Cboe EDGX Exchange, Inc. (“EDGX” or the “Exchange”) filed with the Securities and Exchange Commission (“Commission”), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”),¹ and Rule 19b–4 thereunder,² a proposed rule change to modify Rule 11.21 to adopt a Retail Price Improvement program (“Retail Price Improvement Program”). The Exchange also proposes to modify Rule 11.6(e)(2) and Rule 11.10(a)(4)(C)–(D) in order to describe the behavior of orders containing a “Non-Displayed” instruction. The proposed rule change was published for comment in the **Federal Register** on October 3, 2025.³ On November 3, 2025, pursuant to Section 19(b)(2) of the Act,⁴ the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.⁵

The Commission is publishing this order to institute proceedings under Section 19(b)(2)(B) of the Act⁶ to determine whether to approve or disapprove the proposed rule change.

II. Summary of the Proposal

As described in more detail in the Notice,⁷ the Exchange proposes to

modify Rule 11.21 to add a Retail Price Improvement Program, and to modify Rules 11.6(e)(2) and Rule 11.10(a)(4)(C)–(D) in order to describe the behavior of orders containing a “Non-Displayed” instruction.⁸

According to the Exchange, its proposed Retail Price Improvement Program, designed to provide price improvement to Retail Orders,⁹ is generally consistent with similar programs offered by other national securities exchanges with the following main differences:¹⁰ (1) Retail Orders entered on the Exchange may be entered with a time-in-force other than Immediate-or-Cancel (“IOC”);¹¹ (2) Retail Price Improvement Orders¹² will only be eligible to execute against

⁸ EDGX Rule 11.6(e) defines “Display Options,” and EDGX Rule 11.6(e)(2) provides that a “Non-Displayed” instruction is an instruction the User (defined in EDGX Rule 1.5(ee)) may attach to an order stating that the order is not to be displayed by the System (defined in EDGX Rule 1.5(cc)) on the EDGX Book (defined in EDGX Rule 1.5(d)). An order with a Non-Displayed instruction that is to be re-routed pursuant to the “Post to Away” routing option set forth in EDGX Rule 11.11(g)(12) will be identified as Non-Displayed when routed to an away Trading Center (defined in EDGX Rule 2.11(a)).

⁹ Pursuant to EDGX Rule 11.21(a)(2), a “Retail Order” is an agency order or riskless principal order that meets the criteria of FINRA Rule 5320.03 that originates from a natural person and is submitted to the Exchange by a Retail Member Organization, provided that no change is made to the terms of the order with respect to price or side of market and the order does not originate from a trading algorithm or any other computerized methodology.

¹⁰ See Notice, *supra* note 3, at 48099.

¹¹ See EDGX Rule 11.6(g)(1). Immediate-or-Cancel (“IOC”) is an instruction the User may attach to an order stating the order is to be executed in whole or in part as soon as such order is received. The portion not executed immediately on the Exchange or another trading center is treated as cancelled and is not posted to the EDGX Book. An order with an IOC instruction that does not include a Book Only instruction (defined in EDGX Rule 21.1(d)(7)) and that cannot be executed in accordance with EDGX Rule 11.10(a)(4) on the System when reaching the Exchange will be eligible for routing away pursuant to EDGX Rule 11.11. Under the proposal, because Retail Orders may be entered with a time-in-force other than IOC, Retail Orders will be allowed to post to the EDGX Book or route to away trading centers according to User instructions. See Notice, *supra* note 3, at 48099.

¹² Under the proposed Retail Price Improvement Program, “Retail Price Improvement Orders” consist of non-displayed interest on the Exchange that is eligible to interact with incoming Retail Orders and that is identified as such. To be executable, a Retail Price Improvement Order must be priced at least \$0.001 better than the Protected NBB or Protected NBO (each as defined in EDGX Rule 1.5(f)) and may be priced in \$0.001 increments (e.g., \$10.001). The Exchange states that it plans to submit a request for an exemption under Regulation NMS Rule 612 that would permit it to accept and rank non-displayed Retail Price Improvement interest. See Notice, *supra* note 3, at 48100, n.22. Rule 612 generally prohibits a national securities exchange from accepting, displaying, or ranking bids, offers, orders and indications of interest in an increment smaller than the minimum pricing increment. See 17 CFR 242.612.

incoming Retail Orders and will not be eligible to remove resting Retail Orders from the EDGX Book; and (3) Users will have the ability to enter the proposed Retail Price Improvement Order as a MidPoint Peg Order as described in Rule 11.8(d).¹³

The Exchange also proposes to amend Rule 11.6(e)(2) and Rule 11.10(a)(4)(C)–(D) in order to describe the price at which a Non-Displayed Order is posted and ranked to the EDGX Book and at what price a Non-Displayed Order may execute in certain situations.¹⁴

III. Proceedings To Determine Whether To Approve or Disapprove SR–CboeEDGX–2025–072 and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act¹⁵ to determine whether the proposed rule change should be approved or disapproved. Institution of proceedings is appropriate at this time in view of the legal and policy issues raised by the proposal. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, as described below, the Commission seeks and encourages interested persons to provide comments on the proposed rule change.

Pursuant to Section 19(b)(2)(B) of the Act,¹⁶ the Commission is providing notice of the grounds for disapproval under consideration. As described above, the Exchange has proposed to modify its rules to add a Retail Price Improvement Program, as well as to modify its rules relating to how orders with Non-Displayed instructions will be posted, ranked, and executed. The Commission is instituting proceedings to allow for additional analysis of, and input from commenters with respect to, the proposal’s consistency with the Act, and in particular with Section 6(b)(5)¹⁷ of the Act. Section 6(b)(5) of the Act requires that the rules of a national securities exchange be designed, among other things, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest, and not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

¹³ See proposed EDGX Rule 11.21(a)(3). See also Notice, *supra* note 3, at 48103.

¹⁴ See Notice, *supra* note 3, at 48104.

¹⁵ 15 U.S.C. 78s(b)(2)(B).

¹⁶ *Id.*

¹⁷ 15 U.S.C. 78f(b)(5).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ See Securities Exchange Act Release No. 104153 (Sept. 30, 2025), 90 FR 48098 (“Notice”). The Commission has not received any comments on the proposed rule change.

⁴ 15 U.S.C. 78s(b)(2).

⁵ See Securities Exchange Act Release No. 104173, 90 FR 51424 (Nov. 17, 2025) (designating January 1, 2026, as the date by which the Commission shall either approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule changes).

⁶ 15 U.S.C. 78s(b)(2)(B).

⁷ See Notice, *supra* note 3.

The Commission asks that commenters address the sufficiency of the Exchange's statements in support of the proposal, in addition to any other comments they may wish to submit about the proposed rule change. In particular, the Commission seeks comment on whether the proposal, which would add a Retail Price Improvement Program and modify rules relating to Non-Displayed order instructions: would protect investors and the public interest, is not designed to permit unfair discrimination, or raises any new or novel concerns not previously contemplated by the Commission.

IV. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their data, views, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposal. In particular, the Commission invites the written views of interested persons concerning whether the proposed rule change is consistent with Section 6(b)(5) or any other provision of the Act, and the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of data, views, and arguments, the Commission will consider, pursuant to Rule 19b-4 under the Act,¹⁸ any request for an opportunity to make an oral presentation.¹⁹

Interested persons are invited to submit written data, views, and arguments regarding whether the proposed rule change should be approved or disapproved by January 20, 2026. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by February 2, 2026.

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or

- Send an email to rule-comments@sec.gov. Please include file number SR-CboeEDGX-2025-072 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090. All submissions should refer to file number SR-CboeEDGX-2025-072. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-CboeEDGX-2025-072 and should be submitted by January 20, 2026. Rebuttal comments should be submitted by February 2, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁰

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025-23814 Filed 12-23-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[OMB Control No. 3235-0290]

Agency Information Collection Activities; Proposed Collection; Comment Request; Extension: Rule 17f-1(g)

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549-2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. § 3501 *et seq.*), the Securities and Exchange Commission (SEC or "Commission") is soliciting comments on the proposed collection of information.

Paragraph (g) of Rule 17f-1, 17 CFR 240.17f-1(g), requires that all reporting

institutions (*i.e.*, every national securities exchange, member thereof, registered securities association, broker, dealer, municipal securities dealer, registered transfer agent, registered clearing agency, participant therein, member of the Federal Reserve System and bank insured by the FDIC) maintain and preserve a number of documents related to their participation in the Lost and Stolen Securities Program ("Program") under Rule 17f-1. The following documents must be kept in an easily accessible place for three years, according to paragraph (g): (1) copies of all reports of theft or loss (Form X-17F-1A) filed with the Commission's designee; (2) all agreements between reporting institutions regarding registration in the Program or other aspects of Rule 17f-1; and (3) all confirmations or other information received from the Commission or its designee as a result of inquiry.

Reporting institutions utilize these records and reports (a) to report missing, lost, stolen or counterfeit securities to the database; (b) to confirm inquiry of the database; and (c) to demonstrate compliance with Rule 17f-1. The Commission and the reporting institutions' examining authorities utilize these records to monitor the incidence of thefts and losses incurred by reporting institutions and to determine compliance with Rule 17f-1. If such records were not retained by reporting institutions, compliance with Rule 17f-1 could not be monitored effectively.

The Commission estimates that there are approximately 10,018 reporting institutions (respondents) and, on average, each respondent would need to retain 33 records annually, with each retention requiring approximately 1 minute (a total of 33 minutes or 0.5511 hours per respondent per year). Thus, the total estimated annual time burden for all respondents is 5,521 hours (10,018 × 0.5511 hours = 5,521). Assuming an average hourly cost for clerical work of \$50.00, the average total yearly record retention internal cost of compliance for each respondent would be \$31.35 (\$57 × 0.55 hours). Based on these estimates, the total annual internal compliance cost for the estimated 10,018 reporting institutions would be approximately \$314,064.3 (10,018 × \$31.35).

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.

Written comments are invited on: (a) whether this proposed collection of information is necessary for the proper

¹⁸ 17 CFR 240.19b-4.

¹⁹ Section 19(b)(2) of the Act, as amended by the Securities Acts Amendments of 1975, Public Law 94-29 (Jun. 4, 1975), grants to the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. See Securities Acts Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

²⁰ 17 CFR 200.30-3(a)(57).

performance of the functions of the SEC, including whether the information will have practical utility; (b) the accuracy of the SEC's estimate of the burden imposed by the proposed collection of information, including the validity of the methodology and the assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated, electronic collection techniques or other forms of information technology.

Please direct your written comments on this 60-Day Collection Notice to Austin Gerig, Director/Chief Data Officer, Securities and Exchange Commission, c/o Tanya Ruttenberg via email to PaperworkReductionAct@sec.gov by February 27, 2026. There will be a second opportunity to comment on this SEC request following the **Federal Register** publishing a 30-Day Submission Notice.

Dated: December 22, 2025.

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025-23869 Filed 12-23-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-104475; File No. SR-CBOE-2025-094]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fee Schedules To Establish New Fees for Its 10 Gigabit per Second ("Gb") Physical Port Connection to the Exchange

December 19, 2025.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on December 18, 2025, Cboe Exchange, Inc. (the "Exchange" or "Cboe Options") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the "Exchange" or "Cboe Options") proposes to amend its fee schedules to establish new fees for its 10 gigabit per second ("Gb") physical port connection to the Exchange. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Commission's website (<https://www.sec.gov/rules/sro.shtml>), the Exchange's website (https://www.cboe.com/us/options/regulation/rule_filings/bzx/), and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its fee schedule relating to physical port connectivity to the Exchange.³ Specifically, the Exchange seeks to amend its fee schedule to establish a new fee for its physical port for a 10 gigabit per second ("Gb") circuit. By way of background, a physical port is utilized by a Trading Permit Holder ("TPH")⁴ or non-TPH to connect to the Exchange at the data centers where the Exchange's servers are located. The Exchange currently assesses the following physical connectivity fees for TPHs and non-TPHs on a monthly basis: \$7,000 per physical port for a 10 Gb circuit. The Exchange now seeks to raise the monthly per physical port fee for a 10 Gb circuit from \$7,000 to \$8,000. The Exchange notes the proposed fee change will better enable it to continue to maintain and improve its market technology and services and also notes

that the proposed fee amount, even as amended, continues to be in line with, or even lower than, amounts assessed by another exchange that offers similar functionality.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the "Act") and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.⁷ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)8 requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)9 [sic] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange also believes the proposed rule change is consistent with Section 6(b)(4)10 [sic] of the Act, which requires that Exchange rules provide for the equitable allocation of reasonable dues, fees, and other charges among its Members and other persons using its facilities. This belief is based on various factors as described below.

The Exchange believes the proposed fee is reasonable as it is lower than the amounts assessed by other exchanges for analogous market access connections and which were similarly adopted via the rule filing process and filed with the Commission. For instance, the Exchange notes that Nasdaq PHLX LLC ("PHLX") currently charges its members a \$1,650 installation fee and an ongoing \$18,500 monthly fee for its 10Gb Ultra fiber connection.⁵ Similarly, PHLX also charges its members a \$1,000 installation fee and an ongoing monthly fee of \$11,000 for its 10Gb fiber connection.⁶ Comparatively, the Exchange's proposed fee of \$8,000 is \$10,500 less than the ongoing monthly

³ The proposed fees will take effect on January 2, 2026.

⁴ The terms "Trading Permit Holder" and "TPH" have the meaning set forth in the Bylaws. See Rule 1.1.

⁵ See NASDAQ PHLX Rulebook Book, General 8—Connectivity, available at: <https://listingcenter.nasdaq.com/rulebook/phlx/rules/Phlx%20General%208>.

⁶ *Id.*

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

fee PHLX charges its members for its 10Gb ultra fiber connection, and \$3,000 less than the ongoing monthly fee for PHLX's 10Gb fiber connection. Moreover, unlike PHLX, the Exchange does not charge its TPHs and non-TPHs an installation fee for its 10 Gb physical port connection.

The Exchange also believes the proposed fee change is reasonable as it will better align the price of this connectivity option to the value it offers to the market participants that utilize it. It will also better enable the Exchange to maintain and improve its connectivity services and facilities. Finally, the proposed fee change is reasonable as the resulting 10 Gb physical port fee will be lower than the amounts assessed by PHLX for similar market access connections. Additionally, the Exchange believes that the proposal will be an equitable allocation of fees and will not discriminate unfairly against market participants. The proposed fee change is an equitable allocation of fees because it reflects the substantial value that the 10Gb circuit provides to TPHs and non-TPHs. This connectivity option is particularly attractive to TPHs and non-TPHs that desire low latency connectivity to the Exchange because it provides sufficient capacity to support most of their activities on the Exchange and does so at a reasonable comparative price point. The proposal is not unfairly discriminatory because 10 Gb physical port connectivity will be available to all customers at the same price. Furthermore, 10 Gb physical port connectivity is an optional connectivity product, and TPHs and non-TPHs are not required to purchase a 10 Gb physical port in order to access the Exchange. Indeed, TPHs and non-TPHs have a variety of options to connect to the Exchange, including amongst others, the 1 Gb physical port, the pricing for which is less expensive and remains unchanged. While the proposed price increase will impact users of the 10 Gb physical port connection, the Exchange believes this is fair because users of a 10 Gb physical port connection generally consume more resources from the Exchange than do other participants.

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 fee change will not impact intramarket competition because it will apply to all similarly situated TPS and non-TPHs equally (*i.e.*, all market

participants that choose to purchase the 10 Gb physical port). Additionally, the Exchange does not believe its proposed pricing will impose a barrier to entry to smaller participants and notes that its proposed connectivity pricing is associated with relative usage of the various market participants. For example, market participants with modest capacity needs can continue to buy the less expensive 1 Gb physical port (which cost is not changing) or may choose to obtain access via a third-party re-seller. While pricing may be increased for the larger capacity physical ports, such options provide far more capacity and are purchased by those that consume more resources from the network. Accordingly, the proposed connectivity fee does not favor certain categories of market participants in a manner that would impose a burden on competition; rather, the allocation reflects the network resources consumed by the various size of market participants—lowest bandwidth consuming members pay the least, and highest bandwidth consuming members pay the most.

The proposed fee change also does not impose a burden on competition or on other Self-Regulatory Organizations that is not necessary or appropriate. As described above, in establishing its proposed fee change the Exchange compared its proposed fee increase to that of a competitor exchange's analogous offering. As noted above, the proposed fee of \$8,000 is \$10,500 less than the ongoing monthly fee PHLX charges its members for its 10Gb ultra fiber connection, and \$3,000 less than the fee PHLX charges its members for its 10Gb fiber connection. Moreover, unlike PHLX, the Exchange does not charge its TPHs and non-TPHs an installation fee for its 10 Gb physical port connection.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act⁷ and paragraph (f) of Rule 19b-4⁸ thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if

it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-CBOE-2025-094 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-CBOE-2025-094. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-CBOE-2025-094 and should be submitted on or before January 20, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁹

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025-23819 Filed 12-23-25; 8:45 am]

BILLING CODE 8011-01-P

⁷ 15 U.S.C. 78s(b)(3)(A).

⁸ 17 CFR 240.19b-4(f).

⁹ 17 CFR 200.30-3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[OMB Control No. 3235-0324]

Agency Information Collection Activities; Proposed Collection; Comment Request; Extension: Form S-4—Registration Statement

Upon Written Request, Copies Available

From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549-2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (“Commission”) is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Form S-4 (17 CFR 239.25) is the form used for registration under the Securities Act of 1933 (15 U.S.C. 77a *et seq.*) of securities issued in business combinations transactions. The information collected is intended to ensure the adequacy of information available to investors in connection with business combination transactions. We estimate that Form S-4 takes approximately 3,816.24 hours per response to prepare and is filed once per year by approximately 228 issuers annually. We estimate that 25% of the 3,816.24 hours per response is carried internally by the issuer for an annual reporting burden of approximately 217,526 hours (3,816.24 hours per response $\times$ 25% $\times$ 228 responses annually). We estimate that 75% of the 3,816.24 hours per response is carried externally by outside professionals retained by the issuer at an estimated rate of \$600 per hour for a total annual cost burden of approximately \$391,546,224 (3,816.244 hours per response $\times$ 75% $\times$ \$600 per hour $\times$ 228 responses annually).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Written comments are invited on: (a) whether this proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency’s estimate of the burden imposed by the collection of information; (c) ways to enhance the quality, utility, and clarity of the

information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Please direct your written comments on this 60-Day Collection Notice to Austin Gerig, Director/Chief Data Officer, Securities and Exchange Commission, c/o Tanya Ruttenberg via email to PaperworkReductionAct@sec.gov by February 27, 2026. There will be a second opportunity to comment on this SEC request following the **Federal Register** publishing a 30-Day Submission Notice.

Dated: December 22, 2025.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025-23899 Filed 12-23-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-104471; File No. SR-Phlx-2025-75]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend SQF Port Fees

December 19, 2025.

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 December 16, 2025, Nasdaq PHLX, LLC (“Phlx” or “Exchange”) filed with the Securities and Exchange Commission (“SEC” or “Commission”) the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Specialized Quote Feed³ or “SQF” Port

pricing at Options 7, Section 9, B, “Port Fees.”⁴

While the changes proposed herein are effective upon filing, the Exchange has designated the amendments become operative on January 1, 2026.

The text of the proposed rule change is available on the Exchange’s website at <https://listingcenter.nasdaq.com/rulebook/phlx/rulefilings>, and at the principal office of the Exchange.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Phlx proposes to amend its SQF Port pricing at Options 7, Section 9, B, “Port Fees” by offering an incentive to Market Makers⁵ to lower their SQF Port Fees.

Pursuant to a prior rule change, as of January 1, 2026, Phlx will assess an SQF Port Fee of \$1,185 per port, per month.⁶

Cancel Order messages; (7) risk protection triggers and purge notifications; (8) opening imbalance messages; (9) auction notifications; and (10) auction responses. The SQF Purge Interface only receives and notifies of purge requests from the Lead Market Maker, SQT or RSQT. Lead Market Makers, SQTs and RSQTs may only enter interest into SQF in their assigned options series. Immediate-or-Cancel Orders entered into SQF are not subject to the Order Price Protection, the Market Order Spread Protection, or Size Limitation in Options 3, Section 15(a)(1), (a)(2) and (b)(2), respectively. See Options 3, Section 7(a)(i)(B).

⁴ On December 8, 2025 the Exchange filed SR-Phlx-2025-69. On December 16, 2025 the Exchange withdrew SR-Phlx-2025-69 and filed this rule change.

⁵ The term “Market Maker” is defined in Options 1, Section 1(b)(28) as a member of the Exchange who is registered as an options Market Maker pursuant to Options 2, Section 12(a). A Market Maker includes SQTs and RSQTs as well as Floor Market Makers. See Options 7, Section 1(c). The term “Floor Market Maker” is a Market Maker who is neither an SQT or an RSQT. A Floor Market Maker may provide a quote in open outcry. See Options 8, Section 2(a)(4). Only Market Makers utilize SQF Ports for quoting purposes.

⁶ See Securities Exchange Act Release No. 103889 (September 5, 2025), 90 FR 43662 (September 10, 2025) (SR-Phlx-2025-40) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Phlx Options 7, Section 9).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ “Specialized Quote Feed” or “SQF” is an interface that allows Lead Market Makers, Streaming Quote Traders (“SQTs”) and Remote Streaming Quote Traders (“RSQTs”) to connect, send, and receive messages related to quotes, Immediate-or-Cancel Orders, and auction responses into and from the Exchange. Features include the following: (1) options symbol directory messages (e.g., underlying and complex instruments); (2) system event messages (e.g., start of trading hours messages and start of opening); (3) trading action messages (e.g., halts and resumes); (4) execution messages; (5) quote messages; (6) Immediate-or-

At this time, the Exchange proposes to offer an opportunity to lower SQF Port Fees as of January 1, 2026. Specifically, the Exchange proposes to offer certain discounts to Market Makers that have transacted a certain percentage of Total National Volume in the prior month. For purposes of this proposal, the

percentage of Total National Volume is calculated by taking the total Market Maker Penny Symbol and Market Maker Non-Penny Symbol volume (excluding index options) executed on the Exchange in the prior month and attributing a multiple of five times to that Non-Penny Symbol volume

(numerator) and dividing that by Market Maker volume (“M” capacity at The Options Clearing Corporation (“OCC”)) in multiply listed options across all options exchanges (denominator or Total National Volume).

Tier	Percentage of Total National Volume	Percentage SQF Port discount
1	less than 0.10%	0
2	greater than or equal to 0.10% and less than 0.25%	10
3	greater than or equal to 0.25% and less than 0.40%	30
4	greater than or equal to 0.40%	50

With this proposal, a Market Maker that transacted less than 0.10% of Total National Volume in the prior month would not receive a discount on SQF Port Fees. A Market Maker that transacted greater than or equal to 0.10% and less than 0.25% of Total National Volume in the prior month will be afforded a discount of 10% on their SQF Port Fees. A Market Maker that transacted greater than or equal to 0.25% and less than 0.40% of Total National Volume in the prior month will be afforded a discount of 30% on their SQF Port Fees. Finally, a Market Maker that transacted greater than or equal to 0.40% of Total National Volume in the prior month will be afforded a discount of 50% on their SQF Port Fees. By way of example, a Market Maker that executed 3,000,000 in Penny Volume and 200,000 in Non-Penny Volume in a given month on the Exchange, where the Total National Volume was 1,000,000,000, would qualify for a discount of 50% on their SQF Port Fees ((200,000 × 5 = 1,000,000) + 3,000,000 = 4,000,000 which is 0.40% of 1,000,000,000).

The Exchange proposes to calculate Market Maker Non-Penny Symbol volume at five times the weight as compared to Market Maker Penny Symbol volume because Non-Penny Symbols tend to have lower volumes and this incentive should encourage a greater amount of volume in Non-Penny Symbols. Overall, the proposed discounts should encourage Market Makers to transact additional order flow on Phlx with which other market participants may interact, for an opportunity to lower SQF Port Fees. The Exchange proposes to exclude index options as index options are generally not multiply listed.

The Exchange also proposes to add back the text which provided, “A Market Maker may not subscribe to more than 250 SQF Ports per month.” This rule text was inadvertently omitted in the rule text to SR-Phlx-2025-40

which did not indicate that rule text was to be removed. Additionally, the Exchange proposes to remove the text that states, “for ports that receive inbound quotes at any time within that month (“active port”).” SR-Phlx-2025-40 replaced Phlx’s SQF Port Fee with an SQF Port Fee that was identical to Nasdaq ISE, LLC (“ISE”).

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,⁷ in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,⁸ in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system “has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.”⁹

Likewise, in *NetCoalition v. Securities and Exchange Commission*¹⁰ (“NetCoalition”) the D.C. Circuit upheld the Commission’s use of a market-based approach in evaluating the fairness of market data fees against a challenge

claiming that Congress mandated a cost-based approach.¹¹ As the court emphasized, the Commission “intended in Regulation NMS that ‘market forces, rather than regulatory requirements’ play a role in determining the market data . . . to be made available to investors and at what cost.”¹²

Further, “[n]o one disputes that competition for order flow is ‘fierce.’ . . . As the SEC explained, ‘[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution’; [and] ‘no exchange can afford to take its market share percentages for granted’ because ‘no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers’”¹³ Although the court and the SEC were discussing the cash equities markets, the Exchange believes that these views apply with equal force to the options markets.

The proposed fee discounts for Phlx SQF Ports are reasonable because they will attract a greater amount of order flow to Phlx with which other market participants may interact while also lowering costs for certain Market Makers that are able to transact greater than 0.10% of Total National Volume in the prior month. The Exchange believes it is reasonable to lower costs for certain Market Makers that transact greater than 0.10% of Total National Volume on Phlx because those Market Makers are affording other Phlx members and member organizations an opportunity to interact with that order flow. The proposal provides an incremental incentive for Market Makers that transact at least 0.10% of Total National Volume, which provides a higher

⁷ 15 U.S.C. 78f(b).

⁸ 15 U.S.C. 78f(b)(4) and (5).

⁹ Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (“Regulation NMS Adopting Release”).

¹⁰ *NetCoalition v. SEC*, 615 F.3d 525 (D.C. Cir. 2010).

¹¹ See *NetCoalition*, at 534–535.

¹² *Id.* at 537.

¹³ *Id.* at 539 (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

benefit for satisfying increasingly more stringent criteria. The Exchange believes that the value of the proposed discounts is commensurate with the difficulty to achieve the corresponding threshold. Additionally, the discounts may incentivize and attract more volume and liquidity to the Exchange, which will benefit all Exchange participants through increased opportunities to trade as well as enhancing price discovery. The Exchange's proposed discounts are substantially similar to Cboe Exchange, Inc.'s ("Cboe") credit for their BOE Bulk Port Fees.¹⁴

Phlx believes it is reasonable to offer fee discounts to those Market Makers that primarily provide and post liquidity to the Exchange, as it should encourage Market Makers to continue to participate on the Exchange and add liquidity. Greater liquidity benefits all market participants by providing more trading opportunities and tighter spreads. The proposal would also mitigate the costs incurred by Market Makers on Phlx.

Calculating Market Maker Non-Penny Symbol volume at five times the weight as compared to Penny Symbol volume is reasonable, equitable and not unfairly discriminatory as Non-Penny Symbols tend to have lower volumes and this incentive should encourage a greater amount of volume in Market Maker Non-Penny Symbols.¹⁵ The Exchange proposes to calculate the Market Maker Non-Penny Symbol volume in an uniform manner for all members and member organizations. The Exchange proposes to exclude index options as index options are generally not multiply

listed. Index Options would be uniformly excluded.

A Phlx Market Maker requires only one SQF Port to submit quotes in its assigned options series into Phlx. A Phlx Market Maker may submit all quotes through one SQF Port. While a Phlx Market Maker may elect to obtain multiple SQF Ports to organize its business,¹⁶ only one SQF Port is necessary for a Phlx Market Maker to fulfill its regulatory quoting obligations.¹⁷

The proposed fee discounts for Phlx SQF Ports are equitable and not unfairly discriminatory as they would apply uniformly to each Phlx Market Maker. The Exchange would uniformly calculate the Market Maker's percentage each month. Although only Market Makers may receive the proposed discounts, the Exchange notes that Market Makers are valuable market participants that provide liquidity in the marketplace and incur costs that other market participants do not incur. Unlike other market participants, Market Makers are required to provide continuous two-sided quotes on a daily basis,¹⁸ and are subject to various obligations associated with providing liquidity.¹⁹ While the Exchange is not offering a discount to those Market Makers that transact less than 0.10% of Total National Volume, the Exchange notes that these Market Makers transact a much lower amount of contracts on Phlx as compared to other Market Makers who qualify for a discount. In some cases, these Market Makers are not executing the requisite amount of Penny Symbols or Non-Penny Symbols to obtain the discount. Market Makers are required to demonstrate that they have significant market-making and/or Lead Market Maker experience in a broad array of securities, a proven ability to interact with order flow in all types of markets, and a willingness and ability to make competitive markets on the Exchange and otherwise to promote the Exchange in a manner that is likely to enhance the ability of the Exchange to compete successfully for order flow in the options it trades, among other

things.²⁰ The Exchange believes that all Market Makers are capable of quoting tighter or in a greater amount of options classes to obtain the requisite volume to achieve a discount.

The Exchange's proposal to add back the text which provided, "A Market Maker may not subscribe to more than 250 SQF Ports per month" is reasonable, equitable and not unfairly discriminatory as that rule text was inadvertently not displayed in the rule text to SR-Phlx-2025-40 and was not intended to be removed. There was no mention of its removal in SR-Phlx-2025-40. The Exchange's proposal to remove the words "for ports that receive inbound quotes at any time within that month ("active port")" is reasonable, equitable and not unfairly discriminatory as SR-Phlx-2025-40 replaced Phlx's SQF Port Fee with an SQF Port Fee that was identical to ISE. Other rule text that mentioned active SQF Ports was removed in SR-Phlx-2025-40.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

In terms of intra-market competition, the proposed fee discounts for Phlx SQF Ports do not impose a burden on competition because they would apply uniformly to each Phlx Market Maker and the Exchange would uniformly calculate the Market Maker's percentage each month. Although only Market Makers may receive the proposed discounts, the Exchange notes that Market Makers are valuable market participants that provide liquidity in the marketplace and incur costs that other market participants do not incur. Unlike other market participants, Market Makers are required to provide continuous two-sided quotes on a daily basis,²¹ and are subject to various obligations associated with providing liquidity.²² Further, while the Exchange is not offering a discount to those Market Makers that transact less than 0.10% of Total National Volume, the Exchange notes that these Market Makers transact a much lower amount of contracts on Phlx as compared to other Market Makers that qualify for the discount and/or these Market Makers are not executing the requisite amount of Penny Symbols or Non-Penny Symbols to obtain the discount. The

¹⁴ Cboe currently offers its market makers credits on their monthly BOE Bulk Port Fees. Specifically, if a Cboe market maker affiliate ("affiliate" defined as having at least 75% common ownership between the two entities as reflected on each entity's Form BD, Schedule A) or Cboe Appointed OFP receives a credit under the Exchange's Volume Incentive Program ("VIP"), the Cboe market maker will receive an access credit on their BOE Bulk Ports corresponding to the VIP tier reached. The credit is based on the Performance Tier earned by a market maker under Cboe's Liquidity Provider Sliding Scale Adjustment Table. Tiers 4 and 5 earn a 40% credit on monthly Cboe Bulk Port Fees. Cboe assesses BOE Bulk Logical Ports a fee of \$1,500 for 1 to 5 ports, a fee of \$2,500 for 6 to 30 ports and a fee of \$3,000 for over 30 ports. Additionally, each BOE Bulk Logical Port will incur the logical port fee indicated when used to enter up to 30,000,000 orders per trading day per logical port as measured on average in a single month. Each incremental usage of up to 30,000,000 orders per day per BOE Bulk Logical Port will incur an additional logical port fee of \$3,000 per month. Incremental usage will be determined on a monthly basis based on the average orders per day entered in a single month across all subscribed BOE Bulk Logical Ports.

¹⁵ Penny Symbols typically are more liquid symbols.

¹⁶ For example, a Phlx Market Maker may desire to utilize multiple SQF Ports for accounting purposes, to measure performance, for regulatory reasons or other determinations that are specific to that member organization.

¹⁷ Phlx Market Makers have various regulatory requirements as provided for in Options 2, Section 4. Additionally, Phlx Market Makers have certain quoting requirements with respect to their assigned options series as provided in Options 2, Section 5. SQF Ports are the only quoting protocol available on Phlx and only Market Makers may utilize SQF Ports.

¹⁸ See Phlx Options 2, Section 5.

¹⁹ See Phlx Options 2, Section 4.

²⁰ See Phlx Options 2, Section 1(a)(2).

²¹ See Phlx Options 2, Section 5.

²² See Phlx Options 2, Section 4.

Exchange's proposal does not impose an undue burden on competition because Market Makers are required to demonstrate that they have significant market-making and/or Lead Market Maker experience in a broad array of securities, a proven ability to interact with order flow in all types of markets, and a willingness and ability to make competitive markets on the Exchange and otherwise to promote the Exchange in a manner that is likely to enhance the ability of the Exchange to compete successfully for order flow in the options it trades, among other things.²³ The Exchange believes that all Market Makers are capable of quoting tighter or in a greater amount of options classes to obtain the requisite volume to achieve a discount.

The Exchange's proposal to add back the text which provided, "A Market Maker may not subscribe to more than 250 SQF Ports per month" does not impose an undue burden on competition as that rule text was inadvertently not displayed in the rule text to SR-Phlx-2025-40 and was not intended to be removed. There was no mention of its removal in SR-Phlx-2025-40. Also, the Exchange's proposal to remove the words "for ports that receive inbound quotes at any time within that month ("active port")" does not impose an undue burden on competition as SR-Phlx-2025-40 replaced Phlx's SQF Port Fee with an SQF Port Fee that was identical to ISE. Other rule text that mentioned active SQF Ports was removed in SR-Phlx-2025-40.

In terms of inter-market competition, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other options exchanges. In addition to the Exchange, market participants have alternative options exchanges that they may participate on and direct their order flow. In sum, if the changes proposed herein are unattractive to market participants, it is likely that the Exchange will lose market share as a result. Accordingly, the Exchange does not believe that the proposed changes will impair the ability of members or competing options exchanges to maintain their competitive standing in the financial markets.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.²⁴

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-Phlx-2025-75 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-Phlx-2025-75. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is

obscene or subject to copyright protection. All submissions should refer to file number SR-Phlx-2025-75 and should be submitted on or before January 20, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁵

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025-23815 Filed 12-23-25; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-104485; File No. SR-FICC-2025-025]

Self-Regulatory Organizations; Fixed Income Clearing Corporation; Notice of Filing of Proposed Rule Change To Amend and Restate the Second Amended and Restated Cross-Margining Agreement Between FICC and CME and Amend Related GSD Rules

December 22, 2025.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Exchange Act")¹ and Rule 19b-4 thereunder,² notice is hereby given that on December 12, 2025, Fixed Income Clearing Corporation ("FICC") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the clearing agency.³ On December 19, 2025, FICC filed Partial Amendment No. 1 to the proposed rule change to make certain changes to the narrative description of the filing and exhibits provided by FICC.⁴ The Commission is publishing

²⁵ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ On December 12, 2025, FICC filed this proposed rule change as an advance notice (SR-FICC-2025-801) with the Commission pursuant to Section 806(e)(1) of Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act entitled the Payment, Clearing, and Settlement Supervision Act of 2010, 12 U.S.C. 5465(e)(1), and Rule 19b-4(n)(1)(i) under the Exchange Act, 17 CFR 240.19b-4(n)(1)(i). A copy of the advance notice is available at www.dtcc.com/legal/sec-rule-filings.

⁴ Partial Amendment No. 1 makes clarifications and corrections to the narrative description of the proposed rule change and Exhibit 5A of the filing. Specifically, the Amendment corrects the narrative description of a proposed change to the GSD Rules to accurately reflect the change, as it appears in Exhibit 5A. The Amendment also modifies Exhibit to correct a typographical error and mismarked rule text as compared to the currently effective GSD Rules. These clarifications and corrections have been incorporated, as appropriate, into the description of the proposed rule change in Item II below.

²³ See Phlx Options 2, Section 1(a)(2).

²⁴ 15 U.S.C. 78s(b)(3)(A)(ii).

this notice to solicit comments on the proposed rule change, as modified by Partial Amendment No. 1 (hereafter “the proposed rule change”), from interested persons.

I. Clearing Agency’s Statement of the Terms of Substance of the Proposed Rule Change

FICC is proposing a rule change related to its cross-margining arrangement (the “Cross-Margining Arrangement”) with the Chicago Mercantile Exchange Inc. (“CME,” and collectively with FICC, the “Clearing Organizations” or “Parties”). The proposed rule change consists of (i) a proposed Third Amended and Restated Cross-Margining Agreement (the “Third A&R Agreement”) between FICC and CME, which would replace the Second Amended and Restated Cross-Margining Agreement between the Parties (the “Second A&R Agreement”) in its entirety and would be incorporated into the FICC Government Securities Division (“GSD”) Rulebook (“GSD Rules”), and (ii) a number of related rule changes to the GSD Rules. Together, the proposed changes would extend the availability of the Cross-Margining Arrangement to positions cleared and carried for customers by a dually registered broker-dealer (“BD”) and futures commission merchant (“FCM”) that is a common member of FICC and CME (an “Eligible BD-FCM”).⁵

II. Clearing Agency’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The clearing agency has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

(A) Clearing Agency’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Currently, the Cross-Margining Arrangement allows FICC and CME to recognize for margin purposes the offsetting risk of certain positions in futures on U.S. Treasury securities and other interest rate futures and Treasury market transactions (“Eligible Positions”) maintained by a member of both Clearing Organizations (a “Joint Clearing Member”) for itself or certain eligible affiliates (an “Eligible Affiliate”), or by affiliated members of CME and FICC (each, a “Cross-Margining Affiliate,” and each Joint Clearing Member and each Cross-Margining Affiliate, a “Cross-Margining Participant”), at the two Clearing Organizations in circumstances when the Clearing Organizations can look to all of those positions (and all associated margin) for performance of the Joint Clearing Member’s or a pair of Cross-Margining Affiliates’ obligations (the “Proprietary Cross-Margining Arrangement”). In particular, the Proprietary Cross-Margining Arrangement allows the Clearing Organizations to consider the net risk of a Joint Clearing Member’s and its Eligible Affiliates’ Eligible Positions or a pair of Cross-Margining Affiliates’ Eligible Positions at FICC and CME when setting margin requirements for such positions.⁶ Any resulting margin reductions create capital efficiencies for the Cross-Margining Participants and their Eligible Affiliates and incentivize them to maintain or carry portfolios that present lower overall risk.

FICC and CME have submitted to the Commission and the Commodity Futures Trading Commission (the “CFTC”) petitions for exemptive relief from certain provisions of the Commodity Exchange Act (“CEA”) and Exchange Act that would enable FICC and CME to make cross-margining available to customers (other than an Eligible Affiliate) of an Eligible BD-FCM (“Cross-Margining Customers”).⁷ The proposed rule changes aim to set forth

a customer cross-margining arrangement that is consistent with the descriptions in the Petitions and the requirements of the Proposed Orders (the “Customer Cross-Margining Arrangement”). The Customer Cross-Margining Arrangement would allow Cross-Margining Customers to benefit from the margin reductions that are currently only available to Cross-Margining Participants and their Eligible Affiliates under the Proprietary Cross-Margining Arrangement. As a result, it would facilitate access to clearing for indirect participants, promote the maintenance of more balanced portfolios that present lower risk, and enhance liquidity in, and otherwise promote the resilience and robustness of, the Treasury market.

The Third A&R Agreement would effectuate the Customer Cross-Margining Arrangement via the following features:

- *Eligibility Criteria and Participation Requirements.* The Third A&R Agreement would set out the eligibility criteria for a Joint Clearing Member and its Cross-Margining Customer to participate in the Customer Cross-Margining Arrangement, as well as the requirements that would apply to such a Joint Clearing Member and its Cross-Margining Customer. These include the requirements that:

- A Joint Clearing Member be an Eligible BD-FCM;
- Each Cross-Margining Customer be a “futures customer” within the meaning of CFTC Regulation 1.3 and a “Sponsored Member” or “Executing Firm Customer” as defined under the GSD Rules;
- The Joint Clearing Member enter into a participant agreement with the Clearing Organizations; and
- The Joint Clearing Member enter into an agreement with each Cross-Margining Customer containing certain terms, including that the Cross-Margining Customer agrees to subordinate its claims under the Securities Investor Protection Act of 1970 (“SIPA”) and Subchapter III of Chapter 7 of the U.S. Bankruptcy Code in relation to its cross-margined positions and associated margin (the “Subordination Agreement”).

As discussed in greater detail below, these criteria and requirements for participation are designed to ensure that each participating Cross-Margining Customer and its Joint Clearing Member satisfy certain conditions set forth in the Proposed Orders.

- *Customer Cross-Margining Accounts.* The Third A&R Agreement would include provisions to enable Eligible BD-FCMs to establish “Customer Cross-Margining Accounts” for purposes of recording Eligible

⁵ The Commission recently approved FICC’s proposed rule change to enter into the Second Amended and Restated Cross-Margining Agreement between FICC and CME. See Self-Regulatory Organizations; Fixed Income Clearing Corporation; Order Approving Proposed Rule Change to Amend and Re-state the Cross-Margining Agreement between FICC and CME, 90 FR 22538 (May 28, 2025). The Second A&R Agreement has thus been incorporated in the GSD Rules available at www.dtcc.com/legal/rules-and-procedures. Unless otherwise specified, capitalized terms not defined herein shall have the meanings ascribed to them in the GSD Rules.

⁶ See Section 4 of the Second A&R Agreement, *supra* note 4.

⁷ See Letter from the Fixed Income Clearing Corporation and Chicago Mercantile Exchange Inc. to Vanessa Countryman dated as of December 11, 2025 and filed as Confidential Exhibit 3B (the “SEC Petition”) and Letter from the Fixed Income Clearing Corporation and Chicago Mercantile Exchange Inc. to Christopher J. Kirkpatrick dated as of May 14, 2025 and filed as Confidential Exhibit 3C (the “CFTC Petition”), and collective with the SEC Petition, the “Petitions”, and the proposed Commission and CFTC orders as described in the Petitions, the “Proposed Orders”).

Positions at the Clearing Organizations (such Eligible Positions in a Customer Cross-Margining Account, “Customer Positions”) and set forth a definition of “Proprietary Cross-Margining Accounts” to refer to the accounts established by Eligible BD-FCMs at the Clearing Organizations for the purposes of recording positions subject to the Proprietary Cross-Margining Arrangement (“Proprietary Positions”).

- *Margin Methodology.* The Third A&R Agreement would include provisions describing the methodology for calculating potential reductions to the margin requirements for Customer Positions. As discussed in greater detail below, FICC is proposing to apply the same margin reduction methodology to Customer Positions as it applies to Proprietary Positions, with margin reductions calculated on a customer-by-customer basis for each Cross-Margining Customer.

- *Default Management.* The Third A&R Agreement would include provisions to address how the Clearing Organizations would manage a default of a Cross-Margining Participant (a “Defaulting Member”) carrying positions for Cross-Margining Customers. Under the Third A&R Agreement, the Clearing Organizations would follow substantially the same approach to handling Customer Positions carried by a Defaulting Member as applies to Proprietary Positions. However, Customer Positions and Proprietary Positions and associated margin would form part of separate “Liquidation Portfolios” and therefore would not be netted against one another in calculating Net Gain or Net Loss (or VM Net Gain or VM Net Loss) under the Cross-Margining Agreement. By virtue of these changes, the Clearing Organizations would not be able to apply Customer Positions or associated margin to the obligations arising under a Defaulting Member’s Proprietary Positions. The Third A&R Agreement would also include edits clarifying that the Clearing Organizations may “port” Customer Positions to another clearing member in a default scenario.

In addition to replacing the Second A&R Agreement with the Third A&R Agreement, FICC proposes the following changes to the GSD Rules to effectuate the Customer Cross-Margining Arrangement:

- *Account Structure.* FICC proposes to create a new Account type, the “Cross-Margining Customer Account,” for purposes of recording FICC-cleared Customer Positions.

- *Margin Methodology and Treatment.* As discussed in greater detail below, under the proposed

changes, FICC would collect and hold Cross-Margining Customer Margin in a substantially similar manner to how it collects and holds “Segregated Customer Margin” (as defined under the GSD Rules), with certain adjustments to ensure consistency with the requirements of the Proposed Orders and the general requirements and conventions applicable to futures. Consistent with how it treats Segregated Customer Margin, FICC would credit all Cross-Margining Customer Margin collected from an Eligible BD-FCM to a securities account on its books and records in the name of the Eligible BD-FCM for the benefit of its customers (a “Cross-Margining Customer Margin Custody Account”). FICC would also agree to treat all assets credited to the Cross-Margining Customer Margin Custody Account as “financial assets” credited to a “securities account” for which FICC is the “securities intermediary,” as such terms are used in Article 8 of the Uniform Commercial Code as in effect in the State of New York (“NYUCC”). This treatment is designed to ensure that Cross-Margining Customer Margin does not form part of FICC’s bankruptcy estate and is not exposed to the claims of FICC’s general creditors, and is instead reserved for Eligible BD-FCMs claiming on behalf of their Cross-Margining Customers. Consistent with how it holds Segregated Customer Margin, FICC would hold Cross-Margining Customer Margin in a segregated account at a bank insured by the Federal Deposit Insurance Corporation and at the Federal Reserve Bank of New York (the “FRBNY”). In accordance with the Proposed Orders, any such account (other than one at the FRBNY) would need to be subject to a written notice consistent with the Proposed Orders.

- *Conforming and Clarifying Changes.* FICC proposes to make a number of clarifying and conforming edits to the GSD Rules, including (i) adding references to Cross-Margining Customer, Cross-Margining Customer Margin, Cross-Margining Customer Account, and Cross-Margining Customer Margin Requirements to relevant provisions that refer to Indirect Participants, initial margin collected by FICC, position accounts maintained by FICC, and FICC’s initial margin requirements; (ii) removing the existing prohibition under Section 10(e) of Rule 3A on Sponsored Members from participating in the Cross-Margining Arrangement; (iii) expanding Rule 43, which sets forth certain terms related to the Proprietary Cross-Margining Arrangement, to encompass the

Customer Cross-Margining Arrangement; and (iv) removing references to the Market Professionals cross-margining arrangement, which is no longer offered by FICC.

The Third A&R Agreement would also include a number of clarifying and conforming edits, including to make clear that, with respect to both the Proprietary Cross-Margining Arrangement and Customer Cross-Margining Arrangement, FICC and CME would only manage a default of a Joint Clearing Member independently of one another if a joint management or buy-out by one of the Clearing Organizations were not legally permissible or possible or would result in substantially greater losses to each Clearing Organization.

In addition, the Second A&R Agreement is supplemented by a Service Level Agreement (“SLA”) between FICC and CME. FICC and CME will make edits to the SLA as necessary to ensure conformance with the proposed Third A&R Agreement.⁸

(i) The Proposed Third A&R Agreement

As noted above, FICC proposes to enter into the Third A&R Agreement with CME. The proposed changes to the Second A&R Agreement contained in the Third A&R Agreement are designed to make cross-margining available to Cross-Margining Customers consistently with the framework set out in the Proposed Orders. FICC believes that such amendments would promote the maintenance of more balanced portfolios that present lower risk and facilitate the access of indirect participants to central clearing in accordance with Rule 17ad-22 under the Exchange Act.

A. Eligibility Criteria and Participation Requirements

a. Eligibility Criteria for Joint Clearing Members

The Third A&R Agreement would set forth the eligibility criteria for a Cross-Margining Participant to participate in the Customer Cross-Margining Arrangement. To facilitate compliance with the conditions and limitations of the Proposed Orders, Section 2(a) of the Third A&R Agreement would provide that, to become a Cross-Margining Participant for the Customer Cross-Margining Arrangement and establish a Customer Cross-Margining Account, a Clearing Member would need to be a Joint Clearing Member that is both a BD registered with the Commission and an FCM registered with the CFTC (*i.e.*, an

⁸ The SLA is provided as confidential Exhibit 3 to this proposed rule change.

Eligible BD–FCM).⁹ Section 3(a) of the Third A&R Agreement would further require that the Eligible BD–FCM hold the Cross-Margining Customer's Customer Positions at FICC and associated money, securities and property together with such customer's Customer Positions at CME and the associated “futures customer funds,” as defined in CFTC Regulation 1.3, held by the Eligible BD–FCM, in a “futures account,” as defined in CFTC Regulation 1.3, “in accordance with any conditions set forth in the regulatory approvals of [the Third A&R Agreement] issued by [the Commission] and CFTC and applicable law.”¹⁰

In addition, the Eligible BD–FCM would be required to enter into a participant agreement with FICC and CME in the form of Appendix C to the Third A&R Agreement (the “Customer Cross-Margining Clearing Member Agreement”), which is further described below.¹¹ The definition of “Clearing Member Agreement” would correspondingly be amended to refer, with respect to the Proprietary Cross-Margining Arrangement, to the existing participant agreement currently in Appendix A or Appendix B of the Second A&R Agreement (the “Proprietary Clearing Member Agreement”), as applicable, and with respect to the Customer Cross-Margining Arrangement, to the Customer Cross-Margining Clearing Member Agreement.¹²

As a conforming change, Sections 2(a) and (c) and the first sentence of Section 2(a) of the Third A&R Agreement would also be amended to provide that the pre-existing language therein applies to a Cross-Margining Participant for the Proprietary Cross-Margining Arrangement.¹³

b. Definition of Customer and Non-Customer

The Customer Cross-Margining Arrangement would only be available for the positions carried by an Eligible BD–FCM for “Customers.” To ensure compliance with the limitations under

the Proposed Orders of the types of persons eligible to be Cross-Margining Customers, the Third A&R Agreement would define “Customer” as an indirect clearing participant that meets the definition of futures customer set out in CFTC Regulation 1.3 and is a “Sponsored Member” or “Executing Firm Customer” as defined under the GSD Rules.¹⁴ CFTC Regulation 1.3 defines “futures customer” to mean any person who uses an FCM as an agent in connection with trading in any futures contract, but excludes persons whose futures positions are held in a “proprietary account.”¹⁵ Any Customer wishing to participate in the Customer Cross-Margining Arrangement would need to enter into an agreement with its Eligible BD–FCM that includes certain terms described in greater detail below (the “Customer Agreement”).¹⁶ Because affiliates of the Eligible BD–FCM would generally have their CME-cleared futures positions held in a proprietary account of the Eligible BD–FCM, such affiliates would not constitute “futures customers” under CFTC Regulation 1.3. However, Eligible Affiliates would continue to be able to access cross-margining under the Proprietary Cross-Margining Arrangement so long as they constitute “Non-Customers.”¹⁷ The

¹⁴ See Section 1 of the proposed Third A&R Agreement.

¹⁵ See CFTC Regulation 1.3, definition of “futures customer” (defining “futures customer” as “any person who uses a futures commission merchant, introducing broker, commodity trading advisor, or commodity pool operator as an agent in connection with trading in any contract for the purchase or sale of a commodity for future delivery or any option on such contract; Provided, however, an owner or holder of a proprietary account as defined in this section shall not be deemed to be a futures customer within the meaning of sections 4d(a) and 4d(b) of the [CEA], the regulations in this chapter that implement sections 4d and 4f of the [CEA] and [CFTC Regulation] § 1.35, and such an owner or holder of such a proprietary account shall otherwise be deemed to be a futures customer within the meaning of the [CEA] and [CFTC Regulations] §§ 1.37 and 1.46 and all other sections of these rules, regulations, and orders which do not implement sections 4d and 4f of the [CEA].”); CFTC Regulation 1.3, definition of “proprietary account” (defining “proprietary account” as “futures, commodity option, or swap trading account carried on the books and records of” a person or entity for such person or entity itself or certain affiliates, as well as such account “of which ten percent or more is owned by . . . or an aggregate of ten percent or more of which is owned by more than one” such persons, entities, or affiliates).

¹⁶ See *infra* Part 3(a)(i)(H) “Customer Agreement.”

¹⁷ See Section 3(b) of the proposed Third A&R Agreement (allowing the transactions, positions and margin that are maintained by an “Eligible Affiliate” to be maintained in a Cross-Margining Account provided that certain conditions, which are not proposed to be modified in the Third A&R Agreement, are satisfied); Self-Regulatory Organizations; Fixed Income Clearing Corporation; Order Approving Proposed Rule Change to Amend and Restate the Cross-Margining Agreement

Third A&R Agreement would revise the definition of “Non-Customer” to mean any affiliate of the Eligible BD–FCM or any person that is an officer, director, partner or other related person of the Eligible BD–FCM (i) that is not a “customer” of the Eligible BD–FCM within the meaning of SIPA, Subchapter III of Chapter VII of the U.S. Bankruptcy Code, or Exchange Act Rule 15c3–3, and (ii) whose CME-cleared positions are carried in a proprietary account of the Eligible BD–FCM.¹⁸

c. Relationship Between the Clearing Organizations and Cross-Margining Customers

Because a Cross-Margining Customer's participation in the Customer Cross-Margining Arrangement would be intermediated through the Eligible BD–FCM, Section 2(a) of the Third A&R Agreement would specify that the Clearing Organizations would have no obligation to deal directly with a Cross-Margining Customer, and that a Cross-Margining Customer would have no right to assert a claim against a Clearing Organization with respect to, nor would a Clearing Organization be liable to a Cross-Margining Customer for, any obligations of a Clearing Organization in connection with the Cross-Margining Customer's participation in the Customer Cross-Margining Arrangement pursuant to the Third A&R Agreement.¹⁹ These terms are consistent with those applicable to Eligible Firm Customers under the GSD Rules, as well as those applicable to customers under CME's rules.²⁰

B. Customer Cross-Margining Account

To effectuate the Customer Cross-Margining Arrangement, the Third A&R Agreement would include changes to enable an Eligible BD–FCM to establish a “Customer Cross-Margining Account” separate from any of its “Proprietary Cross-Margining Accounts.”

A Customer Cross-Margining Account would be defined as, with respect to FICC, an Indirect Participants Account (as defined in the GSD Rules) at FICC maintained for Cross-Margining Customers and identified in FICC's books and records as being subject to the Third A&R Agreement (which, as discussed below, would be the “Cross-Margining Customer Account” under the GSD Rules) and with respect to

between FICC and CME, 90 FR 31043 (July 11, 2025).

¹⁸ See Section 1 of the proposed Third A&R Agreement.

¹⁹ See Section 2(a) of the proposed Third A&R Agreement.

²⁰ See GSD Rules, Rule 2, Section 4; Rule 8, Section 6(c)–(e); CME Rulebook, Rule 803.

⁹ See Section 2(a) of the proposed Third A&R Agreement.

¹⁰ See Section 3(a) of the proposed Third A&R Agreement.

¹¹ See *infra* Part 3(a)(i)(G) “Customer Cross-Margining Clearing Member Agreement;” Section 2(d) of the proposed Third A&R Agreement; Appendix C “Fixed Income Clearing Corporation/Chicago Mercantile Exchange Inc. Cross-Margining Participant Agreement (Common Member) [Customer Cross-Margining Program]” of the proposed Third A&R Agreement.

¹² See Section 1 of the proposed Third A&R Agreement.

¹³ See Sections 2(a), (c) of the proposed Third A&R Agreement.

CME, an account carried on the books and records of CME for an Eligible BD-FCM, which contains only the positions, transactions, and margin of that Eligible BD-FCM's Cross-Margining Customers.²¹ A Proprietary Cross-Margining Account would be defined as, with respect to FICC, a Proprietary Account at FICC (as defined in the GSD Rules) or an Indirect Participants Account at FICC that is maintained for Non-Customers and identified in FICC's books and records as being subject to the Third A&R Agreement, and, with respect to CME, an account carried on the books and records of CME for an Eligible BD-FCM, which contains only the positions, transactions, and margin of the "proprietary accounts" (as defined in CFTC Regulation 1.3) of the Eligible BD-FCM.²²

The Third A&R Agreement would also define "Cross-Margining Account" to mean either a Proprietary Cross-Margining Account or a Customer Cross-Margining Account.²³ An Eligible BD-FCM would be required to designate each Cross-Margining Account it opens at the Clearing Organizations as either a Customer Cross-Margining Account or a Proprietary Cross-Margining Account.²⁴

C. Margin Methodology

The Third A&R Agreement would also specify how potential margin reductions would be calculated for Customer Positions carried in a Customer Cross-Margining Account. As with Proprietary Positions, each Clearing Organization would calculate the margin savings that would result from viewing the "Combined Portfolio" of CME-cleared Customer Positions and FICC-cleared Customer Positions as a single portfolio rather than as separate standalone portfolios. The Clearing Organizations would then compare the respective margin reduction percentages, and each would then reduce the margin required for the Combined Portfolio by the lower percentage (subject to a cap of 80%). For Customer Positions, this process would occur on a Cross-Margining Customer-by-Cross-Margining Customer basis. In other words, each Cross-Margining Customer's Customer Positions would form part of a separate Combined Portfolio. This customer-by-customer approach is consistent both with how futures contracts are required to be margined under the rules of the CFTC,

as well as how FICC margins Segregated Indirect Participant positions.²⁵

To implement this margin reduction methodology, the Third A&R Agreement would redefine "Combined Portfolio" to mean, in the case of a Pair of Cross-Margining Accounts consisting of Proprietary Cross-Margining Accounts, all Eligible Positions in such Cross-Margining Accounts, and in the case of a Pair of Cross-Margining Accounts consisting of Customer Cross-Margining Accounts, all Eligible Positions of a single Customer in such Cross-Margining Accounts.²⁶ The term "Pair of Cross-Margining Accounts," in turn, would be defined to mean a Customer Cross-Margining Account at CME and a Customer Cross-Margining Account at FICC or a Proprietary Cross-Margining Account at CME and a Proprietary Cross-Margining Account at FICC.²⁷ The Third A&R Agreement would clarify that an Eligible BD-FCM would only be able to establish one Pair of Cross-Margining Accounts for each type of Indirect Participants Account offered at FICC under the GSD Rules and that the Customer Positions of the same Cross-Margining Customer may not be maintained in multiple Pairs of Cross-Margining Accounts of the same Eligible BD-FCM.²⁸ This limitation is aimed at ensuring that, as is the case with futures contracts, an Eligible BD-FCM would not be permitted to establish a separate account at the Clearing Organization for a particular customer or group of customers.

In addition to these changes, the Third A&R Agreement would include conforming changes in Section 4 to make clear that the margin calculations are performed on the Combined Portfolio and to provide that Sections 4(c) and 4(e), concerning the ability of the Clearing Organizations to require margin equal to or in excess of the Standalone Margin Requirement, would apply in relation to each Cross-Margining Account.²⁹ The Third A&R Agreement would also make conforming changes to a number of defined terms by:

- Revising the definition of "Cross-Margin Requirement" to refer to the joint amount of Margin required by FICC and CME in connection with a Combined Portfolio as provided for in

Section 4(a) of the Third A&R Agreement;

- Revising definitions of "Margin Reduction" and "Variation Margin" to clarify that these terms apply separately with respect to Proprietary Cross-Margining Accounts and Customer Cross-Margining Accounts;

- Further revising the "Variation Margin" definition to reflect that amounts may be owed by or to a Cross-Margining Customer in relation to positions recorded in a Customer Cross-Margining Account;

- Revising the definition of "Stand-Alone Margin Requirement" to provide that it is determined with respect to a particular Cross-Margining Account, and that with regard to a Stand-Alone Margin Requirement of FICC, such requirement is calculated without regard to any netting across positions of multiple Executing Firm Customers in the same Agent Clearing Member Omnibus Account (as such terms are defined in the GSD Rules);

- Revising the definition of "Margin" to include Cross-Margining Customer Margin securing the obligations of a Cross-Margining Customer and to contemplate a Joint Clearing Member having multiple Cross-Margining Accounts; and

- Removing the definition of "Cross-Margin Positions," which would no longer be used.³⁰

Section 6(b) of the Third A&R Agreement would be revised to require FICC and CME to notify each other in the event a material problem arises with respect to a Cross-Margining Customer in the same manner as they are currently required to do with respect to Cross-Margining Participants.³¹

D. Default Management

The Third A&R Agreement would include certain adjustments to the default management provisions to describe how the Clearing Organizations would address a default of an Eligible BD-FCM that is carrying Customer Positions for Cross-Margining Customers, elaborate on the steps the Clearing Organizations may take in a joint liquidation, and clarify when the Clearing Organizations may manage the default of a Cross-Margining Participant independently of one another.

The Third A&R Agreement would subject Customer Positions to substantially the same default management process as Proprietary Positions. In particular, under Section

²⁵ 17 CFR 39.13(g)(8)(i); GSD Rules, Rule 4, Section 1b(b).

²⁶ See Section 1 of the proposed Third A&R Agreement.

²⁷ See *id.*

²⁸ See Section 2(d) of the proposed Third A&R Agreement.

²⁹ See Sections 4(a), (c), and (e) of the proposed Third A&R Agreement.

³⁰ See Section 1 of the proposed Third A&R Agreement.

³¹ See Section 6(b) of the proposed Third A&R Agreement.

²¹ See *id.*

²² See *id.*

²³ See Section 1 of the proposed Third A&R Agreement.

²⁴ See Section 2(a) of the proposed Third A&R Agreement.

7(b) of the Third A&R Agreement, the Clearing Organizations would attempt in good faith to jointly transfer, liquidate, or close-out the Proprietary Positions or Customer Positions, which may include a joint liquidating auction so that hedged positions can be closed-out simultaneously or, in the case of a transfer of Customer Positions, so that the positions of each Cross-Margining Customer in a Combined Portfolio can, if feasible, be transferred to the same clearing firm. Section 7(b) would further provide that if one Clearing Organization determines that such joint action is not feasible or advisable for any Liquidation Portfolio, then either Clearing Organization could buy-out the Proprietary Positions or Customer Positions in such Liquidation Portfolio at the other Clearing Organization in accordance with the existing terms of the Third A&R agreement related to buy-outs. Lastly, Section 7(b) would provide that if one Clearing Organization determines that neither the joint transfer, liquidation, or close-out option nor the buy-out option is legally permissible or possible as to a particular Liquidation Portfolio, or if such methods would result in substantially greater losses to each Clearing Organization than in the case of a separate liquidation by each Clearing Organization, the Clearing Organizations could conduct separate liquidations in accordance with the existing terms related to such separate liquidations.³² The Clearing Organizations do not foresee particular circumstances that could lead to separate liquidations being applicable. To the contrary, the Clearing Organizations believe it is highly unlikely that they would engage in separate liquidations. However, the Clearing Organizations believe it is prudent to have a separate liquidation option so that there is a clear methodology in the very unlikely event that some unforeseen circumstance causes it not to be possible or legally permissible to conduct a joint liquidation or buy-out or for such methods to result in substantially greater costs.

The Third A&R Agreement would also include provisions designed to ensure that Customer Positions and associated margin are not used by either Clearing Organization to satisfy obligations arising from Proprietary Positions. The principal mechanism to achieve this would be a new concept of a "Liquidation Portfolio," which would be defined as, with respect to a

Defaulting Member, all such Defaulting Member's Proprietary Cross-Margining Account(s) or all such Defaulting Member's Customer Cross-Margining Account(s).³³ The definitions of "Collateral on Hand," "Net Gain," "Net Loss," "Cross-Margin VM Gain," "Cross-Margin VM Loss," "Other VM Gain," "Liquidation Cost," and "Share of the Cross-Margining Requirement," in turn, would be revised so that they are separately determined by reference to each Liquidation Portfolio, rather than to a Defaulting Member or Cross-Margining Account.³⁴ The Third A&R Agreement would also provide for the concept of a "Related GSD Account," which would be defined as, with respect to a Liquidation Portfolio of a Defaulting Member consisting of Proprietary Cross-Margining Accounts, the "Proprietary Accounts" (as defined in the GSD Rules) of the Defaulting Member at FICC, and with respect to a Liquidation Portfolio of a Defaulting Member consisting of Customer Cross-Margining Accounts, the Indirect Participant Account(s) of the Defaulting Member at FICC.³⁵

In addition, the Third A&R Agreement would revise Sections 7(b) through (g) to clarify that the provisions thereof would apply separately to each Liquidation Portfolio. These changes include replacing certain references to "Cross-Margining Account" with "Liquidation Portfolio,"³⁶ additional language specifying that provisions apply with respect to each Liquidation Portfolio,³⁷ and deletions of language providing for liquidation actions or calculations to be performed with respect to a Defaulting Member.³⁸ In addition, as mentioned above, the definition of "Combined Portfolio" would be revised to mean, in the case of a Pair of Cross-Margining Accounts consisting of Proprietary Cross-Margining Accounts, all Eligible Positions in such Cross-Margining Accounts, and in the case of a Pair of Cross-Margining Accounts consisting of Customer Cross-Margining Accounts, all Eligible Positions of a single Customer in such Cross-Margining Accounts.³⁹

By virtue of these changes, upon a default of a Joint Clearing Member, the Proprietary Positions and associated margin of the Joint Clearing Member

would be closed-out and netted into a single Net Gain or Net Loss, and the Customer Positions and associated margin would be separately close-out and netted into a separate Net Gain or Net Loss. As a result of these separate calculations, Customer Positions and associated margin could not be used to satisfy obligations arising under any Proprietary Positions. Similarly, variation margin gains in respect of Customer Positions would not be available to address losses on Proprietary Positions. However, the definition of "Other VM Gains" would be modified to make clear that, if there were Cross-Margin VM Gains in relation to Proprietary Positions at a time when the Clearing Organization with those Cross-Margin VM Gains also had losses on account of Customer Positions, the VM Gains may first be applied to satisfy the losses on the Customer Positions before being remitted to the other Clearing Organization.⁴⁰

Although the Clearing Organizations would generally close-out and net the Liquidation Portfolios of a Defaulting Member separately, Section 7(a) of the Third A&R Agreement would provide that the decision as to whether to commence the liquidation process with respect to a Joint Clearing Member would be made based on the Joint Clearing Member itself, rather than a particular Liquidation Portfolio. In accordance with this framework, Section 7(a) of the Third A&R Agreement would provide that if one Clearing Organization decides not to take default action against a Defaulting Member following a Default Event (the "Non-Liquidating CO"), the Non-Liquidating CO shall immediately require the Defaulting Member to pay the Non-Liquidating CO in immediately available funds the sum of (x) its Margin Reduction at the other Clearing Organization for all Combined Portfolios of the Defaulting Member, and (y) its Margin Reduction at the Non-Liquidating CO for all Combined Portfolios of the Defaulting Member, within one hour of demand.⁴¹

E. Conforming Changes

The Third A&R Agreement would also include a number of conforming changes in light of the addition of the Customer Cross-Margining Arrangement. These would include new recitals which describe the purpose of the Third A&R Agreement as to establish the Customer Cross-Margining Arrangement, introduce defined terms

³³ See Section 1 of the proposed Third A&R Agreement.

³⁴ *Id.*

³⁵ *Id.*

³⁶ See Sections 7(c), (d), and (e) of the proposed Third A&R Agreement.

³⁷ See Sections 7(b), (c), (e), (f), and (g) of the proposed Third A&R Agreement.

³⁸ See Section 7(c) of the proposed Third A&R Agreement.

³⁹ See Section 1 of the proposed Third A&R Agreement.

⁴⁰ See *id.*

⁴¹ See Section 7(a) of the proposed Third A&R Agreement.

³² See Section 7(b) of the proposed Third A&R Agreement.

for the “Proprietary Cross-Margining Arrangement” and “Customer Cross-Margining Arrangement,” and define the prior versions of the agreement as the “Original Agreement,” the “First A&R Agreement,” and the “Second A&R Agreement.” They would also include non-substantive revisions and movements of defined terms as shown in Exhibit 5 to conform to the addition of the Customer Cross-Margining Arrangement and the provisions described above.⁴²

The Third A&R Agreement would also revise Section 3(b), which sets out certain requirements applicable to positions of Eligible Affiliates, to provide that it does not apply to Proprietary Positions of a Joint Clearing Member or to Customer Positions.⁴³

In addition, the Third A&R Agreement would revise Section 7(i) to clarify that the requirement for a Defaulting Member to reimburse a Clearing Organization in the event that the Clearing Organization is obligated to make a guaranty payment to the other Clearing Organization in respect of an obligation of such Defaulting Member applies in respect of the obligations of any Cross-Margining Customer.⁴⁴

F. Clarifying Edits

The Third A&R Agreement would also include a number of clarifying edits not specifically related to the Customer Cross-Margining Arrangement. Specifically, Section 2(f) of the Third A&R Agreement would specify that FICC or CME may terminate the participation of a particular Cross-Margining Participant with respect to some or all Cross-Margining Accounts of the Cross-Margining Participant upon two business days’ prior written notice to the other Clearing Organization, provided that no such termination would be effective with respect to any reimbursement obligation or guaranty with respect to such Cross-Margining Participant that was incurred prior to such termination, or with respect to Section 7 of the Third A&R Agreement until the Stand-Alone Margin Requirement with respect to each Cross-

Margining Account subject to such termination has been fully satisfied.⁴⁵

The Third A&R Agreement would also include a new Section 5 to make clear that, as is currently the case, the collateral acceptable to satisfy the Cross-Margin Requirement must meet the respective eligibility requirements of the Clearing Organization to which the collateral is posted.⁴⁶

In addition, the titles of the Proprietary Cross-Margining Agreements in Appendix A and Appendix B of the Third A&R Agreement would be amended to specify that they are for use in connection with the Proprietary Cross-Margining Arrangement.⁴⁷

G. Customer Cross-Margining Clearing Member Agreement

As described above, an Eligible BD-FCM would be required to enter into the Customer Cross-Margining Clearing Member Agreement in order to participate in the Customer Cross-Margining Agreement. The Customer Cross-Margining Clearing Member Agreement would be set forth in Appendix C to the Third A&R Agreement.⁴⁸

The Customer Cross-Margining Clearing Member Agreement would be modeled on the Proprietary Clearing Member Agreement in Appendix A of the Second A&R Agreement (the “Existing Joint Clearing Member Proprietary Clearing Member Agreement”), with changes designed to facilitate compliance with the conditions in the Proposed Orders and to clarify the rights and obligations of the Clearing Organizations, the Eligible BD-FCM, and the Cross-Margining Customers.⁴⁹

The first three paragraphs of the Customer Cross-Margining Clearing Member Agreement would be substantially identical to those of the Existing Joint Clearing Member Proprietary Clearing Member

Agreement, except that the first paragraph would note that the Eligible BD-FCM is electing to become a Cross-Margining Participant for purposes of the Customer Cross-Margining Arrangement, rather than the Cross-Margining Arrangement generally, and the third paragraph (concerning the Eligible BD-FCM’s payment obligations) would reference the payment obligations arising in respect of Customer Cross-Margining Accounts.

The Customer Cross-Margining Clearing Member Agreement would provide that the Eligible BD-FCM makes application to the Clearing Organizations to establish a Customer Cross-Margining Account at CME and one or more Customer Cross-Margining Accounts at FICC in the name of the Eligible BD-FCM, and clarify that each such account would be in addition to any Proprietary Cross-Margining Account of the Eligible BD-FCM established pursuant to the Third A&R Agreement. The Customer Cross-Margining Clearing Member Agreement would provide that each Customer Cross-Margining Account shall be limited to transactions and positions carried by the Eligible BD-FCM for Cross-Margining Customers who have signed a Customer Agreement. The Eligible BD-FCM would be required to agree that it shall not commence clearing transactions through or carrying positions in a Customer Cross-Margining Account for any Cross-Margining Customer until such Cross-Margining Customer has executed a Customer Agreement.

The Eligible BD-FCM would be required under the Customer Cross-Margining Clearing Member Agreement to indemnify and hold harmless the Clearing Organizations, their respective directors, officers and employees and each person, if any, who controls either of the Clearing Organizations against any claims, losses, liabilities and expenses, including, without limitation, reasonable legal fees and expenses and amounts paid or payable in settlement of any action, proceeding or investigation arising from any claim by any party resulting from the carrying of positions in a Customer Cross-Margining Account that belong to any person other than a Cross-Margining Customer for whom a Customer Agreement is in effect.

The Customer Cross-Margining Clearing Member Agreement would provide that the Eligible BD-FCM, as agent for each of its Cross-Margining Customers, (i) unconditionally promises immediate payment of any payment or reimbursement obligations to a Clearing Organization arising under the Third

⁴² See Section 1 of the proposed Third A&R Agreement; *see, e.g.*, Section 3(c) of the proposed Third A&R Agreement (updating references to “Cross-Margining Account(s)” to refer to “Proprietary Cross-Margining Account(s)”; Section 7(a) of the proposed Third A&R Agreement (updating a reference to “Eligible Affiliates” to refer to “Eligible Affiliates or Customers”).

⁴³ See Section 3(b) of the proposed Third A&R Agreement.

⁴⁴ See Section 7(i) of the proposed Third A&R Agreement.

⁴⁵ See Section 2(f) of the proposed Third A&R Agreement.

⁴⁶ See Recitals, Section 1, and Section 5 of the proposed Third A&R Agreement.

⁴⁷ See Appendix A “Fixed Income Clearing Corporation/Chicago Mercantile Exchange Inc. Cross-Margining Participant Agreement (Common Member) [Proprietary Cross-Margining Program]” of the proposed Third A&R Agreement; Appendix B “Fixed Income Clearing Corporation/Chicago Mercantile Exchange Inc. Cross-Margining Participant Agreement (Common Member) [Proprietary Cross-Margining Program]” of the proposed Third A&R Agreement.

⁴⁸ See Appendix C “Fixed Income Clearing Corporation/Chicago Mercantile Exchange Inc. Cross-Margining Participant Agreement (Common Member) [Customer Cross-Margining Program]” of the proposed Third A&R Agreement.

⁴⁹ See *id.*

A&R Agreement or the GSD Rules or rules of CME in respect of a Cross-Margining Customer's positions in a Customer Cross-Margining Account, and (ii) agrees that each Cross-Margining Customer is bound by the GSD Rules and the rules of CME as applicable to them and by the provisions of the Customer Cross-Margining Clearing Member Agreement and the Third A&R Agreement. The Eligible BD-FCM would also be required to represent and warrant to the Clearing Organizations that it has full power and authority to bind each of its Cross-Margining Customers to the terms in the foregoing sentence.

The Customer Cross-Margining Clearing Member Agreement would also provide for the Eligible BD-FCM to pledge, as security for its and its Cross-Margining Customers' present and future payment and reimbursement obligations to FICC and CME arising from its Customer Cross-Margining Accounts or otherwise under the Customer Cross-Margining Clearing Member Agreement on behalf of itself and each Cross-Margining Customer, and grant to each Clearing Organization a first priority continuing security interest in, lien on and right of set-off against all of the positions, margin deposits or other property held by or subject to the control of or owing from either Clearing Organization including any and all Net Gains in respect of the Eligible BD-FCM's Customer Cross-Margining Accounts and the proceeds in respect thereof.

The Eligible BD-FCM would also provide for the Eligible BD-FCM to agree that (i) the rights of each Clearing Organization set forth in the preceding paragraph are in addition to any other rights arising out of the NYUCC or other statute, common law, or governmental regulation, or under their respective rules, (ii) the Eligible BD-FCM will execute, deliver, file and record any financing statement, specific assignment or other document and take any other action necessary or desirable and reasonably requested by FICC or CME to create, preserve, perfect or validate the security interest or lien granted in this paragraph, to enable such Clearing Organization to exercise or enforce its rights, (iii) the Eligible BD-FCM will promptly give notice to the Clearing Organizations of, and defend against, any suit, action, proceeding or lien that involves or could adversely affect the security interest and lien granted by the Eligible BD-FCM, and (iv) the Eligible BD-FCM authorizes FICC to comply with CME's entitlement orders with respect to any Cross-Margining Customer Margin pursuant to the Third

A&R Agreement without further consent of the Eligible BD-FCM or Cross-Margining Customer for whom such Cross-Margining Customer Margin is held. Clauses (i) through (iii) broadly align with the Existing Joint Clearing Member Proprietary Clearing Member Agreement, while clause (iv) would be designed to facilitate the perfection of CME's security interest in the Cross-Margining Customer Margin and help ensure that Cross-Margining Customer Margin is treated as "customer property" under Part 190 of the CFTC's regulations, as described in the Petitions.

The Customer Cross-Margining Clearing Member Agreement would contain the same provision regarding the disclosure of Clearing Data as in the Existing Joint Clearing Member Proprietary Clearing Member Agreement. Consistently with the Existing Joint Clearing Member Proprietary Clearing Member Agreement, it would also provide that neither FICC nor CME guarantees to the Eligible BD-FCM that the calculation of the margin reduction for a Combined Portfolio pursuant to the Third A&R Agreement will yield any, or the highest possible, margin reduction for the Combined Portfolio. The Customer Cross-Margining Clearing Member Agreement would also, as in the Existing Joint Clearing Member Proprietary Clearing Member Agreement, provide that, without limiting any provision of the GSD Rules, the rules of CME or any other agreement between the Eligible BD-FCM and FICC or CME, any transfer by the Eligible BD-FCM or any Cross-Margining Customer of any rights it may have in the Net Gain (or any component thereof) shall be null and void and, in any event, subject to the prior payment in full of all payment and reimbursement obligations under the Third A&R Agreement. The Customer Cross-Margining Clearing Member Agreement would contain the same representations as the Existing Joint Clearing Member Proprietary Clearing Member Agreement, except those concerning the proprietary nature of the positions and Eligible Affiliates.

The Customer Cross-Margining Clearing Member Agreement would specify that the Eligible BD-FCM may terminate the Customer Cross-Margining Clearing Member Agreement upon two business day's written notice to FICC and CME, and that such termination shall be effective upon written acknowledgement by both FICC and CME provided that (i) all positions in the Customer Cross-Margining Accounts have been closed-out or transferred to other accounts in accordance with the

GSD Rules or the rules of CME, and (ii) all Stand-alone Margin Requirement in respect of any such transferred positions and all obligations of the Eligible BD-FCM to the Clearing Organizations in respect of the Customer Cross-Margining Accounts have been fully satisfied.

The Customer Cross-Margining Clearing Member Agreement would also specify that either Clearing Organization may terminate the Eligible BD-FCM's participation with respect to any Customer Cross-Margining Account (defined as an "Affected Customer Cross-Margining Account") of the Eligible BD-FCM at any time upon written notice to the other Clearing Organization pursuant to the Third A&R Agreement and to the Eligible BD-FCM. In connection with such termination, the Clearing Organizations would be permitted to require the Eligible BD-FCM to close-out or transfer all positions in the Affected Customer Cross-Margining Accounts in accordance with the GSD Rules or the rules of CME, and the Customer Cross-Margining Clearing Member Agreement would thereupon terminate with respect to Affected Customer Cross-Margining Accounts, provided that the Stand-alone Margin Requirement in respect of the transferred positions and all obligations of the Eligible BD-FCM to the Clearing Organizations in respect of the Affected Customer Cross-Margining Accounts have been fully satisfied.

The Customer Cross-Margining Clearing Member Agreement would also include the same governing law, choice-of-jurisdiction, and execution in counterparts provisions as the Existing Joint Clearing Member Proprietary Clearing Member Agreement. The Customer Cross-Margining Clearing Member Agreement would also provide that it would become effective upon the later of execution of the Customer Cross-Margining Clearing Member Agreement, or on the receipt of all necessary regulatory approvals from the Commission and the CFTC.

H. Customer Agreement

The Customer Agreement would include the terms of the Subordination Agreement and acknowledgements corresponding to the disclosures required by the Proposed Orders.⁵⁰ In particular, the Customer Agreement would require the Cross-Margining Customer to acknowledge and agree that:

- it agrees to the terms of the Subordination Agreement, under which

⁵⁰ See Appendix C, Exhibit I "Customer Required Terms Annex or Agreement" of the proposed Third A&R Agreement.

the Cross-Margining Customer agrees that all of its Customer Positions and Customer Property (including any margin at FICC) (i) will not receive customer treatment under the Exchange Act or SIPA or be treated as “customer property” as defined in 11 U.S.C. 741 in a liquidation of Clearing Member, and (ii) will be subject to any applicable protections under Subchapter IV of Chapter 7 of the U.S. Bankruptcy Code and rules and regulations thereunder including Part 190 of the CFTC’s Regulations (“Part 190”), and that the Cross-Margining Customer’s claims to “customer property” as defined in SIPA or 11 U.S.C. 741 against the Eligible BD-FCM with respect to its Customer Positions and Customer Property (including any margin held at FICC) will be subordinated to the claims of all other customers, as the term “customer” is defined in 11 U.S.C. 741 or SIPA;⁵¹

- all money, securities and property deposited with the Eligible BD-FCM by the Cross-Margining Customer to margin, guarantee or secure Customer Positions (the “Customer Property”) will be held in a “futures account” as defined in CFTC Regulation 1.3 and subject to CEA Section 4d(a) and (b);⁵²

- its Customer Positions and associated margin may be commingled with the positions and property of other customers of the Eligible BD-FCM and may be used by the Eligible BD-FCM to purchase, margin, secure, settle, or otherwise carry positions on behalf of the Cross-Margining Customer or other futures customers of the Eligible BD-FCM;⁵³

- property held in connection with Customer Positions will be treated in a manner consistent with the CFTC Order and that such property held on the Cross-Margining Customer’s behalf by the Eligible BD-FCM will be customer property received by an FCM to be accounted for, treated and dealt with by such FCM in a manner consistent with Section 4d of the CEA;⁵⁴

- in the event a Clearing Organization suspends or ceases to act for Clearing Member, it shall be within the sole discretion of the Clearing Organizations to determine whether to transfer, liquidate, or settle Customer Positions in the relevant Customer Cross-Margining Account;⁵⁵

- its participation in the Customer Cross-Margining Arrangement is subject to the terms of (i) the Third A&R Agreement, (ii) the Customer Cross-

Margining Clearing Member Agreement, and (iii) the GSD Rules and the rules of CME;⁵⁶ and

- if CME determines at any time that any Eligible Positions of the Cross-Margining Customer cleared through the Customer Cross-Margining Account at CME are non-risk reducing, CME may either restrict the Cross-Margining Customer from adding positions or require the Cross-Margining Customer to move or liquidate Eligible Positions in the Customer Cross-Margining Account at CME;⁵⁷

The Customer Agreement would also require the Cross-Margining Customer to pledge, as security for the Cross-Margining Customer’s present and future payment and delivery obligations in respect of its Customer Positions (including, without limitation, any obligation of the Cross-Margining Customer to reimburse the Eligible BD-FCM as a result of the Eligible BD-FCM’s performance of such obligations), and grant to the Eligible BD-FCM a continuing security interest in, lien on and right of set-off against its right, entitlement, and interest in all of positions in each Customer Cross-Margining Account, all margin posted by the Cross-Margining Customer in connection with such positions, and the proceeds in respect thereof.⁵⁸ The Customer Agreement would also require the Cross-Margining Customer to agree that the Eligible BD-FCM may enter into agreements with the Clearing Organizations on the Cross-Margining Customer’s behalf as set forth in the Customer Cross-Margining Clearing Member Agreement.⁵⁹

(ii) Other Proposed Changes to the GSD Rules

A. Overview

FICC is proposing to make a number of changes to the GSD Rules to effectuate the Customer Cross-Margining Arrangement.

First, FICC proposes to create a new position Account type, the “Cross-Margining Customer Account,” in which Customer Positions would be recorded. The Cross-Margining Customer Account would constitute an “Indirect Participants Account.” A Netting Member that is an Eligible BD-FCM and approved participant in the Customer Cross-Margining Arrangement would be permitted to designate an Indirect Participants Account (other than a Segregated Indirect Participants Account) as a Cross-Margining

Customer Account.⁶⁰ Any such designation would constitute a representation to FICC by the Netting Member that the Netting Member has complied with all regulatory requirements applicable to it in connection with its participation in the Customer Cross-Margining Arrangement, including the conditions in the Proposed Orders, and this representation would be deemed repeated each time the Netting Member deposits Cross-Margining Customer Margin.

Second, FICC proposes to adopt rule changes to set forth how FICC would calculate, collect, and hold margin for positions recorded in a Cross-Margining Customer Account. As noted above, FICC proposes to collect and hold Cross-Margining Customer Margin pursuant to substantially similar provisions as apply to Segregated Customer Margin, with certain modifications to satisfy the requirements of the Proposed Orders and align with the treatment of futures margin. Specifically:

- Consistent with Segregated Customer Margin and in accordance with the Proposed Orders, FICC would credit all Cross-Margining Customer Margin deposited by a Netting Member to a “securities account,” as defined in the NYUCC,⁶¹ on its books and records maintained for that Netting Member for the benefit of its Cross-Margining Customers (*i.e.*, a Cross-Margining Customer Margin Custody Account). The GSD Rules would further provide that all cash and securities credited to the Cross-Margining Customer Margin Custody Account shall be treated as “financial assets” within the meaning of Article 8 of the NYUCC, New York shall be the “securities intermediary’s jurisdiction” for purposes of the NYUCC and New York law shall govern all issues specified in Article 2(1) of the Hague Securities Convention.⁶² Such provisions are designed to ensure the Cross-Margining Customer Margin would not form part of FICC’s estate in the event FICC became subject to insolvency proceedings. They would also facilitate the ability of CME to perfect its security interest in the Cross-Margining Customer Margin. Such

⁶⁰ As mentioned above, the Third A&R Agreement would provide that a Netting Member may only designate one Sponsoring Member Omnibus Account and one Agent Clearing Member Omnibus Account as a Cross-Margining Customer Account. See Section 2(d) of the proposed Third A&R Agreement.

⁶¹ NYUCC § 8–501(a).

⁶² NYUCC § 8–102(9); NYUCC § 8–110(e); The Convention on the Law Applicable to Certain Rights in Respect of Securities Held with an Intermediary, July 5, 2006, 17 U.S.T. 401, 46 I.L.M. 649 (entered into force Apr. 1, 2017).

⁵¹ See *id.*, Section 2(b).

⁵² See *id.*, Section 2(a).

⁵³ See *id.*, Section 2(c).

⁵⁴ See *id.*

⁵⁵ See *id.*, Section 2(d).

⁵⁶ See *id.*, Section 3.

⁵⁷ See *id.*

⁵⁸ See *id.*, Section 4.

⁵⁹ See *id.*, Section 5.

perfection would serve to protect CME, and in turn both the Cross-Margining Customers and the non-participating futures customers in the event of a Cross-Margining Participant default. It would also aim to ensure that the Cross-Margining Customer Margin is treated as “customer property” under Part 190 in the event of an Eligible BD–FCM’s insolvency, by helping to establish that the Cross-Margining Customer Margin is held to secure the futures positions of customers.

- In accordance with the Proposed Orders, FICC would hold Cross-Margining Customer Margin in (i) an account of FICC at a bank insured by the Federal Deposit Insurance Corporation (“FDIC”) that is segregated from any other account of FICC and used exclusively to hold Cross-Margining Customer Margin, and (ii) an account at the FRBNY that is segregated from any other account of FICC and used exclusively to hold Segregated Customer Margin and Cross-Margining Customer Margin. The GSD Rules would provide that any such account (other than one at the FRBNY) would need to be subject to a written notice consistent with the Proposed Orders.

- The same requirements applicable to Segregated Customer Margin with respect to the form and composition of eligible collateral, the minimum amounts of cash and Eligible Clearing Fund Treasury Securities, substitution and withdrawal, and treatment of excess margin would be applicable to Cross-Margining Customer Margin, except that (i) a Netting Member’s rights or FICC’s obligation with respect to any excess Cross-Margining Customer Margin would be subject to the Third A&R Agreement and the Customer Cross-Margining Clearing Member Agreement, and (ii) FICC would be permitted to retain the excess Cross-Margining Customer Margin deposited by a Netting Member with respect to a Cross-Margining Customer when the Netting Member has any outstanding payment or margin obligation arising from any Customer Positions, including those of another Cross-Margining Customer.

With regard to calculation, FICC proposes that, as with Segregated Customer Margin and in accordance with the requirements of the Proposed Orders, FICC would calculate the margin requirement in respect of each Cross-Margining Customer Account (the “Cross-Margining Customer Margin Requirement”) on a gross (*i.e.*, Cross-Margining Customer-by-Cross-Margining Customer) basis, as though each Cross-Margining Customer were a separate Netting Member. However, such margin requirement would be

subject to any margin reduction pursuant to the Third A&R Agreement (which, as discussed above, would be determined using the same margin reduction methodology under Proprietary Cross-Margining Arrangement).

Third, FICC proposes to provide that Cross-Margining Customer Margin would be pledged to FICC to secure all obligations of the Netting Member and its Cross-Margining Customers arising under Customer Positions.⁶³

Fourth, FICC proposes to remove the existing Section 10(e) of Rule 3A, which currently prohibits Sponsored Members from participating in the Cross-Margining Arrangement.

Fifth, FICC proposes to make conforming changes to Rule 43, which sets out the terms related to Cross-Margining Arrangements, so that the Rule encompasses the Customer Cross-Margining Arrangement. In particular, FICC proposes to specify in Rule 43 that a Netting Member that is an Eligible BD–FCM may become a Cross-Margining Participant in connection with the Customer Cross-Margining Arrangement with the consent of FICC and CME. An Eligible BD–FCM would become such a Cross-Margining Participant and be permitted to establish a Cross-Margining Customer Account upon acceptance by FICC and CME of an executed Customer Cross-Margining Clearing Member Agreement. FICC further proposes to make clear that if FICC becomes obligated to make a payment to CME pursuant to the cross-guaranty under the Third A&R Agreement in relation to the obligations of a Cross-Margining Customer, both the Cross-Margining Customer and the relevant Eligible BD–FCM would be responsible for the reimbursement obligation that is owed to FICC as a result. If FICC receives a payment from CME pursuant to the Third A&R Agreement in connection with the Customer Cross-Margining Arrangement, FICC would not be permitted to apply such payment to any obligation other than the obligations of Cross-Margining Customers (whether or not arising in connection with any Eligible Positions).

Lastly, FICC proposes to remove provisions relating to “Market Professional” and “Market Professional

⁶³ We note that in this regard, unlike Segregated Customer Margin, FICC would be able to use all Cross-Margining Customer Margin to satisfy the obligations arising from all Customer Positions recorded in the same Cross-margining Customer Account, even if such Customer Positions are not the particular ones of the individual Cross-Margining Customer that posted such margin. This treatment would be consistent with how futures customer margin is generally treated.

Agreement for Cross-Margining” from the GSD Rules. Those provisions were adopted in connection with a “market professional” cross-margining program between FICC and New York Portfolio Clearing, LLC.⁶⁴ That program—which permitted certain “market professional” customers of Netting Members to participant in cross-margining—is no longer active as New York Portfolio Clearing, LLC has since become defunct.

B. Summary of Proposed Rule Changes

To effectuate the proposed changes described above, FICC proposes to make the following amendments to its Rules.

New Defined Terms. FICC would revise Rule 1 to add the following new defined terms: (1) “Cross-Margining Customer,” (2) “Cross-Margining Customer Account,” (3) “Cross-Margining Customer Margin Custody Account,” (4) “Cross-Margining Customer Margin,” (5) “Cross-Margining Customer Margin Requirement,” and (6) “Customer Cross-Margining Arrangement.”

The term “Cross-Margining Customer” would mean a Sponsored Member or Executing Firm Customer whose Transactions are recorded in a Cross-Margining Customer Account.

The term “Cross-Margining Customer Account” would mean an Indirect Participants Account maintained by FICC for a Sponsoring Member or an Agent Clearing Member that has been designated pursuant to Rule 2B for purposes of recording Transactions of Cross-Margining Customers.

The term “Cross-Margining Customer Margin Custody Account” would mean a securities account within the meaning of the NYUCC maintained by FICC, in its capacity as securities intermediary as such term is used in the NYUCC, for an Agent Clearing Member or Sponsoring Member for the benefit of such Member’s Cross-Margining Customers.

The term “Cross-Margining Customer Margin” would mean all securities and funds deposited by a Sponsoring Member or an Agent Clearing Member with FICC to satisfy its Cross-Margining Customer Margin Requirement.

The term “Cross-Margining Customer Margin Requirement” would mean the amount of cash or Eligible Clearing Fund Securities that an Agent Clearing Member or Sponsoring Member is required to deposit with FICC to support the obligations arising from Transactions recorded in its Cross-

⁶⁴ See Self-Regulatory Organizations; Fixed Income Clearing Corporation; Order Approving Proposed Rule Change To Expand the One-Pot Cross-Margining Program With New York Portfolio Clearing, LLC to Certain “Market Professionals,” 77 FR 30032 (May 21, 2012).

Margining Customer Accounts. Specifically, a Netting Member's Cross-Margining Customer Margin Requirement would be the amount of the item listed in Section 2(a)(vii) of Rule 4 (as described below). This definition would specify that references to the Cross-Margining Customer Margin Requirement "for" or "with respect to" a particular Cross-Margining Customer Account or Cross-Margining Customer (or similar language) would mean the portion of a Netting Member's Cross-Margining Customer Margin Requirement arising from such Account or Cross-Margining Customer.

The term "Customer Cross-Margining Arrangement" would mean a Cross-Margining Arrangement pursuant to which a Cross-Margining Participant, at the discretion of FICC and in accordance with the provisions of Rule 43, may elect to have any of its Cross-Margining Customers' margin requirement in respect of Eligible Positions at FICC and such Cross-Margining Customer's margin requirements in respect of Eligible Positions at a clearing organization for a board of trade designated as a contract market under Section 5 of the CEA that has entered into a Cross-Margining Agreement with FICC (an "FCO") calculated by taking into consideration the net risk of such Eligible Positions at each of the clearing organizations.

Revisions to Defined Terms. In addition, FICC would make conforming revisions to the following defined terms in Rule 1: (1) "Cross-Margining Affiliate," (2) "Cross-Margining Agreement," (3) "Current Net Settlement Positions," (4) "Indirect Participants Account," and (5) "Type of Account" and "Type."

FICC proposes to amend the definition to "Cross-Margining Affiliate" to remove existing prong (ii), which relates to the "market professional" cross-margining program.

FICC proposes to amend the definition to "Cross-Margining Agreement" to encompass the Customer Cross-Margining Arrangement by specifying that the applicable Cross-Margining Participant may have any of its Cross-Margining Customers' margin requirement in respect of Eligible Positions at FICC and such Cross-Margining Customer's margin requirements in respect of Eligible Positions at a relevant FCO calculated by taking into consideration the net risk of such Eligible Positions at each of the clearing organizations. FICC also proposes to remove the last sentence of this definition, which relates to the "market professional" cross-margining program.

FICC proposes to make conforming edits to the definition of "Current Net Settlement Positions" to add references to "Cross-Margining Customer," "Cross-Margining Customer Account," and "Cross-Margining Customer Margin Requirement" after each reference to "Segregated Indirect Participant," "Segregated Indirect Participants Account," and "Segregated Customer Margin Requirement," respectively.

FICC proposes to amend the definitions of "Indirect Participants Account," "Type of Account" and "Type" to include a Cross-Margining Customer Account.

Removal of defined terms. FICC proposes to remove the following defined terms from Rule 1: (1) "Market Professional" and (2) "Market Professional Agreement for Cross-Margining."

Establishment of Cross-Margining Customer Accounts. FICC proposes to amend Section 3 of Rule 2B to provide that a Cross-Margining Customer Account may not be designated as a Segregated Indirect Participants Account.

In addition, FICC proposes to add a new Section 3a of Rule 2B to provide that (i) a Netting Member that is an Eligible BD-FCM and has been approved to become a Cross-Margining Participant in a Customer Cross-Margining Arrangement pursuant to a Cross-Margining Agreement may designate any of its Indirect Participants Accounts (other than a Segregated Indirect Participants Account) as a Cross-Margining Customer Account; (ii) any such designation of an Account shall constitute a representation to FICC by the Netting Member that the Netting Member has complied with all regulatory requirements applicable to it in connection with its participation in the Customer Cross-Margining Arrangement, including the conditions in the Proposed Orders; and (iii) the Netting Member shall be deemed to repeat this representation each time it deposits Cross-Margining Customer Margin.

Treatment of Cross-Margining Customer Margin. FICC proposes to make the following changes in relation to FICC's calculation, collection, and holding of Cross-Margining Customer Margin:

FICC proposes to amend Section 1a of Rule 4 to make clear that FICC's account at the FRBNY that is currently used to hold Segregated Customer Margin would also hold Cross-Margining Customer Margin.

FICC proposes to renumber current Section 1b of Rule 4 to Section 1c and

add a new Section 1b. The new Section 1b would provide that:

- Each Netting Member shall deposit Cross-Margining Customer Margin with FICC in an amount equal to its Cross-Margining Customer Margin Requirement, which requirement shall be determined in accordance with Rule 4 and the Margin Component Schedule. The timing of the satisfaction of the Cross-Margining Customer Margin Requirement shall be determined in accordance with the provisions of Section 9 of Rule 4.

- FICC shall establish and maintain on its books and records a Cross-Margining Customer Margin Custody Account to which all Cross-Margining Customer Margin deposited with FICC shall be credited. The Cross-Margining Customer Margin credited to a Cross-Margining Customer Margin Custody Account shall be used exclusively to secure the present and future payment and reimbursement obligations of the Netting Member and its Cross-Margining Customers in relation to Eligible Positions of the Netting Member's Cross-Margining Customers at FICC and CME.

- All assets credited to each Cross-Margining Customer Margin Custody Account shall be treated as "financial assets" within the meaning of Article 8 of the NYUCC. New York is the "securities intermediary's jurisdiction" for purposes of the NYUCC and New York law shall govern all issues specified in Article 2(1) of the Hague Securities Convention.

- FICC shall hold all Cross-Margining Customer Margin in an account of FICC at an FDIC-insured bank within the meaning of the Exchange Act that is a qualified custodian under the Investment Company Act of 1940, as amended, or at the FRBNY. Any account at an FDIC-insured bank shall be segregated from any other account of FICC and shall be used exclusively to hold Cross-Margining Customer Margin, and shall be subject to a written notice of the bank provided to and retained by FICC consistent with the Proposed Orders. The account at the FRBNY shall be segregated from any other account of FICC and shall be used exclusively to hold Cross-Margining Customer Margin and Segregated Customer Margin (the account at the FRBNY would not be subject to a written notice).

FICC proposes to amend current Section 1b (to be renumbered as Section 1c) of Rule 4 to (i) add references to "Cross-Margining Customer Accounts" after references to "Segregated Indirect Participants Accounts" in current Section 1b(a), and (ii) add a new sentence at the end of current Section 1b(b) to provide that FICC would

calculate the Cross-Margining Customer Margin Requirement for a Cross-Margining Customer Account as the sum of the requirements applicable to each Cross-Margining Customer whose Transactions are recorded in such Account, as though each such Cross-Margining Customer were a separate Netting Member with a single Margin Portfolio consisting of such Transactions, in accordance with the Margin Component Schedule.

FICC proposes to amend Section 2 of Rule 4 by (i) adding references to “Cross-Margining Customer Margin Requirement” after references to “Segregated Customer Margin Requirement” in the title of Section 2 and Section 2(a), and (ii) adding a new clause (vii) of Section 2(a) to specify that the Cross-Margining Customer Margin Requirement would be an amount calculated with respect to the Netting Member’s Cross-Margining Customer Accounts.

FICC proposes to add a new Section 2c of Rule 4 entitled “Cross-Margining Customer Margin Requirement” to provide that (i) each Netting Member shall deposit any Cross-Margining Customer Margin with FICC by the Required Fund Deposit Deadline through a separate Deposit ID established by the Netting Member for each Cross-Margining Customer Account, and (ii) FICC shall report the Cross-Margining Customer Margin Requirements to each Netting Member twice daily in a Report which shall specify the Cross-Margining Customer Margin Requirement for each Cross-Margining Customer Account.

FICC proposes to add a new Section 3(d) of Rule 4 and insert it before the last sentence of Section 3. The new Section 3(d) would provide that each Cross-Margining Customer Margin Requirement for a particular Cross-Margining Customer Account would be subject to the requirements that (i) a minimum of 40 percent of the Cross-Margining Customer Margin Requirement for such Account shall be satisfied with cash and/or Eligible Clearing Fund Treasury Securities, and (ii) a minimum of the product of \$1 million and the number of Cross-Margining Customers whose Transactions are recorded in such Cross-Margining Account must be made and maintained in cash. In addition, FICC proposes to amend the last sentence of Section 3 by adding a reference to “Cross-Margining Customer Margin Requirement” after the reference to “Segregated Indirect Participants Requirement.”

FICC proposes to amend Section 3a of Rule 4 to add a reference to “Cross-

Margining Customers” after the reference to “Segregated Indirect Participants.” FICC also proposes to amend Section 3b of Rule 4 to add a reference to “Cross-Margining Customer Margin Custody Account” after the reference to “Segregated Customer Margin Custody Account.”

FICC proposes to amend Sections 3a, 3b, and 9 of Rule 4 to add references to “Cross-Margining Customer Margin,” after each reference to “Segregated Customer Margin.” FICC also proposes to amend Sections 3b and 9 of Rule 4 to add references to “Cross-Margining Customer Margin Requirement,” after each reference to “Segregated Customer Margin Requirement.”

FICC proposes to add a new Section 4(c) of Rule 4 to provide that (i) as security for any and all obligations and liabilities of a Netting Member and any of its Cross-Margining Customers to FICC arising out of or in connection with any Cross-Margining Customer Accounts of such Netting Member or Transactions recorded therein, each such Netting Member on behalf of itself and its Cross-Margining Customers grants to FICC a first priority perfected security interest in its right, title and interest in and to all Cross-Margining Customer Margin, each Cross-Margining Customer Margin Custody Account, and all distributions thereon and proceeds thereof, and (ii) FICC shall be entitled to exercise the rights of a pledgee under common law and a secured party under Articles 8 and 9 of the NYUCC with respect to such assets.

FICC proposes to amend Section 5 of Rule 4 by (i) adding a reference to “Cross-Margining Customer Margin” after the reference to “Segregated Customer Margin” in the title of Section 5, and (ii) adding a new paragraph at the end of Section 5 to provide that FICC shall only use Cross-Margining Customer Margin deposited by a Netting Member to (A) secure the Transactions of Cross-Margining Customers of such Netting Member recorded in any Cross-Margining Customer Account and satisfy payment and delivery obligations owing to FICC (including liquidating or otherwise using such Cross-Margining Customer Margin to obtain relevant cash or securities) in connection with a default in respect of such Transactions; and (B) for investment in U.S. Treasury securities with a maturity of one year or less.

FICC proposes to amend Section 10 of Rule 4 by (i) adding a reference to “Cross-Margining Customer Margin” after the reference to “Segregated Customer Margin” in the title of Section 10, (ii) amending the first paragraph of Section 10 to require FICC to separately

determine whether the amount of Cross-Margining Customer Margin supporting a Cross-Margining Customer’s Transactions is in excess of the Cross-Margining Customer Margin Requirement for such Cross-Margining Customer (“Excess Cross-Margining Customer Margin”), and (iii) adding a new Section 10(c) to provide that upon a Member’s request, and in accordance with such procedures as FICC may set forth from time to time, the Corporation shall return to the Member its Excess Cross-Margining Customer Margin, subject to the minimum amount of cash or Eligible Clearing Fund Securities required to be maintained pursuant to the GSD Rules (valued at their collateral value on the day of such withdrawal) and the terms of the Third A&R Agreement and Customer Cross-Margining Clearing Member Agreement, as the Member requests, provided that, subject to the Third A&R Agreement and the Customer Cross-Margining Clearing Member Agreement, and except to the extent required by applicable law or authorized by the Commission, FICC shall not retain Excess Cross-Margining Customer Margin due to any obligations of the Member unrelated to a Cross-Margining Customer Account of such Member. Section 10(c) of Rule 4 would further provide that FICC may, at its discretion, retain some or all of the Excess Cross-Margining Customer Margin if the Member has an outstanding payment or margin obligation to the Corporation with respect to the Transactions of any Cross-Margining Customer.

FICC proposes to amend the Margin Component Schedule to set out how Cross-Margining Customer Margin Requirements would be determined. Specifically, FICC proposes to insert a new paragraph at the end of Section 1 to provide that (i) on each Business Day, each Netting Member for which FICC maintains a Cross-Margining Customer Account shall be required to deposit with FICC Cross-Margining Customer Margin equal to the sum of all Cross-Margining Customer Margin Requirements for all such Accounts, (ii) each Cross-Margining Customer Margin Requirement shall equal the sum of the amounts calculated pursuant to Section 3a of the Margin Component Schedule for each Cross-Margining Customer whose Transactions are recorded in the relevant Cross-Margining Customer Account, and (iii) each such calculation shall be performed twice daily or on a more frequent basis if FICC deems it appropriate pursuant to the Margin Component Schedule and subject to the provisions of Rule 4. Further, FICC

proposes to add a new Section 3a to the Margin Component Schedule titled “Cross-Margining Customer Margin Requirement Calculations” to set out how specifically such requirement would be calculated, which would be substantially identical to how Segregated Customer Margin Requirement is calculated as set out in Section 3 of the Margin Component Schedule. Finally, FICC proposes to amend Section 5 to add references to “Cross-Margining Customer,” “Cross-Margining Customer Account,” and “Cross-Margining Customer Margin Requirement” after each reference to “Segregated Indirect Participant,” “Segregated Indirect Participants Account,” and “Segregated Customer Margin Requirement,” respectively.

Description of the Customer Cross-Margining Arrangement. FICC proposes to amend Rule 43 to explicitly describe the Customer Cross-Margining Arrangement as follows:

FICC proposes to add a new Section 2(c) of Rule 43 to provide that (i) a Netting Member that is an Eligible BD-FCM may become a Cross-Margining Participant in connection with the Customer Cross-Margining Arrangement with the consent of FICC and CME, and (ii) an Eligible BD-FCM that would become such a Cross-Margining Participant shall be permitted to establish a Cross-Margining Customer Account upon acceptance by FICC and CME of an executed Customer Cross-Margining Clearing Member Agreement.

FICC proposes to amend Section 3 of Rule 43 to provide that, if FICC becomes obligated to make a payment to CME pursuant to the cross-guaranty under the Third A&R Agreement in relation to the obligations of a Cross-Margining Participant, its Cross-Margining Affiliate, or its Cross-Margining Customer, the Cross-Margining Participant (and, if FICC becomes obligated to make such a payment in respect of the obligations of a Cross-Margining Customer, the Cross-Margining Customer) shall thereupon immediately be obligated, whether or not FICC has then made payment to CME, to pay to FICC the amount of the reimbursement obligation that is owed to FICC as a result.

FICC proposes to add a new sentence at the end of Section 5 of Rule 43 to provide that, if FICC receives a payment from CME pursuant to the Third A&R Agreement in connection with the Customer Cross-Margining Arrangement, FICC would not be permitted to apply such payment to any obligation other than the obligations of Cross-Margining Customers (whether or

not arising in connection with any Eligible Positions).

Conforming and Clarifying Changes. FICC proposes to make the following conforming or clarifying changes:

FICC proposes to amend Section 4(b)(i) of Rule 2A to make clear that an applicant to become a Netting Member must have sufficient financial ability to make anticipated required deposits to not only Clearing Fund and Segregated Customer Margin, but also any Cross-Margining Customer Margin.

FICC proposes to remove Section 10(e) of Rule 3A to remove the current prohibition of Sponsored Members from participating in any Cross-Margining Arrangements, and accordingly renumber current Section 10(f) of Rule 3A to Section 10(e).

FICC proposes to remove (i) the language in parentheses in the first sentence of Section 1 of Rule 13, (ii) the second sentence in Section 2(b) of Rule 22A, and (iii) the portions of Sections 2(a) and 2(b) of Rule 43 that are crossed out in Exhibit 5, because those provisions relate to the “market professional” cross-margining program, which is no longer active and would not be used if the Customer Cross-Margining Arrangement becomes available.

(iii) Implementation of the Proposal

The proposed Third A&R Agreement would not become effective and replace the Second A&R Agreement until the latest of (i) the date on which all necessary regulatory approvals of the proposed Third A&R Agreement have been received by FICC and CME and (ii) a date agreed by FICC and CME.⁶⁵ Not later than two (2) business days following the date of the Commission’s approval of the proposed rule changes, FICC would add a legend to the proposed Third A&R Agreement to state that the specified changes are approved but not yet operative. The legend would also include the file number of the approved proposed rule change, and would state that once operative, the legend would automatically be removed from the proposed Third A&R Agreement. FICC would issue a notice to members providing notice of the specific operative date at least two weeks prior to such date.

2. Statutory Basis

FICC believes that the proposed rule change is consistent with Section 17A of the Exchange Act⁶⁶ and the rules thereunder applicable to FICC.

Section 17A(b)(3)(F) of the Exchange Act, requires, in part, that the rules of

a clearing agency be designed to assure the safeguarding of securities and funds which are in the custody or control of the clearing agency or for which it is responsible.⁶⁷ FICC believes that the proposed rule change would assure the safeguarding of securities and funds which are in its custody or control for which it is responsible for a number of reasons.

First, the proposed Third A&R Agreement and the proposed changes to the GSD Rules would provide for funds and securities posted by Cross-Margining Participants in respect of Customer Positions, *i.e.*, Cross-Margining Customer Margin, to be credited to the Cross-Margining Customer Margin Custody Account and treated as financial assets within the meaning of the NYUCC. These changes would have the effect of making FICC the “securities intermediary” in respect of such Cross-Margining Customer Margin and the Eligible BD-FCM, on behalf of its Cross-Margining Customers, the “entitlement holder” under the NYUCC.⁶⁸ By virtue of these designations, the Cross-Margining Customer Margin held by FICC would be unavailable to satisfy the claims of FICC’s general creditors and would be reserved for the Eligible BD-FCM (on behalf of its Cross-Margining Customers), including in an FICC insolvency.⁶⁹ Furthermore, the proposed changes would prohibit FICC from using Cross-Margining Customer Margin, except to satisfy the obligations arising from Customer Positions of the Cross-Margining Participant that posted such margin. Accordingly, it would reduce the possibility of such margin being exposed to loss on account of not only FICC’s insolvency, but also the default of the Cross-Margining Participant or another Netting Member. The proposed changes would thus assure the safeguarding of the Cross-Margining Customer Margin.

⁶⁷ 15 U.S.C. 78q-1(b)(3)(F).

⁶⁸ NYUCC § 8-102(7) (“‘Entitlement holder’ means a person identified in the records of a securities intermediary as the person having a security entitlement against the securities intermediary . . .”).

⁶⁹ See UCC § 8-503(a) (“To the extent necessary for a securities intermediary to satisfy all security entitlements with respect to a particular financial asset, all interests in that financial asset held by the securities intermediary are held by the securities intermediary for the entitlement holders, are not property of the securities intermediary, and are not subject to claims of creditors of the securities intermediary, except as otherwise provided in Section 8-511”). The exceptions to the foregoing rule in Section 8-511 only apply in the event that the securities intermediary has pledged the financial assets underlying the security entitlements to creditors, which would not be relevant here. See UCC § 8-511(b)-(c).

⁶⁵ See Section 18(j) of the proposed Third A&R Agreement.

⁶⁶ 15 U.S.C. 78q-1.

Second, the proposed changes adopting and implementing the Customer Cross-Margining Arrangement would reduce the likelihood of FICC, each Netting Member, and indirect participants incurring a loss on account of a default by aligning each Cross-Margining Customer's margin requirements with the risk of such Cross-Margining Customer's Eligible Positions. Such alignment would serve to incentivize a Cross-Margining Customer to maintain portfolios that present lower because such lower risk would generally lead to lower margin requirements. Lower risk portfolios, in turn, would serve to reduce the risk of such Cross-Margining Customer's default and the Cross-Margining Participant's and FICC's exposure thereto. Accordingly, by allowing a Cross-Margining Customer to engage in cross-margining activity, the proposed changes would serve to promote the risk-reducing effects of cross-margining that are currently only available to Cross-Margining Participants and their Eligible Affiliates. They would thus serve to enhance FICC's ability to safeguard the securities and funds in its control or for which it is responsible.

The lower margin requirements which would result from these changes would also incentivize Cross-Margining Customers to post initial margin in respect of their Eligible Positions, rather than rely on their Eligible BD-FCM to do so. Currently, FICC understands that it is common practice for Sponsoring Members and Agent Clearing Members to use their own assets to satisfy the FICC initial margin requirements associated with FICC-cleared positions that Eligible BD-FCMs carry for their customers.⁷⁰ This increases the costs to Sponsoring Members and Agent Clearing Members of offering customer clearing services and limits their capacity to do so. As a result of the proposed changes adopting and implementing the Customer Cross-Margining Arrangement, a Cross-Margining Customer's Eligible Positions at FICC would be eligible for a margin reduction if the Cross-Margining Customer posts the initial margin instead of requiring its Eligible BD-FCM to do so. It would thus incentivize Cross-Margining Customers to post such margin, which would likely result in an associated cost reduction from their Eligible BD-FCMs. Such posting would, in turn, serve to reduce Eligible BD-

FCMs' risk to their Cross-Margining Customers and thereby promote the safeguarding of securities and funds in FICC's control or for which it is responsible.

The proposed changes adopting and implementing the Customer Cross-Margining Arrangement would also promote the safeguarding of funds and securities for which FICC is responsible by ensuring that Customer Positions and Cross-Margining Customer Margin benefit from the customer protection regime applicable to futures contracts and associated margin. They would do this by requiring that Customer Positions and Cross-Margining Customer Margin be carried by the Cross-Margining Participant in a futures account and by satisfying the conditions necessary under the Proposed Orders to allow the Cross-Margining Participant to do that. Because the Customer Positions and Cross-Margining Customer Margin would be carried in a futures account, an Eligible BD-FCM would generally be required to safeguard Customer Positions and Cross-Margining Customer Positions to a substantially similar extent as is required for futures and associated margin. Furthermore, by requiring that Customer Positions and Cross-Margining Customer Margin be carried in a futures account and satisfying the other conditions of the Proposed Orders, the proposed changes would help to ensure that Customer Positions and Cross-Margining Customer Margin constitute "customer property" for purposes of Part 190 and that Cross-Margining Customer claims therefor constitute the claims of "customers" on account of their "net equity" within the meaning of Part 190.⁷¹ Part 190 provides that, in the insolvency of an FCM, "customer property" shall be distributed to "customers" ratably on the basis of their "net equity" claims, in priority to all other claims (except administrative claims related to the administration of customer property).⁷² Accordingly, by ensuring that Customer Positions and Cross-Margining Customer Margin constitute "customer property" and that Cross-Margining Customer claims therefore constitute "customer" "net equity" claims, the proposed changes would aim to provide Cross-Margining Customers with the same priority right to receive distributions on their allowed claims with respect to the Customer Positions and Cross-Margining Customer Margin as other public customers of the insolvent Eligible BD-FCM have in respect of their futures

positions and associated margin. Accordingly, it would promote the safeguarding of Cross-Margining Customer Margin and the cash and securities distributed in respect of Customer Positions from the insolvency of the Cross-Margining Participant.

In addition, the proposed changes would promote the safeguarding of funds and securities for which FICC is responsible by ensuring that customers of an Eligible BD-FCM that do not participate in cross-margining under the Customer Cross-Margining Arrangement (as well as Cross-Margining Customers in relation to positions and margin not subject to the arrangement) remain entitled to the full suite of protections under Section 15(c)(3) of the Exchange Act, Rule 15c3-3 under the Exchange Act, and SIPA. The proposed changes are designed to ensure this protection by requiring that Cross-Margining Customers enter into a Customer Agreement that includes the terms of the Subordination Agreement. Pursuant to such terms, each Cross-Margining Customer would agree that its claims to "customer property" as defined in SIPA or 11 U.S.C. 741 against the Cross-Margining Participant with respect to its Customer Positions at FICC and associated Cross-Margining Customer Margin will be subordinated to the claims of all other customers.⁷³ Such subordination is designed to ensure that the claims of Cross-Margining Customers in relation to Customer Positions or Cross-Margining Customer Margin do not dilute the claims of non-participating customers of Eligible BD-FCMs in relation to Segregated Customer Margin (as well as any claims Cross-Margining Customers in relation to Segregated Customer Margin) in a SIPA proceeding. Accordingly, the Cross-Margining Arrangement would help to ensure that such Segregated Customer Margin remains safeguarded to the same extent as would be the case in the absence of the Customer Cross-Margining Arrangement.

Section 17A(b)(3)(F) of the Exchange Act requires, among other things, that the rules of a clearing agency be designed to remove impediments to and perfect the mechanism of a national system for the prompt and accurate clearance and settlement of securities transactions.⁷⁴ For the reasons set out below, FICC believes that the proposed rule change would remove impediments to and perfect the mechanism of a national system for the prompt and

⁷⁰ See Treasury Market Practices Group, Consultative White Paper: Non-Centrally Cleared Bilateral Repo and Indirect Clearing in the U.S. Treasury Market: Focus on Margining Practices (Feb. 26, 2025).

⁷¹ See 17 CFR 190.01; 190.08; 190.09(a)(1)(i)(A).

⁷² See 17 CFR 190.09.

⁷³ See Appendix C, Exhibit I "[Customer Required Terms Annex or Agreement]" of the proposed Third A&R Agreement.

⁷⁴ 15 U.S.C. 78q-1(b)(3)(F).

accurate clearance and settlement of securities transactions.

The proposed changes would extend the existing cross-margining arrangement to Customer Positions, which is currently only available for clearing members (and certain Eligible Affiliates) at FICC and CME with respect to proprietary positions. By doing so, the proposed changes would serve to eliminate impediments to Cross-Margining Customers submitting transactions for central clearing. Specifically, the proposed rule change would serve to align the margin requirements for Customer Positions with the risk the positions present. As a result, they would eliminate impediments to clearing that can arise from unduly high margin requirements. Furthermore, by aligning margin requirements with risk, the proposed changes would incentivize market participants to submit more Treasury securities transactions eligible to be cross-margined to be cleared at FICC. The maintenance of such incentives to submit transactions for clearance and settlement at FICC would promote the diversity and scope of market participants able to utilize FICC's multilateral netting, trade guaranty and centralized default management services. Therefore, the proposed rule change would also serve to promote prompt and accurate clearance and settlement of securities transactions.⁷⁵ Accordingly, FICC believes that the proposed rule change is designed to remove impediments to and perfect the mechanism of a national system for the prompt and accurate clearance and settlement of securities transactions.⁷⁶

Rule 17ad-22(e)(6)(i) under the Exchange Act requires that a covered clearing agency establish a risk-based margin system that, at a minimum, considers, and produces margin levels commensurate with, the risks and particular attributes of each relevant product, portfolio, and market and, if the covered clearing agency provides central counterparty services for U.S. Treasury securities, calculates, collects, and holds margin amounts from a direct participant for its proprietary positions in Treasury securities separately and independently from margin calculated and collected from that direct participant in connection with U.S. Treasury securities transactions by an indirect participant that relies on the services provided by the direct participant to access the covered clearing agency's payment, clearing, or

settlement facilities.⁷⁷ FICC believes that the proposed changes would ensure the satisfaction of these requirements.

First, the Customer Cross-Margining Arrangement would produce margin levels commensurate with the risks and particular attributes of the Eligible Positions. This is because FICC would calculate initial margin requirements for Customer Positions using the same methodology as under the Proprietary Cross-Margining Arrangement, with each Cross-Margining Customer treated effectively as an independent Netting Member. The Commission recently approved this methodology, finding in particular that it satisfied the requirements of Rule 17ad-22(e)(6).⁷⁸

Second, the proposed changes would provide that FICC-cleared Customer Positions of a Cross-Margining Customer would be recorded in a Cross-Margining Customer Account, which account would be a separate Type of Account for purposes of the GSD Rules.⁷⁹ By virtue of these changes, the margin applicable to Customer Positions would be calculated separately and independently of the margin for any positions recorded in a different Type of Account, including any Proprietary Account of the Cross-Margining Participant. In addition, the proposed rule changes would provide for Customer Cross-Margining Margin to be collected and held in substantially a similar manner to Segregated Customer Margin. The Commission recently approved FICC's arrangements for Segregated Customer Margin, finding in particular that they "should ensure that a Netting Member's proprietary transactions are not netted with indirect participant transactions for margin calculations and that margin for indirect participant transactions is collected and held separately and independently from margin for a Netting Member's proprietary transactions." Accordingly, the proposed rule change would ensure compliance with Rule 17ad-22(e)(6)(i).

Rule 17ad-22(e)(4)(i) under the Exchange Act requires that a covered clearing agency establish, implement, maintain, and enforce written policies and procedures reasonably designed to effectively identify, measure, monitor, and manage its credit exposures to participants and those arising from its payment, clearing, and settlement processes by maintaining sufficient

financial resources to cover its credit exposure to each participant fully with a high degree of confidence.⁸⁰ FICC believes that the proposed changes would ensure that FICC continues to effectively measure and manage its credit exposure to participants by maintaining sufficient financial resources to cover its exposure thereto with a high degree of confidence. This is because, under the Customer Cross-Margining Arrangement, FICC would calculate the margin requirement applicable to Customer Positions on a gross (*i.e.*, Cross-Margining Customer-by-Cross-Margining Customer) basis, with margin reductions for offsetting positions calculated using a methodology that the Commission recently approved.⁸¹ Examining the similar customer-by-customer gross margining arrangements adopted by FICC for Segregated Indirect Participants, the Commission found that they would "better isolate the risk profiles of individual indirect participants from Netting Members, which should help FICC better understand and monitor each individual participant's risk exposures."⁸² In addition, the proposed rule change would require each Eligible BD-FCM for whom FICC maintains one or more Cross-Margining Customer Account(s) to deposit to FICC cash or eligible securities to meet the Cross-Margining Customer Margin Requirement that is calibrated to the risks of each Cross-Margining Customer's portfolio. Such Eligible BD-FCM would also be required to enter into a Customer Cross-Margining Clearing Member Agreement with FICC and CME, pursuant to which the Eligible BD-FCM would pledge to FICC, on behalf of itself and each Cross-Margining Customer, the positions and margin subject to the Customer Cross-Margining Arrangement at both FICC and CME. This pledge, coupled with the cross-guarantee set forth in the Third A&R Agreement, would ensure that FICC and CME are able to look to the full portfolio of Customer Positions and associated margin at FICC and CME in order to satisfy any obligations arising

⁸⁰ 17 CFR 240.17ad-22(e)(4)(i).

⁸¹ See Self-Regulatory Organizations; the Fixed Income Clearing Corporation; Order Granting Approval of Proposed Rule Change To Amend and Restate the Cross-Margining Agreement Between FICC and CME, 88 FR 63185 (Sept. 15, 2023).

⁸² See Self-Regulatory Organizations; Fixed Income Clearing Corporation; Order Approving Proposed Rule Change, as Modified by Partial Amendment No. 1, To Modify the GSD Rules (i) Regarding the Separate Calculation, Collection and Holding of Margin for Proprietary Transactions and That for Indirect Participant Transactions, and (ii) To Address the Conditions of Note H to Rule 15c3-3a, 89 FR 93763, 93776 (Nov. 27, 2024).

⁷⁵ *Id.*

⁷⁶ 15 U.S.C. 78q-1(b)(3)(F).

⁷⁷ 17 CFR 240.17ad-22(e)(6)(i).

⁷⁸ See Order Granting Approval of Proposed Rule Change To Amend and Restate the Cross-Margining Agreement Between FICC and CME, Securities Exchange Act Release No. 98327 (Sept. 8, 2023), 88 FR 63185 (Sept. 14, 2023).

⁷⁹ See Section 1, "Definitions," of the proposed Third A&R Agreement.

under Customer Positions. Accordingly, the proposed changes would ensure that FICC will have sufficient resources to rely on to cover cross-margining exposures under the Customer Cross-Margining Arrangement.

Rule 17ad-22(e)(18)(iv)(C) under the Exchange Act requires, among other things, that a covered clearing agency that provides central counterparty services for transactions in U.S. Treasury securities ensure that it has appropriate means to facilitate access to clearance and settlement services of all eligible secondary market transactions in U.S. Treasury securities, including those of indirect participants. As described above, the proposed changes would expand the Cross-Margining Arrangement, which currently is only available for proprietary positions of Cross-Margining Participants and those of their Eligible Affiliates, to Customer Positions. This expansion would serve to facilitate access for indirect participants to FICC's clearance and settlement services for Treasury transactions by aligning the margin requirements applicable to such participants' positions with the risk those positions present. Such alignment would serve to eliminate impediments to access that can arise when there is a mismatch between margin and risk. Furthermore, by creating an incentive for Cross-Margining Customers to cover the margin requirements for their own positions, the proposed rule change would serve to reduce the need for Netting Members to use their own resources to cover such margin obligations. As a result, it would reduce the costs and increase the capacity of Netting Members to provide clearing services, which would in turn allow Netting Members to increase the volume of transactions they clear and reduce the prices at which they provide such clearing services. Moreover, by creating significant cost savings and efficiencies for Cross-Margining Customers that consolidate offsetting positions into a single clearing member regardless of execution counterparty, the proposed changes would create a natural incentive for Netting Members to offer done-away clearing services. For such Netting Members, carrying Treasury securities positions entered into by a customer with other parties would provide a potential opportunity to reduce the risk of the customer's futures positions and earn clearing revenue without the cost of funding the customer's margin obligations, and such clearing services could create opportunities to increase the Netting Member's scope of customers.

Therefore, the proposed changes would facilitate access to clearance and settlement services of all eligible secondary market transactions in U.S. Treasury securities, including those of indirect participants.⁸³

(B) Clearing Agency's Statement on Burden on Competition

FICC believes that the proposed changes to the GSD Rules and the Third A&R Agreement would promote competition by enabling customers of Eligible BD-FCMs to benefit from cross-margining.

As described above, under the Existing Agreement, cross-margining is currently only available for a Cross-Margining Participant's proprietary positions and those of an Eligible Affiliate. Accordingly, customers of Cross-Margining Participants are not able to benefit from cross-margining; they must continue to have their Eligible Securities Positions margined without regard to potential risk offsets involving other Eligible Futures Positions. By extending availability of cross-margining to Customer Positions, the proposed rule change would serve to place customers of Eligible BD-FCMs on a more level playing field with Cross-Margining Participants and Eligible Affiliates. It would ensure that such customers have the ability to achieve similar margin efficiencies and pursue similar trading strategies on similar terms as Cross-Margining Participants and Eligible Affiliates. As a result, the proposed changes would improve competitive parity in the U.S. Treasury market between direct participants and indirect participants at FICC.

The proposed rule change would also promote competition by allowing all customers of Eligible BD-FCMs, rather than only market professionals or a similar subset, to access central clearing. As a result, the proposed rule change would ensure that introducing cross-margining maintains competitive parity among customers of Eligible BD-FCMs.

FICC believes that the proposed rule change would introduce a burden of competition as between Eligible BD-FCMs and other Netting Members because the Customer Cross-Margining Arrangement would only be available for Customer Positions carried by Eligible BD-FCMs. However, FICC believes that this burden on competition is necessary in order to ensure that Customer Positions and associated Cross-Margining Customer Margin are safeguarded pursuant to robust customer protections. In particular, the dual registration of an Eligible BD-FCM

as a broker-dealer and FCM is necessary to ensure that the Customer Positions and associated margin can be carried in a futures account under the CEA and applicable CFTC regulations and that they benefit from the Part 190 distributional rules in the event of the clearing member's failure. FICC has concluded that it would not be feasible to achieve similar customer protections if Customer Positions were carried at a Netting Member not registered as a BD and FCM. Indeed, FICC has observed that other U.S. cross-margining arrangements involving customers similarly require such dual registration as a condition to participation in the arrangement.⁸⁴

In addition, the proposed rule change would promote competition by providing market participants with greater flexibility in the methods through which transactions in U.S. Treasury securities can be cleared. With the introduction of the Customer Cross-Margining Arrangement, clearing members will be able to offer a wider variety of clearing methods to their indirect participant customers. Such indirect participants will accordingly be able to participate in a wider variety of clearing methods, and will be able to choose whether to clear transactions under the Customer Cross-Margining Arrangement or whether to clear transactions at FICC without engaging in cross-margining.

Accordingly, the proposed rule change would promote competition by allowing Cross-Margining Customers to obtain the benefits associated with cross-margining, ensuring that Cross-Margining Customers are not at an undue competitive disadvantage relative to clearing members and certain Eligible Affiliates who are currently able to access such benefits under the Proprietary Cross-Margining Arrangement, and providing market participants with greater flexibility in the access models available for the clearing of transactions in U.S. treasury securities.

⁸⁴ See Order Granting Conditional Exemptions Under the Securities Exchange Act of 1934 in Connection With the Portfolio Margining of Cleared Swaps and Security-Based Swaps That Are Credit Default Swaps, Securities Exchange Act Release No. 93501 (Nov. 1, 2021), 86 FR 61357 (Nov. 5, 2021); Order Granting Conditional Exemptions Under the Securities Exchange Act of 1934 in Connection With Portfolio Margining of Swaps and Security-Based Swaps, Securities Exchange Act Release No. 68433 (Dec. 14, 2012), 77 FR 75211 (Dec. 19, 2012); Order, Treatment of Funds Held in Connection with Clearing by LCH SA of Single-Name Credit Default Swaps, Including Spun-Out Component Transactions (Nov. 1, 2021); Order, Treatment of Funds Held in Connection with Clearing by ICE Clear Credit of Credit Default Swaps (Jan. 14, 2013).

⁸³ 17 CFR 240.17ad-22(e)(18)(iv)(C).

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

FICC has not received or solicited any written comments relating to this proposal. If any written comments are received, they will be publicly filed as an Exhibit 2 to this filing, as required by Form 19b-4 and the General Instructions thereto.

Persons submitting comments are cautioned that, according to Section IV (Solicitation of Comments) of the Exhibit 1A in the General Instructions to Form 19b-4, the Commission does not edit personal identifying information from comment submissions. Commenters should submit only information that they wish to make available publicly, including their name, email address, and any other identifying information.

All prospective commenters should follow the Commission's instructions on how to submit comments, *available at* www.sec.gov/rules-regulations/how-submit-comment. General questions regarding the rule filing process or logistical questions regarding this filing should be directed to the Main Office of the Commission's Division of Trading and Markets at tradingandmarkets@sec.gov or 202-551-5777.

FICC reserves the right to not respond to any comments received.

III. Date of Effectiveness of the Proposed Rule Change, and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

- (A) by order approve or disapprove such proposed rule change, or
- (B) institute proceedings to determine whether the proposed rule change should be disapproved.

The proposal shall not take effect until all regulatory actions required with respect to the proposal are completed.

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 Exchange 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-FICC-2025-025 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.
- All submissions should refer to file number SR-FICC-2025-025. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of FICC and on DTCC's website (www.dtcc.com/legal/sec-rule-filings). 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-FICC-2025-025 and should be submitted on or before January 20, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁸⁵

Sherry R. Haywood,
Assistant Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-104462; File No. SR-PEARL-2025-50]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing of a Proposed Rule Change To Allow Post-Only Orders in Sub-Dollar Securities

December 19, 2025.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on December 10, 2025, MIAX PEARL, LLC ("MIAX Pearl" 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 Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend subparagraph (c)(2) of Exchange Rule 2614, Orders and Order Instructions, to allow the Post Only order instruction to be applied to orders in securities priced below \$1.00 on its equity trading platform (referred to herein as "MIAX Pearl Equities").³ The Exchange also proposes to adopt Exchange Rule 2614(c)(2)(i)(A) to reprice non-displayed orders in securities priced below \$1.00 to the locking price to help reduce the occurrence of an internally crossed book. Additionally, the Exchange proposes to make a related change to subparagraph (a)(4)(iv) of Exchange Rule 2617, Order Execution and Routing, to also apply to orders in securities priced below \$1.00 with a Post Only order instruction to help alleviate an internally locked or crossed book in the rare event they do occur. These proposed changes are designed to allow the Exchange to better compete with other exchanges with like functionality for order flow in securities trading below \$1.00 while also seeking to attract more liquidity in securities that trade below \$1.00 onto an exchange, where those orders may benefit from price discovery and improved market transparency.

The text of the proposed rule change is available on the Exchange's website at <https://www.miaxglobal.com/markets/us-equities/pearl-equities/rule-filings>, at MIAX Pearl's principal office.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, MIAX Pearl 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. MIAX Pearl has prepared summaries, set forth in sections A, B, and C below, of the

⁸⁵ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ All references to the "Exchange" in this filing refer to MIAX Pearl Equities. Any references to the options trading facility of MIAX PEARL, LLC will specifically be referred to as "MIAX Pearl Options."

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

Currently, with the exception of the Post Only instruction (described below), all order types and order instructions are available to orders in all securities regardless of price. Only the Post Only instruction is currently limited to securities priced at or above \$1.00. The Exchange proposes to remove this exception and amend subparagraph (c)(2) of Exchange Rule 2614, Orders and Order Instructions, to allow the Post Only order instruction to be applied to orders in securities priced below \$1.00 on MIAX Pearl Equities. As explained below, this portion of the proposal is currently available on other equities exchanges. This proposal is, therefore, designed to increase competition among exchanges for order flow in securities priced below \$1.00 and to make all order types and order instructions available equally to orders in all securities regardless of the order's price.

This proposal is not intended to encourage an increase in the overall volume or order flow in sub-dollar securities. Trading in sub-dollar securities both on- and off-exchange has grown significantly since the Exchange adopted Exchange Rule 2614(c)(2) and launched operations in September 2020. For example, average daily sub-dollar trading volume comprised approximately 9% of the overall daily volume in September 2025. In fact, the Exchange found that overall volume in sub-dollar securities has been slowly decreasing since June 2025 from approximately 14% to 9% in September 2025. Meanwhile, off-exchange market share in sub-dollar securities remained high averaging over 60%.⁴

There are numerous other factors that contribute to sub-dollar trading volumes, the majority of which occurs off-exchange.⁵ The Exchange believes

this proposal will increase exchange competition by allowing the Exchange to provide functionality that would allow it to attract a greater slice of the current volume in sub-dollar securities by encouraging market participants to send their sub-dollar trading volume to an exchange-level pool of liquidity, rather than the opaque off-exchange trading venues (*i.e.*, dark pools), which are less transparent. In addition, various Equity Members⁶ have recently requested the Exchange modify its functionality to allow the Post Only instruction to be available for orders in securities priced below \$1.00.

The Exchange notes that differences exist between the market structures for securities priced at or above \$1.00 and those below \$1.00 that impact how the Post Only order instruction may function. This includes different fee levels and minimum price increments which allow for both an internally locked or crossed market to be caused by an order with a Post Only instruction priced below \$1.00. Meanwhile, these different fee levels and minimum price increments allow for only an internally locked market to be caused by an order with a Post Only instruction priced at or above \$1.00.

The Exchange reviewed its data and found that internally locked and crossed markets are rare events and should continue to be rare under this proposal. Based on the Exchange's data for securities priced at or above \$1.00, an internally non-displayed locked or crossed market caused by an order that includes a Minimum Execution Quantity ("MEQ") instruction (described below) or an internally non-displayed locked market caused by an order with a Post Only instruction (also described below) is extremely rare.⁷ For securities priced at or above \$1.00, the Exchange reviewed a sampling of data that included high volume securities with increased usage of the Post Only and MEQ instructions on active trading days. The selected securities also experienced an increased usage of the MEQ and/or Post Only instructions.

s-equities-volume-drivers-retail-trading-in-subdollar-securities/; and Off Exchange Trading Increases Across all Types of Stocks, dated February 13, 2025, available at <https://www.nasdaq.com/articles/exchange-trading-increases-across-all-types-stocks#:~:text=The%20rise%20is%20largely%20driven,ATS%20trades%20printed%20off%2Dexchange.>

⁶ The term "Equity Member" is a Member authorized by the Exchange to transact business on MIAX Pearl Equities. See Exchange Rule 1901.

⁷ The Exchange notes that it reviewed these two order instructions because they are the only instructions available on the Exchange that may cause an internally non-displayed locked or crossed book.

Based on this sampling, the Exchange experienced an internally locked book for the selected securities priced at or above \$1.00 in approximately 1.00% of all order book updates and an internally crossed book in approximately 0.10% of all order book updates.

The Exchange conducted a similar review for securities priced below \$1.00 but focused on a sampling of data that included high volume sub-dollar securities on active trading days that experienced an increased usage of the MEQ instruction. Unlike the above review of securities priced at or above \$1.00, the Exchange could not review securities priced below \$1.00 with a Post Only instruction because the Exchange does not currently offer such functionality and proposes to do so herein. Based on this review, the Exchange found that an internally non-displayed locked or crossed book in sub-dollar securities caused by an order that includes an MEQ instruction did not occur during a sampling of active trading days in any of the high volume sub-dollar securities the Exchange observed.⁸ Based on the Exchange's expertise and experience, the differing uses of the Post Only instruction and MEQ instruction, as well as other external factors, the Exchange does not anticipate that expanding the Post Only instruction to sub-dollar securities would cause a disproportionate increase in the use of the Post Only instruction as compared to the MEQ instruction with orders in securities priced below \$1.00 that could result in anything other than, at most, a potential de minimis increase of internally non-displayed locked or crossed markets on the Exchange. Based on the Exchange's observations and experience, in the rare event they do occur, an internally non-displayed locked or crossed book is typically alleviated almost immediately or within an extremely short period of time of their initial occurrence.

Nonetheless, the Exchange has mechanisms to both avoid an internally crossed market and to alleviate an internally locked or crossed market, in the rare event they occur. First, the Exchange proposes to adopt Exchange Rule 2614(c)(2)(i)(A) to reprice non-displayed orders in securities priced below \$1.00 to the locking price of the displayed order resting on the MIAX Pearl Equities Book to help reduce the occurrence of an internally crossed

⁸ The Exchange will not file a proposed fee change with the Commission to amend its fee structure for securities priced below \$1.00 to levels that may cause more than a de minimis increase in the occurrence of an internally non-displayed locked or crossed market on the Exchange.

⁴ See MEMX LLC's December 2024 Exchange Highlights, dated January 10, 2025, available at <https://memx.com/exchange-highlights-key-trading-trends-that-defined-another-banner-year-in-the-markets/>.

⁵ The increase in sub-dollar trading volume has not been due to any new or novel exchange order types, but rather increased retail participation, especially since the Covid-19 pandemic and social media-fueled hype; rise of off-exchange trading, including dark pools; reverse stock splits; and high market volatility causing prices to fall and making them prone to trading below \$1.00. See, e.g., U.S. Equities Volume Drivers: Retail Trading in Subdollar Securities, dated November 24, 2024, available at <https://www.cboe.com/insights/posts/u->

book.⁹ Proposed Exchange Rule 2614(c)(2)(i)(A) is based on Exchange Rule 2617(a)(4)(iv), which describes similar re-pricing of orders with an MEQ instruction that cross a contra-side displayed order.

In addition, should an internally locked or crossed market occur, the Exchange has a current mechanism under Exchange Rule 2617(a)(4)(iv) to alleviate those occurrences while honoring intra-market price priority. Specifically, Exchange Rule 2617(a)(4)(iv) provides that, for securities priced equal to or greater than \$1.00, in the case where a non-displayed order to sell (buy) is posted on the MIAX Pearl Equities Book at a price that locks or crosses a displayed order to buy (sell), an Aggressing Order¹⁰ or an incoming order to buy (sell) that is a Market Order¹¹ or a Limit Order¹² priced more aggressively than the order to buy (sell) displayed on the MIAX Pearl Equities Book will execute against the non-displayed order to sell (buy) resting on the MIAX Pearl Equities Book at one-half minimum price variation greater (less) than the price of the resting displayed order to buy (sell).

The Exchange proposes to expand this mechanism under Exchange Rule 2617(a)(4)(iv) to securities priced below \$1.00, which would allow for consistent treatment of all securities during an internally locked or crossed market, regardless of price. Expanding the re-pricing mechanism described in Exchange Rule 2617(a)(4)(iv) would allow the Exchange to treat orders in securities priced below \$1.00 in the same manner as orders in securities priced at or above \$1.00. This change would also ensure that intra-market price priority continues to be honored

⁹ The Exchange notes that this functionality would also apply to orders in securities priced at or above \$1.00 in the unlikely event that an incoming order in a security priced at or above \$1.00 with a Post Only instruction would post to the MIAX Pearl Equities Book and result in an internally non-displayed crossed market.

¹⁰ The term "Aggressing Order" is an order to buy (sell) that is or becomes marketable against sell (buy) interest on the MIAX Pearl Equities Book. A resting order may become an Aggressing Order if its working price changes, if the PBBO or NBBO is updated, because of changes to other orders on the MIAX Pearl Equities Book, or when processing inbound messages. See Exchange Rule 1901.

¹¹ An order to buy (sell) a stated amount of a security that is to be executed at the PBO (PBB) or better. A Market Order shall not trade through a Protected Quotation. See Exchange Rule 2614(a)(2).

¹² An order to buy or sell a stated amount of a security at a specified price or better. A "marketable" Limit Order to buy (sell) will trade with all orders to sell (buy) priced at or below (above) the PBO (PBB) for the security. Once no longer marketable, the Limit Order will be ranked on the MIAX Pearl Equities Book pursuant to Exchange Rule 2616. An incoming Limit Order may be designated as ISO. See Exchange Rule 2614(a)(1).

by treating all orders with a Post Only instruction in a similar manner regardless of price. Therefore, this portion of the proposal would facilitate transactions in securities as well as remove impediments to and perfect the mechanism of a free and open market and a national market system in accordance with the Act. This functionality has also been considered by the Commission numerous times and does not raise any new or novel issues.¹³

Each of these changes proposed herein are described in more detail below.

Expanding Post Only Instruction to Sub-Dollar Securities

Exchange Rule 2614(c)(2) describes the Post Only order instruction and provides that an order designated as Post Only is a non-routable order that is ranked and executed on the MIAX Pearl Equities Book pursuant to Exchange Rule 2616 and Exchange Rule 2617(a)(4). Exchange Rule 2614(c)(2) further provides that an order designated as Post Only will only remove liquidity from the MIAX Pearl Equities Book when: (A) *the order is for a security priced below \$1.00*; ¹⁴ or (B) the value of such execution when removing liquidity equals or exceeds the value of such execution if the order instead posted to the MIAX Pearl Equities Book and subsequently provided liquidity including the applicable fees charged or rebates paid.¹⁵ An order designated as Post

¹³ See Securities Exchange Act Release Nos. 89563 (August 14, 2020), 85 FR 51510 (August 20, 2020) (SR-PEARL-2020-03) (Order Approving a Proposed Rule Change, as Modified by Amendment No. 1, to Establish Rules Governing the Trading of Equity Securities); 88806 (May 4, 2020), 85 FR 27451 (May 8, 2020) (File No. 10-237) (In the Matter of the Application of MEMX LLC for Registration as a National Securities Exchange; Findings, Opinion, and Order of the Commission); 102650 (March 13, 2025), 90 FR 12590 (March 18, 2025) (File No. 10-247) (In the Matter of the Application of MX2 LLC for Registration as a National Securities Exchange; Findings, Opinion, and Order of the Commission). See also LTSE Rule 11.230(a)(4)(D); Cboe BZX Rule 11.13(a)(4)(D); Cboe EDGX Rule 11.10(a)(4)(D).

¹⁴ The Exchange notes that an order in a security priced below \$1.00 that includes the Post Only instruction will not remove liquidity when there is no marketable contra-side liquidity resting on the MIAX Pearl Equities Book, either due to the limit price of the resting and incoming orders or there being no contra-side liquidity available.

¹⁵ To determine at the time of a potential execution whether the value of such execution when removing liquidity equals or exceeds the value of such execution if the order instead posted to the MIAX Pearl Equities Book and subsequently provided liquidity, the Exchange will use the highest possible rebate paid and highest possible fee charged for such executions on the Exchange. The Exchange provides for a maker/taker fee structure. For displayed orders in securities priced

Only is subject to the price sliding processes set forth in Exchange Rule 2614(g), unless otherwise instructed by the User¹⁶ (*i.e.*, the User elects that the order be cancelled rather than subject to a price sliding process). The Post Only instruction is available for Limit Orders¹⁷ and Pegged Orders only.¹⁸

The Exchange now proposes to provide the Post Only instruction to orders in securities priced below \$1.00. To effectuate this change, the Exchange proposes to delete subparagraph (2)(i)(A) of Exchange Rule 2614(c) that limits the availability of the Post Only instruction to securities priced at or above \$1.00. As a result, Exchange Rule 2614(c)(2) would provide that an order designated as Post Only will only remove liquidity from the MIAX Pearl Equities Book when the value of such execution when removing liquidity equals or exceeds the value of such execution if the order instead posted to the MIAX Pearl Equities Book and subsequently provided liquidity including the applicable fees charged or rebates paid.¹⁹ The Exchange believes this proposal is reasonable because it is competitive in nature, designed to attract additional liquidity and quoting on the Exchange, and provides Equity Members with consistent order handling of all their orders, regardless of price.

In sum, the Post Only instruction provides Equity Members with the ability to increase the likelihood that their order will add liquidity to the order book and will not remove liquidity unless certain price improvement requirements are satisfied. This effectively guarantees that the order will only trade at a price better than its limit price when removing liquidity, while potentially receiving rebates for adding liquidity to the

at or above \$1.00, the highest possible fee is currently \$0.00300 for removing liquidity and the highest possible rebate is currently (\$0.0037) for providing liquidity, requiring at least \$0.0067 of price improvement. See MIAX Pearl Equities Fee Schedule, Section 1)a). For non-displayed orders in securities priced at or above \$1.00, the highest possible fee is currently \$0.00300 for removing liquidity and the highest possible rebate is currently (\$0.00200) for providing liquidity, requiring at least \$0.005 of price improvement. *Id.*

¹⁶ The term "User" shall mean any Member or Sponsored Participant who is authorized to obtain access to the System pursuant to Exchange Rule 2602. See Exchange Rule 1901.

¹⁷ See Exchange Rule 2614(a)(1)(iv).

¹⁸ See Exchange Rule 2614(a)(3)(v).

¹⁹ See *supra* note 15. The Exchange provides for a maker/taker fee structure. For both displayed and non-displayed orders in securities priced below \$1.00, the highest possible fee is currently 0.20% of the trade's dollar value for removing liquidity and the highest possible rebate is currently (0.15%) of the trade's dollar value for providing liquidity, requiring at least 0.35% of the trade's value as price improvement. See MIAX Pearl Equities Fee Schedule, Section 1)a).

market. This is designed to incentivize market participants to post aggressively priced liquidity and improve price discovery. By adding orders to the order book, orders with a Post Only instruction contribute to improved liquidity, market depth and, if displayed, price transparency.

The Exchange believes this proposed rule change to expand Post Only functionality to orders in sub-dollar securities would provide an additional exchange-level pool of liquidity for market participants that utilize Post Only functionality for sub-dollar securities. As such, the proposed rule change may encourage market participants to send additional sub-dollar trading volume to an exchange, rather than off-exchange marketplaces (*i.e.*, dark pools), which provide less transparent pricing. In general, the Post Only instruction allows for an order to be posted to the MIAX Pearl Equities Book at its limit price and, therefore, serves to improve on-exchange liquidity, which benefits all market participants by providing more trading opportunities. Orders with a Post Only instruction entered onto an exchange may also serve to improve price transparency if the entering firm elected such order to be displayed and made available via an exchange's data feeds and disseminated by the applicable Securities Information Processor ("SIP"). This proposal serves to benefit market participants by expanding existing functionality available to orders in securities priced at or above \$1.00 to orders in securities priced below \$1.00, with no functional difference.

The Exchange initially adopted its Post Only order instruction behavior as part of its broader proposal to adopt rules governing trading of equity securities, in which it sought to operate its equity market in a manner similar to that of other equity exchanges that it based its rules and functionality upon several years ago. This included adopting functionality that limited the functionality of the Post Only instruction to orders in securities priced at or above \$1.00. The Exchange did not adopt this limitation due to fear of some potential nefarious activity in sub-dollar securities trading, but rather due to lack of interest by market participants in such functionality at the time MIAX Pearl Equities was being developed and had filed its initial rule set with the Commission for approval.

Applying Post Only treatment to sub-dollar securities is also not unique. Today, a number of other equities exchanges allow securities priced below \$1.00 to be treated as "post only." For example, The Nasdaq Stock Market LLC

("Nasdaq") provides a Post Only Order, which offers market participants the ability to submit an order that is not eligible for routing to away markets and posts to the Nasdaq book at prices below \$1.00.²⁰ Specifically, Nasdaq's Post Only Order acts like the Exchange's Post Only order instruction in securities priced at or above \$1.00 and provides, in sum, that a "Post-Only Order will be posted, ranked, and displayed at its limit price; provided, however, the Post-Only Order will execute if it is priced at \$1.00 or more and the value of price improvement associated with executing against an Order on the Nasdaq Book equals or exceeds \$0.01 per share."²¹ Nasdaq applies the same behavior to Post-Only Orders in securities priced below \$1.00 and provides that the Post-Only Order would execute if "the value of price improvement associated with executing against an Order on the Nasdaq Book (as measured against the original limit price of the Order) equals or exceeds the sum of fees charged for such execution and the value of any rebate that would be provided if the Order posted to the Nasdaq Book and subsequently provided liquidity".²² This is identical to the functionality that the Exchange proposes herein and is also available on Nasdaq's affiliate exchanges that trade equity securities.²³ The New York Stock Exchange LLC ("NYSE") and its affiliate exchanges also provide similar "post only" functionality in the form of Add Liquidity Only ("ALO") orders, which is also available to securities priced below \$1.00.²⁴ This proposal would expand the population of exchanges that offer "post only" treatment for securities priced below \$1.00 and would not only allow the Exchange to compete with exchanges that currently offer such functionality to sub-dollar securities, but also enable the Exchange to provide an additional exchange-level pool of liquidity where market participants may send such orders.

²⁰ See Nasdaq Equity 4, Rule 4702(b)(4) ("Post-Only Order").

²¹ *Id.* See also *supra* note 15 for a description of the Exchange's price improvement requirements for orders priced at or above \$1.00 with a Post Only instruction.

²² Nasdaq provides for Minimum Quantity Orders, which, like a Post Only instruction, may result in an internally non-displayed locked or crossed market, as discussed herein. See Nasdaq Equity 4, Rule 4703(e) ("Minimum Quantity Order").

²³ See Nasdaq BX, Inc. Equity 4, Rule 4702(b)(4)(A) ("Post-Only Order"). See also Nasdaq PHLX, Inc. Equity 4, Rule 3301A(b)(4)(A) ("Post-Only Order").

²⁴ See, *e.g.*, NYSE Rule 7.31(e)(2).

Expanding Existing Functionality To Avoid or Alleviate Internally Locked or Crossed Markets to Securities Priced Below \$1.00 With a Post Only Instruction

As mentioned above, differences exist between the market structures for securities priced at or above \$1.00 and those below \$1.00, such as differing fee levels and minimum price increments. Due to these differences, orders in securities priced at or above \$1.00 that contain a Post Only instruction do not result in an internally crossed market because the minimum tick increments allows the order to receive the required amount of price improvement to execute against a contra-side order. On the contrary, the minimum price increments and different fee levels for securities priced below \$1.00 would not always ensure that an order with a Post Only instruction would receive the necessary price improvement to execute. As a result, unlike an order in a security priced at or above \$1.00, an order in a security priced below \$1.00 with a Post Only instruction may post at a price that results in an internally crossed market. According to the data discussed above, the Exchange does not expect a material increase in internally locked and crossed markets due to this proposal. However, should they occur, the Exchange has mechanisms in place today to avoid or alleviate an internally locked and crossed market that it proposes to expand to locked or crossed markets that may result from an order priced below \$1.00 with a Post Only instruction.

First, the Exchange proposes to adopt Exchange Rule 2614(c)(2)(i)(A) to reprice non-displayed orders in securities priced below \$1.00 to the locking price of the displayed order to help reduce the occurrence of an internally crossed book.²⁵ As mentioned above, proposed Exchange Rule 2614(c)(2)(i)(A) is based on Exchange Rule 2617(a)(4)(iv), which describes similar re-pricing of orders with an MEQ instruction that cross a contra-side displayed order.

Second, the Exchange proposes to make a related change to Exchange Rule 2617(a)(4)(iv) to treat securities priced below \$1.00 in the same manner as it currently treats securities priced at or above \$1.00 during an internally locked or crossed market. Expanding Exchange Rule 2617(a)(4)(iv) as proposed herein

²⁵ The Exchange notes that this functionality would also apply to orders in securities priced at or above \$1.00 in the unlikely event that an incoming order in a security priced at or above \$1.00 with a Post Only instruction would post to the MIAX Pearl Equities Book and result in an internally non-displayed crossed market.

would allow the Exchange to treat orders in securities priced below \$1.00 with a Post Only order instruction the same as orders in securities priced at or above \$1.00 by allowing an execution at one-half minimum price variation greater (less) than the price of the resting displayed order to buy (sell) as set forth in the Rule.

Both of these proposals are an expansion of existing functionality and Exchange Rules, and, therefore, do not raise any new or novel issues. Each of these changes are described separately below.

Re-Pricing Non-Displayed Orders to the Locking Price To Decrease the Occurrence of an Internally Crossed Market

As discussed above, if this proposal is approved, an order designated as Post Only in a security priced below \$1.00 may post to the MIAX Pearl Equities Book at a price that results in an internally crossed market.²⁶ However, the Exchange will never post a displayed or non-displayed order to the MIAX Pearl Equities Book at a price that would cross a contra-side displayed order.

In keeping with this principle, the Exchange proposes to reprice non-displayed orders in securities priced below \$1.00 in a similar scenario to help reduce the occurrence of an internally crossed book.²⁷ As proposed, Exchange Rule 2614(c)(2)(i)(A) would describe how a resting displayed order and an incoming non-displayed order designated as Post Only would be re-priced. Specifically, Exchange Rule 2614(c)(2)(i)(A) would provide that a non-displayed order designated as Post Only to buy (sell) that does not remove liquidity pursuant to Exchange Rule 2614(c)(2)(i), and that incoming non-displayed order, if posted at its limit price, would cross a displayed order to sell (buy) resting on the MIAX Pearl

Equities Book, the non-displayed order will have a working price equal to the price of the displayed order to sell (buy). Proposed Exchange Rule 2614(c)(2)(i)(A) would also describe how a resting non-displayed order that would be crossed by an incoming displayed order with a Post Only instruction would be re-priced to have a working price equal to the locking price of the incoming displayed order. Specifically, proposed Exchange Rule 2614(c)(2)(i)(A) would provide that where a displayed order designated as Post Only to buy (sell) does not remove liquidity pursuant to Exchange Rule 2614(c)(2)(i), and that displayed order, if posted at its limit price, would cross a non-displayed order to sell (buy) resting on the MIAX Pearl Equities Book, the non-displayed order will have a working price equal to the price of the displayed order to sell (buy).

The Exchange notes that this portion of the proposal is consistent with how it currently re-prices orders with an MEQ instruction in the same circumstances. Specifically, for orders with an MEQ instruction, Exchange Rule 2614(c)(7)(B)(ii) provides that where there is insufficient size to satisfy the minimum quantity condition of an incoming order to buy (sell) and that incoming order, if posted at its limit price, would cross a displayed order to sell (buy) resting on the MIAX Pearl Equities Book, the order to buy (sell) with the MEQ instruction will have a working price equal to the price of the displayed order to sell (buy). The Exchange proposes to apply the same behavior to other non-displayed orders as described herein.

Not only is proposed Exchange Rule 2614(c)(2)(i)(A) similar to how the Exchange re-prices orders with an MEQ instruction under Exchange Rule 2614(c)(7)(B)(ii), it is also similar to how the Exchange currently re-prices non-displayed orders that cross the Protected Quotation of an external market.²⁸ Both IEX and Nasdaq re-price non-displayed orders to avoid an internally crossed market. In certain circumstances, Nasdaq re-prices non-displayed orders to buy (sell) to one minimum price increment below (above) the lowest (highest) price of resting orders to avoid an internally crossed market.²⁹ Likewise, IEX re-prices non-displayed orders that include a limit price more

aggressive than the midpoint of the NBBO to the midpoint of the NBBO to prevent such orders from being posted at a price that crossed their midpoint of the NBBO.³⁰

The Exchange believes that this portion of the proposal is consistent with the Act because it enables the Exchange to avoid an internally crossed book. Proposed Exchange Rule 2614(c)(2)(i)(A) is also not new or novel as it is based on existing functionality in place on the Exchange and other equity exchanges to avoid internally crossed markets. The Exchange also believes re-pricing a non-displayed order as proposed herein is not unfairly discriminatory because it seeks to avoid an abnormal market condition, *i.e.*, an internally crossed book, in favor of an order with Post Only instruction that could represent more aggressively priced liquidity and price improvement opportunities for other contra-side orders. Like the Exchange provides today for orders with an MEQ instruction, Equity Members would be immediately notified if their order is re-priced as proposed herein and may re-enter such order with a new price if they choose to do so.

The following examples illustrate this proposed functionality.

Example No. 1

A non-displayed order with a Post Only instruction to buy at \$0.8009 ("Order 1") is entered and there is a displayed order resting on the MIAX Pearl Equities Book to sell at \$0.8008 ("Order 2"). Order 1 does not remove liquidity upon entry pursuant to the Exchange's economic best interest functionality under Exchange Rule 2614(c)(2) because it would not receive the requisite price improvement. The price of Order 1, if posted to the MIAX Pearl Equities Book, would cross the price of Order 2. In such case, to avoid an internally crossed book, the System will re-price Order 1 to \$0.8008, the locking price of the displayed order resting on the MIAX Pearl Equities Book.

Example No. 2

A non-displayed order to buy at \$0.8009 is resting on the MIAX Pearl Equities Book ("Order 1"). A displayed order with a Post Only instruction to sell at \$0.8008 is entered ("Order 2"). Order 2 does not remove liquidity upon entry pursuant to the Exchange's economic best interest functionality under Exchange Rule 2614(c)(2) because it would not receive the requisite price improvement. The price of Order 2, if

²⁶ One byproduct of the Post Only order instruction is that it may result in the order for a security priced at or above \$1.00 posting to the MIAX Pearl Equities Book at a price that results in an internally locked market on the Exchange. The Exchange notes that due to its fee structure, an incoming order in a security priced at or above \$1.00 designated as Post Only that crosses a contra-side order resting on the MIAX Pearl Equities Book will execute upon entry because it would receive the necessary amount of price improvement in accordance with Exchange Rule 2614(c)(2). Therefore, such orders will not post to the MIAX Pearl Equities Book and cause an internally crossed market in securities priced at or above \$1.00.

²⁷ The Exchange notes that this functionality would also apply to orders in securities priced at or above \$1.00 in the unlikely event that an incoming order in a security priced at or above \$1.00 with a Post Only instruction would post to the MIAX Pearl Equities Book and result in an internally non-displayed crossed market.

²⁸ See Exchange Rule 2614(g)(2).

²⁹ See Nasdaq Rule 4703(e). For example, Nasdaq Rule 4703(e) provides that if there was an order to buy at \$11 with a minimum quantity condition of 500 shares, and there were resting orders on the Nasdaq Book to sell 200 shares at \$10.99 and 300 shares at \$11, the order would be repriced to \$10.98 and ranked at that price.

³⁰ See IEX Rule 11.190(h)(2).

posted to the MIAX Pearl Equities Book, would cross the price of Order 1. In such case, to avoid an internally crossed book, the System will re-price Order 1 to \$0.8008, the locking price of the incoming displayed order.

Example No. 3

The following example describes when an incoming non-displayed order with a Post Only instruction is re-priced to the locking price pursuant to proposed Exchange Rule 2614(c)(2)(i)(A). Assume the PBBO is \$0.50 by \$0.53. A non-displayed Limit Order to buy at \$0.5003 is entered and placed on the MIAX Pearl Equities Book ("Order 1"). Then, a non-displayed Limit Order to sell with a Post Only instruction at \$0.5001 ("Order 2") is entered. Order 2 cannot execute against Order 1 and remove liquidity upon entry pursuant to the Exchange's economic best interest functionality under Exchange Rule 2614(c)(2) because it would not receive the requisite price improvement.³¹ Therefore, Order 2 will be re-priced and posted to the MIAX Pearl Equities Book and be non-displayed at \$0.5003, the price of the displayed contra-side order, Order 1, pursuant to proposed Exchange Rule 2614(c)(2)(1)(A) discussed above, resulting in an internally non-displayed locked book. Then, a displayed Limit Order to buy at \$0.5004 ("Order 3") is entered and executes against Order 2 at \$0.50035, providing one-half minimum price increment of price improvement as compared to the price the order was posted at of \$0.5003. However, if Order 3 was an order to sell at \$0.5003, it would execute against Order 1 at \$0.5003, Order 1's displayed price. If Order 3 was an order to sell at \$0.5004, it would not execute because there is no marketable contra-side interest, and would be posted to the MIAX Pearl Equities Book at \$0.5004.

Expanding Current Internally Locked or Crossed Book Order Handling To Alleviate an Internally Locked or Crossed Market to Securities Priced Below \$1.00

By way of background, Exchange Rules 2617(a)(4)(i) and (ii) describe the process for matching incoming and Aggressing Orders for execution against contra-side orders resting on the MIAX Pearl Equities Book.³² An Aggressing

Order and an incoming order to buy (sell) will be automatically executed to the extent that it is priced at an amount that equals or exceeds (is less than) any order to sell (buy) on the MIAX Pearl Equities Book and is executable. Such order to buy (sell) will be matched for execution against sell (buy) orders resting on the MIAX Pearl Equities Book according to the price-time priority ranking of the resting orders.

Exchange Rule 2617(a)(4)(iii) provides that certain orders, based on their operation and User instructions, are permitted to post and rest on the MIAX Pearl Equities Book at prices that lock or cross contra-side liquidity, provided, however, that the System³³ will never display a locked or crossed market.³⁴ Exchange Rule 2617(a)(4)(iii) further provides that if an Aggressing Order or an incoming order to buy (sell) would execute upon entry against an order to sell (buy) at the same or worse price as a displayed order to buy (sell), the Aggressing Order or incoming order to buy (sell) would be cancelled or posted to the MIAX Pearl Equities Book and ranked in accordance with Exchange Rule 2616.

Again, one byproduct of the Post Only order instruction, and the MEQ instruction discussed above, is that they may result in the order posting to the MIAX Pearl Equities Book at a price that results in an internally locked or crossed market on the Exchange where one or both of the locking or crossing orders are non-displayed.³⁵ In the context of an order with a Post Only instruction, this may happen where an

order does not remove all contra-side marketable resting liquidity pursuant to the Exchange's economic best interest functionality under Exchange Rule 2614(c)(2) and is, therefore, posted to the MIAX Pearl Equities Book.

As discussed above, based on the Exchange's expertise, experience and data set forth above, the Exchange does not anticipate that expanding the Post Only instruction to sub-dollar securities would cause anything other a potential de minimis increase, if any, of internally non-displayed locked or crossed markets on the Exchange. Based on the Exchange's observations and experience, in the rare event that an internally non-displayed locked or crossed book on Exchange does occur, such instances are typically alleviated almost immediately or within extremely short period of time of their initial occurrence.

In the rare occurrence an internally non-displayed locked or crossed market does occur, the Exchange has method to resolve such instances in a manner that honors intra-market price priority. This mechanism is set forth under Exchange Rule 2617(a)(4)(iv), which governs the price at which a non-displayed order is executable when there is a contra-side displayed order at a price that results in an internally locked or crossed book. Today, for securities priced equal to or greater than \$1.00 per share, in the case where a non-displayed order to sell (buy) is posted on the MIAX Pearl Equities Book at a price that locks a displayed order to buy (sell) pursuant to Exchange Rule 2617(a)(4)(iii) described above, an Aggressing Order or an incoming order to buy (sell) described in Exchange Rules 2617(a)(4)(i) and (ii) that is a Market Order or a Limit Order priced more aggressively than the order to buy (sell) displayed on the MIAX Pearl Equities Book, that Aggressing Order or incoming order will execute against the non-displayed order to sell (buy) resting on the MIAX Pearl Equities Book at one-half minimum price variation³⁶ greater (less) than the price of the resting displayed order to buy (sell).³⁷ The Exchange proposes to

11.13(a)(4)(A)–(B), and Cboe EDGA and Cboe EDGX Rules 11.10(a)(4)(A)–(B).

³³ The term "System" means the automated trading system used by the Exchange for the trading of securities. See Exchange Rule 100.

³⁴ Exchange Rule 2617(a)(4)(iii) is based on Cboe BZX and Cboe BYX Rules 11.13(a)(4)(C), and Cboe EDGA and Cboe EDGX Rules 11.10(a)(4)(C).

³⁵ The Exchange notes that its rules and the Act prohibit the Exchange from displaying a locked or crossed market and an order that would create a displayed locked or crossed market on the Exchange would be rejected, if incoming, or cancelled, if resting. See, e.g., Exchange Rules 2617(a)(4) (providing that "[a]n order will be cancelled back to the User if, based on market conditions, User instructions, applicable Exchange Rules and/or the Act and the rules and regulations thereunder, such order is not executable, cannot be routed to another Trading Center pursuant to paragraph (b) of this Exchange Rule 2617 below and cannot be posted to the MIAX Pearl Equities Book"); 2617(a)(4)(iii) (stating that "that the System will never display a locked or crossed market"); and 2624(b) (stating that "the System shall not make available for dissemination, and Users shall reasonably avoid displaying, and shall not engage in a pattern or practice of displaying, any quotations that lock or cross a Protected Quotation, and any Manual Quotations that lock or cross a quotation previously disseminated pursuant to an Effective National Market System Plan"). See also Rules 610 and 611 of Regulation NMS.

³¹ See *supra* note 15. Price improvement of \$0.0004 does not exceed the required 0.35% of the trade's value for there to be an execution pursuant to the Exchange's economic best interest functionality under Exchange Rule 2614(c)(2).

³² Exchange Rules 2617(a)(4)(i)–(ii) are based on NYSE Rule 7.37(a), Cboe BZX and Cboe BYX Rules

³⁶ See Exchange Rule 2612, Minimum Price Variations. Exchange Rule 2612(a) provides that bids, offers, orders or indications of interests in securities traded on the Exchange shall not be made in an increment smaller than: (1) \$0.01 if those bids, offers or indications of interests are priced equal to or greater than \$1.00 per share; or (2) \$0.0001 if those bids, offers or indications of interests are priced less than \$1.00 per share.

³⁷ This functionality is well established and has been previously approved by the Commission. See Securities Exchange Act Release No. 89563 (August 14, 2020), 85 FR 51510 (August 20, 2020) (SR–PEARL–2020–03) (adopting rules for MIAX Pearl Equities, including Exchange Rule 2617(a)(4)). See

amend Exchange Rule 2617(a)(4)(iv) to remove the phrase “for securities priced equal to or greater than \$1.00 per share” and, therefore, provide the same behavior for bids or offers in securities priced below \$1.00 per share as the Exchange does today for securities priced at or above \$1.00 when executing orders during times when the Exchange is experiencing a non-displayed internally locked or crossed book.

Exchange Rule 2616 sets forth the priority among orders resting on the MIAX Pearl Equities Book and there is no priority relationship between an incoming order and a same side resting order up to and until each order is resting on the MIAX Pearl Equities Book.³⁸ It is also well established that in the case of both an incoming order or between resting orders (as in the case when one order is an Aggressing Order) that, to comply with intra-market price priority, a resting order to buy (sell) will not be eligible to trade: (1) at a price equal to or above (below) any sell (buy) displayed orders that have a ranked price equal to or below (above) the price of such resting buy (sell) order; or (2) at a price above (below) any sell (buy) non-displayed order that has a ranked price below (above) the price of such resting buy (sell) order.³⁹ This behavior also allows the Exchange to manage an internally locked book while continuing to honor each order’s instructions while working to alleviate this infrequent, but abnormal market occurrence, and maintain a fair and orderly market.

In keeping with the above principles, the Exchange would apply the same standards to securities priced below \$1.00 as it does today for securities priced at or above \$1.00 under Exchange Rule 2617(a)(4)(iv). In doing so, the Exchange would honor intra-market price priority by preventing an incoming or Aggressing Order from executing at the same price as a same-side displayed order on the MIAX Pearl Equities Book.

This portion of the proposal is an expansion of existing rules and functionality available to securities priced at or above \$1.00, and therefore, does not raise any new or novel issues

not already considered by the Commission.⁴⁰

* * * * *

The following examples illustrate: (i) how the Exchange currently handles securities priced at or above \$1.00 pursuant to Exchange Rule 2617(a)(4)(iv); and (ii) how the Exchange would handle securities priced below \$1.00 pursuant to expanded Exchange Rule 2617(a)(4)(iv), as proposed to be amended herein. For each example, assume there are no orders resting on the MIAX Pearl Equities book.

Securities Priced at or Above \$1.00 (Current Behavior)

The following examples illustrate how the Exchange handles securities priced at or above \$1.00 pursuant to Exchange Rule 2617(a)(4)(iv) for both incoming orders as well as when the Exchange reevaluates the MIAX Pearl Equities Book due to an external event, such as a change to the Limit Up-Limit Down (“LULD”) Price Bands and an Aggressing Order executes against contra-side interest.

Incoming Order

Assume the PBBO was \$16.10 by \$16.11 resulting in a midpoint of \$16.105. An order to buy at \$16.11 is resting non-displayed on the MIAX Pearl Equities Book (“Order 1”). A displayed Limit Order to sell at \$16.11 designated as Post Only is subsequently entered (“Order 2”). Assume that Order 2 will not remove any liquidity upon entry pursuant to the Exchange’s economic best interest functionality under Exchange Rule 2614(c)(2), and will post to the MIAX Pearl Equities Book and be displayed at \$16.11. The display of Order 2 will, in turn, make the resting Order 1 not executable at \$16.11. An incoming order to sell at \$16.11 is then entered (“Order 3”). Order 3 will execute against Order 1 at \$16.105 per share upon entry, thus providing a half-penny of price improvement as compared to the Order 1’s limit price of \$16.11.⁴¹

⁴⁰ See *supra* note 13.

⁴¹ The Exchange notes that internally locked or crossed markets may occur on Nasdaq due to orders with a minimum quantity requirement or where one side of the market is non-displayed. In the scenario set forth in the above example, as well as similar scenario set forth in the below examples, the Exchange understands that during an internally locked or crossed market Nasdaq would execute Orders 1 and 3 at the locking price of \$16.11. The Exchange believes it is preferential to execute these orders at a price other than the locking price because doing so honors the first principle of intra-market price priority, namely that a resting order to buy (sell) will not be eligible to trade: (i) at a price equal to or above (below) any sell (buy) displayed orders that have a ranked price equal to or below

The following example describes where the execution occurs at a sub-penny price that is not at the midpoint of the PBBO. Assume the PBBO is \$16.08 by \$16.10 resulting in a midpoint of \$16.09. An order to sell at \$16.08 is resting non-displayed on the MIAX Pearl Equities Book (“Order 1”). A displayed Limit Order to buy at \$16.08 designated as Post Only is subsequently entered (“Order 2”). Assume that Order 2 will not remove any liquidity upon entry pursuant to the Exchange’s economic best interest functionality under Exchange Rule 2614(c)(2), and will post to the MIAX Pearl Equities Book and be displayed at \$16.08. The display of Order 2 will, in turn, make Order 1 not executable at \$16.08. An incoming order to buy at \$16.09 is entered (“Order 3”). Order 1 will execute against Order 3 at \$16.085 per share, thus providing a half-penny of price improvement as compared to the Order 1’s limit price of \$16.08.

Re-Evaluation of MIAX Pearl Equities Book Due to External Event

Assume the PBBO is \$50.00 by \$53.00, and the LULD Price Bands disseminated by the applicable SIP are \$49.00 by \$50.00. A non-displayed Limit Order to sell at \$50.07 is entered and placed on the MIAX Pearl Equities Book (“Order 1”). Then, a displayed Limit Order to buy at \$50.07 with a Post Only instruction is entered (“Order 2”). Order 2 cannot execute against Order 1 and remove liquidity upon entry because of the LULD Price Bands, which result in Order 2 being posted to the MIAX Pearl Equities Book and re-priced to \$50.00, the upper LULD Price Band pursuant to Exchange Rule 2622(h)(2)(A)5.b. The Exchange BBO is now \$50.00 by \$50.07. Then, a displayed Limit Order to buy at \$50.08 is entered and is also re-priced to \$50.00, the upper LULD Price Band pursuant to Exchange Rule 2622(h)(2)(A)5.b (“Order 3”). The LULD Price Bands disseminated by the applicable SIP are then updated to \$48.00 by \$51.00, causing the Exchange to evaluate its book for potential executions. First, Order 2 is re-priced to \$50.07, resulting in an internally non-displayed locked book. Order 2, the Aggressing Order, cannot execute against Order 1 and remove liquidity upon entry pursuant to the Exchange’s economic best interest functionality under Exchange Rule 2614(c)(2). Order 3 is then evaluated and executes against Order 1 at \$50.075, providing one-half minimum price increment of price

(above) the price of such resting buy (sell) order, as discussed above.

also, e.g., Choe EDGA and Choe EDGX Rules 11.10(a)(4) and Choe BYX and Choe BZX Rules 11.13(a)(4).

³⁸ See generally Exchange Rules 2616 and 2617(a)(4).

³⁹ See, e.g., Exchange Rule 2614(c)(7)(ii)(C), NYSE Rule 7.31(i)(3)(C), and Choe EDGX Rule 11.6(h) for a description of intra-market price priority in the context of a non-displayed locked or crossed market created by minimum execution quantity order types.

improvement as compared to the order's limit price of \$50.07.

Securities Priced Below \$1.00 (Proposed)

As stated above, the Exchange proposes to treat all securities the same pursuant to Exchange Rule 2617(a)(4)(iv) regardless of price. The following example illustrates this behavior and describes how the Exchange would handle securities priced below \$1.00 in the same manner as securities priced at or above \$1.00 pursuant to amended Exchange Rule 2617(a)(4)(iv) for both incoming orders as well as how an Aggressing Order would behave when the Exchange reevaluates the MIAX Pearl Equities Book due to an external event, such as a change to the Limit Up-Limit Down Price Bands.

Incoming Order

The following examples illustrates how the Exchange handles securities priced below \$1.00 pursuant to Exchange Rule 2617(a)(4)(iv).

Example No. 1

Assume the PBBO is \$0.500 by \$0.502 resulting in a midpoint of \$0.501. A Midpoint Peg Order to sell at \$0.501 is resting non-displayed on the MIAX Pearl Equities Book at \$0.501, which is also the midpoint of the PBBO ("Order 1"). A displayed Limit Order to buy 50 shares at \$0.501 designated as Post Only is subsequently entered ("Order 2"). Order 2 is an odd lot size and does not result in an update to the PBBO. Order 2 will not remove any liquidity upon entry pursuant to the Exchange's economic best interest functionality under Exchange Rule 2614(c)(2) because it would not receive the requisite price improvement, and will post to the MIAX Pearl Equities Book and be displayed at \$0.501. The display of this order will, in turn, result in an internally locked book and make Order 1 not executable at \$0.501. If an incoming order to buy is entered into the MIAX Pearl Equities Book at a price of \$0.5011 ("Order 3"), Order 1, originally priced at \$0.501, will execute against Order 3 at \$0.50105 per share, thus providing one-half minimum price increment of price improvement as compared to the order's pegged price (*i.e.* midpoint of PBBO), which also equaled its limit price, of \$0.501.

Example No. 2

The following example is a variation of the above example. Assume the PBBO is \$0.50 by \$0.53. A non-displayed Limit Order to sell at \$0.5003 is entered and placed on the MIAX Pearl Equities

Book ("Order 1"). Then, a displayed Limit Order to buy with a Post Only instruction at \$0.5007 ("Order 2") is entered. Order 2 cannot execute against Order 1 and remove liquidity upon entry pursuant to the Exchange's economic best interest functionality under Exchange Rule 2614(c)(2) because it would not receive the requisite price improvement.⁴² Therefore, Order 2 will post to the MIAX Pearl Equities Book and be displayed at \$0.5007. As a result, Order 1 will be re-priced to \$0.5007, the price of the displayed contra-side order, Order 2, pursuant to proposed Exchange Rule 2614(c)(2)(1)(A) discussed above, resulting in an internally non-displayed locked book. Then, a displayed Limit Order to buy at \$0.5008 is entered and executes against Order 1 at \$0.50075, providing one-half minimum price increment of price improvement as compared to the order's limit price of \$0.5007. However, if Order 3 was an order to sell, it would execute against Order 2 at \$0.5007, Order 2's displayed price.

Example No. 3

The following example describes when the execution occurs at a sub-penny price that is not at the midpoint of the PBBO. Assume the PBBO is \$0.5000 by \$0.5030 resulting in a midpoint of \$0.5015. An order to sell at \$0.5020 is resting non-displayed on the MIAX Pearl Equities Book. A displayed Limit Order to buy at \$0.5020 designated as Post Only is subsequently entered. Assume that the displayed order to buy designated as Post Only will not remove any liquidity upon entry pursuant to the Exchange's economic best interest functionality under Exchange Rule 2614(c)(2), and will post to the MIAX Pearl Equities Book and be displayed at \$0.5020. The display of this order will, in turn, result in an internally non-displayed locked book and make the resting non-displayed order to sell not executable at \$0.5020. If an incoming order to buy is entered into the MIAX Pearl Equities Book at a price equal to or greater than \$0.5021, the resting non-displayed order to sell originally priced at \$0.5020 will execute against the incoming order to buy at \$0.50205 per share, thus providing one-half minimum price increment of price improvement as compared to the order's limit price of \$0.5020.

⁴² See *supra* note 15. Price improvement of \$0.0004 does not exceed the required 0.35% of the trade's value for there to be an execution pursuant to the Exchange's economic best interest functionality under Exchange Rule 2614(c)(2).

Example No. 4

The following example describes when the execution occurs when the Exchange is experiencing an internally crossed market due to two contra-side non-displayed orders. Assume the PBBO is \$0.5000 by \$0.5030 resulting in a midpoint of \$0.5015. An order to buy at \$0.5003 is resting non-displayed on the MIAX Pearl Equities Book ("Order 1"). A non-displayed Limit Order to sell at \$0.5000 designated as Post Only is subsequently entered ("Order 2"). Assume Order 2 will not remove any liquidity upon entry pursuant to the Exchange's economic best interest functionality under Exchange Rule 2614(c)(2), and will post to the MIAX Pearl Equities Book non-displayed at \$0.5000. This will, in turn, result in an internally non-displayed crossed book of \$0.5003 by \$0.5000. An incoming order to sell is entered into the MIAX Pearl Equities Book at a price equal to or less than \$0.5000 will execute against Order 1 at \$0.5003.

Re-Evaluation of MIAX Pearl Equities Book Due to External Event

Assume the PBBO is \$0.50 by \$0.53, and the LULD Price Bands disseminated by the applicable SIP are \$0.49 by \$0.50. A non-displayed Limit Order to sell at \$0.5003 is entered and placed on the MIAX Pearl Equities Book ("Order 1"). Then, a displayed Limit Order to buy with a Post Only instruction to buy at \$0.5007 ("Order 2"). Order 2 cannot execute against Order 1 due to the LULD Price Bands which cause Order 2 to be posted to the MIAX Pearl Equities Book and re-priced to \$0.50, the upper LULD Price Band pursuant to Exchange Rule 2622(h)(2)(A)5.b. The Exchange BBO is now \$0.50 by \$0.5003. Then, a displayed Limit Order to buy at \$0.5008 is entered and is also re-priced to \$0.50, the upper LULD Price Band pursuant to Exchange Rule 2622(h)(2)(A)5.b ("Order 3"). The LULD Price Bands disseminated by the applicable SIP are then updated to \$0.48 by \$0.51, causing the Exchange to evaluate its book for potential executions. First, Order 2 is re-priced to \$0.5007 and cannot execute against Order 1 and remove liquidity pursuant to the Exchange's economic best interest functionality under Exchange Rule 2614(c)(2). As a result, Order 1 will be re-priced to \$0.5007, the price of the displayed contra-side order, Order 2 pursuant to proposed Exchange Rule 2614(c)(2)(1)(A) discussed above, resulting in an internally non-displayed locked book. Order 2, the Aggressing Order, cannot execute against Order 1 and remove liquidity upon entry pursuant to the Exchange's economic

best interest functionality under Exchange Rule 2614(c)(2). Order 3 executes against Order 1 at \$0.50075, providing one-half minimum price variation of price improvement as compared to the order's limit price of \$0.5007.

Implementation

Should the Commission approve this proposal, the Exchange will issue a trading alert publicly announcing the implementation date of the proposed amendments.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with Section 6(b) of the Act,⁴³ in general, and furthers the objectives of Section 6(b)(5),⁴⁴ in particular, because it is designed to prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest.

Expanding Post Only Instruction to Sub-Dollar Securities

In sum, the Exchange believes the proposed amendments to Exchange Rule 2614(c)(2) to extend the Post Only instruction to securities priced below \$1.00 will remove impediments to and perfect the mechanism of a free and open market and a national market system because it would provide for similar treatment to all orders in all securities regardless of price. This portion of the proposal also promotes just and equitable principles of trade because it will allow Equity Members to utilize the Post Only instruction on an order for a security at any price, rather than being limited to securities priced at or above \$1.00. The Post Only instruction is an important tool in U.S. equities markets because it allows Equity Members to post aggressively priced liquidity, and provides certainty as to the fee or rebate that will be applied by the Exchange if their order is executed. Without such ability, the Exchange believes that certain Equity Members would simply post less aggressively priced liquidity, and prices available for market participants, including retail investors, may be adversely impacted. Orders with a Post

Only instruction contribute to improved liquidity, market depth and, if displayed, price transparency. Expanding Post Only functionality to orders in sub-dollar securities would provide an additional exchange-level pool of liquidity for market participants that utilize Post Only functionality for sub-dollar securities. As such, the proposed rule change may encourage market participants to send additional sub-dollar trading volume to the Exchange, rather than the off-exchange marketplace, and, therefore, serve to improve on-exchange liquidity and price transparency in sub-dollar securities. Orders with a Post Only instruction entered on the Exchange could improve price transparency if the entering firm elected such order to be displayed and made available via an Exchange's data feeds and disseminated by the applicable SIP. Allowing an order in a security priced below \$1.00 to contain a Post Only instruction would also deepen the Exchange's pool of available liquidity in sub-dollar securities, which is a growing area of trading, particularly for retail investors. A deeper and more liquid market supports the quality of price discovery, promotes market transparency, and improves market quality for all investors.

As noted above, the Exchange adopted its current Post Only behavior as part of its broader proposal to adopt rules governing trading of equity securities, in which it sought to operate its equity market in a manner similar to that of other equity exchanges that it based its rules and functionality upon several years ago. This included adopting functionality that limited the availability of the Post Only instruction to orders in securities priced at or above \$1.00. Again, and importantly, the Exchange did not adopt this limitation due to fear of some potential nefarious activity in sub-dollar securities trading, but rather due to lack of interest by market participants in such functionality at the time MIAx Pearl Equities was being developed and filing its initial rule set with the Commission for approval.

This portion of the proposal also does not raise any new or novel issues as identical functionality is available on other equities exchanges. As discussed above, Nasdaq and their affiliated markets provide Post Only Orders to all securities regardless of price, which are posted, ranked, and displayed or posted non-displayed, as applicable, at their limit price upon entry. However, Nasdaq permits a Post-Only Order to execute upon entry if "the value of price improvement associated with executing

against an Order on the Nasdaq Book (as measured against the original limit price of the Order) equals or exceeds the sum of fees charged for such execution and the value of any rebate that would be provided if the Order posted to the Nasdaq Book and subsequently provided liquidity".⁴⁵ This is analogous to the Exchange's current behavior for orders with a Post Only instruction in securities priced at or above \$1.00 as well as the Exchange's proposed changes described herein for securities priced below \$1.00. The NYSE and its affiliate exchanges also provide similar "post only" functionality in the form of ALO orders, which is also available to securities priced below \$1.00.⁴⁶ This portion of the Exchange's proposal would remove impediments to and perfect the mechanism of a free and open national market system because it seeks to expand the population of exchanges that offer "post only" treatment for securities priced below \$1.00 by allowing the Exchange to provide an additional exchange-level pool of liquidity where market participants may send such orders.

This proposal is designed to facilitate transactions in securities by increasing competition among exchanges for the currently available order flow in securities priced below \$1.00 by ensuring that all order types and order instructions are available equally to all securities regardless of the order's price. As explained above, providing "post only" treatment in securities priced below \$1.00 should not increase the overall volume or order flow in sub-dollar securities but could encourage more aggressively priced liquidity, improve liquidity, market depth and, if displayed, price transparency in such securities. The Exchange believes this proposal will facilitate transactions in sub-dollar securities by increasing exchange competition by allowing the Exchange to provide functionality that would allow it to attract a greater slice of the current volume in sub-dollar securities, while also encouraging market participants to send their sub-dollar trading volume to an exchange-level pool of liquidity, rather than opaque off-exchange trading venues (*i.e.*, dark pools), which are less transparent. Therefore, the Exchange believes this proposal will enhance exchange competition, facilitate transactions in sub-dollar securities, and not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

⁴³ 15 U.S.C. 78f(b).

⁴⁴ 15 U.S.C. 78f(b)(5).

⁴⁵ See Nasdaq Equity 4, Rule 4702(b)(4).

⁴⁶ See, *e.g.*, NYSE Rule 7.31(e)(2).

This proposal is not intended to encourage an increase in the overall volume or order flow in sub-dollar securities. Trading in sub-dollar securities both on- and off-exchange has grown significantly since the Exchange adopted Exchange Rule 2614(c)(2) and launched operations in September 2020. For example, average daily sub-dollar trading volume comprised approximately 9% of the overall daily volume in September 2025. In fact, the Exchange found that overall volume in sub-dollar securities has been slowly decreasing since June 2025 from approximately 14% to 9% in September 2025. Meanwhile, off-exchange market share in sub-dollar securities remained high averaging over 60%.⁴⁷

As mentioned above, there are numerous factors that have contributed to the increase in sub-dollar trading volumes and approval of this proposal, alone, would not further encourage or contribute to an increase in sub-dollar trading volumes. Rather, the Exchange believes this proposal will remove impediments to a free and open market by increasing inter-market competition. The proposed changes will allow the Exchange to provide functionality to attract a greater slice of the current volume in sub-dollar securities by encouraging market participants to send their sub-dollar trading volume to another exchange-level pool of liquidity, rather than the opaque off-exchange trading venues (*i.e.*, dark pools), which are less transparent. In addition, Equity Members recently requested the Exchange modify its Post Only instruction as proposed. The Exchange, therefore, believes this portion of the proposal is consistent with the Act.

In addition, amended Exchange Rule 2614(c)(2) is not unfairly discriminatory, but rather promotes equal treatment of all Equity Members, as it will permit the Post Only instruction to be used by all Equity Members that submit orders for securities at any price and the order instruction will no longer be limited to securities priced at or above \$1.00.

Expanding Existing Functionality To Avoid or Alleviate Internally Locked or Crossed Markets to Securities Priced Below \$1.00 With a Post Only Instruction

As discussed above, differences exist between the market structures for securities priced at or above \$1.00 and those below \$1.00 that impact how the

Post Only order instruction may function. This includes different fee levels and minimum price increments which could allow an order with a Post Only instruction to only result in an internally locked market in securities priced at or above \$1.00 and both an internally locked or crossed market in securities priced below \$1.00. Also, as discussed above, the Exchange reviewed its own data and found that internally locked and crossed markets are rare events and should continue to be rare under this proposal. Based on the Exchange's expertise and experience, the Exchange anticipates that expanding the Post Only instruction to sub-dollar securities would cause at most, a potential de minimis, if any, increase of internally non-displayed locked or crossed markets on the Exchange. Also, based on the Exchange's observations and experience, in the rare event such instances do occur, an internally non-displayed locked or crossed book is typically alleviated almost immediately or within extremely short period of time of their initial occurrence.

Nonetheless, in the rare event they do occur, the Exchange has well established mechanisms to both avoid an internally locked or crossed market and to alleviate an internally locked or crossed market. This includes expanding current re-pricing functionality by adopting Exchange Rule 2614(c)(2)(i)(A) to reprice non-displayed orders in securities priced below \$1.00 to the locking price of the displayed order resting on the MIAX Pearl Equities Book to help reduce the occurrence of an internally crossed book.⁴⁸ In addition, should an internally locked or crossed market occur, the Exchange has a current mechanism under Exchange Rule 2617(a)(4)(iv) to alleviate those occurrences while honoring intra-market price priority. Expanding this mechanism under Exchange Rule 2617(a)(4)(iv) to securities priced below \$1.00 would allow for the Exchange to alleviate an internally locked or crossed book and would provide for the consistent treatment of all securities during an internally locked or crossed market, regardless of price.

⁴⁸ The Exchange notes that this functionality would also apply to orders in securities priced at or above \$1.00 in the unlikely event that an incoming order in a security priced at or above \$1.00 with a Post Only instruction would post to the MIAX Pearl Equities Book and result in an internally non-displayed crossed market.

Re-Pricing Non-Displayed Orders to the Locking Price To Decrease the Occurrence of an Internally Crossed Market

The Exchange believes proposed Exchange Rule 2614(c)(2)(i)(A) to re-price non-displayed orders to the locking price, including those with a Post Only instruction that would cross a contra-side displayed order promotes just and equitable principles of trade because it would serve to decrease the occurrence of the Exchange experiencing an abnormal market condition in the form of a non-displayed internally crossed book. The Exchange will never post a displayed or non-displayed order to the MIAX Pearl Equities Book at a price that would cross a contra-side displayed order.

In addition, proposed Exchange Rule 2614(c)(2)(i)(A) is analogous to how the Exchange currently reprices orders with an MEQ instruction pursuant to Exchange Rule 2614(c)(7)(B)(ii).⁴⁹ The Exchange believes utilizing this re-pricing mechanism for sub-dollar securities with a Post Only instruction promotes just and equitable principles of trade because this functionality would be consistent with how the Exchange currently reprices orders with a MEQ instruction, which has previously been considered by the Commission.⁵⁰ This proposal simply seeks to expand such functionality without raising new discrimination concerns among orders below and above (or at) \$1.00. Re-pricing non-displayed orders with a Post Only instruction to the locking price of the displayed order, as proposed, is appropriate and necessary to avoid an internally crossed market. Doing so in favor of the displayed order allows the displayed order to continue to contribute to price discovery at that price level while the non-displayed order does not provide

⁴⁹ Exchange Rule 2614(c)(7)(B)(ii) provides that where there is insufficient size to satisfy the minimum quantity condition of an incoming order to buy (sell) and that incoming order, if posted at its limit price, would cross a displayed order to sell (buy) resting on the MIAX Pearl Equities Book, the order to buy (sell) with the MEQ instruction will have a working price equal to the price of the displayed order to sell (buy).

⁵⁰ This functionality is not unique and is similar to the Exchange's current Non-Displayed Price Sliding Process where the Exchange re-prices a non-displayed order to buy (sell) that would cross the PBO (PBB) of an away Trading Center to the locking price. See Exchange Rule 2614(g)(2). The only difference being that the Exchange would re-price a non-displayed order, like it currently does for an order with a Minimum Execution Quantity instruction, that crosses the PBO (PBB) of the Exchange in addition to the PBO (PBB) of an away Trading Center. The Exchange also notes that both NASDAQ and IEX also re-price orders with a minimum quantity condition upon entry. See NASDAQ Rule 4703(e) and IEX Rule 11.190(h)(2).

⁴⁷ See MEMX LLC's December 2024 Exchange Highlights, dated January 10, 2024, available at <https://memx.com/exchange-highlights-key-trading-trends-that-defined-another-banner-year-in-the-markets/>.

like pre-trade price transparency. The Exchange's rules would be clear as to when a non-displayed order may be re-priced to the locking price when there is contra-side displayed interest resting on the MIAX Pearl Equities Book and, thus, avoid an internally crossed market. Market participants who do not want their orders to be re-priced may enter the non-displayed order with a limit price that would prevent the order from being re-priced to an undesirable price level or those market participants may immediately cancel such order if they choose to do so. Equity Members are also free to choose which trading venues to route orders to and those that seek to avoid this functionality are free to route their non-displayed orders to another exchange.

This is also analogous to the Exchange's current Non-Displayed Price Sliding Process set forth under Exchange Rule 2614(g)(2) where the Exchange would also reprice a non-displayed order to the locking price. Pursuant to Exchange Rule 2614(g)(2), to avoid potentially trading through Protected Quotations of an away Trading Center, a non-displayed, non-routable order to buy (sell) that, upon entry or due to a change in the PBO (PBB), would cross the PBO (PBB) of an away Trading Center will be assigned a working price by the System equal to the PBO (PBB). Both IEX and Nasdaq re-price non-displayed orders to avoid an internally crossed market. In certain circumstances, Nasdaq re-prices non-displayed orders to buy (sell) to one minimum price increment below (above) the lowest (highest) price of resting orders to avoid an internally crossed market.⁵¹ Likewise, IEX re-prices non-displayed orders that include a limit price more aggressive than the midpoint of the NBBO to the midpoint of the NBBO to prevent such orders from being posted at a price that crossed their midpoint of the NBBO.⁵² The Exchange, therefore, believes that this portion of the proposal is consistent with the Act because it enables the Exchange to avoid an internally crossed book and is based on existing functionality in place on the Exchange and other equity exchanges to avoid internally crossed markets. The Exchange also believes re-pricing a non-displayed order as proposed herein promotes just and equitable principles

of trade because it seeks to avoid an abnormal market condition, *i.e.*, an internally crossed book, in favor of an order with the Post Only instruction that could represent more aggressively priced liquidity and price improvement opportunities for other contra-side orders. Like the Exchange provides today for orders with an MEQ instruction, Equity Members would be immediately notified if their order is re-priced as proposed herein and may re-enter such order with a new price if they choose to do so. The Exchange, therefore, believes the proposed changes do not raise any new or novel issues not already considered by the Commission.

The Exchange believes it is appropriate and not unfairly discriminatory to reprice the non-displayed order as proposed above, and consistent with how it currently reprices orders with a MEQ instruction, which has previously been considered by the Commission.⁵³ This proposal simply seeks to expand such functionality without raising new discrimination concerns. Re-pricing non-displayed orders with a Post Only instruction to the locking price of the displayed order, as proposed, is appropriate and necessary to avoid an internally crossed market. Doing so in favor of the displayed order allows the displayed order to continue to contribute to price discovery at that price level while the non-displayed order does not provide like pre-trade price transparency. The Exchange's rules would be clear as to when a non-displayed order may be re-priced to the locking price when there is contra-side displayed interest resting on the MIAX Pearl Equities Book and, thus, avoid an internally crossed market. Market participants who do not want their orders to be re-priced may enter the non-displayed order with a limit price that would prevent the order from being re-priced to an undesirable price level or those market participants may immediately cancel such order if they choose to do so. Equity Members are also free to choose which trading venues to route orders to and those that seek to avoid this functionality are free to route

their non-displayed orders to another exchange.

Expanding Current Internally Locked or Crossed Book Order Handling To Alleviate an Internally Locked or Crossed Market to Securities Priced Below \$1.00

The occurrence of a non-displayed internally locked or crossed market on the Exchange is an extremely rare occurrence, and the Exchange does not anticipate that this proposal would cause anything more than a potential de minimis increase, if any. Should they occur, the Exchange has an effective mechanism in place today for securities priced at or above \$1.00 that it simply seeks to expand to securities priced below \$1.00 to alleviate an internally locked or crossed book. Specifically, expanding Exchange Rule 2617(a)(4)(iv) to securities priced below \$1.00 would facilitate transactions in securities during the extremely rare occurrence of a non-displayed internally locked or crossed market where a resting contra-side displayed order would otherwise prohibit such order from execution against an incoming or Aggressing Order by allowing an execution at one-half minimum price variation greater (less) than the price of the resting displayed order to buy (sell), as set forth in the Rule. In doing so, the proposal would also provide that all orders, regardless of price, are executable at the applicable one-half minimum price increment during a non-displayed internally locked or crossed market, while also ensuring that the Exchange continues to honor the intra-market price priority of all orders in such circumstances.

As discussed above, the principle of intra-market price priority provides that, in the case of both an incoming order or between resting orders that a resting order to buy (sell) will not be eligible to trade: (1) at a price equal to or above (below) any sell (buy) displayed orders that have a ranked price equal to or below (above) the price of such resting buy (sell) order; or (2) at a price above (below) any sell (buy) non-displayed order that has a ranked price below (above) the price of such resting buy (sell) order.⁵⁴ The Exchange proposes to apply the same intra-market price priority standards to securities priced below \$1.00 as it does today for securities priced at or above \$1.00 under Exchange Rule 2617(a)(4)(iv). Doing so would ensure the Exchange continues to

⁵³ This functionality is not unique and is similar to the Exchange's current Non-Displayed Price Sliding Process where the Exchange re-prices a non-displayed order to buy (sell) that would cross the PBO (PBB) of an away Trading Center to the locking price. See Exchange Rule 2614(g)(2). The only difference being that the Exchange would re-price a non-displayed order, like it currently does for an order with a Minimum Execution Quantity instruction, that crosses the PBO (PBB) of the Exchange in addition to the PBO (PBB) of an away Trading Center. The Exchange also notes that both NASDAQ and IEX also re-price orders with a minimum quantity condition upon entry. See NASDAQ Rule 4703(e) and IEX Rule 11.190(h)(2).

⁵¹ See Nasdaq Rule 4703(e). For example, Nasdaq Rule 4703(e) provides that if there was an order to buy at \$11 with a minimum quantity condition of 500 shares, and there were resting orders on the Nasdaq Book to sell 200 shares at \$10.99 and 300 shares at \$11, the order would be re-priced to \$10.98 and ranked at that price.

⁵² See IEX Rule 11.190(h)(2).

⁵⁴ See, *e.g.*, Exchange Rule 2614(c)(7)(ii)(C), NYSE Rule 7.31(i)(3)(C), and Cboe EDGX Rule 11.6(h) for a description of intra-market price priority in the context of a non-displayed locked or crossed market created by minimum execution quantity order types).

honor intra-market price priority in securities priced below \$1.00 by preventing an incoming or resting order from executing at the same or better price as a displayed order or same price as a non-displayed order resting on the MIAX Pearl Equities Book. In doing so, the Exchange would not violate intra-market price priority for sub-dollar securities when trading out of an internally locked or crossed market.

This portion of the proposal would allow the Exchange to treat orders in securities below \$1.00 in a similar manner as securities priced at or above \$1.00, thereby providing market participants with consistent handling of all orders regardless of price. This order handling is necessary in order to address specific conditions that are present on the MIAX Pearl Equities Book when an order containing a Post Only instruction is displayed opposite the ranked price of a non-displayed order resulting in an internally locked or crossed book. The proposal would also facilitate transactions in securities by making orders eligible for execution where a resting contra-side displayed order would otherwise prohibit such order from execution against an incoming or Aggressing Order.

In sum, this would allow all orders to be treated in a similar manner, regardless of price by providing, under limited circumstances, a resting order priced below \$1.00 that would otherwise be non-executable due to the presence of a displayed order, including a displayed order containing a Post Only instruction. Pursuant to Exchange Rule 2617(a)(4)(iv) an order that is currently unable to execute at the locking price due to the presence of a contra-side displayed order would be eligible to execute against an incoming order priced more aggressively than the contra-side displayed order at one-half minimum price increment above (below) the locking price.

For the reasons set forth above, the Exchange believes amended Exchange Rule 2617(a)(4)(iv) is consistent with the Act because it would allow the Exchange to facilitate transactions in securities, honor intra-market price priority, and alleviate an internally non-displayed locked or crossed book that may occur due to expanding the availability of the Post Only instruction to securities priced below \$1.00. The current one-half minimum price increment functionality for securities priced at or above \$1.00 under Exchange Rule 2617(a)(4)(iv) has in fact been approved repeatedly by the Commission in the past and that identical functionality should be expanded to

cover securities priced below \$1.00.⁵⁵ The Exchange simply seeks to expand this functionality to securities priced below \$1.00, therefore, believes its proposal is consistent with Section 6(b)(5) of the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Intra-Market Competition

The Exchange does not believe that the proposed rule change will impose any burden on intra-market competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed changes to Exchange Rule 2614(c)(2) will apply equally to all Equity Members and all Equity Members will be eligible to utilize the Post Only instruction for securities priced below \$1.00, just as they do today for securities priced at or above \$1.00.

Similarly, the proposed change to Exchange Rule 2617(a)(4)(iv) applies similarly to all Equity Members because the proposed order handling behavior changes abide by the principles of intra-market price priority and will treat all securities in a similar fashion, regardless of price. Each proposed change is designed to expand an existing Exchange order instruction and existing order handling behavior to securities priced below \$1.00, with no change, due to the growth in sub-dollar trading volumes that the Exchange has experienced since it launched operations in September 2020.

Proposed Exchange Rule 2614(c)(2)(i)(A) to re-price to the locking price of non-displayed orders, including

⁵⁵ See, e.g., Securities Exchange Act Release Nos. 88806 (May 4, 2020), 85 FR 27451 (May 8, 2020) (File No. 10-237) (Approving MEMX LLC's exchange application which included MEMX Rule 11.10(a)(4)); 73468 (October 29, 2014), 79 FR 65450 (November 4, 2014) SR-EDGX-2014-18 (Notice of Filing of Amendment Nos. 1 and 3 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1 and 3, To Amend EDGX Rule 1.5 and Chapter XI Regarding Current System Functionality Including the Operation of Order Types and Order Instructions, which included Cboe EDGX Rule 11.10(a)(4)) (SR-EDGX-2014-18); and 73592 (November 13, 2014), 79 FR 68937 (November 19, 2014) (SR-EDGA-2014-20) ("Notice of Filing of Amendment Nos. 1 and 2 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1 and 2, To Amend EDGA Rule 1.5 and Chapter XI Regarding Current System Functionality Including the Operation of Order Types and Order Instructions, which included Cboe EDGA Rule 11.10(a)(4)). See also, e.g., Cboe EDGA Rule 11.10(a)(4). See also Cboe BYX and Cboe BZX Rules 11.13(a)(4).

those with a Post Only instruction, that would cross a contra-side displayed order is similar to how the Exchange currently reprices orders with a MEQ instruction pursuant to Exchange Rule 2614(c)(7)(B)(ii). This portion of the proposal simply seeks to provide consistent treatment of similarly situated orders and should not impose any burden on intra-market competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Overall, the Exchange believes its proposal will not impose any burden on intra-market competition because the proposed functionality would be available to all Equity Members who may choose to utilize the proposed change based on their own business decisions and trading behaviors.

Inter-Market Competition

The Exchange similarly does not believe that the proposed rule change will impose any burden on inter-market competition that is not necessary or appropriate in furtherance of the purposes of the Act. In fact, the Exchange notes other national equities exchanges already offer identical "post only" treatment of orders priced below \$1.00.⁵⁶ There are numerous other factors that contribute to sub-dollar trading volumes, the majority of which occurs off-exchange.⁵⁷ This proposal would expand the population of exchanges that offer "post only" treatment for securities priced below \$1.00 and would not only allow the Exchange to compete with exchanges that currently offer such functionality to sub-dollar securities, but also enable the Exchange to provide an additional exchange-level pool of liquidity where market participants may send such orders. The Exchange believes this proposal will increase exchange competition by allowing the Exchange to provide functionality that would allow it to attract a greater slice of the current volume in sub-dollar securities

⁵⁶ See *supra* notes 22, 23, and 24.

⁵⁷ The increase in sub-dollar trading volume has not been due to any new or novel exchange order types, but rather increased retail participation, especially since the Covid-19 pandemic and social media fueled hype; rise of off-exchange trading, including dark pools; reverse stock splits; and high market volatility causing prices to fall and making them prone to trading below \$1.00. See, e.g., U.S. Equities Volume Drivers: Retail Trading in Subdollar Securities, dated November 24, 2024, available at <https://www.cboe.com/insights/posts/u-s-equities-volume-drivers-retail-trading-in-subdollar-securities/>; and Off Exchange Trading Increases Across all Types of Stocks, dated February 13, 2025, available at <https://www.nasdaq.com/articles/exchange-trading-increases-across-all-types-stocks#::-text=The%20rise%20is%20largely%20driven.ATS%20trades%20printed%20off%20Dexchange.>

by encouraging market participants to send their sub-dollar trading volume to an exchange-level pool of liquidity, rather than the opaque off-exchange trading venues (*i.e.*, dark pools), which are less transparent. The Exchange believes its proposal to expand the use of the Post Only instruction to securities priced below \$1.00 will promote competition between the Exchange and other exchanges for volume in sub-dollar securities.

The Exchange similarly believes that its proposal to amend Exchange Rule 2617(a)(4)(iv) does not impose a burden on inter-market competition as the change is not designed to address any competitive issue, but rather to address order handling behavior in a similar manner to how the Exchange treats orders priced at or above \$1.00 while continuing to abide by the above stated principles of intra-market price priority.

Proposed Exchange Rule 2614(c)(2)(i)(A) to re-price to the locking price of a non-displayed orders, including those with a Post Only instruction, that would cross a contra-side is similar to how the Exchange currently reprices orders with a Minimum Execution Quantity instruction pursuant to Exchange Rule 2614(c)(7)(B)(ii). This portion of the proposal simply seeks to provide consistent treatment of similarly situated orders and should not impose any burden on inter-market competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

A. by order approve or disapprove such proposed rule change, or

B. institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing,

including whether the proposed rule change 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-PEARL-2025-50 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-PEARL-2025-50. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-PEARL-2025-50 and should be submitted on or before January 20, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁵⁸

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025-23809 Filed 12-23-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-104463; File No. SR-CboeBYX-2025-036]

Self-Regulatory Organizations; Cboe BYX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 11.9(c)(8) To Clarify Pegged Order Operation and To Align BYX Rule 11.9(c)(8) With the Corresponding Rule of Its Affiliate Exchanges, Cboe EDGA Exchange, Inc. ("EDGA") and Cboe EDGX Exchange, Inc. ("EDGX")

December 19, 2025.

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 December 16, 2025, Cboe BYX Exchange, Inc. (the "Exchange" or "BYX") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a "non-controversial" proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act³ and Rule 19b-4(f)(6) thereunder.⁴ The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BYX Exchange, Inc. ("BYX" or the "Exchange") is filing with the Securities and Exchange Commission (the "Commission") a proposed rule change to amend Rule 11.9(c)(8) to clarify Pegged Order operation and to align BYX Rule 11.9(c)(8) with the corresponding rule of its affiliate exchanges, Cboe EDGA Exchange, Inc. ("EDGA") and Cboe EDGX Exchange, Inc. ("EDGX"). The text of the proposed rule changes is in Exhibit 5.

The text of the proposed rule change is also available on the Commission's website (<https://www.sec.gov/rules/sro.shtml>), the Exchange's website (https://www.cboe.com/us/equities/regulation/rule_filings/bzx/), and at the principal office of the Exchange.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 78s(b)(3)(A)(iii).

⁴ 17 CFR 240.19b-4(f)(6).

⁵⁸ 17 CFR 200.30-3(a)(12).

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 11.9(c)(8) to clarify Pegged Order operation and to align BYX Rules with the rules of its affiliate exchanges in order to provide consistency amongst the Exchange and its affiliates. The Exchange notes that the proposed rule text is based on EDGA/EDGX Rule 11.6(j) and is different only to the extent necessary to conform to the Exchange's current rules.⁵ The proposed amendment does not propose to implement new or unique functionality that has not been previously filed with the Commission or is not available on EDGA or EDGX.

By way of background, Exchange Rule 11.9, Orders and Modifiers, lists and describes the types of orders Users⁶ may enter into the System,⁷ including Pegged Orders as described in Exchange Rule 11.9(c)(8). A Pegged Order⁸ is a limit order that after entry into the System, the price of the order is automatically adjusted by the System in response to changes in the NBBO.⁹ A Pegged Order will peg to the NBB or NBO or a certain amount away from the

NBB¹⁰ or NBO,¹¹ as described in Exchange Rules 11.9(c)(8)(A) and 11.9(c)(8)(B). Pegged Orders are not eligible for routing pursuant to Exchange Rule 11.13(b).¹² A new time stamp is created for a Pegged Order each time it is automatically adjusted.¹³

A Pegged Order may be a Primary Pegged Order or a Market Pegged Order.¹⁴ A Primary Pegged Order will have its price pegged by the System to the NBB, for a buy order, or the NBO for a sell order.¹⁵ A User may, but is not required to, specify that such order's price will offset the inside quote on the same side of the market by an amount set by the User (the "Primary Offset Amount").¹⁶ A Primary Pegged Order is eligible to be displayed or non-displayed, however, the Primary Offset Amount for a displayed Primary Pegged Order must result in the price of such order being inferior to or equal to the inside quote on the same side of the market.¹⁷ A displayed Primary Pegged Order with a Primary Offset Amount shall only include a time-in-force of RHO,¹⁸ or if entered during Regular Trading Hours,¹⁹ a time-in-force of Day.²⁰

A Market Pegged Order has its price pegged by the System to the NBB, for a sell order, or the NBO, for a buy order.²¹ A User entering a Market Pegged Order can specify that such order's price will offset the inside quote on the contra side of the market by an amount set by the User (the "Offset Amount").²² A Market

Pegged Order is not eligible to be displayed on the Exchange.²³

Now, the Exchange proposes to amend the description of a Pegged Order under Rule 11.9(c)(8) to align with EDGA/EDGX Rule 11.6(j) and to clarify that a Pegged Order will not be eligible for execution where the NBB or NBO, as applicable, is no longer available. Further, the proposed rule text will provide that a new timestamp is created for an order that has been ineligible for execution and again becomes eligible for execution because the NBB or NBO it is pegged to becomes unavailable [sic].

Currently, when the NBB or NBO becomes unavailable, a Pegged Order is cancelled back to the User. As proposed, instead of being cancelled back to the User, a Pegged Order will remain on the BYX Book. When the NBB or NBO that the Pegged Order is pegged to becomes available again, the order will receive a new time stamp and be eligible for execution. The proposed rule change provides additional detail with regard to the operation of Pegged Orders when the NBB or NBO, as applicable, is unavailable, that is currently not included in Exchange Rule 11.9(c). This proposed rule change does not propose to implement new or unique functionality that has not been previously filed with the Commission or is not available on EDGA or EDGX.

Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the "Act") and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.²⁴ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)²⁵ requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)²⁶ requirement that

¹⁰ See Rule 1.5(o). The term "NBB" shall mean the national best bid.

¹¹ See Rule 1.5(o). The term "NBO" shall mean the national best offer.

¹² See Rule 11.9(c)(8).

¹³ *Id.*

¹⁴ *Id.*

¹⁵ See Rule 11.9(c)(8)(A).

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ See Rule 11.9(b)(7). A time-in-force of Regular Hours Only ("RHO") may be applied to a limit or market order that is designated for execution only during Regular Trading Hours, which includes the Opening Auction, the Closing Auction, and IPO/Halt Auctions for BYX listed securities and the Opening Process for non-BYX-listed securities (as such terms are defined in Rule 11.23 and 11.24). Any portion of a market RHO order will be cancelled immediately following any auction in which it is not executed.

¹⁹ See Rule 1.5(w). The term "Regular Trading Hours" means the time between 9:30 a.m. and 4:00 p.m. Eastern Time.

²⁰ See Rule 11.8(b)(2). A time-in-force of Day may be applied to a limit order to buy or sell, which, if not executed, expires at the end of Regular Trading Hours. Any Day Order entered into the System before the opening of business on the Exchange as determined pursuant to Rule 11.1, or after the closing of Regular Trading Hours, will be rejected.

²¹ See Rule 11.9(c)(8)(B).

²² *Id.*

²³ *Id.*

²⁴ 15 U.S.C. 78f(b).

²⁵ 15 U.S.C. 78f(b)(5).

²⁶ *Id.*

⁵ To the extent a proposed rule change is based on existing EDGA and EDGX Rules, the language of the EDGA, EDGX, and Exchange Rules may differ to extent necessary to conform with existing Exchange rule text or to account for details or descriptions included in the Exchange Rules but not currently included in EDGA and EDGX Rules based on the current structure of such rules.

⁶ See Exchange Rule 1.5(cc). A "User" is defined as "any Member or Sponsored Participant who is authorized to obtain access to the System pursuant to Rule 11.3."

⁷ See Exchange Rule 1.5(aa). The "System" is defined as "the electronic communications and trading facility designated by the Board through which securities orders of Users are consolidated for ranking, execution and, when applicable, routing away."

⁸ See Rule 11.9(c)(8).

⁹ See Rule 1.5(o). The term "NBBO" shall mean the national best bid or offer.

the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The proposed rule change is designed to support the principles of Section 11A(a)(1)²⁷ of the Act in that it seeks to assure fair competition among brokers and dealers and among exchange markets.

The proposed rule change is intended to more thoroughly describe Pegged Order operation and to align BYX Rules with the rules of its affiliate exchanges in order to provide consistent offerings amongst the Exchange and its affiliates, which the Exchange believes is designed to remove impediments to and perfect the mechanism of a free and open market and a national market system, thereby protecting investors and the public interest. Consistency amongst the rules of the Exchange and its affiliates, in turn, will promote rule compliance for Users of the Exchange that are also participants on EDGA and/or EDGX. The proposed rule change does not propose to implement new or unique functionality that has not been previously filed with the Commission or is not described in the rules of its affiliate exchanges. By aligning BYX Rules with the rules of EDGA and EDGX, the Exchange believes the proposed rule change will remove impediments to the mechanism of a free and open market and protect investors by providing investors with increased transparency regarding rules that reflect the behavior of Pegged Order on the Exchange when the NBB or NBO, as applicable, becomes unavailable. As a result, the Exchange's proposal will promote just and equitable principles of trade and remove impediments to and perfect the mechanism of a free and open market and a national market system. Additionally, the proposal does not permit unfair discrimination among customers, brokers, or dealers because the proposed Pegged Order behavior will apply to all Users equally in that any User's Pegged Order will become non-executable in the event that the NBB or NBO, as applicable, becomes unavailable and a Pegged Order will receive a new timestamp when the NBB or NBO becomes available and the order again becomes eligible for execution.

As described above, the proposed amendment is designed to ensure clarity in the Exchange's rulebook with respect to the operation of Pegged Orders in the event that the NBB or NBO, as applicable, becomes unavailable. The Exchange notes that the proposed amendment is based on EDGA/EDGX Rule 11.6(j) and is different only to the

extent necessary to conform to the Exchange's current rules. Thus, the proposed amendment to Rule 11.9(c)(8) is directly targeted at removing impediments to and perfecting the mechanism of a free and open market and national market system, as well as to assure fair competition among brokers and dealers and among exchange markets.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange notes that the proposed amendment to clarify Pegged Order behavior will provide consistent offerings amongst the Exchange and its affiliates. The Exchange does not believe the proposed change will have any impact on intermarket competition as the proposal is not being made for competitive reasons, but rather to align the text of BYX Rule 11.9(c)(8) with the corresponding rule text of its affiliate exchanges. In addition, the Exchange believes the proposed rule change will benefit all Users in that Users will have a more complete understanding of Pegged Order behavior when the NBB or NBO, as applicable, becomes unavailable. The proposed rule change will apply equally to all Users of Pegged Orders.

The Exchange does not believe that the proposed amendments will impose any burden on intra-market competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange provides services in a highly competitive market in which participants may avail themselves of a wide variety of order types and order operations offered by self-regulatory organizations, other broker-dealers, market participants' own proprietary routing systems, and service bureaus. In such an environment, more detailed descriptions of the types of orders Users may enter into the System, such as the changes proposed in this rule filing do not burden competition, because they can succeed in attracting order flow to the Exchange only if they offer investors higher quality and better value than services offered by others. The Exchange reiterates that the proposed rule change to clarify Pegged Order behavior is being proposed in an effort to add consistency to offerings across the Exchange and its affiliates.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

A. significantly affect the protection of investors or the public interest;

B. impose any significant burden on competition; and

C. 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)²⁹ thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-CboeBYX-2025-036 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-CboeBYX-2025-036. 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

²⁷ 15 U.S.C. 78k-1(a)(1).

²⁸ 15 U.S.C. 78s(b)(3)(A).

²⁹ 17 CFR 240.19b-4(f)(6).

only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-CboeBYX-2025-036 and should be submitted on or before January 20, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.³⁰

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025-23810 Filed 12-23-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-104477; File No. SR-MSRB-2025-02]

Self-Regulatory Organizations; Municipal Securities Rulemaking Board; Order Granting Approval of a Proposed Rule Change To Amend MSRB Rules A-11 and A-13 Pursuant to a Multi-Year Rate Card and To Make Related Technical Amendments

December 19, 2025.

I. Introduction

On September 30, 2025, the Municipal Securities Rulemaking Board ("MSRB") filed with the Securities and Exchange Commission ("SEC" or "Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act" or "Exchange Act")¹ and Rule 19b-4 thereunder,² a proposed rule change to (i) amend MSRB Rule A-11, on assessments for municipal advisor professionals ("Rule A-11"), to establish new rates of certain assessments on municipal advisors pursuant to a multi-year rate card, (ii) amend MSRB Rule A-13, on underwriting and transaction assessments for brokers, dealers, and municipal securities dealers ("Rule A-13"), to establish new rates of certain assessments on brokers, dealers, and municipal securities dealers (collectively, "dealers" and, together with municipal advisors, "regulated

entities") pursuant to a multi-year rate card, and (iii) make certain related technical amendments to Rules A-11 and A-13 (collectively, the "proposed rule change").³

The MSRB requested that the proposed rule change be approved with an effective date of January 1, 2026, provided that if approved by the Commission after January 1, 2026, the proposed rule change be made effective as of the first day of the month following Commission approval.⁴

The proposed rule change was published for comment in the **Federal Register** on October 3, 2025.⁵ The Commission received four comment letters⁶ on the proposed rule change. Pursuant to a notice published in the **Federal Register** on November 17, 2025, the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change was extended from November 17, 2025, to January 1, 2026.⁷ On December 2, 2025, the MSRB responded to the comment letters.⁸ As described further below, the Commission is approving the proposed rule change with an effective date of January 1, 2026.

II. Description of the Proposed Rule Change

A. Background

The MSRB established its annual rate card model in 2022.⁹ Pursuant to the annual rate card model, in November

³ See Exchange Act Release No. 104154 (Sept. 30, 2025), 90 FR 48082 (Oct. 3, 2025) (File No. SR-MSRB-2025-02) ("Notice").

⁴ See Notice, 90 FR at 48082.

⁵ See *id.*

⁶ See Letter from Leslie M. Norwood, Managing Director and Associate General Counsel, Securities Industry and Financial Markets Association, dated October 24, 2025 ("SIFMA Letter"); Letter from Susan Gaffney, Executive Director, National Association of Municipal Advisors, dated October 24, 2025 ("NAMA Letter"); Letter from Michael Decker, Senior Vice President, Bond Dealers of America, dated October 24, 2025 ("BDA Letter"); and Letter from Robert Laorno, General Counsel, ICE Bonds Securities Corporation, dated October 24, 2025 ("ICE Bonds Letter").

⁷ See Exchange Act Release No. 104173 (Nov. 3, 2025), 90 FR 51424, 51424-25 (Nov. 17, 2025) (File No. SR-MSRB-2025-02).

⁸ See Letter to Secretary, Commission, from Ernesto A. Lanza, Chief Regulatory and Policy Officer, MSRB, dated December 2, 2025 ("MSRB Letter").

⁹ See Exchange Act Release No. 95417 (Aug. 3, 2022), 87 FR 48530 (Aug. 9, 2022) (File No. SR-MSRB-2022-06). See also MSRB Notice 2022-06, MSRB Revises and Resubmits Annual Rate Card Amendments (July 29, 2022), available at <https://www.msrb.org/sites/default/files/2022-09/2022-06.pdf>. The amendments to Rules A-11 and A-13 made by the 2022 filing, together with the MSRB's then-current funding policy, constituted the rate card model instituted at that time. See Notice, 90 FR at 48083, note 4.

2023, the MSRB filed with the Commission proposed amendments to Rules A-11 and A-13 to institute the rate card fees for 2024 (the "2024 Rate Card Proposal").¹⁰ Five comment letters were submitted to the Commission in response to the 2024 Rate Card Proposal, all of which highlighted concerns, among others, related to the MSRB's rate setting processes and the volatility and unpredictability of rates under the annual rate card model.¹¹ On January 29, 2024, the Commission temporarily suspended and instituted proceedings to determine whether to approve or disapprove the 2024 Rate Card Proposal.¹² The MSRB then withdrew the 2024 Rate Card Proposal on February 16, 2024.¹³

Since withdrawing the 2024 Rate Card Proposal, the MSRB has reported that it has held outreach meetings with industry groups representing regulated entities and other stakeholders to discuss the MSRB's budget and rate card process.¹⁴ The MSRB also issued a Request for Information ("RFI") on its rate card process on October 30, 2024, soliciting feedback from stakeholders on the MSRB's rate setting process, the distribution of fees across regulated entities generally, and the MSRB's management of its organizational reserve funds.¹⁵ The MSRB received comments in response to the RFI, focusing on, among other matters, the volatility and unpredictability of the annual rate card model and strategies for management of reserve levels.¹⁶ The MSRB subsequently revised its funding policy, effective October 1, 2025 ("Revised Funding Policy"), to replace its annual rate setting process with a new multi-year rate setting process (the "Multi-Year Rate Card Process").¹⁷

¹⁰ See Exchange Act Release No. 99096 (Dec. 6, 2023), 88 FR 86188 (Dec. 12, 2023) (File No. SR-MSRB-2023-06).

¹¹ All comment letters received in connection with 2024 Rate Card Proposal, and the MSRB's response thereto, are available at <https://www.sec.gov/comments/sr-msrb-2023-06/srmsrb202306.htm>.

¹² See Exchange Act Release No. 99444 (Jan. 29, 2024), 89 FR 7424 (Feb. 2, 2024) (File No. SR-MSRB-2023-06).

¹³ See Exchange Act Release No. 99577 (Feb. 21, 2024), 89 FR 14552 (Feb. 27, 2024) (File No. SR-MSRB-2023-06).

¹⁴ See Notice, 90 FR at 48083, note 10.

¹⁵ See MSRB Notice 2024-14, Request for Information on the MSRB's Rate Card Process (Oct. 30, 2024), available at <https://www.msrb.org/sites/default/files/2024-10/MSRB-Notice-2024-14.pdf>. See also Notice, 90 FR at 48083.

¹⁶ All comment letters received in response to the RFI are available at <https://www.msrb.org/sites/default/files/2025-02/All-Comments-to-Notice-2024-14.pdf>.

¹⁷ The Revised Funding Policy is available at <https://www.msrb.org/MSRB-Funding-Policy-1>. The prior Funding Policy is available at <https://www.msrb.org/MSRB-Funding-Policy-1>.

³⁰ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

According to the MSRB, this Multi-Year Rate Card Process, the MSRB's fiscal year 2026 budget, and the proposed rule change were developed after considering the RFI responses and feedback received from the MSRB's outreach to stakeholders.¹⁸

B. Summary of the Proposed Rule Change

As discussed below and in the Notice, the proposed rule change would amend Rules A-11 and A-13 to establish new rates of certain assessments on municipal advisors under Rule A-11 and dealers under Rule A-13 pursuant to the new Multi-Year Rate Card Process, as well as to make certain related technical amendments.¹⁹ Rule A-11 currently requires municipal advisors to pay to the MSRB a recurring annual fee (the "Municipal Advisor Professional Fee") for each associated person qualified as a municipal advisor representative under MSRB Rule G-3 and for whom the municipal advisor has on file with the Commission an active Form MA-I as of January 31 of the applicable year ("covered

professional"). Rule A-13 currently requires dealers to pay (a) an underwriting fee under Rule A-13(b) (the "Underwriting Fee") for municipal securities purchased from an issuer by or through such dealer as part of a primary offering, (b) a transaction fee under Rule A-13(d)(i) and (ii) (the "Transaction Fee") based on the par amount traded in inter-dealer trades and customer sales, and (c) a trade count fee under Rule A-13(d)(iv)(a) and (b) (the "Trade Count Fee") based on the number of inter-dealer trades and customer sales (collectively, the "Market Activity Fees," and together with the Municipal Advisor Professional Fee, the "Rate Card Fees").

Proposed Multi-Year Rate Card Fees

The proposed rule change would establish Rate Card Fees for the next four calendar years: 2026, 2027, 2028, and 2029 (the "proposed Multi-Year Rate Card").²⁰ The Municipal Advisor Professional Fee included in the proposed Rate Card Fees for each of these years would be operative from January 1 of each calendar year until

December 31 for that year and the Market Activity Fees included in the proposed Rate Card Fees would be operative from January 1, 2026 until December 31, 2029.²¹ The proposed rule change would also require that any subsequent multi-year rate cards be established by amendment to Rules A-11 and A-13 and in accordance with the principles and guidelines of the MSRB's Revised Funding Policy, available at <https://www.msrb.org/MSRB-Funding-Policy-1>.²²

Additionally, the proposed rule change would establish credits ("Temporary Credits") of 45% applied to Market Activity Fees in 2026 and 2027, which would result in a reduction in the amounts to be assessed to and paid by dealers for Market Activity Fees during such years.²³ The following table sets forth (a) the Rate Card Fees currently in effect under Rules A-11 and A-13, and (b) the Rate Card Fees that the MSRB would establish under its proposed Multi-Year Rate Card, together with the net rates of assessment proposed for each year (taking into account the Temporary Credits):²⁴

	Assessment/ credit basis	Current	2026	2027	2028	2029
Underwriting Fee	Per \$1,000 Par Underwritten	\$0.0297	\$0.0297	\$0.0297	\$0.0297	\$0.0297
	45% Temporary Credit	N/A	(0.0134)	(0.0134)	0	0
	Net Rate of Assessment	0.0297	0.0163	0.0163	0.0297	0.0297
Transaction Fee	Per \$1,000 Par Transacted	0.0107	0.0107	0.0107	0.0107	0.0107
	45% Temporary Credit	N/A	(0.0048)	(0.0048)	0	0
	Net Rate of Assessment	0.0107	0.0059	0.0059	0.0107	0.0107
Trade Count Fee	Per Trade	1.10	1.10	1.10	1.10	1.10
	45% Temporary Credit	N/A	(0.49)	(0.49)	0	0
	Net Rate of Assessment	1.10	0.61	0.61	1.10	1.10
Municipal Advisor Professional Fee ..	Per Covered Professional	* 1,060	1,130	1,200	1,270	1,340

* The Municipal Advisor Professional Fee provided under Supplementary Material .01 of MSRB Rule A-11 is currently \$1,060 per covered professional. Exhibit 5 of the MSRB's Rule 19b-4 filing for the proposed rule change erroneously shows the current rate as \$1,160 per covered professional.

[web.archive.org/web/20250715224839/https://www.msrb.org/MSRB-Funding-Policy-0](https://www.msrb.org/web/20250715224839/https://www.msrb.org/MSRB-Funding-Policy-0).

¹⁸ See Notice, 90 FR at 48083.

¹⁹ See Notice, 90 FR at 48082-85. Underwriting assessments charged pursuant to Rule A-13(c) to dealers acting as underwriters of certain municipal fund securities are not included in the assessment rates that would be amended by this proposed rule change. See Notice, 90 FR at 48082, note 3.

²⁰ See Notice, 90 FR at 48083-84. The Municipal Advisor Professional Fee included in the proposed new Rate Card Fees, for each year covered by the proposed rule change, would be set out in Supplementary Material .01 of Rule A-11. See Notice, 90 FR at 48084, note 14. Each of the Market Activity Fees included in the proposed new Rate Card Fees would be set out in Supplementary Material .01(a)(i)-(iii) of Rule A-13. See *id.*

²¹ See Notice, 90 FR at 48084.

²² See *id.* As noted above, the Revised Funding Policy became effective as of October 1, 2025. Any future revisions to the Revised Funding Policy must

be approved by the MSRB's board of directors and would be posted on the MSRB website at <https://www.msrb.org/MSRB-Funding-Policy-1>. See Notice, 90 FR at 48084, note 17. Revisions to the Revised Funding Policy would not result in changes to the rates of filed Rate Card Fees absent a rule filing with the Commission, but instead would have an impact on future rate-setting through MSRB rulemaking. See *id.* The proposed rule change would amend Supplementary Material .01 to Rule A-11 and Supplementary Material .01(b) to Rule A-13 to delete language describing aspects of the prior rate setting process that would be superseded by the Multi-Year Rate Card Process, to explicitly state that if no new rate card is established at the end of the period covered by the proposed rule change then the applicable rates would remain at the same level as in effect prior to the end of that period, and to provide for the ongoing availability of the Revised Funding Policy, and any future revisions thereto, on the MSRB website so long as the Revised Funding

Policy sets forth, in whole or in part, the MSRB's rate card process. See *id.*

²³ See Notice, 90 FR at 48084. The Temporary Credits that would be applied to the Market Activity Fees included in the proposed new Rate Card Fees for the calendar years 2026 and 2027 would be set out in Supplementary Material .01(c) of Rule A-13. See Notice, 90 FR at 48084, note 19. The Temporary Credits included in this proposed rule change would not apply to the Municipal Advisor Professional Fee. See Notice, 90 FR at 48084. The proposed rule change's Temporary Credits apply to dealer Market Activity Fees because the MSRB's excess reserves resulted from revenue derived from extraordinary market trading and issuance volume between 2023 and 2025. See Notice, 90 FR at 48086, note 40.

²⁴ See Notice, 90 FR at 48084. The net amount of Market Activity Fees, taking into account any applicable Temporary Credits, would be set out in Supplementary Material .01(c)(i)-(iii) of Rule A-13. See Notice, 90 FR at 48084, note 20.

Multi-Year Rate Card Process

As part of the new Multi-Year Rate Card Process, the proposed rule change would also establish a maximum annual increase or decrease in any baseline Rate Card Fee of 15% (the “Annual Rate Change Limit”) within a multi-year rate card period (as compared to the annual 25% cap on increases and no cap on decreases that are currently in effect),²⁵ subject to potential Temporary Credits.²⁶

The MSRB states that under the Rate Card Fees proposed in the proposed rule change, the baseline rates of the Market Activity Fees would remain unchanged both from the rates currently in effect under the prior rate card and throughout the course of the proposed Multi-Year Rate Card.²⁷ The MSRB further notes that the Municipal Advisor Professional Fee for 2026 would increase by approximately 6.6% from the rate currently in effect and would increase on an annual basis during the course of the proposed Multi-Year Rate Card by approximately 6% per year.²⁸

Related Technical Amendments

The proposed rule change would include certain technical language changes. For example, references to the current “annual” process would be eliminated throughout Rules A–11 and A–13 and instead would reflect the four-year term of the proposed Multi-Year Rate Card in the proposed rule change.²⁹ The proposed rule change language would also refer to the rates that would be in effect (including any net rates due to Temporary Credits, as applicable) for

each year within the course of the proposed Multi-Year Rate Card.³⁰

III. Summary of Comments Received and the MSRB’s Response

The Commission received four comment letters³¹ on the proposed rule change, as well as a response³² from the MSRB to the comment letters. Three commenters expressed support for the proposed rule change,³³ one commenter stated that it did not oppose the proposed rule change,³⁴ and no commenters objected to the proposed rule change.

One commenter expressed support for the proposed shift to a multi-year rate card, opining that it will improve the stability and predictability of rate card fees for regulated entities.³⁵ That commenter also stated that the MSRB should consider adopting an alternative fee structure applicable to municipal dealer operators of alternative trading systems.³⁶ In its response letter, the MSRB stated that it would engage in dialogue with stakeholders regarding potential alternative fee mechanisms for certain market participants.³⁷

One commenter expressed support for the proposed shift to a multi-year rate card but stated that it believes that a four-year fee window is probably too long to accurately predict market trends in issuance and trade volume as well as demands on MSRB resources, and a two-year window may be more appropriate.³⁸ The commenter also stated that the fees paid by municipal advisors are too small as a percentage of the MSRB’s revenue, and a market-activity based fee for municipal advisors would be appropriate.³⁹ The commenter also requested that the MSRB adopt a formalized process to periodically review its revenue throughout the proposed four-year fee-setting window.⁴⁰ In its response letter, the

MSRB stated that it would engage in dialogue with stakeholders regarding the formulation of future charges, fees, and rate cards.⁴¹ The MSRB also stated that it will conduct a periodic review of its organizational reserves target and will evaluate and consider actions if organizational reserves exceed or fall below the established target by 20% or greater, as required by the MSRB’s Revised Funding Policy.⁴²

One commenter expressed support for the lowered operational reserves target presented in the MSRB’s fiscal year 2026 budget and the proposed shift to a multi-year rate card as reducing fee volatility and ensuring more predictability.⁴³ The commenter also urged the MSRB to consider increasing municipal advisor fees and/or imposing municipal advisor market activity fees in the future.⁴⁴ In its response letter, the MSRB stated that it would engage in dialogue with stakeholders regarding the formulation of future charges, fees, and rate cards.⁴⁵

One commenter stated that it did not oppose the proposed rule change and that the MSRB should not change its current approach of collecting fees from municipal advisors on a per-municipal advisor basis.⁴⁶ The commenter also stated that it supports the proposed four-year fee-setting window but expressed concern with how the MSRB will develop budgets during that four-year period to ensure that expenses adhere to its regulatory mandates under the Exchange Act so that fees are assessed on a reasonable basis.⁴⁷ The commenter also expressed a desire to engage in dialogue with the MSRB about recent changes to the MSRB’s Funding Policy, including the removal of language regarding the fair allocation of fee burdens on different classes of regulated entities.⁴⁸ In its response letter, the MSRB stated that it would engage in dialogue with stakeholders regarding the formulation of future charges, fees, and rate cards.⁴⁹ The MSRB also stated that it does not believe that its Revised Funding Policy diminishes the commitments laid out in its prior Funding Policy or alter any of the requirements imposed on the MSRB by statute.⁵⁰

The MSRB stated that it believes that it has undertaken a meaningful review

²⁵ See Notice, 90 FR at 48084. The Annual Rate Change Limit would be set out in Supplementary Material .01 of Rule A–11 and Supplementary Material .01(b) of Rule A–13. See Notice, 90 FR at 48084, note 23.

²⁶ See Notice, 90 FR at 48084. The Revised Funding Policy allows the MSRB to elect to utilize one or more Temporary Credits within the proposed Multi-Year Rate Card or in a future multi-year rate card. See Notice, 90 FR at 48085 (citing Revised Funding Policy, *supra* note 17, at “Organizational Reserves” and “Multi-Year Rate Card”). If Temporary Credits are applied to a baseline Rate Card Fee, the Annual Rate Change Limit may be exceeded. See *id.* For example, the proposed rule change includes Temporary Credits during the first two years which result in the net rates of assessments for the Market Activity Fees increasing between 2027 and 2028 by more than the percentage of the Annual Rate Change Limit, notwithstanding the fact that the baseline rates would not change. See *id.*

²⁷ See Notice, 90 FR at 48084–85.

²⁸ See Notice, 90 FR at 48085.

²⁹ See *id.* The word “annual” would be removed in references to “annual rate card” in Rule A–11(b), Supplementary Material .01 to Rule A–11, Rule A–13(b), Rule A–13(d)(i)–(ii), Rule A–13(d)(iv)(a)–(b), and Supplementary Material .01 and .01(b). See Notice, 90 FR at 48085, note 32.

³⁰ See Notice, 90 FR at 48085. In the case of the Municipal Advisor Professional Fee, language would be added in Supplementary Material .01 to Rule A–11 to make explicit that the charge is based on the number of covered professionals in the respective year for which the fee is to be assessed, and the rates for each year would be listed in clauses (a)–(d) thereof. See Notice, 90 FR at 48085, note 33. The net rate of assessment of the Market Activity Fees for the first two years would be listed in Supplementary Material .01(c)(i)–(iii). See *id.*

³¹ See SIFMA Letter; NAMA Letter; BDA Letter; ICE Bonds Letter.

³² See MSRB Letter.

³³ See SIFMA Letter; BDA Letter; ICE Bonds Letter.

³⁴ See NAMA Letter.

³⁵ See ICE Letter at 1.

³⁶ See ICE Letter at 1–2.

³⁷ See MSRB Letter at 3.

³⁸ See BDA Letter at 1–2.

³⁹ See BDA Letter at 1.

⁴⁰ See BDA Letter at 2.

⁴¹ See MSRB Letter at 3.

⁴² See *id.*

⁴³ See SIFMA Letter at 2.

⁴⁴ See SIFMA Letter at 3.

⁴⁵ See MSRB Letter at 3.

⁴⁶ See NAMA Letter at 1.

⁴⁷ See *id.*

⁴⁸ See *id.*

⁴⁹ See MSRB Letter at 3.

⁵⁰ See MSRB Letter at 3–4.

of its fees, charges, and the rate card process, and that the proposed rule change is consistent with the Exchange Act.⁵¹

IV. Discussion and Commission Findings

The Commission has carefully considered the proposed rule change, the comment letters received, and the MSRB's response thereto. The Commission has also considered supplemental, non-public information regarding the MSRB's expenses that the MSRB provided to the Commission at the Commission's request. The Commission finds that the proposed rule change is consistent with the requirements of the Exchange Act and the rules and regulations thereunder applicable to the MSRB. In particular, the Commission finds that the proposed rule change is consistent with the provisions of Sections 15B(b)(2)(J),⁵² 3(f),⁵³ 15B(b)(2)(C),⁵⁴ and 15B(b)(2)(L)(iv)⁵⁵ of the Exchange Act.

A. Reasonable Fees and Charges as May Be Necessary or Appropriate To Defray the Costs and Expenses of Operating and Administering the MSRB

For the reasons outlined below, and in particular the MSRB's commitment to the continued stakeholder outreach described below, the Commission finds that the proposed rule change is consistent with the provisions of Section 15B(b)(2)(J) of the Exchange Act.⁵⁶ Section 15B(b)(2)(J) of the Exchange Act requires the MSRB's rules to provide that each regulated entity shall pay to the MSRB such reasonable fees and charges as may be necessary or appropriate to defray the costs and expenses of operating and administering the MSRB.⁵⁷ Such rules shall specify the amount of such fees and charges, which may include charges for failure to submit to the MSRB, or to any information system operated by the MSRB, within the prescribed timeframes, any items of information or documents required to be submitted under any rule issued by the MSRB.⁵⁸

As noted by the MSRB, the proposed rule change is designed to fund the operation and administration of the MSRB through the establishment of a fee structure that: (i) improves the stability and predictability of Rate Card Fees over time; (ii) maintains an

appropriate balance of assessments on regulated entities; and (iii) improves the MSRB's ability to manage organizational reserves responsibly while minimizing fee volatility and other operational disruptions to regulated entities.⁵⁹ The Commission finds that the proposed rule change represents a reasonable approach to achieve these goals by, among other changes, moving the process for determining Rate Card Fees from an annually calculated adjustment to a fixed multi-year rate schedule, establishing parameters to limit the degree of annual changes to Rate Card Fees (*i.e.*, the Annual Rate Change Limit), establishing a framework to address surplus reserves through rate adjustments to Market Activity Fees (*i.e.*, the Temporary Credits), and maintaining the MSRB's target balance of Rate Card Fees between dealers and municipal advisors.⁶⁰

With respect to the proposed Multi-Year Rate Card, the Commission finds that the proposed Rate Card Fees are appropriate to defray the anticipated costs and expenses of operating and administering the MSRB over the next four years. The MSRB's 2026 budgeted expenses total \$46.2 million (a 5.2% decrease in expenses compared to its fiscal year 2025 budgeted expenses)⁶¹ and the MSRB assumes an annual average expense growth rate of 3.4% for fiscal years 2027 through 2029, primarily due to the costs of inflation.⁶² The MSRB anticipates the revenue from the proposed Rate Card Fees to represent 78% of total revenues in fiscal year 2026, with the remaining 22% of revenues comprised of data subscription fees, underwriting assessments for certain municipal fund securities offerings under MSRB Rule A-13(c), annual and initial fees under MSRB Rule A-12(b) and (c), investment income, fine revenue, and other miscellaneous revenue (including examination fees under MSRB Rule A-16).⁶³ Although the proposed rule change would also reduce the MSRB's reserves balance through the use of a 45% Temporary Credit for Market Activity Fees (as discussed above),⁶⁴ the

MSRB maintains a targeted level of reserve funding in accordance with its Revised Funding Policy, which establishes a tolerance for variation from the organizational reserves target of $\pm 20\%$ of its target level (the "Reserve Target Tolerance"), and provides for an evaluation, at the mid-point of a multi-year rate card, as to whether the Reserve Target Tolerance has been exceeded.⁶⁵

Finally, the MSRB stated that it developed its fiscal year 2026 budget, its Revised Funding Policy, and the proposed rule change after considering the RFI responses and feedback received from the MSRB's outreach to stakeholders.⁶⁶ Based on commitments made by the MSRB,⁶⁷ the Commission expects that the MSRB will continue

⁵¹ See Notice, 90 FR at 48085.

⁵² See Notice, 90 FR at 48083, 48089.

⁵³ See, *e.g.*, MSRB Letter at 3 ("The MSRB is committed to continuing its ongoing dialogue with stakeholders regarding the issues raised in the comment letters, including formulation of future charges, fees, and rate cards, as well as future, potential alternative fee mechanisms for certain market participants. . . . The MSRB expects its future stakeholder outreach to encompass a broad range of relevant issues and factors beyond the baseline requirements of the Funding Policy."); MSRB Letter at 3-4, note 12 ("[T]he changes in the Funding Policy do not alter or diminish the MSRB's commitment to engaging with stakeholders on a going-forward basis."); Notice, 90 FR at 48088 ("[T]he MSRB commits to engage with stakeholders to discuss possible alternative methods for municipal advisor fees."); Notice, 90 FR at 48083, note 13 ("The MSRB remains committed to ongoing engagement with stakeholders to continue to explore whether additional, longer-term changes to the MSRB's approach should be implemented in the course of developing future rate cards beyond 2029."); RFI at 4, note 7 ("Separate from the retrospective review of the Rate Card Process, this outreach has been critical to the MSRB addressing the concerns regarding transparency and the MSRB budget process, with respect to which the MSRB will continue its engagement with stakeholders outside of this RFI."). See also, *e.g.*, Letter to Secretary, Commission, from Ernesto A. Lanza, Chief Regulatory and Policy Officer, MSRB, dated January 26, 2024 (File No. SR-MSRB-2023-06), at 8, available at <https://www.sec.gov/comments/sr-msrb-2023-06/srmsrb202306-416059-985442.pdf> ("Approval of an organization's budget is a core governance function that is the responsibility of the board of directors Nonetheless, the MSRB looks to provide appropriate opportunities for market participants (including the commenters, other municipal market stakeholders and fellow regulators inclusive of the Commission) to offer input, through discussions or otherwise, at a point in time that would allow the MSRB board of directors to consider such input as it approves the budget. Further, while the MSRB currently reaches out to some of the commenters or their member firms to seek input on estimated levels of underwriting and trading activity for the coming year to develop this aspect of the input into the Rate Card Process, the MSRB could consider a more formalized manner of surveying relevant market participants ahead of the final rate setting process."); *id.* at 6 ("The MSRB commits to continued engagement with commenters and other interested stakeholders to provide even greater budget transparency by providing more granular breakdowns of program expenditures, particularly with respect to technology-related expenses.").

⁵⁹ See Notice, 90 FR at 48086.

⁶⁰ See Notice, 90 FR at 48083. The proposed rule change maintains the contribution targets set forth when the MSRB established its annual rate card process in 2022, which the MSRB believes remain appropriate as no durable, material shift in market structure has occurred to warrant alteration of current target contribution levels. See Notice, 90 FR at 48086, note 40.

⁶¹ See Notice, 90 FR at 48086; MSRB Fiscal Year 2026 Budget (Oct. 1, 2025), <https://www.msrb.org/sites/default/files/2025-10/MSRB-FY-2026-Budget-Summary.pdf> ("MSRB Fiscal Year 2026 Budget").

⁶² See Notice, 90 FR at 48086.

⁶³ See *id.*

⁵¹ See MSRB Letter at 4.

⁵² 15 U.S.C. 78o-4(b)(2)(J).

⁵³ 15 U.S.C. 78c(f).

⁵⁴ 15 U.S.C. 78o-4(b)(2)(C).

⁵⁵ 15 U.S.C. 78o-4(b)(2)(L)(iv).

⁵⁶ 15 U.S.C. 78o-4(b)(2)(J).

⁵⁷ *Id.*

⁵⁸ *Id.*

such outreach, which is key to a determination by the Commission that the proposed rule change establishes reasonable fees and charges to be paid by regulated entities. Although the proposed Multi-Year Rate Card is a fixed rate schedule for its four-year term and is generally not intended to be modified during its effective term,⁶⁸ the MSRB has committed to continuing its stakeholder outreach during this four year term regarding the MSRB's rate setting process, the distribution of fees across regulated entities generally, and the MSRB's budget and management of its reserve funds.⁶⁹ Based on commitments made by the MSRB,⁷⁰ the Commission also expects that the MSRB will engage with the Commission and stakeholders regarding what additional data and information the MSRB should publicly disclose (that it does not currently publicly disclose) regarding the MSRB's budget. The Commission also expects that, despite removing from its Revised Funding Policy certain previously included language affirming that stakeholder engagement is a funding priority of the MSRB,⁷¹ the MSRB will engage with stakeholders to ensure that future budgets adhere to the MSRB's regulatory mandates under the Exchange Act.⁷²

For these reasons, the Commission finds that the proposed rule change establishes reasonable fees and charges to be paid by regulated entities consistent with Section 15B(b)(2)(J) of the Exchange Act.

B. Impact on Efficiency, Competition, and Capital Formation, and Related Provisions

In approving the proposed rule change, the Commission has also considered the proposed rule change's impact on efficiency, competition, and capital formation under Section 3(f) of the Exchange Act.⁷³ The Commission finds that the record for the proposed rule change does not contain any information to indicate that the proposed rule change would have a negative impact on efficiency, competition, or capital formation.⁷⁴ In fact, transitioning to the proposed Multi-Year Rate Card could promote market efficiency and capital formation because regulated entities will now know their Rate Card Fees through 2029 instead of facing uncertainty under a one- or two-year rate card process.

The Commission also finds that the proposed rule change is consistent with the provisions of Section 15B(b)(2)(C) of the Exchange Act.⁷⁵ Section 15B(b)(2)(C) of the Exchange Act requires that MSRB rules not be designed to impose any burden on competition that is not necessary or appropriate in furtherance of the

purposes of the Exchange Act.⁷⁶ The Commission finds that the proposed rule change would not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Exchange Act because the proposed Rate Card Fees are applicable to *all* dealers and municipal advisors over the course of the four years covered by the proposed Multi-Year Rate Card, and the MSRB's projected fee proportions would maintain balance between Municipal Advisor Professional Fees and Dealer Market Activity Fees, as well as among the three dealer fees that make up the Market Activity Fees.⁷⁷ Additionally, the proposed increases under the Rate Card Fees will be proportionately distributed across regulated entities.⁷⁸

The Commission further finds that the proposed rule change is consistent with the provisions of Section 15B(b)(2)(L)(iv) of the Exchange Act.⁷⁹ Section 15B(b)(2)(L)(iv) of the Exchange Act⁸⁰ requires that MSRB rules not impose a regulatory burden on small municipal advisors that is not necessary or appropriate in the public interest and for the protection of investors, municipal entities, and obligated persons, provided that there is robust protection of investors against fraud. The Commission finds that the proposed Municipal Advisor Professional Fee would not impose an unnecessary or inappropriate regulatory burden on small municipal advisors since the total amount of the assessment payable by each municipal advisory firm would continue to be proportional to the number of Form MA-Is filed by a firm and, therefore, would result in lower relative assessments for smaller firms.⁸¹ Based on the number of persons engaging in municipal advisory activities on behalf of a firm, the total fee would therefore bear a reasonable relationship to the level of regulated

⁶⁸ See Notice, 90 FR at 48084.

⁶⁹ See MSRB Letter at 3–4. See also Notice, 90 FR at 48083, note 13.

⁷⁰ See, e.g., *supra*, note 67. See also, e.g., MSRB Fiscal Year 2026 Budget, *supra* note 61, at 5 (“Providing MSRB’s external stakeholders with a meaningful understanding of MSRB’s budget, its development process and the considerations that flow into the next annual budget are core to MSRB’s commitment to financial transparency and budgeting philosophy.”).

⁷¹ The prior Funding Policy, available at <https://web.archive.org/web/20250715224839/https://www.msrb.org/MSRB-Funding-Policy-0>, provided that: “Certain funding priorities exist based on the MSRB’s Strategic Plan, in support of its responsibilities as [a self-regulatory organization], consistent with its congressional mandate as outlined in the Exchange Act. These priorities are: . . . 5. funding for stakeholder engagement activities and education, including receiving information from municipal market participants and other stakeholders to provide input that informs the rulemaking process, as well as ensuring that these stakeholders are aware of regulatory developments that may affect them and are educated on the MSRB rules.”

⁷² See, e.g., MSRB Fiscal Year 2026 Budget (Oct. 1, 2025), *supra* note 61, at 3 (“Fiscal stewardship, budget transparency and public accountability remain of paramount importance to MSRB. It’s in this spirit that we have maintained an open dialogue with our stakeholders, seeking their feedback and perspectives to inform our initiatives, including the development of our FY 2026 budget and next Strategic Plan. We continue to listen carefully to stakeholder concerns and are taking them into consideration as we position MSRB for the future.”); *id.* at 5 (“Ongoing stakeholder engagement and feedback directly informs the development of MSRB’s annual budget and the information and discussion provided in this FY 2026 Public Budget Report. Continued engagement

on this topic is important to MSRB and its commitment to transparency.”); MSRB Letter at 3–4, note 12 (“[T]he changes in the Funding Policy do not alter or diminish the MSRB’s commitment to engaging with stakeholders on a going-forward basis.”). See also, e.g., MSRB Notice 2024–13, MSRB Seeks Volunteers for Advisory Groups Including a New Group on Technology, at 1–2 (Oct. 28, 2024), available at <https://www.msrb.org/sites/default/files/2024-10/MSRB-Notice-2024-13.pdf> (“[O]ur highest priority is to fulfill our congressional mandate to protect investors, municipal entities, and the public interest by promoting a fair and efficient market. We strive to engage with stakeholders and market participants to further this objective and ensure the market works for everyone. Establishing advisory groups is one of the many ways the Board and staff facilitate effective stakeholder engagement. . . . [The Technology Advisory Group (TAG)] may discuss a broad range of topics such as . . . the MSRB’s technology investment priorities and strategy . . . and technology implementation costs of regulatory initiatives.”); MSRB Notice 2025–07, MSRB Seeks Volunteers for Compliance Advisory Group, at 1 (Oct. 30, 2025), available at <https://www.msrb.org/sites/default/files/2025-10/MSRB-Notice-2025-07.pdf> (“[O]ur highest priority is to fulfill our congressional mandate to protect investors, municipal entities, and the public interest by promoting a fair and efficient market. We strive to engage with stakeholders and market participants to further this objective and ensure the market works for all.”).

⁷³ See 15 U.S.C. 78c(f).

⁷⁴ See 15 U.S.C. 78c(f).

⁷⁵ 15 U.S.C. 78o–4(b)(2)(C).

⁷⁶ 15 U.S.C. 78o–4(b)(2)(C).

⁷⁷ See Notice, 90 FR at 48086–87. As noted above, the proposed rule change maintains the contribution targets set forth when the MSRB established its annual rate card process in 2022, which the MSRB believes remain appropriate as no durable, material shift in market structure has occurred to warrant alteration of current target contribution levels. See Notice, 90 FR at 48086, note 40.

⁷⁸ See Notice, 90 FR at 48089. As noted above, the proposed rule change’s Temporary Credits apply to dealer Market Activity Fees because the MSRB’s excess reserves resulted from revenue derived from extraordinary market trading and issuance volume between 2023 and 2025. See Notice, 90 FR at 48086, note 40.

⁷⁹ 15 U.S.C. 78o–4(b)(2)(L)(iv).

⁸⁰ 15 U.S.C. 78o–4(b)(2)(L)(iv).

⁸¹ See Notice, 90 FR at 48089.

municipal advisory activities that are undertaken by each firm.⁸²

For the reasons noted above, the Commission finds that the proposed rule change is consistent with the Exchange Act.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Exchange Act,⁸³ that the proposed rule change (SR–MSRB–2025–02) be, and hereby is, approved.

For the Commission, pursuant to delegated authority.⁸⁴

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025–23821 Filed 12–23–25; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–104480; File No. SR–FICC–2025–026]

Self-Regulatory Organizations; Fixed Income Clearing Corporation; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Update a Definition and Certain Provisions Related to Components of GSD's Funds-Only Settlement

December 22, 2025.

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 December 19, 2025, Fixed Income Clearing Corporation (“FICC”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I, II and III below, which Items have been prepared by the clearing agency. FICC filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act³ and Rule 19b–4(f)(4) thereunder.⁴ The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change consists of amendments to FICC's Government Securities Division (“GSD”) Rulebook

(“Rules”)⁵ to (1) update the definition of “Overnight Investment Rate” to reflect that such rate is applicable to cash held by FICC in connection with funds-only settlement; (2) change the frequency of GCF Interest Adjustment Payments and Interest Adjustment Payments to monthly, rather than daily, in certain circumstances; and (3) remove an outdated reference from a statement in Rule 13.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The clearing agency has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

FICC is proposing changes to the Rules that would update a definition and certain provisions related to the components of GSD's funds-only settlement, or “FOS.” Specifically, the proposed changes would update and clarify the definition of Overnight Investment Rate, which is the interest rate used in the calculation of two components of FOS, the GCF Interest Adjustment Payment and the Interest Adjustment Payment. The proposed changes would also update the frequency of GCF Interest Adjustment Payments and Interest Adjustment Payments to monthly, rather than daily, in certain circumstances. Finally, the proposed changes would remove an outdated reference from a statement in Rule 13, which was retained in the Rules in error. These proposed changes would update, clarify and correct the Rules related to FOS, providing Netting Members with a clearer understanding of these provisions and their rights thereunder.

Overview of Funds-Only Settlement

FOS is a twice-daily process of generating a net credit or debit cash amount for each Netting Member and settling those cash amounts between Netting Members and FICC. FOS is

described in Rule 13 and is a cash pass-through process, meaning Netting Members who are in a debit position submit payments that are then used to pay Netting Members in a credit position.⁶

Twice each Business Day, each Netting Member must pay (or is entitled to collect) an aggregate Funds-Only Settlement Amount across all CUSIPs in which it has outstanding positions. The main components of this amount include, among other payments, a mark-to-market amount for every Net Settlement Position, a mark-to-market amount for every Forward Net Settlement Position, fail marks for obligations that were scheduled to settle and have not yet settled, coupon payments and other adjustments.⁷

The settlement ultimately occurs through the National Settlement Service (“NSS”), a payment system operated by the Federal Reserve System (“FRS”).⁸ Cash debits and credits are paid out by Funds-Only Settling Bank Members, who are appointed by Netting Members. The individual debits and credits of each Netting Member using the same Funds-Only Settling Bank Member are totaled. Once the net debits and credits are approved by Funds-Only Settling Bank Members, the New York Federal Reserve Bank debits or credits each Funds-Only Settling Bank Member. Funds-Only Settling Bank Members then debit or credit the account of each Netting Member for which it settles. Funds transfers become final at the time the funds are moved through NSS.

Proposed Changes to the Definition of Overnight Investment Rate

The Rules define Overnight Investment Rate as the interest rate earned by FICC on the investment of the portion of the cash deposited to its Clearing Fund that is invested overnight. However, this term is currently only used in the definitions of two components of FOS—the GCF Interest Adjustment Payment and the Interest Adjustment Payment—and is not used in reference to FICC's deposits

⁶ Rule 13 (Funds-Only Settlement), *id.*

⁷ Each component of FOS is described in Rule 13 (Funds-Only Settlement), *id.*

⁸ NSS is a settlement service operated by the Federal Reserve Banks available to depository institutions that settle for participants in clearinghouses, financial exchanges and other clearing and settlement groups. Settlement agents, acting on behalf of those depository institutions in a settlement arrangement, electronically submit settlement files to the Federal Reserve Banks. Files are processed on receipt, and entries are automatically posted to the depository institutions' Federal Reserve Bank accounts. FICC's affiliate, The Depository Trust Company, maintains an account at the New York Federal Reserve Bank and acts as agent for FICC for FOS.

⁸² See Notice, 90 FR at 48089.

⁸³ 15 U.S.C. 78s(b)(2).

⁸⁴ 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).

⁴ 17 CFR 240.19b–4(f)(4).

⁵ Terms not defined herein are defined in the Rules, available at <http://www.dtcc.com/legal/rules-and-procedures>.

of cash that Netting Members may deposit to satisfy their Required Fund Deposits to the Clearing Fund.⁹

Therefore, FICC is proposing to correct and clarify the definition of Overnight Investment Rate to mean the interest rate earned by FICC on the investment of cash held by FICC in connection with certain FOS debits that are invested overnight. The proposed change would correct the definition of this term, making the Rules clearer in describing the related components of FOS.

Proposed Changes to Frequency of Certain FOS Component Processing

The components of FOS credit and debit payments are described in Section 1 of Rule 13, and Netting Members are required to make such credit and debit payments “one or more times each Business Day”.¹⁰ As stated above, in practice, FOS credit and debits are currently processed twice each Business Day.

Because FOS is a pass-through process, if FICC debits a Netting Member for one component of FOS but does not have an equivalent credit to pay to another Netting Member, then FICC must hold and invest the cash amount it has debited overnight, until it can pay that amount to a Netting Member the next Business Day. This may occur in connection with the credit and debit payments of the Debit Forward Mark Adjustment Payments and the corresponding Credit Forward Mark Adjustment Payment, or with the Debit GCF Forward Mark Adjustment Payments and the corresponding Credit GCF Forward Mark Adjustment Payment.¹¹

The interest rate that FICC earns on such investments is the Overnight Investment Rate. The Interest Adjustment Payment and GCF Interest Adjustment Payment are components of FOS related to the overnight interest earned on such investments and, as noted above, may be assessed by FICC on the Debit Forward Mark Adjustment Payment, Credit Forward Mark Adjustment Payment, Debit GCF Forward Mark Adjustment Payment,

and Credit GCF Forward Mark Adjustment Payment amounts.

Historically, FICC has deposited amounts related to these FOS components at commercial banks that have paid interest on a daily basis, allowing FICC to pay its portion of the GCF Interest Adjustment Payment and the Interest Adjustment Payment components of FOS on a daily basis, within the timeframes specified in Rule 13.

However, fewer investment counterparties pay interest on deposits on a daily basis, and those that do offer daily interest payments do so at an interest rate that is not aligned with prevailing market rates.

In order for FICC to earn an interest rate on its investments related to FOS debits that is more aligned with the market, FICC would begin depositing these amounts with investment counterparties that do not pay interest on a daily basis. Therefore, FICC is proposing to amend Rule 13 to reflect a less frequent payment of the accrued GCF Interest Adjustment Payment and Interest Adjustment Payment components of FOS, to a monthly basis.

In order to reflect this change, FICC would amend Section 1 of Rule 13 to describe the circumstances in which it would pay the Credit Interest Adjustment Payment and the GCF Interest Adjustment Payment components of FOS on a less frequent basis than other components of FOS. Specifically, FICC would add a subsection (i) to Section 1(d) of Rule 13 to provide that, when a Debit Forward Mark Adjustment Payment is collected, for which FICC does not have an equivalent Credit Forward Mark Adjustment Payment to pay to another Netting Member, the related Credit Interest Adjustment Payment would be paid on a monthly basis. FICC would also add a subsection (i) to Section 1(l) of Rule 13 to similarly provide that, when a Debit GCF Forward Mark Adjustment Payment is collected, for which FICC does not have an equivalent Credit GCF Forward Mark Adjustment Payment to pay to another Netting Member, the related Credit GCF Interest Adjustment Payment would be paid on a monthly basis.

Proposed Changes To Remove Outdated Reference From Rule 13

FICC is proposing to delete a reference to Section 3 of Rule 13 from a statement in Section 1 of Rule 13 because Section 3 of Rule 13 was removed from the Rules in a prior proposed rule change. This reference to Section 3 was retained in the Rule in error.

The relevant statement currently provides that, other than as provided for in Section 3, all payment obligations and collection rights with respect to the FOS components must be satisfied each Business Day on a net total basis through payment or collection, as set forth in Section 2 of Rule 13, of the Funds-Only Settlement Amount. The proposed rule change would correct this statement by replacing the reference to Section 3 of Rule 13 in this statement with a more general reference to “this Rule”.

Implementation Timeframe

FICC would implement the proposed rule change by no later than February 28, 2026 and would announce the implementation date of the proposed changes by an Important Notice posted to FICC’s website.

2. Statutory Basis

FICC believes the proposed rule changes are consistent with the requirements of the Act and the rules and regulations thereunder applicable to a registered clearing agency. In particular, FICC believes the proposed rule changes are consistent with Section 17A(b)(3)(F) of the Act¹² and Rule 17ad-22(e)(23)(ii), promulgated under the Act,¹³ for the reasons described below.

Section 17A(b)(3)(F) of the Act requires, in part, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and assure the safeguarding of securities and funds which are in the custody or control of the clearing agency or for which it is responsible.¹⁴ The proposed changes would describe a change in the timing of the Credit Interest Adjustment Payment and the Credit GCF Interest Adjustment Payment, and the circumstances in which that less frequent timing would be applicable, as described in more detail above. This proposed change is driven by a change in practice by FICC that would provide Netting Members with an interest rate on deposits of cash related to FOS payments and debits that is more aligned with prevailing market rates. In this way, the proposed rule change would assure the safeguarding of funds which are in the custody or control of FICC, consistent with Section 17A(b)(3)(F) of the Act.¹⁵

The proposed rule changes would also update the defined term for

⁹ See Rule 1 (Definitions) (defined terms for “GCF Interest Adjustment Payment” and “Interest Adjustment Payment”) and Section 3a of Rule 4 (Clearing Fund and Loss Allocation) (which describes the investment of cash deposits to the Clearing Fund without reference to the Overnight Investment Rate, *supra* note 5).

¹⁰ Section 1 of Rule 13, *id.*

¹¹ See Rule 1 (Definitions) (defined terms for “Debit Forward Mark Adjustment Payment”, “Credit Forward Mark Adjustment Payment”, “Debit GCF Forward Mark Adjustment Payment” and “Credit GCF Forward Mark Adjustment Payment”) and Rule 13, Sections 1(d) and (l), *id.*

¹² 15 U.S.C. 78q-1(b)(3)(F).

¹³ 17 CFR 240.17ad-22(e)(23)(ii).

¹⁴ 15 U.S.C. 78q-1(b)(3)(F).

¹⁵ *Id.*

Overnight Investment Rate in the Rules and would remove a reference in Rule 13 that was retained in error. These two proposed changes would correct the Rules, ensuring they are clear and easily understood by Netting Members. When participants better understand their rights and obligations regarding the Rules, such participants are more likely to act in accordance with the Rules, which FICC believes would promote the prompt and accurate clearance and settlement of securities transactions. Therefore, FICC believes that the proposed changes are consistent with Section 17A(b)(3)(F) of the Act.¹⁶

Rule 17ad-22(e)(23)(ii) under the Act requires that FICC establish, implement, maintain and enforce written policies and procedures reasonably designed to provide sufficient information to enable participants to identify and evaluate the risks, fees, and other material costs they incur by participating in the covered clearing agency.¹⁷ As stated above, the proposed rule changes would correct the Rules by updating the definition of Overnight Investment Rate and removing an incorrect reference in Section 1 of Rule 13. As such, these proposed changes would further improve the public disclosures in the Rules regarding FOS and the timing of certain payments related to the FOS process. Therefore, FICC believes that the proposed changes are consistent with Rule 17ad-22(e)(23)(ii) under the Act.¹⁸

(B) Clearing Agency's Statement on Burden on Competition

FICC does not believe the proposed rule changes would have any impact on competition. First, the proposed changes regarding the timing of certain FOS payments would apply equally to all Netting Members. Further, the proposed changes to the definition of Overnight Investment Rate and the correction to Rule 13 are designed to improve market participants' understanding of the provisions in the Rules governing FOS. As such, FICC does not believe such proposed amendments would have any effect on participants' respective competitive positions.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

FICC has not received or solicited any written comments relating to this proposal. If any written comments are

received, they will be publicly filed as Exhibit 2 to this filing, as required by Form 19b-4 and the General Instructions thereto.

Persons submitting comments are cautioned that, according to Section IV (Solicitation of Comments) of the Exhibit 1A in the General Instructions to Form 19b-4, the Commission does not edit personal identifying information from comment submissions. Commenters should submit only information that they wish to make available publicly, including their name, email address, and any other identifying information.

All prospective commenters should follow the Commission's instructions on how to submit comments, available at www.sec.gov/rules-regulations/how-submit-comment. General questions regarding the rule filing process or logistical questions regarding this filing should be directed to the Main Office of the SEC's Division of Trading and Markets at tradingandmarkets@sec.gov or 202-551-5777.

FICC reserves the right to not respond to any comments received.

III. Date of Effectiveness of the Proposed Rule Change, and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act¹⁹ and paragraph (f) of Rule 19b-4 thereunder.²⁰ At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules-regulations/self-regulatory-organization-rulemaking>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-FICC-2025-026 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange

Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR-FICC-2025-026. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules-regulations/self-regulatory-organization-rulemaking>). Copies of the filing will be available for inspection and copying at the principal office of FICC and on DTCC's website (www.dtcc.com/legal/sec-rule-filings). 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-FICC-2025-026 and should be submitted on or before January 20, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²¹

Sherry R. Haywood,

Assistant Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-104464; File No. SR-NASDAQ-2025-104]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Provide Nasdaq With Limited Discretion To Deny Initial Listing to Certain Companies

December 19, 2025.

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 December 12, 2025, The Nasdaq Stock Market LLC ("Nasdaq" or "Exchange") 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 the Exchange. The Commission is publishing this notice to

¹⁶ *Id.*

¹⁷ 17 CFR 240.17ad-22(e)(23)(ii).

¹⁸ *Id.*

¹⁹ 15 U.S.C. 78s(b)(3)(A).

²⁰ 17 CFR 240.19b-4(f).

²¹ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

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 provide Nasdaq with limited discretion to deny initial listing to companies, even where the applicant meets all stated listing requirements.

The text of the proposed rule change is available on the Exchange's website at <https://listingcenter.nasdaq.com/rulebook/nasdaq/rulefilings>, and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Recently, Nasdaq has observed problematic or unusual trading in certain listed companies. Further, the Commission has imposed temporary trading suspensions pursuant to Section 12(k) of the Act on several listed securities based, generally, on concerns about potential manipulation in the securities effectuated through recommendations made to investors by unknown persons via social media to purchase, hold, and/or sell the securities. The Commission stated its belief that these recommendations appear to be designed to artificially inflate the price and volume of the securities and that the public interest and the protection of investors require a suspension of trading in the securities.³ In most cases, the affected

securities were listed for less than one year.

The Commission Suspension Orders generally appear to be based on activities of third parties, and there are no specific allegations in the Commission Suspension Orders against the companies, or persons associated with the companies, as being involved in the potentially manipulative trading activity. Nasdaq's listing requirements, which these companies satisfied both at the time of listing and on an ongoing basis, are based on the characteristics of the company itself and the securities it seeks to list. Likewise, Nasdaq Rule 5101, in conjunction with IM-5101-1, provides some discretion to deny listing where the company itself has engaged in misconduct or where an individual with a history of regulatory misconduct is associated with the company.⁴ Nasdaq Rule 5101 does not allow denial of a listing based on the potential for one or more unaffiliated third parties to engage in misconduct impacting a company's securities.⁵ The Commission is obliged to set aside a decision to deny listing that does not comport with Nasdaq rules.⁶ Therefore, Nasdaq requires additional authority to exercise discretion to deny a listing based on the potential for one or more third parties to engage in misconduct impacting a company's securities. Similarly, Nasdaq rules do not presently allow it to deny listing to a company based on its review of trading patterns of other companies with similar characteristics or based on considerations related to the company's advisors, and it requires additional

(Premium Catering (Holdings) Limited), 34-104169 (October 22, 2025) (Robot Consulting Co., Ltd.), 34-104176 (November 11, 2025) (Charming Medical Limited), 34-104180 (November 14, 2025) (MaxsMaking Inc.), 34-104317 (December 4, 2025) (Robot Consulting Co., Ltd.) (collectively, the "Commission Suspension Orders").

⁴ See Listing Rule IM-5101-1. In approving the predecessor to Rule 5101, the Commission stated that it believed the rule change provided "greater assurance [to existing or prospective investors] that the risk associated with investing in Nasdaq is market risk rather than the risk that the promoter or other persons exercising substantial influence over the company is acting in an illegal manner." Exchange Act Release No. 34151 (June 3, 1994), 59 FR 29843 (June 9, 1994) at 29845; *id.* at 29844, citing as the reason for the proposed rule concerns about "an increase in recent years in the number of applications for inclusion in Nasdaq by issuers that are managed, controlled or influenced by persons with a history of significant securities or commodities violations."

⁵ See *id.* at 29845 (noting concerns raised during the comment process that "discretion accorded the NASD was unlimited and could lead the NASD to exclude an issuer from Nasdaq on a basis wholly unrelated to the legitimate concerns of administering Nasdaq.")

⁶ 15 U.S.C. 78s(f).

authority to exercise discretion to do so.⁷

Nasdaq is concerned about the allegedly manipulative trading taking place in listed securities and that pending applicants, despite meeting all listing requirements, have characteristics similar to those subject to the Commission's trading suspensions and therefore may be susceptible to similar manipulation. While Nasdaq proposed certain changes to the listing requirements in September 2025,⁸ those changes remain pending⁹ and Nasdaq believes that additional rules would help to address the concerns identified in the Commission Suspension Orders. For example, Nasdaq may identify similarities between companies seeking initial listing and the advisors to the companies that are the subject of the Commission Suspension Orders (including auditors, underwriters, law firms, brokers, clearing firms, or other professional service providers). For another example, Nasdaq may consider the impact of foreign laws on the potential recourse available to U.S. regulators or investors in the event of misconduct. Accordingly, Nasdaq proposes to adopt a new rule, IM-5101-3, providing Nasdaq with authority under Rule 5101 to deny initial listing based on factors that could make the listed security susceptible to manipulation related to concerns Nasdaq and other regulators have identified with previously listed companies that are similarly situated to the company or based on considerations related to the company's advisors (including auditors, underwriters, law firms, brokers, clearing firms, or other professional service providers), even where the applicant meets all stated listing requirements.

The proposed rule change includes a series of non-exclusive factors that Nasdaq will consider in determining whether to apply this discretion. These factors include the following:

- where the company is located, including the availability of legal remedies to U.S. shareholders in that jurisdiction, the existence of blocking

⁷ Cf. Section 104.00 of the NYSE Listed Company Manual and Section 201 of NYSE American Company Guide requiring that companies go through a pre-review process before they are permitted to apply for listing.

⁸ Exchange Act Release No. 103982 (September 16, 2025), 90 FR 45280 (September 19, 2025) (SR-Nasdaq-2025-068); Exchange Act Release No. 103979 (September 16, 2025), 90 FR 45298 (September 19, 2025) (SR-Nasdaq-2025-069).

⁹ Exchange Act Release No. 104058 (September 25, 2025), 90 FR 46973 (September 30, 2025) (designating December 18, 2025, as the date the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, SR-Nasdaq-2025-069).

³ See, e.g., Securities Exchange Act Releases 34-104112 (September 26, 2025) (Smart Digital Group, Limited), 34-104113 (September 26, 2025) (QMMM Holding Limited), 34-104163 (October 3, 2025) (Etoiles Capital Group Co., Ltd.), 34-104164 (October 3, 2025) (Platinum Analytics Cayman Limited), 34-104165 (October 3, 2025) (Pitanium Limited), 34-104166 (October 8, 2025) (Empiro Group Inc.), 34-104167 (October 8, 2025) (NusaTrip Incorporated), 34-104168 (October 16, 2025)

statutes, data privacy laws and other laws in foreign jurisdictions that may present challenges to regulators seeking to enforce rules against the company, the ability of parties to conduct comprehensive due diligence in that jurisdiction, and the transparency of regulators in the jurisdiction;

- whether a person or entity exercises substantial influence over the company¹⁰ and, if so, where that person or entity is located, including the availability of legal remedies to U.S. shareholders in that jurisdiction, the existence of blocking statutes, data privacy laws and other laws in foreign jurisdictions that may present challenges to regulators seeking to enforce rules against the person or entity, the ability of parties to conduct comprehensive due diligence in that jurisdiction, and the transparency of regulators in the jurisdiction;

- whether the expected public float and dissemination of the share distribution, based on a review of underwriter, broker and clearing allocations and consideration of prior deals involving those service providers, at the time of the IPO and post offering, raises concerns about adequate liquidity and potential concentration;

- whether there are issues concerning the company's advisors (including auditors, underwriters, law firms, brokers, clearing firms, or other professional service providers), based on factors including, but not limited to, whether the advisor has been reviewed by applicable regulators and, if so, what were the results of those reviews;

- if the company's advisor is a new entity, whether the advisor's principals were involved with other firms with a regulatory history;

- whether any of the company's advisors were involved in prior transactions where the securities became subject to a pattern of concerning or volatile trading;

- whether the company's management and Board has experience or familiarity with U.S. public company requirements, including regulatory and reporting requirements under Nasdaq rules and federal securities laws;

- whether there are any FINRA, SEC or other regulatory referrals related to the company or its advisors, which can be included in the record of the matter and, if applicable, the results of those referrals;

- whether the company currently has, or recently has had, a going concern

audit opinion and, if so, what is the Company's plan to continue as a going concern; and

- whether there are other factors that raise concerns about the integrity of the Company's board, management, significant shareholders, or advisors.

By giving Nasdaq the authority to exercise discretion in this manner, Nasdaq believes it can better address situations where a company satisfies Nasdaq's listing requirements, but has characteristics similar to other companies' securities where trading problems were observed and could make the company susceptible to manipulation. While Nasdaq may not otherwise have access to the facts underlying problematic or unusual trading that takes place across multiple U.S. exchanges as well as off-exchange, the factors will help identify situations where similar characteristics exist that are likely to create conditions that could allow problematic or unusual trading to also occur in the applicant's securities. Moreover, the proposed rule change will also give Nasdaq the authority to consider the involvement of advisors to the company and gatekeepers in other transactions that had problematic or unusual trading, and to take action to deny initial listing to a company involved with these entities.

When Nasdaq uses its authority to exercise discretion to deny listing, Nasdaq Staff will issue a written determination describing the basis for its decision. A Company must, within four business days from the date of Staff's written determination, make a public announcement in a press release or other Regulation FD compliant manner about the receipt of the determination and the Rule(s) upon which the determination is based, describing each specific basis and concern identified by Nasdaq in reaching its determination.¹¹ The Company may within seven calendar days of when its application is denied seek review by a Hearings Panel, as set forth in Rule 5815.

This proposed rule change is immediately effective, and Nasdaq proposes to apply the proposed rule to all companies currently in the application process.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,¹² in general, and furthers the objectives of Section 6(b)(5) of the Act,¹³ in particular, in that it is designed to

prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. Further, the Exchange believes that this proposal is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Commission has previously opined on the importance of meaningful listing standards for the protection of investors and the public interest.¹⁴ In particular, the Commission has stated:

The development and enforcement of meaningful listing standards for an exchange is of critical importance to financial markets and the investing public. Among other things, such listing standards help ensure that exchange-listed companies will have sufficient public float, investor base, and trading interest to provide the depth and liquidity to promote fair and orderly markets.¹⁵

Nasdaq believes that granting limited additional discretion to deny initial listing to companies, even when an applicant meets all stated listing requirements, is consistent with the requirements in Section 6(b)(5) of the Exchange Act. As noted, Nasdaq has observed trading patterns in certain securities—such as price swings unrelated to company news—and the Commission has issued multiple suspension orders alleging market manipulation in similar circumstances. The proposed factors will help provide transparency to situations where Nasdaq believes an applicant's securities may be more susceptible to manipulation, based on comparable characteristics or the involvement of similar advisors. Accordingly, Nasdaq believes that adopting this additional authority is consistent with the requirements to protect investors and the public interest. Further, while Nasdaq's use of this discretion may prevent some companies that otherwise meet the stated listing requirements from listing, such distinction between companies is not unfair because the affected companies will exhibit traits that increase their susceptibility to manipulation or share advisors with companies that previously demonstrated problematic or unusual trading patterns. Therefore the proposed

¹⁰ Nasdaq believes it is important to consider the location of a person or entity that exercises substantial influence over the company to ensure that such individuals and entities are accountable to shareholders and regulators, as appropriate.

¹¹ Rule 5815(i)(2).

¹² 15 U.S.C. 78f(b).

¹³ 15 U.S.C. 78f(b)(5).

¹⁴ Securities Exchange Act Release No. 102622 (March 12, 2025), 90 FR 12608 (March 18, 2025) (approving SR-Nasdaq-2024-084 adopting initial listing liquidity requirements for companies applying to list or uplist on the Nasdaq Global Market or Nasdaq Capital Market).

¹⁵ *Id.* at 12609.

rule change is consistent with Section 6(b)(5).

Nasdaq also believes that any impact on competition among companies as a result of the proposed rule change is necessary in furtherance of the investor protection goals of the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change will not impose any burden on competition among exchanges, since other exchanges either already have, or are able to adopt, similar rules providing them with discretion to deny initial listing. The proposed rule change may impose a burden on companies that are denied listing, but this burden is necessary to protect investors and the public interest, which is a primary purpose of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act¹⁶ and Rule 19b-4(f)(6)¹⁷ thereunder.

A proposed rule change filed under Rule 19b-4(f)(6)¹⁸ normally does not become operative prior to 30 days after the date of filing. However, pursuant to Rule 19b-4(f)(6)(iii),¹⁹ the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange asked that the Commission waive the 30-day operative delay so that

the proposal may become operative immediately upon filing. The Exchange states that waiver of the 30-day operative delay will immediately provide the Exchange with additional authority to exercise discretion to deny initial listing based on factors that could make the listed security susceptible to manipulation. The Exchange further states that applying this authority to any companies that may otherwise seek to list during the 30-day period could potentially minimize subsequent manipulative trading in those companies' securities. For these reasons, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.²⁰

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 (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-NASDAQ-2025-104 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-NASDAQ-2025-104. 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

²⁰ For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-NASDAQ-2025-104 and should be submitted on or before January 20, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²¹

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025-23811 Filed 12-23-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-104472; File No. SR-CboeBZX-2025-163]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Modify the Minimum Performance Standards Applicable to the Exchange's Lead Market Maker ("LMM") Program in BZX-Listed Exchange-Traded Product ("ETP") Securities as Provided in Footnote 14 of the Exchange's Fee Schedule and To Remove Closed-End Funds ("CEFs") From the ETP LMM Program

December 19, 2025.

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 December 12, 2025, Cboe BZX Exchange, Inc. ("Exchange" or "BZX") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

²¹ 17 CFR 200.30-3(a)(12), (59).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

¹⁶ 15 U.S.C. 78s(b)(3)(A)(iii).

¹⁷ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

¹⁸ 17 CFR 240.19b-4(f)(6).

¹⁹ 17 CFR 240.19b-4(f)(6)(iii).

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BZX Exchange, Inc. ("BZX" or the "Exchange") is filing with the Securities and Exchange Commission ("Commission" or "SEC") a proposed rule change to modify the Minimum Performance Standards applicable to the Exchange's Lead Market Maker ("LMM") program in BZX-listed exchange-traded product ("ETP") securities as provided in footnote 14 of the Exchange's fee schedule and to remove Closed-End Funds ("CEFs") from the ETP LMM program. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Commission's website (<https://www.sec.gov/rules/sro.shtml>), the Exchange's website (https://www.cboe.com/us/equities/regulation/rule_filings/bzx/), and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fee Schedule applicable to its equities trading platform ("BZX Equities") to (1) modify the Minimum Performance Standards³ applicable to the ETP LMM program⁴ by changing the criteria

needed to earn the Base Rates and Enhanced Rates provided in footnote 14(B) of the fee schedule; (2) memorialize those Minimum Performance Standards in the fee schedule; and (3) remove CEFs from the ETP LMM Program. The Exchange proposes to implement these changes effective December 1, 2025.⁵

The Exchange first notes that its listings business operates in a highly-competitive market in which market participants, which includes issuers of securities, LMMs, and other liquidity providers, can readily transfer their listings, opt not to participate, or direct order flow to competing venues if they deem fee levels, liquidity provision incentive programs, or any other factor at a particular venue to be insufficient or excessive. The proposed rule changes reflect a competitive pricing structure designed to incentivize market participants to participate as LMMs in the Exchange's LMM Program, which the Exchange believes will enhance market quality in all securities listed on the Exchange and encourage issuers to list new products and transfer existing products to the Exchange.

The Exchange currently offers daily incentives for LMMs in ETPs and CEFs and listed on the Exchange for which the LMM meets certain "Base" or "Enhanced" Minimum Performance Standards.⁶ Such daily incentives are determined based on the number of BZX-listed ETPs/CEFs for which the LMM meets such Minimum Performance Standards and the average auction volume across such securities. Generally speaking, the more LMM Securities⁷ for which the LMM meets the Minimum Performance Standards and the higher the auction volume across those ETPs/CEFs, the greater the total daily incentive to the LMM.

The Exchange first proposes to eliminate CEFs from the ETP LMM Program provided under footnote 14(B) of the fee schedule. To effect this change, the Exchange proposes to remove CEFs from the definition of "Qualified ETP LMM" and adopt a new

term "Qualified CEF LMM" in the fee schedule. The Exchange proposes to define "Qualified CEF LMM" to mean an LMM in a BZX-listed CEF security that meets the LMM performance standards set forth in Rule 11.8(e)(1)(E)(ii). The Exchange proposes to modify the existing definition of "Qualified ETP LMM" to mean an LMM in a BZX-listed ETP that is registered as a market maker in good standing on the Exchange that meets the Base or Enhanced Minimum Performance Standards set forth in footnote 14(B). The Exchange also proposes to eliminate all references to CEFs in footnote 14(B) of the fee schedule. The Exchange proposes to adopt a new definition for the term "ETP Minimum Performance Standards" which would mean the "Base" or "Enhanced" standards set forth in footnote 14(B) of the fee schedule. The Exchange also proposes to modify references to Standard Rates in footnote 14(B) to Base Rates.

The Exchange also proposes to amend both the Base and Enhanced Minimum Performance Standards under which an ETP LMM would qualify for the daily incentive. The Exchange proposes no changes to the amount of the daily incentives currently provided in the fee schedule.

The Original Filing provided that the Exchange expects the Minimum Performance Standards to include the below, and before diverging significantly from those ranges, the Exchange would submit a rule filing to the Commission describing such proposed changes. Specifically, the Minimum Performance Standards included in Original Filing required:

(i) registration as a market maker in good standing with the Exchange;

(ii) time at the inside requirements (generally between 3% and 15% of Regular Trading Hours for Base Minimum Performance Standards and between 5% to 50% for Enhanced Minimum Performance Standards, depending on the average daily volume of the applicable LMM Security);

(iii) auction participation requirements (generally requiring that the auction price is between 3% and 5% of the last Reference Price, as defined in Rule 11.23(a)(19), for Base Minimum Performance Standards and 1%–3% for Enhanced Minimum Performance Standards);

(iv) market-wide NBB and NBO spread and size requirements (generally requiring between 200 and 750 shares at both the NBB and NBO for both Base and Enhanced Minimum Performance Standards with an NBBO spread between 1% and 10% for Base

³ As defined in Rule 11.8(e)(1)(E), the term "Minimum Performance Standards" means a set of standards applicable to an LMM that may be determined from time to time by the Exchange. Such standards will vary between LMM Securities depending on the price, liquidity, and volatility of the LMM Security in which the LMM is registered. The performance measurements will include: (A) percent of time at the NBBO; (B) percent of executions better than the NBBO; (C) average displayed size; and (D) average quoted spread.

⁴ The ETP LMM Program was adopted in 2019 and was designed to encourage LMMs to maintain better market quality in BZX-listed securities, and, in particular, in lower volume securities where transaction-based compensation (*i.e.*, rebates) may

not be sufficient. See Securities Exchange Act No. 91151 (February 10, 2021) 86 FR 11372 (February 24, 2021) (SR-CboeBZX-2021-016) (the "Original Filing").

⁵ The Exchange initially filed the proposed fee changes on November 21, 2025 (SR-CboeBZX-2025-150), withdrew that filing on December 4, 2025, and submitted a replacement filing (SR-CboeBZX-2025-160). The Exchange withdrew SR-CboeBZX-2025-160 on December 12, 2025, and submitted this filing.

⁶ Minimum Performance Standards generally refers to a set of standards applicable to an LMM that may be determined from time to time by the Exchange. See *e.g.*, Exchange Rule 11.8(e)(1)(E).

⁷ The term "LMM Security" means BZX-listed securities for which a Member is an LMM.

Minimum Performance Standards and .25% to 4% for Enhanced Minimum Performance Standards, depending on price of the ETP and underlying asset class); and

(v) depth of book requirements (generally requiring between \$25,000 and \$250,000 of displayed posted liquidity for both Base and Enhanced Minimum Performance Standards within 1% to 10% of both the NBB and NBO for Base Minimum Performance Standards and 0.25% and 5% for Enhanced Minimum Performance Standards, depending on price of the ETP and underlying asset class).

Now, the Exchange proposes to modify the Base and Enhanced

Minimum Performance Standards and memorialize those Minimum Performance Standards in the fee schedule.

First, the Exchange proposes to provide under footnote 14(B) introductory language related to a Qualified ETP LMM. Specifically, the Exchange proposes to provide that Qualified ETP LMMs that meet the Base or Enhanced Minimum Performance Standards below are entitled to the Qualified ETP LMM daily incentive. Each assigned ETP is grouped based on an asset class categorization.⁸ An ETP LMM is considered to have met the Base and Enhanced Minimum Performance Standard for an assigned ETP for the

trading day if it meets each of the following Base or Enhanced requirements:

(1) *Time with Two-Sided Quotation*: ETP LMM must maintain both bid(s) and offer(s) at least a certain percentage of the time the security is in a trading state during Regular Trading Hours (“RTH”).⁹ Specifically, across all six asset class categories and for Base and Enhanced Minimum Performance Standards, the ETP LMM must maintain both bid(s) and off(s) at least 98% of the time the security is in a trading state during RTH, as follows:

	US equity (%)	Single stock (%)	Outcome based (%)	Fixed income (%)	International equity (%)	Other (%)
Base	98	98	98	98	98	98
Enhanced	98	98	98	98	98	98

(2) *Time at the National Best Bid and Offer (“NBBO”)*: ETP LMM must maintain both bid(s) and offer(s) at the NBBO at least a certain percentage of

the time the security is in a trading state during RTH, as summarized in the table below.¹⁰ The Base and Enhanced Minimum Performance Standard is

applied based on consolidated average daily volume (“CADV”) of the ETP LMM Security.

	US equity (%)	Single stock (%)	Outcome based (%)	Fixed income (%)	International equity (%)	Other (%)
Base:						
CADV ≥500,000	5	5	5	5	5	5
CADV <500,000	20	20	20	20	20	20
Enhanced:						
CADV ≥500,000	15	15	15	15	15	15
CADV <500,000	60	60	60	60	60	60

As provided above, the ETP LMM must maintain bid(s) and offer(s) at the NBB or NBO, respectively, at least 5% of the time the security is in a trading state during RTH for ETP LMM Securities with a CADV equal than or greater than 500,000 shares across all six asset categories to meet the Base Minimum Performance Standard. For ETP LMM Securities with a CADV less than 500,000 shares, the ETP LMM must maintain bid(s) and offer(s) at the NBB or NBO, respectively, at least 20% of the time the security is in a trading state

during RTH for ETP LMM Securities with a CADV equal than or greater than 500,000 shares across all six asset categories to meet the Base Minimum Performance Standard.

The Enhanced Minimum Performance Standard requires the ETP LMM must maintain bid(s) and offer(s) at the NBB or NBO, respectively, at least 15% of the time the security is in a trading state during RTH for ETP LMM Securities with a CADV equal than or greater than 500,000 shares across all six asset categories. For ETP LMM Securities

with a CADV less than 500,000 shares, the ETP LMM must maintain bid(s) and offer(s) at the NBB or NBO, respectively, at least 60% of the time the security is in a trading state during RTH for ETP LMM Securities with a CADV less than 500,000 shares across all six asset categories.

(3) *Depth of Book*: ETP LMM must maintain a minimum notional value of both bid(s) and offer(s) within a certain percentage of the NBBO for at least 90%¹¹ during the time the security is in a trading state during RTH, as follows:

	US equity	Single stock	Outcome based	Fixed income	International equity	Other
Base	\$150,000 1%	\$150,000 2%	\$150,000 2%	\$150,000 2%	\$150,000 2%	\$150,000 2%

⁸ The Exchange proposes six asset class categories as follows: (1) US Equity, (2) Single Stock, (3) Outcome Based, (4) Fixed Income, (5) International Equity, and (6) Other.

⁹ See Exchange Rule 1.5(w).

¹⁰ The Exchange calculates time at the NBBO by separately determining the percentage of time the LMM is at the NBB and at the NBO, then averaging those two percentages.

¹¹ To calculate the time that the LMM meets the depth of book requirement, the Exchange considers

the time during which the LMM has both bid(s) and offer(s) (*i.e.*, a two-sided quote) posted to the Exchange that satisfy the notional value and price requirements.

	US equity	Single stock	Outcome based	Fixed income	International equity	Other
Enhanced	\$150,000 0.25%	\$150,000 0.50%	\$175,000 0.35%	\$175,000 0.25%	\$150,000 0.40%	\$150,000 0.50%

Based on the above, for the Base Minimum Performance Standard the ETP LMM must maintain a notional value of \$150,000 on both the bid and the offer within at least 1–2% (dependent on the asset category) of the NBB and NBO, respectively, across the six asset categories. The Enhanced

Minimum Performance Standard requires the LMM maintain a notional value ranging from \$150,000 to \$175,000 on both the bid and offer within at least 0.25–0.50% of the NBB and NBO, respectively, across the six asset categories.

(4) *Minimum Size at NBBO*: market-wide NBBO must have a minimum number of shares available at both the NBB and NBO at least 50% during the time the security is in a trading state during RTH, as follows:¹²

	US equity (%)	Single stock (%)	Outcome based (%)	Fixed income (%)	International equity (%)	Other (%)
Base	500	300	300	300	300	300
Enhanced	1,000	1,300	1,200	1,200	1,000	1,000

As indicated above, the Base Minimum Performance Standard requires 300 to 500 shares available at the NBB and NBO across all market centers for at least 50% of the trading day based on the asset categorization of the LMM ETP Security. The Enhanced

Minimum Performance Standard requires 1,000 to 1,300 shares available at the NBB and NBO across all market centers for at least 50% of the trading day based on the asset categorization of the LMM ETP Security.

(5) *Maximum NBBO Spread*: market-wide NBBO spread must be within a certain percentage for at least 95% during the time the security is in a trading state during RTH, as follows:

	US equity (%)	Single stock (%)	Outcome based (%)	Fixed income (%)	International equity (%)	Other (%)
Base	0.50	1	0.75	0.50	1	1.50
Enhanced	0.25	0.50	0.35	0.25	0.40	0.50

As indicated above, the Base Minimum Performance Standard requires the NBBO spread across all market centers be within 0.50–1% for at least 95% of the trading day based on the asset categorization of the LMM ETP

Security. The Enhanced Minimum Performance Standard requires the NBBO spread across all market centers be within 0.25–0.50% for at least 95% of the trading day based on the asset categorization of the LMM ETP Security.

(6) *BZX Official Opening/Closing Price Requirement*: the BZX Official Opening Price¹³ and BZX Official Closing Price¹⁴ must be within a certain percentage of the last Reference Price.¹⁵

	US equity (%)	Single stock (%)	Outcome based (%)	Fixed income (%)	International equity (%)	Other (%)
Base:						
Opening Price	2	2	2	2	2	2
Closing Price	1.50	1.50	1.50	1.50	1.50	1.50
Enhanced:						
Opening Price	0.50	0.50	0.50	0.50	0.50	0.50
Closing Price	0.25	0.25	0.25	0.25	0.25	0.25

As provided above, the Base Minimum Performance Standard requires that the BZX Official Opening Price be within 2% of the last Reference Price across all six asset categories, and the BZX Official Closing Price be within 1.50% of the last Reference Price across

all six asset categories. The Enhanced Minimum Performance Standard requires that the BZX Official Opening Price be within 0.50% of the last Reference Price across all six asset categories, and the BZX Official Closing Price be within 0.25% of the last

Reference Price across all six asset categories.

The Exchange believes the proposed amendments to the ETP LMM Program, including the removal of CEFs, memorialization of Minimum Performance Standards, and adoption of asset class-based requirements, are

¹² The Exchange calculates the minimum size at the NBBO by separately determining the percentage

of time the LMM is at the NBB and at the NBO, then averaging those two percentages.

¹³ See Exchange Rule 11.23(a)(5).

¹⁴ See Exchange Rule 11.23(a)(3).

¹⁵ See Exchange Rule 11.23(a)(19).

consistent with the requirements of the Act for the reasons discussed below.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.¹⁶ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹⁷ requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹⁸ requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers as well as Section 6(b)(4)¹⁹ as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities.

The Exchange believes that the proposed changes to the ETP LMM Program are consistent with Section 6(b)(5) of the Act because they are designed to enhance market quality and liquidity in Exchange-listed securities. Specifically, the proposed rule change memorializes the Minimum Performance Standards applicable to ETP LMMs in the fee schedule, providing greater transparency and clarity to market participants regarding the obligations and expectations for LMMs participating in the program. The Exchange notes that it is appropriate to memorialize the ETP Minimum Performance Standards in the Fee Schedule rather than the rule book, as this approach is consistent with NYSE Arca's treatment of similar standards.²⁰ This transparency removes impediments to and perfects the mechanism of a free and open market by ensuring that all market participants

have clear notice of the standards that must be met to qualify for LMM incentives.

The Exchange believes that segmenting the Minimum Performance Standards into asset classes is consistent with Section 6(b)(5) of the Act and is in line with how the Exchange understands market makers to take on and quote ETP assignments. Different asset classes—including US Equity, Single Stock, Outcome Based, Fixed Income, International Equity, and Other—have distinct trading characteristics, liquidity profiles, and market dynamics that affect how market makers can effectively provide liquidity. By tailoring the performance standards to reflect these differences, the Exchange believes that aligning asset classes with respective quoting obligations will result in more correlated market making support to the tickers that fall in each asset class. This approach promotes just and equitable principles of trade by establishing performance standards that are appropriately calibrated to the unique characteristics of each asset class, which in turn enhances liquidity provision and market quality for investors trading in these securities.

The proposed asset class-based structure benefits investors and protects the public interest by ensuring that LMMs are held to standards that reflect the realities of providing liquidity in different types of ETPs. For example, Fixed Income ETPs may have different spread and depth characteristics than US Equity ETPs, and International Equity ETPs may face different pricing dynamics than Single Stock ETPs. By recognizing these differences in the Minimum Performance Standards, the Exchange creates incentives for LMMs to provide high-quality, consistent liquidity that is appropriate for each product type. This tailored approach removes impediments to and perfects the mechanism of a free and open market by encouraging market making activity that is well-suited to the specific needs of each asset class.

The Exchange also believes that removing CEFs from the ETP LMM Program and establishing a separate "Qualified CEF LMM" definition is consistent with Section 6(b)(5) of the Act. This change recognizes the distinct trading characteristics and liquidity profiles of CEFs compared to ETPs and allows the Exchange to tailor its LMM programs appropriately to each product type. By applying the LMM performance standards set forth in Rule 11.8(e)(1)(E)(ii) to CEFs, the Exchange ensures that CEF LMMs are subject to appropriate standards while focusing

the proposed ETP LMM Program standards on ETPs, where such standards are better suited to the product characteristics. This tailored approach promotes just and equitable principles of trade and protects investors by ensuring that LMM obligations are appropriately calibrated to the securities for which they are responsible.

Furthermore, the proposed rule change is consistent with Section 6(b)(5) because it operates in a competitive environment where market participants can readily choose among competing venues. The Exchange's LMM Program is designed to attract and retain LMMs by offering competitive incentives in exchange for meeting rigorous performance standards. This competitive structure ensures that the Exchange's fees and incentive programs remain fair and reasonable, as LMMs and issuers can direct their business elsewhere if they find the Exchange's terms to be insufficient or excessive. The proposed changes reflect the Exchange's efforts to balance the need for high-quality market making with appropriate incentives, which ultimately benefits all market participants and promotes the public interest.

Finally, the Exchange believes that memorializing the specific Minimum Performance Standards in the fee schedule, including the detailed requirements across different asset class categories and CADV thresholds, enhances transparency and removes impediments to a free and open market. Market participants will have clear, accessible information about the standards applicable to the ETP LMM Program, enabling them to make informed decisions about participation and allowing for more effective monitoring and compliance. This transparency is consistent with the Act's objectives of promoting just and equitable principles of trade and protecting investors.

For these reasons, the Exchange believes the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather, the

¹⁶ 15 U.S.C. 78f(b).

¹⁷ 15 U.S.C. 78f(b)(5).

¹⁸ *Id.*

¹⁹ 15 U.S.C. 78f(b)(4).

²⁰ See NYSE Arca fee schedule at section III available at https://www.nyse.com/publicdocs/nyse/vmarkets/nyse-arca/NYSE_cArca_Marketplace_Fees.pdf.

Exchange believes the proposed rule change will enhance competition.

The Exchange does not believe the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed Minimum Performance Standards apply equally to all ETP LMMs that choose to participate in the ETP LMM Program. All ETP LMMs have the opportunity to qualify for the daily incentives by meeting either the Base or Enhanced Minimum Performance Standards, and the standards are transparent and objective. The Exchange notes that participation in the ETP LMM Program is voluntary, and market makers can choose whether to participate based on their assessment of whether they can meet the performance standards and whether the incentives are attractive relative to their costs.

The proposed asset class-based structure does not impose a burden on intramarket competition because it reflects the different characteristics and trading dynamics of various ETP types. Market makers specializing in different asset classes face different operational requirements and market conditions, and the tailored standards recognize these differences rather than creating competitive advantages or disadvantages. An ETP LMM's ability to meet the standards for any particular asset class depends on its operational capabilities and market making strategies, which are within the control of each market participant.

Additionally, the removal of CEFs from the ETP LMM Program does not burden intramarket competition. CEF LMMs will continue to be subject to the LMM performance standards set forth in Rule 11.8(e)(1)(E)(ii), ensuring that all CEF LMMs are treated equally. The separation of CEFs from ETPs in the LMM Program structure simply recognizes the distinct nature of these products and allows the Exchange to apply appropriate standards to each product type.

The Exchange does not believe the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange operates in a highly competitive market in which market participants can readily direct their business to competing venues if they deem fee levels, incentive programs, or other factors at a particular venue to be insufficient or excessive. The proposed changes to the ETP LMM Program are designed to attract and retain LMMs by offering competitive incentives in

exchange for meeting performance standards that enhance market quality.

To the extent the proposed rule change makes the Exchange's LMM Program more attractive to market makers or issuers, any resulting competitive impact would be the result of the Exchange's competitive pricing and program design, which is appropriate and consistent with the Act. Other exchanges are free to adopt similar or different LMM programs and incentive structures to compete for market maker participation and issuer listings. The Exchange believes that competition among venues for LMM participation and listings benefits investors by encouraging exchanges to develop programs that promote liquidity and market quality.

Furthermore, the proposed rule change may enhance intermarket competition by encouraging other exchanges to evaluate and potentially improve their own LMM programs. This type of competitive dynamic promotes innovation and improvement in market structure, which ultimately benefits investors and the broader market ecosystem.

The Exchange also notes that the proposed Minimum Performance Standards are designed to enhance liquidity in Exchange-listed ETPs, which benefits all market participants regardless of where they choose to trade. Improved liquidity and tighter spreads resulting from the enhanced LMM Program contribute to better price discovery and more efficient markets across all trading venues, as the benefits of improved market quality are not limited to the Exchange's platform.

For these reasons, the Exchange does not believe the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act²¹ and paragraph (f) of Rule 19b-4²² thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may

temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-CboeBZX-2025-163 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-CboeBZX-2025-163. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-CboeBZX-2025-163 and should be submitted on or before January 20, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²³

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025-23816 Filed 12-23-25; 8:45 am]

BILLING CODE 8011-01-P

²¹ 15 U.S.C. 78s(b)(3)(A).

²² 17 CFR 240.19b-4(f).

²³ 17 CFR 200.30-3(a)(12).

SECURITIES AND EXCHANGE
COMMISSION

[Release No. 34–104468; File No. SR–BX–
2025–034]

Self-Regulatory Organizations; Nasdaq
BX, Inc.; Notice of Filing and
Immediate Effectiveness of Proposed
Rule Change To Amend SQF Port and
SQF Purge Port Fees

December 19, 2025.

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 December 16, 2025, Nasdaq BX, Inc. (“BX” or “Exchange”) filed with the Securities and Exchange Commission (“SEC” or “Commission”) the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s
Statement of the Terms of Substance of
the Proposed Rule Change

The Exchange proposes to amend its Specialized Quote Feed³ or “SQF” Port and SQF Purge Port pricing at Options 7, Section 3, BX Options Market—Ports and other Services. The Exchange also proposes to remove outdated rule text at Options 7, Section 2, BX Options Market—Fees and Rebates.⁴

While the changes proposed herein are effective upon filing, the Exchange has designated the amendments become operative on January 1, 2026.

The text of the proposed rule change is available on the Exchange’s website at <https://listingcenter.nasdaq.com/>

rulebook/bx/rulefilings, and at the principal office of the Exchange.

II. Self-Regulatory Organization’s
Statement of the Purpose of, and
Statutory Basis for, the Proposed Rule
Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s
Statement of the Purpose of, and
Statutory Basis for, the Proposed Rule
Change

1. Purpose

BX proposes to amend its SQF Port and SQF Purge Port pricing at Options 7, Section 3, BX Options Market—Ports and other Services by offering an incentive to Market Makers⁵ to lower their SQF Port and SQF Purge Port Fees. The Exchange also proposes to remove outdated rule text at Options 7, Section 2, BX Options Market—Fees and Rebates. SQF Port and SQF Purge Port Fees

Pursuant to a prior rule change,⁶ as of January 1, 2026, BX will assess an SQF Port Fee and SQF Purge Port Fee as follows: The first 5 ports (1–5) would be assessed \$1,620 per port, per month; the next 15 ports (6–20) would be assessed \$1,080 per port, per month; and all ports over 20 ports (21 and above) would be

assessed \$540 per port, per month. SR–BX–2025–016 amended its SQF Port and SQF Purge Port Fees to be identical to NOM’s SQF Port and SQF Purge Port Fees. Today, NOM aggregates its SQF Port and SQF Purge Port Fees for purposes of the tier qualification. At this time, to make clear the manner in which BX will determine qualifications for the SQF Port and SQF Purge Port tiers, the Exchange proposes to note that, “The SQF Port Fee and the SQF Purge Port Fee are aggregated for the below incremental tiers as follows.”⁷ Additionally, the Exchange would relocate the tier qualifications to one table instead of two separate tables. The Exchange intends to calculate SQF Ports and SQF Purge Ports on January 1, 2026, the effective date of SR–BX–2025–016, identical to NOM.

Additionally, at this time, the Exchange proposes to offer an opportunity to lower SQF Port and SQF Purge Port Fees. Specifically, the Exchange proposes to offer certain discounts to Market Makers that have transacted a certain percentage of Total National Volume in the prior month. For purposes of this proposal, the percentage of Total National Volume is calculated by taking the total Market Maker Penny Symbol and Market Maker Non-Penny Symbol volume (excluding index options) executed on the Exchange in the prior month and attributing a multiple of five times to that Non-Penny Symbol volume (numerator) and dividing that by Market Maker volume (“M” capacity at The Options Clearing Corporation (“OCC”)) in multiply listed options across all options exchanges (denominator or Total National Volume).

Tier	Percentage of total national volume	Percentage SQF port and SQF purge port discount
1	less than 0.10%	0%
2	greater than or equal to 0.10% and less than 0.25%	10
3	greater than or equal to 0.25% and less than 0.40%	30
4	greater than or equal to 0.40%	50

¹ 15 U.S.C. 78s(b)(1).
² 17 CFR 240.19b–4.
³ “Specialized Quote Feed” or “SQF” is an interface that allows Market Makers to connect, send, and receive messages related to quotes, Immediate-or-Cancel Orders, and auction responses into and from the Exchange. Features include the following: (1) options symbol directory messages (e.g., underlying instruments); (2) system event messages (e.g., start of trading hours messages and start of opening); (3) trading action messages (e.g., halts and resumes); (4) execution messages; (5) quote messages; (6) Immediate-or-Cancel Order

messages; (7) risk protection triggers and purge notifications; (8) opening imbalance messages; (9) auction notifications; and (10) auction responses. The SQF Purge Interface only receives and notifies of purge requests from the Market Maker. Market Makers may only enter interest into SQF in their assigned options series. Immediate-or-Cancel Orders entered into SQF are not subject to the Order Price Protection, Market Order Spread Protection, or Size Limitation Protection in Options 3, Section 15(a)(1), (a)(2), and (b)(2) respectively. See Options 3, Section 7(e)(1)(B).

⁴ On December 8, 2025 the Exchange filed SR–BX–2025–030. On December 16, 2025 SR–BX–2025–030 was withdrawn and this rule change was filed.
⁵ A “Market Maker” means a Streaming Quote Trader or a Remote Streaming Quote Trader who enters quotations for his own account electronically into the System. See Options 1, Section 1(a)(28).
⁶ See Securities Exchange Act Release No. 103888 (September 5, 2025). 90 FR 43716 (September 10, 2025) (SR–BX–2025–016).
⁷ NOM is proposing a similar sentence in its Pricing Schedule in a separate rule change.

With this proposal, a Market Maker that transacted less than 0.10% of Total National Volume in the prior month would not receive a discount on SQF Port and SQF Purge Port Fees. A Market Maker that transacted greater than or equal to 0.10% and less than 0.25% of Total National Volume in the prior month will be afforded a discount of 10% on their SQF Port and SQF Purge Port Fees. A Market Maker that transacted greater than or equal to 0.25% and less than 0.40% of Total National Volume in the prior month will be afforded a discount of 30% on their SQF Port and SQF Purge Port Fees. Finally, a Market Maker that transacted greater than or equal to 0.40% of Total National Volume in the prior month will be afforded a discount of 50% on their SQF Port and SQF Purge Port Fees. By way of example, a Market Maker that executed 3,000,000 in Penny Volume and 200,000 in Non-Penny Volume in a given month on the Exchange, where the Total National Volume was 1,000,000,000, would qualify for a discount of 50% on their SQF Port and SQF Purge Port Fees ($(200,000 \times 5 = 1,000,000) + 3,000,000 = 4,000,000$ which is 0.40% of 1,000,000,000).

The Exchange proposes to calculate Market Maker Non-Penny Symbol volume at five times the weight as compared to Market Maker Penny Symbol volume because Non-Penny Symbols tend to have lower volumes and this incentive should encourage a greater amount of volume in Non-Penny Symbols. Overall, the proposed discounts should encourage Market Makers to transact additional order flow on BX with which other market participants may interact, for an opportunity to lower SQF Port and SQF Purge Port Fees. The Exchange proposes to exclude index options as index options are generally not multiply listed.

Options 7, Section 2

The Exchange proposes to remove note 4 of Options 7, Section 2 which states,

Participants that increase their executed Customer volume which removes liquidity in a given month by at least 70% above their September 2024 volume as measured by a percentage of TCv will receive a Taker Fee discount of \$0.05 per contract in Penny Symbols excluding AAPL, SPY, QQQ, and IWM. Participants with no Customer volume in the remove liquidity segment for the month of September 2024 may qualify for the Taker Fee discount by having any new volume considered as added volume. This note 4 incentive will be available through April 30, 2025.

The incentive located at note 4 of Options 7, Section 2 was available through April 30, 2025 and is now outdated.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,⁸ in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,⁹ in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system “has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.”¹⁰

Likewise, in *NetCoalition v. Securities and Exchange Commission*¹¹ (“NetCoalition”) the D.C. Circuit upheld the Commission’s use of a market-based approach in evaluating the fairness of market data fees against a challenge claiming that Congress mandated a cost-based approach.¹² As the court emphasized, the Commission “intended in Regulation NMS that ‘market forces, rather than regulatory requirements’ play a role in determining the market data . . . to be made available to investors and at what cost.”¹³

Further, “[n]o one disputes that competition for order flow is ‘fierce.’ . . . As the SEC explained, ‘[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution’; [and] ‘no exchange can afford to take its market share percentages for granted’ because ‘no exchange possesses a monopoly, regulatory or otherwise, in

the execution of order flow from broker dealers’”¹⁴ Although the court and the SEC were discussing the cash equities markets, the Exchange believes that these views apply with equal force to the options markets.

SQF Port and SQF Purge Port Fees

The proposed fee discounts for SQF Ports and SQF Purge Ports are reasonable because they will attract a greater amount of order flow to BX with which other market participants may interact while also lowering costs for certain Market Makers that are able to transact greater than 0.10% of Total National Volume in the prior month. The Exchange believes it is reasonable to lower costs for certain Market Makers that transact greater than 0.10% of Total National Volume on BX because those Market Makers are affording other BX Participants an opportunity to interact with that order flow. The proposal provides an incremental incentive for Market Makers that transact at least 0.10% of Total National Volume, which provides a higher benefit for satisfying increasingly more stringent criteria. The Exchange believes that the value of the proposed discounts is commensurate with the difficulty to achieve the corresponding threshold. Additionally, the discounts may incentivize and attract more volume and liquidity to the Exchange, which will benefit all Exchange participants through increased opportunities to trade as well as enhancing price discovery. The Exchange’s proposed discounts are substantially similar to Cboe Exchange, Inc.’s (“Cboe”) credit for their BOE Bulk Port Fees.¹⁵

¹⁴ *Id.* at 539 (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

¹⁵ Cboe currently offers its market makers credits on their monthly BOE Bulk Port Fees. Specifically, if a Cboe market maker affiliate (“affiliate” defined as having at least 75% common ownership between the two entities as reflected on each entity’s Form BD, Schedule A) or Cboe Appointed OFP receives a credit under the Exchange’s Volume Incentive Program (“VIP”), the Cboe market maker will receive an access credit on their BOE Bulk Ports corresponding to the VIP tier reached. The credit is based on the Performance Tier earned by a market maker under Cboe’s Liquidity Provider Sliding Scale Adjustment Table. Tiers 4 and 5 earn a 40% credit on monthly Cboe Bulk Port Fees. Cboe assesses BOE Bulk Logical Ports a fee of \$1,500 for 1 to 5 ports, a fee of \$2,500 for 6 to 30 ports and a fee of \$3,000 for over 30 ports. Additionally, each BOE Bulk Logical Port will incur the logical port fee indicated when used to enter up to 30,000,000 orders per trading day per logical port as measured on average in a single month. Each incremental usage of up to 30,000,000 orders per day per BOE Bulk Logical Port will incur an additional logical port fee of \$3,000 per month. Incremental usage will be determined on a monthly basis based on the

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⁸ 15 U.S.C. 78f(b).

⁹ 15 U.S.C. 78f(b)(4) and (5).

¹⁰ Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (“Regulation NMS Adopting Release”).

¹¹ *NetCoalition v. SEC*, 615 F.3d 525 (D.C. Cir. 2010).

¹² See *NetCoalition*, at 534–535.

¹³ *Id.* at 537.

BX believes it is reasonable to offer fee discounts to those Market Makers that primarily provide and post liquidity to the Exchange, as it should encourage Market Makers to continue to participate on the Exchange and add liquidity. Greater liquidity benefits all market participants by providing more trading opportunities and tighter spreads. The proposal would also mitigate the costs incurred by Market Makers on BX.

Calculating Market Maker Non-Penny Symbol volume at five times the weight as compared to Penny Symbol volume is reasonable, equitable and not unfairly discriminatory as Non-Penny Symbols tend to have lower volumes and this incentive should encourage a greater amount of volume in Market Maker Non-Penny Symbols.¹⁶ The Exchange proposes to calculate the Market Maker Non-Penny Symbol volume in a uniform manner for all Participants. The Exchange proposes to exclude index options as index options are generally not multiply listed. Index Options would be uniformly excluded.

A BX Market Maker requires only one SQF Port to submit quotes in its assigned options series into BX. A Market Maker may submit all quotes through one SQF Port. This is also the case for an SQF Purge Port. While a Market Maker may elect to obtain multiple SQF Ports and SQF Purge Ports to organize its business,¹⁷ only one SQF Port is necessary for a BX Market Maker to fulfill its regulatory quoting obligations.¹⁸

The proposed fee discounts for SQF Ports and SQF Purge Ports are equitable and not unfairly discriminatory as they would apply uniformly to each BX Market Maker. The Exchange would uniformly calculate the Market Maker's percentage each month. Although only Market Makers may receive the proposed discounts, the Exchange notes that Market Makers are valuable market participants that provide liquidity in the marketplace and incur costs that other market participants do not incur. Unlike other market participants, Market Makers are required to provide

continuous two-sided quotes on a daily basis,¹⁹ and are subject to various obligations associated with providing liquidity.²⁰ While the Exchange is not offering a discount to those Market Makers that transact less than 0.10% of Total National Volume, the Exchange notes that these Market Makers transact a much lower amount of contracts on BX as compared to other Market Makers who qualify for a discount. In some cases, these Market Makers are not executing the requisite amount of Penny Symbols or Non-Penny Symbols to obtain the discount. Market Makers are required to compete with other Market Makers and maintain active markets in all options in which the Market Maker is registered.²¹ The Exchange believes that all Market Makers are capable of quoting tighter or in a greater amount of options classes to obtain the requisite volume to achieve a discount.

The Exchange's proposal to note that, "The SQF Port Fee and the SQF Purge Port Fee are aggregated for the below incremental tiers as follows" and to relocate the tier qualifications to one table instead of two separate tables is reasonable, equitable and not unfairly discriminatory as it will reflect that BX intends to calculate the SQF Port Fee and the SQF Purge Port Fees by aggregating them for purposes of the tier calculation. This reflects the intent of SR-BX-2025-016, which stated that the BX SQF Port Fee and the SQF Purge Port Fees would be identical to the NOM SQF Port Fee and the SQF Purge Port Fees.

Options 7, Section 2

The Exchange's proposal to remove note 4 of Options 7, Section 2 is reasonable because the incentive was available through April 30, 2025 and is now outdated. The Exchange's proposal to remove note 4 of Options 7, Section 2 is equitable and not unfairly discriminatory because no Participant would be eligible for this incentive.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

In terms of intra-market competition, the proposed fee discounts for SQF Ports and SQF Purge Ports do not impose a burden on competition because they would apply uniformly to each Market Maker and the Exchange

would uniformly calculate the Market Maker's percentage each month. Although only Market Makers may receive the proposed discounts, the Exchange notes that Market Makers are valuable market participants that provide liquidity in the marketplace and incur costs that other market participants do not incur. Unlike other market participants, Market Makers are required to provide continuous two-sided quotes on a daily basis,²² and are subject to various obligations associated with providing liquidity.²³ Further, while the Exchange is not offering a discount to those Market Makers that transact less than 0.10% of Total National Volume, the Exchange notes that these Market Makers transact a much lower amount of contracts on BX as compared to other Market Makers that qualify for the discount and/or these Market Makers are not executing the requisite amount of Penny Symbols or Non-Penny Symbols to obtain the discount. The Exchange's proposal does not impose an undue burden on competition because Market Makers are required to compete with other Market Makers and maintain active markets in all options in which the Market Maker is registered.²⁴ The Exchange believes that all Market Makers are capable of quoting tighter or in a greater amount of options classes to obtain the requisite volume to achieve a discount.

The Exchange's proposal to note that, "The SQF Port Fee and the SQF Purge Port Fee are aggregated for the below incremental tiers as follows" and to relocate the tier qualifications to one table instead of two separate tables does not impose an undue burden on competition as it will reflect that BX intends to calculate the SQF Port Fee and the SQF Purge Port Fees by aggregating them for purposes of the tier calculation. This reflects the intent of SR-BX-2025-016, which stated that the BX SQF Port Fee and the SQF Purge Port Fees would be identical to the NOM SQF Port Fee and the SQF Purge Port Fees.

The Exchange's proposal to remove note 4 of Options 7, Section 2 does not impose an undue burden on competition because no Participant would be eligible for this incentive.

In terms of inter-market competition, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities

average orders per day entered in a single month across all subscribed BOE Bulk Logical Ports.

¹⁶ Penny Symbols typically are more liquid symbols.

¹⁷ For example, a Market Maker may desire to utilize multiple SQF Ports for accounting purposes, to measure performance, for regulatory reasons or other determinations that are specific to that Participant.

¹⁸ Market Makers have various regulatory requirements as provided for in Options 2, Section 4. Additionally, Market Makers have certain quoting requirements with respect to their assigned options series as provided in Options 2, Section 5. SQF is the only quoting protocol offered on BX.

¹⁹ See Options 2, Section 5.

²⁰ See Options 2, Section 4.

²¹ See Options 2, Section 4(a)(3) and (6).

²² See Options 2, Section 5.

²³ See Options 2, Section 4.

²⁴ See Options 2, Section 4(a)(3) and (6).

available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other options exchanges. In addition to the Exchange, market participants have alternative options exchanges that they may participate on and direct their order flow. In sum, if the changes proposed herein are unattractive to market participants, it is likely that the Exchange will lose market share as a result. Accordingly, the Exchange does not believe that the proposed changes will impair the ability of members or competing options exchanges to maintain their competitive standing in the financial markets.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.²⁵

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-BX-2025-034 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-BX-2025-034. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-BX-2025-034 and should be submitted on or before January 20, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁶

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025-23812 Filed 12-23-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-104469; File No. SR-NASDAQ-2025-107]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend SQF Port and SQF Purge Port Fees

December 19, 2025.

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 December 16, 2025, The Nasdaq Stock Market LLC ("Nasdaq" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend The Nasdaq Options Market LLC ("NOM")

Specialized Quote Feed³ or "SQF" Port and SQF Purge Port pricing at Options 7, Section 3, Nasdaq Options Market—Ports and other Services.⁴

While the changes proposed herein are effective upon filing, the Exchange has designated the amendments become operative on January 1, 2026.

The text of the proposed rule change is available on the Exchange's website at <https://listingcenter.nasdaq.com/rulebook/nasdaq/rulefilings>, and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

NOM proposes to amend its SQF Port and SQF Purge Port pricing at Options 7, Section 3, Nasdaq Options Market—Ports and other Services by offering an incentive to Market Makers⁵ to lower their SQF Port and SQF Purge Port Fees.

³ "Specialized Quote Feed" or "SQF" is an interface that allows Market Makers to connect, send, and receive messages related to quotes, Immediate-or-Cancel Orders, and auction responses into and from the Exchange. Features include the following: (1) options symbol directory messages (e.g., underlying instruments); (2) system event messages (e.g., start of trading hours messages and start of opening); (3) trading action messages (e.g., halts and resumes); (4) execution messages; (5) quote messages; (6) Immediate-or-Cancel Order messages; (7) risk protection triggers and purge notifications; (8) opening imbalance messages; (9) auction notifications; and (10) auction responses. The SQF Purge Interface only receives and notifies of purge requests from the Market Maker. Market Makers may only enter interest into SQF in their assigned options series. Immediate-or-Cancel Orders entered into SQF are not subject to the Order Price Protection, Market Order Spread Protection, or Size Limitation Protection in Options 3, Section 15(a)(1), (a)(2), and (b)(2) respectively. See Options 3, Section 7(e)(1)(B).

⁴ On December 8, 2025 the Exchange filed SR-NASDAQ-2025-100. On December 16, 2025 the Exchange withdrew SR-NASDAQ-2025-100 and filed this rule change.

⁵ The term "NOM Market Maker" or ("M") is a Participant that has registered as a Market Maker on NOM pursuant to Options 2, Section 1, and must

Continued

²⁵ 15 U.S.C. 78s(b)(3)(A)(ii).

²⁶ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

NOM currently assess an SQF Port Fee and an SQF Purge Port Fee as follows: The first 5 ports (1–5) would be assessed \$1,620 per port, per month; the next 15 ports (6–20) would be assessed \$1,080 per port, per month; and all ports over 20 ports (21 and above) would be assessed \$540 per port, per month. Today, NOM aggregates the SQF Port and SQF Purge Ports for purposes of determining the applicable tier qualification.

At this time, the Exchange proposes to amend the rule text to state, “The SQF

Port Fee and the SQF Purge Port Fee are aggregated for the below incremental tiers as follows.” The addition of this language will add clarity to the current billing of these port.

Additionally, at this time, the Exchange proposes to offer an opportunity to lower SQF Port and SQF Purge Port Fees. Specifically, the Exchange proposes to offer certain discounts to Market Makers that have transacted a certain percentage of Total National Volume in the prior month. For purposes of this proposal, the

percentage of Total National Volume is calculated by taking the total Market Maker Penny Symbol and Market Maker Non-Penny Symbol volume (excluding index options) executed on the Exchange in the prior month and attributing a multiple of five times to that Non-Penny Symbol volume (numerator) and dividing that by Market Maker volume (“M” capacity at The Options Clearing Corporation (“OCC”)) in multiply listed options across all options exchanges (denominator or Total National Volume).

Tier	Percentage of Total National Volume	Percentage SQF Port and SQF Purge Port discount
1	less than 0.10%	0
2	greater than or equal to 0.10% and less than 0.25%	10
3	greater than or equal to 0.25% and less than 0.40%	30
4	greater than or equal to 0.40%	50

With this proposal, a Market Maker that transacted less than 0.10% of Total National Volume in the prior month would not receive a discount on SQF Port and SQF Purge Port Fees. A Market Maker that transacted greater than or equal to 0.10% and less than 0.25% of Total National Volume in the prior month will be afforded a discount of 10% on their SQF Port and SQF Purge Port Fees. A Market Maker that transacted greater than or equal to 0.25% and less than 0.40% of Total National Volume in the prior month will be afforded a discount of 30% on their SQF Port and SQF Purge Port Fees. Finally, a Market Maker that transacted greater than or equal to 0.40% of Total National Volume in the prior month will be afforded a discount of 50% on their SQF Port and SQF Purge Port Fees. By way of example, a Market Maker that executed 3,000,000 in Penny Volume and 200,000 in Non-Penny Volume in a given month on the Exchange, where the Total National Volume was 1,000,000,000, would qualify for a discount of 50% on their SQF Port and SQF Purge Port Fees ((200,000 × 5 = 1,000,000) + 3,000,000 = 4,000,000 which is 0.40% of 1,000,000,000).

The Exchange proposes to calculate Market Maker Non-Penny Symbol volume at five times the weight as compared to Market Maker Penny Symbol volume because Non-Penny Symbols tend to have lower volumes and this incentive should encourage a

greater amount of volume in Non-Penny Symbols. Overall, the proposed discounts should encourage Market Makers to transact additional order flow on NOM with which other market participants may interact, for an opportunity to lower SQF Port and SQF Purge Port Fees. The Exchange proposes to exclude index options as index options are generally not multiply listed.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,⁶ in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,⁷ in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system “has been remarkably successful in promoting market competition in its

broader forms that are most important to investors and listed companies.”⁸

Likewise, in *NetCoalition v. Securities and Exchange Commission*⁹ (“NetCoalition”) the D.C. Circuit upheld the Commission’s use of a market-based approach in evaluating the fairness of market data fees against a challenge claiming that Congress mandated a cost-based approach.¹⁰ As the court emphasized, the Commission “intended in Regulation NMS that ‘market forces, rather than regulatory requirements’ play a role in determining the market data . . . to be made available to investors and at what cost.”¹¹

Further, “[n]o one disputes that competition for order flow is ‘fierce.’ . . . As the SEC explained, ‘[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution’; [and] ‘no exchange can afford to take its market share percentages for granted’ because ‘no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers’. . . .”¹² Although the court and the SEC were discussing the cash equities markets, the Exchange believes that these views apply with equal force to the options markets.

The proposed fee discounts for SQF Ports and SQF Purge Ports are reasonable because they will attract a greater amount of order flow to NOM with which other market participants

also remain in good standing pursuant to Options 2, Section 9. In order to receive NOM Market Maker pricing in all securities, the Participant must be registered as a NOM Market Maker in at least one security. See Options 1, Section 1(a).

⁶ 15 U.S.C. 78f(b).

⁷ 15 U.S.C. 78f(b)(4) and (5).

⁸ Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (“Regulation NMS Adopting Release”).

⁹ *NetCoalition v. SEC*, 615 F.3d 525 (D.C. Cir. 2010).

¹⁰ See *NetCoalition*, at 534–535.

¹¹ *Id.* at 537.

¹² *Id.* at 539 (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

may interact while also lowering costs for certain Market Makers that are able to transact greater than 0.10% of Total National Volume in the prior month. The Exchange believes it is reasonable to lower costs for certain Market Makers that transact greater than 0.10% of Total National Volume on NOM because those Market Makers are affording other NOM Participants an opportunity to interact with that order flow. The proposal provides an incremental incentive for Market Makers that transact at least 0.10% of Total National Volume, which provides a higher benefit for satisfying increasingly more stringent criteria. The Exchange believes that the value of the proposed discounts is commensurate with the difficulty to achieve the corresponding threshold. Additionally, the discounts may incentivize and attract more volume and liquidity to the Exchange, which will benefit all Exchange participants through increased opportunities to trade as well as enhancing price discovery. The Exchange's proposed discounts are substantially similar to Cboe Exchange, Inc.'s ("Cboe") credit for their BOE Bulk Port Fees.¹³

NOM believes it is reasonable to offer fee discounts to those Market Makers that primarily provide and post liquidity to the Exchange, as it should encourage Market Makers to continue to participate on the Exchange and add liquidity. Greater liquidity benefits all market participants by providing more trading opportunities and tighter spreads. The proposal would also mitigate the costs incurred by Market Makers on NOM.

Calculating Market Maker Non-Penny Symbol volume at five times the weight as compared to Penny Symbol volume is reasonable, equitable and not unfairly

discriminatory as Non-Penny Symbols tend to have lower volumes and this incentive should encourage a greater amount of volume in Market Maker Non-Penny Symbols.¹⁴ The Exchange proposes to calculate the Market Maker Non-Penny Symbol volume in an uniform manner for all Participants. The Exchange proposes to exclude index options as index options are generally not multiply listed. Index Options would be uniformly excluded.

A NOM Market Maker requires only one SQF Port to submit quotes in its assigned options series into NOM. A Market Maker may submit all quotes through one SQF Port. This is also the case for an SQF Purge Port. While a Market Maker may elect to obtain multiple SQF Ports and SQF Purge Ports to organize its business,¹⁵ only one SQF Port is necessary for a NOM Market Maker to fulfill its regulatory quoting obligations.¹⁶

The proposed fee discounts for SQF Ports and SQF Purge Ports are equitable and not unfairly discriminatory as they would apply uniformly to each NOM Market Maker. The Exchange would uniformly calculate the Market Maker's percentage each month. Although only Market Makers may receive the proposed discounts, the Exchange notes that Market Makers are valuable market participants that provide liquidity in the marketplace and incur costs that other market participants do not incur. Unlike other market participants, Market Makers are required to provide continuous two-sided quotes on a daily basis,¹⁷ and are subject to various obligations associated with providing liquidity.¹⁸ While the Exchange is not offering a discount to those Market Makers that transact less than 0.10% of Total National Volume, the Exchange notes that these Market Makers transact a much lower amount of contracts on NOM as compared to other Market Makers who qualify for a discount. In some cases, these Market Makers are not executing the requisite amount of Penny Symbols or Non-Penny Symbols to obtain the discount. Market Makers are

required to compete with other Market Makers and maintain active markets in all options in which the Market Maker is registered.¹⁹ The Exchange believes that all Market Makers are capable of quoting tighter or in a greater amount of options classes to obtain the requisite volume to achieve a discount.

The Exchange's proposal to amend the rule text to state, "The SQF Port Fee and the SQF Purge Port Fee are aggregated for the below incremental tiers as follows" is reasonable, equitable and not unfairly discriminatory. The addition of this language will add clarity to the current billing of these port.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

In terms of intra-market competition, the proposed fee discounts for SQF Ports and SQF Purge Ports do not impose a burden on competition because they would apply uniformly to each Market Maker and the Exchange would uniformly calculate the Market Maker's percentage each month. Although only Market Makers may receive the proposed discounts, the Exchange notes that Market Makers are valuable market participants that provide liquidity in the marketplace and incur costs that other market participants do not incur. Unlike other market participants, Market Makers are required to provide continuous two-sided quotes on a daily basis,²⁰ and are subject to various obligations associated with providing liquidity.²¹ Further, while the Exchange is not offering a discount to those Market Makers that transact less than 0.10% of Total National Volume, the Exchange notes that these Market Makers transact a much lower amount of contracts on NOM as compared to other Market Makers that qualify for the discount and/or these Market Makers are not executing the requisite amount of Penny Symbols or Non-Penny Symbols to obtain the discount. The Exchange's proposal does not impose an undue burden on competition because Market Makers are required to compete with other Market Makers and maintain active markets in all options in which the Market Maker is registered.²² The

¹³ Cboe currently offers its market makers credits on their monthly BOE Bulk Port Fees. Specifically, if a Cboe market maker affiliate ("affiliate" defined as having at least 75% common ownership between the two entities as reflected on each entity's Form BD, Schedule A) or Cboe Appointed OFP receives a credit under the Exchange's Volume Incentive Program ("VIP"), the Cboe market maker will receive an access credit on their BOE Bulk Ports corresponding to the VIP tier reached. The credit is based on the Performance Tier earned by a market maker under Cboe's Liquidity Provider Sliding Scale Adjustment Table. Tiers 4 and 5 earn a 40% credit on monthly Cboe Bulk Port Fees. Cboe assesses BOE Bulk Logical Ports a fee of \$1,500 for 1 to 5 ports, a fee of \$2,500 for 6 to 30 ports and a fee of \$3,000 for over 30 ports. Additionally, each BOE Bulk Logical Port will incur the logical port fee indicated when used to enter up to 30,000,000 orders per trading day per logical port as measured on average in a single month. Each incremental usage of up to 30,000,000 orders per day per BOE Bulk Logical Port will incur an additional logical port fee of \$3,000 per month. Incremental usage will be determined on a monthly basis based on the average orders per day entered in a single month across all subscribed BOE Bulk Logical Ports.

¹⁴ Penny Symbols typically are more liquid symbols.

¹⁵ For example, a Market Maker may desire to utilize multiple SQF Ports for accounting purposes, to measure performance, for regulatory reasons or other determinations that are specific to that Participant.

¹⁶ Market Makers have various regulatory requirements as provided for in Options 2, Section 4. Additionally, Market Makers have certain quoting requirements with respect to their assigned options series as provided in Options 2, Section 5. NOM also offers a QUO protocol. Orders submitted by Market Makers into QUO are treated as quotes.

¹⁷ See Options 2, Section 5.

¹⁸ See Options 2, Section 4.

¹⁹ See Options 2, Section 4(a)(3) and (6).

²⁰ See Options 2, Section 5.

²¹ See Options 2, Section 4.

²² See Options 2, Section 4(a)(3) and (6).

Exchange believes that all Market Makers are capable of quoting tighter or in a greater amount of options classes to obtain the requisite volume to achieve a discount.

The Exchange's proposal to amend the rule text to state, "The SQF Port Fee and the SQF Purge Port Fee are aggregated for the below incremental tiers as follows" does not impose an undue burden on competition because the addition of this language will add clarity to the current billing of these port.

In terms of inter-market competition, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other options exchanges. In addition to the Exchange, market participants have alternative options exchanges that they may participate on and direct their order flow. In sum, if the changes proposed herein are unattractive to market participants, it is likely that the Exchange will lose market share as a result. Accordingly, the Exchange does not believe that the proposed changes will impair the ability of members or competing options exchanges to maintain their competitive standing in the financial markets.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.²³

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-NASDAQ-2025-107 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-NASDAQ-2025-107. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection.

All submissions should refer to file number SR-NASDAQ-2025-107 and should be submitted on or before January 20, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁴

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025-23813 Filed 12-23-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-104474; File No. SR-LTSE-2025-28]

Self-Regulatory Organizations; Long-Term Stock Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Exchange Rules 11.180 and Rule 14.002 To Conform With Recent Amendment to Definition of Round Lot Under Rule 600 of Regulation NMS

December 19, 2025.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on December 17, 2025, Long-Term Stock Exchange, Inc. ("LTSE" or the "Exchange") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing with the Securities and Exchange Commission ("Commission") a proposed rule change to amend Exchange Rules 11.180 and Rule 14.002 to conform with a recent amendment to the definition of Round Lot under Rule 600 of Regulation NMS recently approved by the Commission.³

The text of the proposed rule change is available at the Exchange's website at <https://longtermstockexchange.com/> and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 101070 (September 18, 2024), 89 FR 81620 (October 8, 2024) (S7-30-22).

²³ 15 U.S.C. 78s(b)(3)(A)(ii).

²⁴ 17 CFR 200.30-3(a)(12).

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Exchange Rules 11.180 and 14.002 to conform with a recent amendment to the definition of Round Lot under Rule 600 of Regulation NMS recently approved by the Commission.⁴ The Exchange also proposes to make conforming non-substantive changes to Exchange Rules 11.151(a)(1), Two-Sided Quote Obligation, 11.220, Priority of Orders, and 14.310, Initial Listing Requirements for Primary Equity Securities.

In 2020, the Commission adopted amendments to Regulation NMS to modernize the NMS information provided within the national market system for the benefit of market participants and to better achieve Section 11A's goals of assuring "the availability to brokers, dealers, and investors of information with respect to quotations for and transactions in securities that is prompt, accurate, reliable, and fair" ("MDI Rules").⁵ These changes included an amendment to Rule 600 of Regulation NMS to include a definition of "round lot" that assigns each NMS stock to a round lot size based on the stock's average closing price. Prior to this change, a "round lot" was not defined in the Act or Regulation NMS. The definition of a "round lot" was included in the rules of each exchange, including Exchange Rules 11.180 and 14.002, which typically defined a "Round Lot" as 100 shares, but they also allowed the exchange, or the primary listing exchange for the stock, discretion to define it otherwise.

In light of delays in the implementation of the MDI Rules, including the definition of round lot, on September 18, 2024, the Commission, among other things, accelerated the implementation of the round lot definition. The Commission also revised the round lot definition as set forth below.⁶ Rule 600(b)(93) of Regulation NMS, as adopted by the MDI Rules and as amended in 2024,⁷ defines a round lot for NMS stocks⁸ that have an average closing price on the primary listing exchange during the prior

Evaluation Period⁹ of: (1) \$250.00 or less per share as 100 shares; (2) \$250.01 to \$1,000.00 per share as 40 shares; (3) \$1,000.01 to \$10,000.00 per share as 10 shares; and (4) \$10,000.01 or more per share as 1 share. For any security that becomes an NMS Stock during an operative period, as described in Rule 600(b)(93)(iv),¹⁰ a round lot is 100 shares. Adjustments to the round lot size for a security will occur on a semiannual basis and the calculation of the average closing price on the primary listing exchange will be based on a one month "Evaluation Period."

The implementation of the Commission's revised definition was required to be completed on November 3, 2025, and the Commission provided temporary exemptive relief to exchanges from the requirement to file proposed rule changes to amend their rules to reflect the round lot definition in Rule 600(b)(93) of Regulation NMS until 30 calendar days following the end of the lapse of appropriations.¹¹ The Exchange now proposes to amend Exchange Rules 11.180 and 14.002 to conform with the definition of Round Lot under Rule 600 of the Regulation NMS.

Exchange Rule 11.180(q)(1) provides that "[o]ne hundred (100) shares or any multiple thereof shall constitute a Round Lot, unless an alternative number of shares is established as a Round Lot by the listing exchange for the security." The Exchange proposes to replace this definition with a sentence that explicitly refers to the definition of round lots under Rule 600 of Regulation NMS. As a result, the above sentence will be deleted and replaced with the following, "For any NMS stock, the "Round Lot" shall be the size assigned by the primary listing market pursuant to Rule 600 of Regulation NMS under the Exchange Act."

Similarly, Exchange Rule 14.002(a)(1) provides "'Round Lot" or "Normal Unit of Trading" means 100 shares of a

security[.]" and provides that the Exchange may determine when a "Round Lot" would not mean 100 shares. The Exchange now proposes to also amend Exchange Rule 14.002(a)(1) to explicitly refer to the definition of a round lot under Rule 600 of Regulation NMS. Again, the Exchange proposes these changes solely to conform to the Exchange's definition of Round Lot under Exchange Rule 11.180(q)(1) and Exchange Rule 14.002(a)(1) to the new definition of Round Lot under Rule 600 of Regulation NMS.

The Exchange also proposes to make conforming non-substantive changes to Exchange Rule 11.151(a)(1), Two-Sided Quote Obligation. Exchange Rule 11.151(a)(1) currently provides that "[u]nless otherwise designated, a 'normal unit of trading' shall be 100 shares." The Exchange proposes to replace the aforementioned sentence with a sentence that conforms to the newly adopted definition of Round Lot in the Exchange's Rulebook. As a result, the above sentence will be removed and replaced with the following: "[u]nless otherwise designated, a 'normal unit of trading' shall be a Round Lot as defined in Exchange Rule 11.180." The Exchange also proposes to make conforming non-substantive changes to Exchange Rules 11.220, Priority of Orders and 14.310, Initial Listing Requirements for Primary Equity Securities. The Exchange proposes to capitalize the term Round Lot in each of these rules. The purpose of these changes is to provide greater clarity to exchange members and the public regarding the Rulebook. The Exchange does not propose any additional changes to these rules.

Implementation Date

The proposed rule changes will be implemented on December 12, 2025.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,¹² in general, and furthers the objectives of Section 6(b)(1)¹³ in particular, in that it enables the Exchange to be so organized as to have the capacity to be able to carry out the purposes of the Act and to comply, and to enforce compliance by its exchange members and persons associated with its exchange members, with the provisions of the Act, the rules and regulations thereunder, and the rules of the Exchange. The Exchange also believed that the proposed rule change is consistent with Section 6(b)(5)

⁴ See *supra* note 3.

⁵ See Securities Exchange Act Release No. 90610 (December 9, 2020), 86 FR 18596 (April 9, 2021) ("MDI Adopting Release").

⁶ See *supra* note 3.

⁷ *Id.*

⁸ "NMS stock" is defined under Regulation NMS as any NMS security other than an option. 17 CFR 242.600(b)(65).

⁹ Rule 600(b)(93)(iii) of Regulation NMS defines the Evaluation Period as (A) all trading days in March for the round lot assigned on the first business day in May and (B) all trading days in September for the round lot assigned on the first business day of November during which the average closing price of an NMS stock on the primary listing exchange shall be measured by the primary listing exchange to determine the round lot for each NMS stock.

¹⁰ Pursuant to Rule 600(b)(93)(iv) of Regulation NMS the round lot assigned under this section shall be operative on: (A) The first business day of May for the March Evaluation Period and continue through the last business day of October of the calendar year; and (B) The first business day of November for the September Evaluation Period and continue through the last business day of April of the next calendar year.

¹¹ See Securities Exchange Act Release No. 104172 (Oct. 31, 2025) (Order Granting Temporary Exemptive Relief).

¹² 15 U.S.C. 78f(b).

¹³ 15 U.S.C. 78f(b)(1).

of the Act¹⁴ in that it is designed 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 proposes to amend Exchange Rules 11.180 and 14.002 to conform with the definition of Round Lot under Rule 600 of the Regulation NMS that is to be implemented in November 2025.¹⁵ These changes are being proposed solely to conform the Exchange's definition of "Round Lot" under Exchange Rules 11.180 and 14.002 to the new definition of Round Lot under Rule 600 of Regulation NMS. The Exchange also proposes to make conforming nonsubstantive changes to Rules 11.151(a)(1), Two-Sided Quote Obligation, 11.220, Priority of Orders, and 14.310, Initial Listing Requirements for Primary Equity Securities. These changes are limited to capitalizing the term Round Lot in each of these rules to conform with the changes to Exchange Rules 11.180 and 14.002.

The proposed rule changes would reduce potential investor and market participant confusion and therefore remove impediments to and perfect the mechanism of a free and open market and a national market system by ensuring that the Exchange's rules properly reflect the requirements of Rule 600 of Regulation NMS. The Exchange also believes that the proposed rule changes would remove impediments to and perfects the mechanism of a free and open market by ensuring that persons subject to the Exchange's jurisdiction, regulators, and the investing public can more easily navigate and understand the Exchange's rules. The proposed rule changes would not be inconsistent with the public interest and the protection of investors because investors will not be harmed and in fact would benefit from the increased transparency and clarity, thereby reducing potential confusion.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange believes the proposed rule changes do not impose any burden on intramarket or intermarket

competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule changes to amend the definition of Round Lot are not intended to address competitive issues but rather are concerned solely with amending the Exchange's Rules to conform with the amended definition of Round Lot under Rule 600 of the Regulation NMS.¹⁶ The proposed rule change to capitalize the term Round Lot in additional rules is conforming and non-substantive in nature, and is not intended to address competitive issues.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act¹⁷ and Rule 19b-4(f)(6)¹⁸ thereunder. 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 Act¹⁹ and Rule 19b-4(f)(6)²⁰ thereunder.

A proposed rule change filed under Rule 19b-4(f)(6)²¹ normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b-4(f)(6)(iii),²² the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative immediately upon filing. The Exchange

states that the proposed changes will not adversely impact investors and are solely designed to comply with the revised definition of Round Lot under Rule 600 of Regulation NMS recently approved by the Commission.²³ The Exchange also states that it is the public interest for the Rulebook to be specific, clear, and transparent, and that the proposed change would promote those interests. For these reasons, and because the proposed rule change does not raise any novel legal or regulatory issues, the Commission finds that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the 30-day operative delay and designates the proposed rule change to be operative upon filing.²⁴

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-LTSE-2025-28 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.
- All submissions should refer to file number SR-LTSE-2025-28. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use

²³ See *supra* note 3.

²⁴ For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

¹⁴ 15 U.S.C. 78f(b)(5).

¹⁵ See *supra* note 3.

¹⁶ *Id.*

¹⁷ 15 U.S.C. 78s(b)(3)(A).

¹⁸ 17 CFR 240.19b-4(f)(6).

¹⁹ 15 U.S.C. 78s(b)(3)(A).

²⁰ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

²¹ 17 CFR 240.19b-4(f)(6).

²² 17 CFR 240.19b-4(f)(6)(iii).

only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-LTSE-2025-28 and should be submitted on or before January 20, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁵

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025-23818 Filed 12-23-25; 8:45 am]

BILLING CODE 8011-01-P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #21386 and #21387; MINNESOTA Disaster Number MN-20024]

Administrative Declaration of a Disaster for the State of Minnesota

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of Minnesota dated December 22, 2025.

Incident: Skyline Tower Apartment Complex Fire and Severe Water Damage.

DATES: Issued on December 22, 2025.

Incident Period: October, 26 2025.

Physical Loan Application Deadline Date: February 20, 2026.

Economic Injury (EIDL) Loan Application Deadline Date: September 22, 2026.

ADDRESSES: Visit the MySBA Loan Portal at <https://lending.sba.gov> to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Sharon Henderson, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205-6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be submitted online using the MySBA

Loan Portal <https://lending.sba.gov> or other locally announced locations. Please contact the SBA disaster assistance customer service center by email at disastercustomerservice@sba.gov or by phone at 1-800-659-2955 for further assistance.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Ramsey.

Contiguous Counties:

Minnesota: Anoka, Dakota, Hennepin, Washington.

The Interest Rates are:

	Percent
<i>For Physical Damage:</i>	
Homeowners with Credit Available Elsewhere	6.000
Homeowners without Credit Available Elsewhere	3.000
Businesses with Credit Available Elsewhere	8.000
Businesses without Credit Available Elsewhere	4.000
Non-Profit Organizations with Credit Available Elsewhere ...	3.625
Non-Profit Organizations without Credit Available Elsewhere	3.625
<i>For Economic Injury:</i>	
Business and Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Non-Profit Organizations without Credit Available Elsewhere	3.625

The number assigned to this disaster for physical damage is 213865 and for economic injury is 213870.

The State which received a disaster Declaration is Minnesota.

(Catalog of Federal Domestic Assistance Number 59008)

(Authority: 13 CFR 1234.3(b).)

James Stallings,

Associate Administrator, Office of Disaster Recovery and Resilience.

[FR Doc. 2025-23887 Filed 12-23-25; 8:45 am]

BILLING CODE 8026-09-P

SMALL BUSINESS ADMINISTRATION

Data Collection Available for Public Comments.

ACTION: 60-Day notice and request for comments.

SUMMARY: The Small Business Administration (SBA) intends to request approval from the Office of Management and Budget (OMB) for the collection of information described below. The Paperwork Reduction Act (PRA) requires federal agencies to publish a notice in the **Federal Register**

concerning each proposed collection of information before submission to OMB, and to allow 60 days for public comment in response to the notice. This notice complies with that requirement.

DATES: Submit comments on or before February 27, 2026.

ADDRESSES: Send all comments to the Office of Communications and Public Liaison, Office of Strategic Alliances, Kelly LoTempio, Program Analyst, kelly.lotempio@sba.gov, 409 3rd Street SW, Washington, DC 20416, Small Business Administration.

FOR FURTHER INFORMATION CONTACT: Office of Communications and Public Liaison, Office of Strategic Alliances, Kelly LoTempio, Program Analyst, kelly.lotempio@sba.gov or (716) 551-3249. and Shauniece Carter, Interim Agency Clearance Officer, Shauniece.carter@sba.gov, (202) 935-6942.

SUPPLEMENTARY INFORMATION: Small business owners or advocates who have been nominated for an SBA recognition award submit this information for use in evaluating nominee's eligibility for an award: Verifying accuracy of information submitted and determining whether there are any actual or potential conflicts of interest. Awards are presented to winners during the Presidentially declared Small Business Week.

Solicitation of Public Comments

SBA is requesting comments on (a) Whether the collection of information is necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the information.

Summary of Information Collection

PRA Number: PRA 3245-0360.

Title: U.S. Small Business Administration Award Nominations.

Description of Respondents: Nominated Small Business Owners.

Form Number: 3300-3315/2025 Nomination Guidelines.

Total Estimated Annual Responses: 600.

Total Estimated Annual Hour Burden: 1200.

Shauniece Carter,
Interim Agency Clearance Officer.

[FR Doc. 2025-23877 Filed 12-23-25; 8:45 am]

BILLING CODE 8026-09-P

²⁵ 17 CFR 200.30-3(a)(12), (59).

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Notice of Action: China's Acts, Policies, and Practices Related to Targeting of the Semiconductor Industry for Dominance

AGENCY: Office of the United States Trade Representative.

ACTION: Notice of action.

SUMMARY: The United States Trade Representative (U.S. Trade Representative) has determined that China's acts, policies, and practices are actionable under Section 301 of the Trade Act of 1974 and that appropriate responsive action includes taking tariff action now on semiconductors from China, with an initial tariff level of 0 percent, increasing in 18 months on June 23, 2027, to a rate to be announced not fewer than 30 days prior to that date, as described below.

DATES: *December 23, 2025:* The effective date of the action.

FOR FURTHER INFORMATION CONTACT: Philip Butler, Chair of the Section 301 Committee or Nathaniel Halvorson, Deputy Assistant U.S. Trade Representative for Monitoring & Enforcement at (202) 395-5725.

SUPPLEMENTARY INFORMATION:

I. Background

On December 23, 2024, the U.S. Trade Representative initiated a section 301 investigation of China's acts, policies, and practices related to targeting of the semiconductor industry for dominance, including to the extent that China's semiconductors are incorporated as components into downstream products for critical industries like defense, automotive, medical devices, aerospace, telecommunications, and power generation and the electrical grid.¹ The U.S. Trade Representative also requested consultations with the Government of China pursuant to Section 303 of the Trade Act (19 U.S.C. 2413). The Government of China declined to hold consultations regarding the investigation under this statutory framework. The notice of initiation solicited written comments on, *inter alia*:

- China's acts, policies, and practices related to its targeting of the semiconductor industry for dominance.
- Anticompetitive and non-market means employed by the PRC in pursuit of its semiconductor industry targeting objectives, including political guidance, directives, and control within state and private enterprises, activities of state-

owned or state-controlled enterprises, market access restrictions, opaque regulatory preferences and discrimination, wage-suppressing labor practices, massive state support of industry (including government guidance funds), and forced technology transfer (including state-directed cyber intrusions and cybertheft of intellectual property).

- Whether China's acts, policies, and practices are unreasonable or discriminatory.
- Whether China's acts, policies, and practices burden or restrict U.S. commerce, and if so, the nature and level of the burden or restriction. This would include economic assessments of the burden or restriction on semiconductors, semiconductor manufacturing including foundries, silicon carbide substrates or other wafers, and downstream products, with a particular focus on critical industries, such as defense, automotive, medical devices, aerospace, telecommunications, and power generation and the electrical grid.
- Whether China's acts, policies, and practices are actionable under section 301(b) of the Trade Act, and what action, if any, should be taken, including tariff and non-tariff actions.

Interested persons filed 26 comments. In addition, USTR and the Section 301 Committee convened a public hearing on March 11, 2025, during which witnesses provided testimony and responded to questions. The public submissions are available at: <https://comments.ustr.gov/s/> in docket number USTR-2024-0024, and a transcript of the hearing is available on USTR's website.

II. Determination of Actionability

Based on information obtained during the investigation, and in consultation with the Section 301 Committee, China's targeting of the semiconductor industry for dominance is unreasonable and burdens or restricts U.S. commerce and thus is actionable.

For decades, China has targeted the semiconductor industry for dominance and has employed increasingly aggressive and sweeping non-market policies and practices in pursuing dominance of the sector. China's pursuit of its dominance goals has severely disadvantaged U.S. companies, workers, and the U.S. economy generally through lessened competition and commercial opportunities and through the creation of economic security risks from dependencies and vulnerabilities.

Top-down industrial planning is a critical feature of China's state-led, non-market economic system. China

organizes the development of its economy through broad, national-level five-year economic and social development plans. It then employs industry-specific plans and local plans at central and sub-central levels of government that typically align chronologically with the national five-year plans. These plans often contain detailed quantitative and qualitative targets, including for production, domestic content, domestic and international market shares, and outline the non-market policies and practices China should use to achieve these targets.

Over the last 25 years, China has promulgated over 100 central and sub-central industrial plans that address the semiconductor industry, articulating over 300 qualitative and 170 quantitative targets that seek to capture global and domestic market share, transfer technology, and indigenize the equipment needed to manufacture semiconductors. In its last publicly-released market share target for the semiconductor sector, China aimed to capture 56 percent of sales in the international market and 80 percent in the domestic market, according to industrial plans. Market share targets necessitate substitution by Chinese companies at the expense of foreign competitors—for Chinese companies to gain market share, they must displace foreign companies in existing markets and take new markets as they develop in the future. Across both qualitative and quantitative targets, China's industrial plans target every major segment of the semiconductor supply chain, including fabrication; design; assembly, testing, and packaging (ATP); and materials & equipment.

Unreasonable Acts, Policies, and Practices

In particular, the U.S. Trade Representative has determined that China's targeting of the semiconductor industry for dominance is unreasonable, including for the following reasons:

First, China's targeting of the semiconductor industry is unreasonable because China exerts extraordinary control over the semiconductor industry, and other economic actors, in order to achieve its targeted dominance, including through political guidance, directives, and control within state and private enterprises, activities of state-owned or state-controlled enterprises. Adherence to the objectives of China's industrial plans is effectively mandatory. Both state actors and Chinese companies move toward the goals set by the central government and have little discretion to ignore China's

¹ 89 FR 106725 (Dec. 30, 2025).

industrial targets. The Chinese Communist Party also exerts control through personnel and enterprise structures. China's control over economic actors enables China to direct and influence their commercial behavior in pursuit of its targeted dominance, in ways that run counter to fair competition and market-oriented principles.

Through its control of economic actors and sectors, China directs non-market advantages to China's semiconductor industry across every major segment of the semiconductor supply chain, including fabrication, design, ATP, materials, critical minerals, chemicals, photoresists, and manufacturing equipment. These non-market advantages include massive and persistent state financial support of industry, including market access restrictions and direction; government guidance funds; forced technology transfer and intellectual property theft; opaque regulatory preferences and discrimination; and wage-suppressing labor practices. Thus, China's targeting of the semiconductor industry for dominance is unreasonable because of China's extraordinary control over its economic actors and ability to direct non-market advantages to its semiconductor industry.

Second, China's targeting of the semiconductor industry for dominance is unreasonable because it does not reflect market competition and is unconstrained by market forces. China's targeting, both by design and in effect, displaces foreign firms, deprives market-oriented businesses and their workers of commercial opportunities, and lessens competition. China's plans, including as demonstrated by specific market share targets, are to achieve a long-term dominant position in these economic sectors. Its targeting of the industry for dominance necessarily means displacing foreign firms from existing markets, and taking new markets as they arise, diminishing competition. Foreign firms are increasingly unable to compete with the resources of the Chinese state, resulting in lost sales, under-investment in capacity, diminished ability to attract financing, and lost jobs and lower wages. The dominant positions China seeks, and increasingly achieves, in numerous segments of the semiconductor industry give it market power over global supply, pricing, and access.

Third, China's targeting of the semiconductor industry for dominance harms foreign competitors and purchasers by creating and exploiting dependencies. China's objective is to

ultimately displace foreign competitors throughout the semiconductor value chain in domestic and foreign markets, which increases the world's dependence on its companies, products, services, and technology. The creation of dependencies also increases risk for individual firms and their workers, for economic sectors (including workers' communities), and for supply chain resilience. China has demonstrated in the past its willingness to weaponize dependencies for purposes of economic coercion, including in this sector through export restrictions on gallium, germanium, antimony, and other critical minerals. China has applied these export restrictions broadly without regard to end-use or end-users. China's targeting of this sector for dominance is therefore unreasonable also due to the creation of dependencies and resulting vulnerabilities and risks.

Burden or Restriction on U.S. Commerce

Furthermore, the U.S. Trade Representative determined that China's targeting of the semiconductor industry for dominance burdens or restricts U.S. commerce, including for the following reasons:

First, China's targeted dominance burdens or restricts U.S. commerce because it undercuts business opportunities for and investments in the U.S. semiconductor industry. China has targeted the semiconductor industry for dominance for decades and increasingly dominates segments of the semiconductor value chain. Indeed, China continues to build upon its dominance and seeks to expand into new segments of the value chain. China's targeting for dominance contributes to lost sales, chronic underinvestment in numerous segments, and a diminished U.S. industry, constituting a burden and restriction on U.S. commerce.

Second, China's targeting for dominance burdens or restricts U.S. commerce because it creates economic security risks from dependence and vulnerabilities in sectors critical to the functioning of the U.S. economy. China's targeting for dominance has created, and will continue to accelerate, dependencies for the U.S. semiconductor industry and for purchasers of semiconductors, creating vulnerabilities across the U.S. economy. China has also revealed the capacity and willingness to weaponize dependencies and vulnerabilities through economic coercion. Over-reliance on a single economy for semiconductors and related technology or products increases the cost of any disruption. The economic security risks U.S. firms and

the U.S. economy bear from these dependencies and vulnerabilities, through their potential for disruption and coercion, burden or restrict U.S. commerce.

III. Determination of Appropriate Action

Section 301(b) provides that upon determining that the acts, policies, and practices under investigation are actionable and that action is appropriate, the U.S. Trade Representative shall take all appropriate and feasible action authorized under Section 301(c), subject to the specific direction, if any, of the President regarding such action, and all other appropriate and feasible action within the power of the President that the President may direct the U.S. Trade Representative to take under Section 301(b), to obtain the elimination of that act, policy, or practice. Section 301(c) of the Trade Act authorizes the U.S. Trade Representative to take certain actions for purposes of carrying out the provisions of Section 301(b). For example, Section 301(c)(1)(B) authorizes the U.S. Trade Representative to "impose duties or other import restrictions on the goods of [the foreign country subject to the investigation] and, notwithstanding any other provision of law, fees or restrictions on the services of, such foreign country for such time as the Trade Representative determines appropriate." Section 301(c)(3)(A) provides that actions that the U.S. Trade Representative is authorized to take may be taken against any good or economic sector on a non-discriminatory basis or solely against the foreign country concerned.

Pursuant to Sections 301(b) and (c), the U.S. Trade Representative has determined that responsive action is appropriate and that appropriate responsive action includes taking tariff action now on semiconductors from China, with an initial tariff level of 0 percent, increasing in 18 months on June 23, 2027, to a rate to be announced not fewer than 30 days prior to that date. These new Section 301 tariffs would be additional to the existing 50 percent Section 301 tariff on semiconductors from China imposed pursuant to the Section 301 investigation related to forced technology transfer. The U.S. Trade Representative will continue to monitor the efficacy of this action, the progress made toward resolution of this matter, and the need for any additional action.

This action applies to the following 8-digit subheadings:

Tariff code	HS description
28046100	Silicon containing by weight not less than 99.99 percent of silicon.
38180000	Chemical elements doped for use in electronics, in the form of discs, wafers etc., chemical compounds doped for electronic use.
85411000	Diodes, other than photosensitive or light-emitting diodes.
85412100	Transistors, other than photosensitive transistors, with a dissipation rating of less than 1 W.
85412900	Transistors, other than photosensitive transistors, with a dissipation rating of 1 W or more.
85413000	Thyristors, diacs and triacs, other than photosensitive devices.
85414910	Other photosensitive semiconductor diodes, other than light-emitting.
85414970	Photosensitive transistors.
85414980	Photosensitive semiconductor devices nesoi, optical coupled isolators.
85414995	Other photosensitive semiconductor devices, other than diodes or transistors, nesoi.
85415100	Other semiconductor-based transducers, other than photosensitive transducers.
85415900	Other semiconductor devices, other than semiconductor-based transducers, other than photosensitive devices, nesoi.
85419000	Parts of diodes, transistors, similar semiconductor devices, photosensitive semiconductor devices, LED's and mounted piezoelectric crystals.
85423100	Electronic integrated circuits: processors and controllers.
85423200	Electronic integrated circuits: memories.
85423300	Electronic integrated circuits: amplifiers..
85423900	Electronic integrated circuits: other.
85429000	Parts of electronic integrated circuits and microassemblies.

In order to implement the Trade Representative’s determination, subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States (HTSUS) is modified by the Annex of this notice, effective December 23, 2025.

Products of China that are provided for in HTSUS heading 9903.91.05 and described in subdivision (f)(ii) of note 31 to subchapter III of chapter 99 of the HTSUS, as established by the Annex of this notice, shall continue to be subject to antidumping, countervailing, or other duties, fees, exactions and charges that apply to such products. Any product covered by the Annex to this notice, except any product that is eligible for admission under ‘domestic status’ as defined in 19 CFR 146.43, which is subject to the additional duty imposed by this determination, and is admitted into a U.S. foreign trade zone on or after the effective date of the additional duties only may be admitted as ‘privileged foreign status’ as defined in 19 CFR 146.41. Such products will be subject upon entry for consumption to any ad valorem rates of duty or quantitative limitations related to the classification under the applicable HTSUS subheading.

Annex

Subdivision (f) of U.S. note 31 to subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States is amended:

1. by deleting “Heading 9903.91.05” and by inserting “(i) Heading 9903.91.05” in lieu thereof; and

2. by inserting the following in numerical order:

“(ii) The additional rate of duty under heading 9903.91.05 shall be increased

on June 23, 2027. The U.S. Trade Representative will announce the amount of the increase in a **Federal Register** notice that is issued at least 30 days prior to that date.”

Jennifer Thornton
General Counsel, Office of the United States Trade Representative.
[FR Doc. 2025–23912 Filed 12–23–25; 8:45 am]
BILLING CODE 3390–F4–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Notice of Implementation of Action: Nicaragua’s Acts, Policies, and Practices Related to Labor Rights, Human Rights and Fundamental Freedoms, and the Rule of Law

AGENCY: Office of the United States Trade Representative.

ACTION: Notice of implementation of action.

SUMMARY: Pursuant to Section 305(a) of the Trade Act (19 U.S.C. 2415(a)(1)), this notice implements action determined by the United States Trade Representative (U.S. Trade Representative) in this investigation and announced on December 10, 2025.

DATES: As set out in the Annex to this notice, tariff increases in 2026, 2027, and 2028 are applicable with respect to products that are entered for consumption, or withdrawn from warehouse for consumption, on or after January 1 of the corresponding year.

FOR FURTHER INFORMATION CONTACT: Philip Butler, Chair of the Section 301 Committee, Leigh Bacon, Chief Counsel for Negotiations, Legislation, and Administrative Law, or Nathaniel

Halvorson, Deputy Assistant U.S. Trade Representative for Monitoring & Enforcement, at (202) 395–5725.

SUPPLEMENTARY INFORMATION:

I. Proceedings in the Investigation

On December 10, 2024, the U.S. Trade Representative initiated an investigation regarding Nicaragua’s acts, policies, and practices related to labor rights, human rights, and the rule of law pursuant to 302(b)(1) of the Trade Act of 1974, as amended (Trade Act) (19 U.S.C. 2412(b)(1)). *See* 89 FR 101088 (December 13, 2024).

On October 20, 2025, USTR announced the U.S. Trade Representative’s determination that Nicaragua’s acts, policies, and practices under investigation are unreasonable and burden or restrict U.S. commerce, and are thus actionable under sections 301(b) and 304(a) of the Trade Act (19 U.S.C. 2411(b) and 2414(a)). *See* 90 FR 48511 (October 23, 2025) (October 23 notice).

In the October 23 notice, the U.S. Trade Representative proposed a range of actions including the suspension, withdrawal, or prevention of application of benefits of the Dominican Republic-Central America-United States Free Trade Agreement (CAFTA–DR) benefits to Nicaragua, and additional duties of up to 100 percent on some or all products of Nicaragua. *See* 90 FR 48511. USTR requested public comments regarding the proposed actions and in response received 2,006 written comments. Commenters included representatives from numerous manufacturing and agricultural sectors as well as a submission from the Nicaraguan government.

On December 10, 2025, USTR announced the U.S. Trade Representative's determination that action is appropriate, and that appropriate and feasible action in this investigation includes the imposition of a tariff that is phased-in over two years on all imported Nicaraguan goods that are not originating under CAFTA–DR. See 90 FR 57807 (December 12, 2025) (the December 12 notice). Specifically, all imported Nicaraguan goods that are not originating under CAFTA–DR will be subject to a 15 percent tariff that is phased-in, with the tariff set at zero percent on January 1, 2026, 10 percent on January 1, 2027, and 15 percent on January 1, 2028. Pursuant to Section 305(a) of the Trade Act (19 U.S.C. 2415(a)(1)), USTR announced that it would issue a subsequent notice to implement this action.

II. Implementation of Action

In order to implement the U.S. Trade Representative's determination, subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States (HTSUS) is modified by

the Annex of this notice, effective January 1, 2026.

Products of Nicaragua that are provided for in the new HTSUS heading 9903.89.01, as established by the Annex of this notice, shall continue to be subject to antidumping, countervailing, or other duties, fees, exactions and charges that apply to such products. Any product covered by the Annex to this notice, except any product that is eligible for admission under 'domestic status,' as defined in 19 CFR 146.43, which is subject to the additional duty imposed by this determination, and is admitted into a U.S. foreign trade zone on or after the effective date of the additional duties, only may be admitted as 'privileged foreign status,' as defined in 19 CFR 146.41. Such products will be subject upon entry for consumption to any *ad valorem* rates of duty or quantitative limitations related to the classification under the applicable HTSUS subheading.

As provided in the December 12 notice, the U.S. Trade Representative will continue to monitor the effects of the trade action and the progress made

toward resolution of this matter.

Additionally, the U.S. Trade Representative will continue to examine the efficacy of these actions. If it is determined that additional leverage is needed to encourage Nicaragua to eliminate the investigated acts, policies, and practices, the U.S. Trade Representative will consider taking additional action.

Annex

A. Effective with respect to articles of Nicaragua entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern time on January 1, 2026, subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States (HTSUS) is modified:

1. by inserting new heading 9903.89.01 in numerical sequence, with the material in the new heading inserted in the columns of the HTSUS labeled "Heading/Subheading", "Article Description", "Rates of Duty 1-General", "Rates of Duty 1-Special" and "Rates of Duty 2", respectively:

Heading/ subheading	Article description	Rates of duty		
		1		2
		General	Special	
"9903.89.01	Articles the product of Nicaragua, as provided for in U.S. note 29 to this subchapter.	The duty provided in the applicable sub-heading + 0%.	No change".	

2. by inserting new additional U.S. note 29 in numerical sequence:

"29. (a) Heading 9903.89.01 imposes additional duties on imports of articles the product of Nicaragua, as provided in this note. The additional duties apply to products of Nicaragua that are subject to the rates of duty provided for in column 1-general. The additional duties do not apply to originating goods of Nicaragua under the Dominican Republic-Central America-United States Free Trade Agreement (CAFTA–DR), as defined in general note 29 to the HTSUS. Notwithstanding U.S. note 1 to subchapter III of chapter 99 of the HTSUS, the articles of Nicaragua that are subject to the additional duties imposed by heading 9903.89.01 shall also be subject to the additional duties imposed on articles the product of Nicaragua by heading 9903.02.47.

The additional duties imposed by heading 9903.89.01 do not apply to goods for which entry is properly claimed under a provision of chapter 98 of the HTSUS, except for goods entered under subheadings 9802.00.40, 9802.00.50, and 9802.00.60, and

heading 9802.00.80. For subheadings 9802.00.40, 9802.00.50, and 9802.00.60, the additional duties apply to the value of repairs, alterations, or processing performed abroad, as described in the applicable subheading. For heading 9802.00.80, the additional duties apply to the value of the article less the cost or value of such products of the United States, as described in heading 9802.00.80.

Products of Nicaragua that are provided for in heading 9903.89.01 shall continue to be subject to antidumping, countervailing, or other duties, fees, exactions and charges that apply to such products.

(b) The additional rates of duty that apply to articles the product of Nicaragua under column 1-general of heading 9903.89.01 shall be phased-in as follows:

If entered during the period from January 1, 2026, though December 31, 2026, . . . 0%

If entered during the period from January 1, 2027, though December 31, 2027, . . . 10%

If entered on or after January 1, 2028, . . . 15%".

B. Effective with respect to articles of Nicaragua entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern time on January 1, 2027, the rate of duty 1-general column of heading 9903.89.01 is modified by deleting "0%" and by inserting "10%" in lieu thereof.

C. Effective with respect to articles of Nicaragua entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern time on January 1, 2028, the rate of duty 1-general column of heading 9903.89.01 is modified by deleting "10%" and by inserting "15%" in lieu thereof.

Jennifer Thornton,

General Counsel, Office of the United States Trade Representative.

[FR Doc. 2025–23892 Filed 12–23–25; 8:45 am]

BILLING CODE 3390–F4–P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration**

[Docket No.: FAA–2025–0001; Summary Notice No. 2025–68]

Petition for Exemption; Summary of Petition Received; Victor Lee & Associates, Inc.

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

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion nor omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before January 20, 2026.

ADDRESSES: Send comments identified by docket number FAA–2025–0001 using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov> and follow the online instructions for sending your comments electronically.

- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

- *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to <http://www.regulations.gov>, as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at <http://www.dot.gov/privacy>.

Docket: Background documents or comments received may be read at <http://www.regulations.gov> at any time.

Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mickenzie Roby, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591, at 202–267–9677.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC.

Dan A. Ngo,

Manager, Part 11 Petitions Branch, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2025–0001.

Petitioner: Victor Lee & Associates, Inc.

Section(s) of 14 CFR Affected: §§ 61.3(a)(1)(i), 61.3(c)(1), 61.23(a)(2), 91.7(a), 91.119(c), 91.121, 91.151(b), 91.403(b), 91.405(a), 91.407(a)(1), 91.409(a)(1), 91.409(a)(2), 91.417(a), and 91.417(b).

Description of Relief Sought: Petitioner is requesting to amend their current Exemption No. 23635 to permit reduced horizontal separation from 100 feet to a minimum of 50 feet for consenting filming personnel on closed-set operations. Petitioner states that all reduced-distance operations will occur exclusively within a sterile, access-controlled set with no public presence within or beyond the 500 feet buffer.

[FR Doc. 2025–23838 Filed 12–23–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration**

[Docket No. FAA–2025–5568]

Agency Information Collection Activities: Request for Comments; Clearance of a New Approval of Information Collection: Designated Pilot Examiners: Post Activity Survey

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request Office of Management and Budget (OMB) approval for a new information collection. The collection includes a

voluntary survey for pilots evaluated by private citizens who have been granted examination authority by the FAA.

DATES: Written comments should be submitted by February 27, 2026.

ADDRESSES: Please send written comments:

By Electronic Docket: www.regulations.gov (Enter docket number into search field).

By mail: Christopher Morris, Flight Standards Service, 800 Independence Ave. SW, Washington, DC 20591.

By email: Chris.Morris@faa.gov.

FOR FURTHER INFORMATION CONTACT: AFG–970 Delegation and Resource Branch by email at: 9-AVS-AFG-970@faa.gov; phone: 405–954–6400.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

OMB Control Number: 2120–XXXX.

Title: Designated Pilot Examiners: Post-Activity Survey.

Form Numbers: N/A.

Type of Review: This is a new information collection request.

Background: The FAA delegates pilot-examination authority to qualified private citizens in accordance with section 183.23 of title 14, Code of Federal Regulations. In Section 833 of the FAA Reauthorization Act of 2024, Congress mandated that the FAA enhance its oversight of designated pilot examiners (DPEs) by, among other things, “[d]eploying a survey system to track the performance and merit of such examiners.” Because such a survey will necessarily constitute a time burden on pilots, the FAA is seeking OMB approval to collect pilots’ feedback through such a survey system.

The FAA will ask pilots to complete a survey following practical examinations conducted by DPEs. The survey will consist of approximately twelve yes-or-no questions regarding DPEs’ level of professionalism; the suitability of the exam environment; the content of the exam; and the duration of the ground portion and the flight portion of the exam. The FAA will use the information collected to track the performance and merit of DPEs.

Respondents: The FAA estimates that approximately 49,000 applicants will complete the survey each year.

Frequency: On occasion.

Estimated Average Burden per Response: Seven minutes.

Estimated Total Annual Burden: 343,000 minutes.

Issued in Washington, DC, on December 19, 2025.

DC Morris,

Aviation Safety Analyst, Flight Standards Service, General Aviation and Commercial Division.

[FR Doc. 2025-23770 Filed 12-23-25; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No.: FAA-2025-5013; Summary Notice No. 2025-69]

Petition for Exemption; Summary of Petition Received; Honda Research Institute USA, Inc.

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

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion nor omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before January 20, 2026.

ADDRESSES: Send comments identified by docket number FAA-2025-5013 using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov> and follow the online instructions for sending your comments electronically.

- *Mail:* Send comments to Docket Operations, M-30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12-140, West Building Ground Floor, Washington, DC 20590-0001.

- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590-0001, between 9 a.m. and 5 p.m.,

Monday through Friday, except Federal holidays.

- *Fax:* Fax comments to Docket Operations at (202) 493-2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to <http://www.regulations.gov>, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <http://www.dot.gov/privacy>.

Docket: Background documents or comments received may be read at <http://www.regulations.gov> at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590-0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Nia Daniels, (202) 267-7626, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591, at 202-267-9677.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC.

Dan A. Ngo,

Manager, Part 11 Petitions Branch, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA-2025-5013.

Petitioner: Honda Research Institute USA, Inc.

Sections of 14 CFR Affected: § 91.151(b).

Description of Relief Sought: Honda Research Institute (HRI) USA, Inc. seeks an exemption from 14 Code of Federal Regulations to allow it to operate an electronic vertical takeoff and landing (eVTOL) vehicle, referred to as the F1, for purposes of research and development. HRI is seeking relief from the day visual flight rules (VFR) fuel requirement, because the total flight time for the F1 is less than the day VFR requirements.

[FR Doc. 2025-23839 Filed 12-23-25; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No.: FAA-2025-5010; Summary Notice No. 2025-70]

Petition for Exemption; Summary of Petition Received; Redstar Air Shows, Inc. dba Patriots Jet Team

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

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion nor omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before January 20, 2026.

ADDRESSES: Send comments identified by docket number FAA-2025-5010 using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov> and follow the online instructions for sending your comments electronically.

- *Mail:* Send comments to Docket Operations, M-30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12-140, West Building Ground Floor, Washington, DC 20590-0001.

- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590-0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

- *Fax:* Fax comments to Docket Operations at (202) 493-2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to <http://www.regulations.gov>, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <http://www.dot.gov/privacy>.

Docket: Background documents or comments received may be read at <http://www.regulations.gov> at any time.

Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590-0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Kara White, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591, at 202-267-9677.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC.

Dan A. Ngo,

Manager, Part 11 Petitions Branch, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA-2025-5010.

Petitioner: Redstar Air Shows, Inc. dba Patriots Jet Team.

Section(s) of 14 CFR Affected: § 91.319(c).

Description of Relief Sought: Relief from 91.319(c) to allow operation of a L39 Camera Jet with an experimental aircraft certificate to film a flyover over a densely populated area or congested area.

[FR Doc. 2025-23840 Filed 12-23-25; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[FAA-2025-2496]

Agency Information Collection

Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: Survey of Airman Satisfaction With Aeromedical Certification Services

AGENCY: Federal Aviation Administration (FAA), DOT

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget's (OMB) approval to renew an information collection. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on September 22, 2025. The collection involves soliciting feedback from airmen on service quality of Aeromedical Certification Services. The information to be collected will be used

to inform improvements in Aeromedical Certification Services.

DATES: Written comments should be submitted by January 22, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: Dr. Katrina Avers by email at: Katrina.Avers@faa.gov; phone: 405-954-6299.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information.

OMB Control Number: 2120-0707.

Title: Survey of Airman Satisfaction with Aeromedical Certification Services.

Form Numbers: N/A.

Type of Review: Renewal of an information collection.

Background: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on September 22, 2025 (90 FR 45459). The Federal Aviation Administration (FAA), through the Office of Aerospace Medicine (OAM), is responsible for the medical certification of pilots and certain other personnel under 14 CFR part 67 to ensure they are medically qualified to operate aircraft and perform their duties safely. In the accomplishment of this responsibility, OAM provides a number of services to pilots and has established goals for the performance of those services. This is a biennial survey designed to meet the requirement to survey stakeholder satisfaction under Executive Order No. 12862, "Setting Customer Service Standards," and the Government Performance and Results Act of 1993 (GPRA).

The survey of Airman Satisfaction with Aeromedical Certification Services assesses airman opinion of key dimensions of service quality. These dimensions, identified by the OMB Statistical Policy Office in the 1993 "Resource Manual for Customer

Surveys," are courtesy, competence, reliability, and communication. The survey also provides airmen with the opportunity to provide feedback on the services and a medical certificate application tool they use. This information is used to inform improvements in Aeromedical Certification Services.

The survey was initially collected in 2004 and collected approximately every 2 years, most recently in 2023 (OMB Control No. 2120-0707). Across collections, minor revisions have been made to the survey items and response options to reflect changes in operational services and survey technology. To reduce the burden on the individual respondent and potentially improve the response rate, this information collection will be electronic.

Respondents: Approximately 5,700 Airmen who have sought a medical certification within two years of the survey administration.

Frequency: Every two years.

Estimated Average Burden per

Response: 15 minutes.

Estimated Total Annual Burden: 1,425 total burden hours.

Issued in Oklahoma City, Oklahoma on December 22, 2025.

Tammy Ho,

Psychology Technician, NAS Human Factors Safety Research Laboratory (AAM-520).

[FR Doc. 2025-23891 Filed 12-23-25; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket No. DOT-OST-2025-1921]

Agency Requests for Renewal of a Previously Approved Information Collection: TAR Part 1239-Related

AGENCY: Office of the Secretary (OST), U.S. Department of Transportation (DOT).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, and Office of Management and Budget (OMB) regulations, the Department of Transportation (DOT) invites public comments on currently approved Transportation Acquisition Regulation (TAR) part 1239 information collection requests (ICRs) and our intention to request OMB approval to renew the ICRs on an interim basis as abstracted below while DOT undertakes further review to streamline its regulations. The public will be afforded another opportunity to review revised

streamlined TAR content when published as a part of a proposed rule. DOT is required to publish this notice in the **Federal Register** in accordance with the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before January 28, 2026.

ADDRESSES: DOT invites interested persons to submit comments identified by Docket No. DOT–OST–2025–1921 through one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions on the site. This website provides the ability to type short comments directly into the comment field or attach a file for lengthier comments. If there are difficulties submitting comments, see further information contact below.

- *Fax:* 1–202–493–2251.

- *Mail or Hand Delivery:* Docket Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Instructions: All items submitted must cite the OMB control numbers (see abstracts below).

Note: Comments received generally will be posted without change to <https://www.regulations.gov>, including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT:

LaWanda Morton-Chunn, Procurement Analyst, Office of the Secretary, 1200 New Jersey Avenue SE, Washington, DC 20590, telephone: (202) 366–2267 or lawanda.morton-chunn@dot.gov.

SUPPLEMENTARY INFORMATION: DOT invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of the functions of DOT acquisitions, including whether the information will have practical utility; (2) the accuracy of the estimate of the burden of the proposed information collection; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology. OMB has approved this information collection for use through December 31, 2025. DOT proposes that OMB extend its approval for use for three additional years beyond the current expiration date. On October 27, 2025, OST published a 60-day notice in the **Federal**

Register soliciting comment by December 26, 2025 on the ICRs for which it is now seeking OMB approval for the extension of a previously approved collection. *See* 90 FR 48600. OST received no comments in response to this 60-day notice.

Before OMB decides whether to approve the proposed collection of information, it must provide 30 days for public comment. Federal law requires OMB to approve or disapprove paperwork packages between 30 and 60 days after the 30-day notice is published. 44 U.S.C. 3507(b)–(c); 5 CFR 1320.12(d); *see also* 60 FR 44978, 44983, Aug. 29, 1995. OMB believes the 30 day notice informs the regulated community to file relevant comments and affords the agency adequate time to digest public comments before it renders a decision. 60 FR 44983, Aug. 29, 1995. Therefore, respondents should submit their respective comments to OMB within 30 days of publication to best ensure having their full effect.

Need for Extension

As a result of the Revolutionary Federal Acquisition Regulation (FAR) (RFO) Initiative, the Transportation Acquisition Regulation (TAR) is also under review. The TAR must align with on-going interim class deviations to the FAR issued by DOT, as well as a later planned FAR proposed rule to be published in the **Federal Register** by the FAR Council for public comment in 2026. As a part of its review, DOT will consider revising and removing content where needed, adding agency-level statutory requirements, as required, and revising subpart and section numbering in each TAR part to align with new FAR parts. To implement this initiative and to comply with Executive Order 14275 of April 15, 2025, “Restoring Common Sense to Federal Procurement,” and OMB Memorandum M–25–26, “Overhauling the Federal Acquisition Regulation,” May 2, 2025, DOT is conducting a concurrent rigorous review of the TAR to streamline and update coverage, where appropriate or to remove content to internal agency procedures. DOT anticipates there may be substantive revisions to the TAR, revisions to current Code of Federal Regulations (CFR) solicitation provisions and contract clauses under Title 48, CFR chapter 12 (the TAR), part 1252. This may include potential reductions in information collection requirements and burden under this approved OMB control number. This review and update will be worked by OSPE in conjunction with the Office of Information Technology after

appropriate benchmarking and analysis of statutory and other requirements.

DOT requires an extension of the current information collection requirements currently in the TAR at 48 CFR chapter 12 until this analysis is completed, and a proposed TAR rule is developed and published in the **Federal Register** for public comment, anticipated later in 2026.

The summary below describes the ICRs that DOT will submit for OMB clearance as the PRA requires:

OMB Control Number: 2105–0578.

Title: Department of Transportation Acquisition Regulation (TAR) Part 1239 Clauses.

Associated Form(s) TAR part 1252 (TAR 1239-related) clauses: 1252.239–76; 1252–239–77; 1252–239–80; 1252–239–83; 1252–239–85; and 1252–239–88.

Type of Review: Renewal of previously approved information collection.

Background: Form (Clause) Title(s): Cloud Computing Services, Data Jurisdiction, Audit Record Retention for Cloud Service Providers, Incident Reporting Timeframes, Personnel Screening—Background Investigations, Security Alerts, Advisories, and Directives.

Respondents: General Public.

Average Number of Respondents: 534.

Average Number of Responses: 534.

Frequency: Annually.

Minutes Required/per Response: 90.

Total Burden Imposed (Hours): 339.

OMB Control Number: 2105–0579.

Title: Department of Transportation Acquisition Regulation (TAR) Part 1239 Clause.

Associated Form(s) TAR part 1252 (TAR 1239-related) clause: 1252.239–75.

Type of Review: Renewal of previously approved information collection.

Background: DOT Protection of Information About Individuals, PII, and Privacy Risk Management Requirements.

Respondents: General Public.

Average Number of Respondents: 311.

Average Number of Responses: 622.

Frequency: Annually.

Minutes Required/per Response: 60.

Total Burden Imposed (Hours): 622.

OMB Control Number: 2105–0580.

Title: Department of Transportation Acquisition Regulation (TAR) Part 1239 Clauses.

Associated Form(s) TAR part 1252 (TAR 1239-related) clauses: 1252.239–89 and 1252.239–90.

Type of Review: Renewal of previously approved information collection.

Background: Technology Modernization and Technology Upgrades/Refreshment.

Respondents: General Public Average Number of Respondents: 366.

Average Number of Responses: 366.

Frequency: Annually.

Minutes Required/per Response: 90.

Total Burden Imposed (Hours): 550.

OMB Control Number: 2105–0581.

Title: Department of Transportation Acquisition Regulation (TAR) Part 1239 Clauses.

Associated Form(s) TAR part 1252 (TAR 1239-related) clause: 1252.239–70.

Type of Review: Renewal of previously approved information collection.

Background: Security Requirements for Unclassified Information Technology Resources.

Respondents: General Public Average Number of Respondents: 844.

Average Number of Responses: 844.

Frequency: Annually.

Minutes Required/per Response: 30.

Total Burden Imposed (Hours): 422.

OMB Control Number: 2105–0582.

Title: Department of Transportation Acquisition Regulation (TAR) Part 1239 Clauses.

Associated Form(s) TAR part 1252 (TAR 1239-related) clauses: 1252.239–72 and 1252.239–74.

Type of Review: Renewal of previously approved information collection.

Background: Compliance with Safeguarding DOT Sensitive Data Controls and Safeguarding DOT Sensitive Data and Cyber Incident Reporting.

Respondents: General Public Average Number of Respondents: 145.

Average Number of Responses: 145.

Frequency: Annually.

Minutes Required/per Response: 30.

Total Burden Imposed (Hours): 73.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.48.

Karyn Gorman,

Chief Privacy Officer, Office of the Secretary.

[FR Doc. 2025–23879 Filed 12–23–25; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Information Collection Activities: Information Collection Renewal; Comment Request; General Reporting and Recordkeeping Requirements by Savings Associations

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995 (PRA). In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The OCC is soliciting comment concerning the renewal of its information collection titled, “General Reporting and Recordkeeping Requirements by Savings Associations,” which is applicable only to Federal savings associations.

DATES: Comments must be received by February 27, 2026.

ADDRESSES: Commenters are encouraged to submit comments by email, if possible. You may submit comments by any of the following methods:

- *Email:* prainfo@occ.treas.gov.

- *Mail:* Chief Counsel’s Office, Attention: Comment Processing, Office of the Comptroller of the Currency, Attention: 1557–0299, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.

- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E–218, Washington, DC 20219.

- *Fax:* (571) 293–4835.

Instructions: You must include “OCC” as the agency name and “1557–0266” in your comment. In general, the OCC will publish comments on www.reginfo.gov without change, including any business or personal information provided, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Following the close of this notice’s 60-day comment period, the OCC will publish a second notice with a 30-day comment period. You may review comments and other related materials that pertain to this information collection beginning on the date of publication of the second notice for this collection by the method set forth in the next bullet.

- *Viewing Comments Electronically:* Go to www.reginfo.gov. Hover over the “Information Collection Review” tab and click on “Information Collection

Review” from the drop-down menu. From the “Currently under Review” drop-down menu, select “Department of the Treasury” and then click “submit.” This information collection can be located by searching OMB control number “1557–0266” or “General Reporting and Recordkeeping Requirements by Savings Associations.” Upon finding the appropriate information collection, click on the related “ICR Reference Number.” On the next screen, select “View Supporting Statement and Other Documents” and then click on the link to any comment listed at the bottom of the screen.

- For assistance in navigating www.reginfo.gov, please contact the Regulatory Information Service Center at (202) 482–7340.

FOR FURTHER INFORMATION CONTACT:

Shaquita Merritt, Clearance Officer, (202) 649–5490, Chief Counsel’s Office, Office of the Comptroller of the Currency, 400 7th Street SW, Washington, DC 20219. If you are deaf, hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501 *et seq.*), Federal agencies must obtain approval from the OMB for each collection of information that they conduct or sponsor.

“Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests or requirements imposed on ten or more persons, that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of title 44 generally 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, the OCC is publishing notice of the renewal of this collection.

Title: General Reporting and Recordkeeping Requirements by Savings Associations.

OMB Control No.: 1557–0266.

Type of Review: Regular.

Affected Public: Businesses or other for-profit.

Description: Federal savings associations must comply with the following regulations, which require them to establish prudent internal controls, so that examiners will have an accurate picture of their performance and condition:

- 12 CFR 144.8 (communications between members of a Federal mutual savings association);

- 12 CFR 163.47(e) (pension plans—records); and
- 12 CFR 163.76(c) (offers and sales of securities of a Federal savings association or its affiliates in any office of the savings association—form of certification).

Federal savings associations use the reports and records that the regulations require for internal management control purposes, and examiners use them to determine whether savings associations are being operated safely, soundly, and in compliance with regulations. Without these reporting and recordkeeping requirements, it would be difficult for institutions to establish prudent internal controls and would limit the ability of examiners to determine the accurate performance and condition of Federal savings associations.

Estimated Burden

Estimated Frequency of Response: On occasion.

Estimated Number of Respondents: 224.

Estimated Total Annual Burden: 22,569.5 hours.

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

Comments are invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC's estimate of the burden of the collection of information;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Sarah Turney,

Assistant Director, Office of the Comptroller of the Currency.

[FR Doc. 2025-23784 Filed 12-23-25; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Renewal; Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995 (PRA). In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The OCC is soliciting comment concerning the renewal of its information collection titled, "Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery."

DATES: Comments must be received by February 27, 2026.

ADDRESSES: Commenters are encouraged to submit comments by email, if possible. You may submit comments by any of the following methods:

- *Email:* prainfo@occ.treas.gov.

- *Mail:* Chief Counsel's Office, Attention: Comment Processing, Office of the Comptroller of the Currency, Attention: 1557-0248, 400 7th Street SW, Suite 3E-218, Washington, DC 20219.

- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E-218, Washington, DC 20219.

- *Fax:* (571) 293-4835.

Instructions: You must include "OCC" as the agency name and "1557-0248" in your comment. In general, the OCC will publish comments on www.reginfo.gov without change, including any business or personal information provided, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Following the close of this notice's 60-day comment period, the OCC will publish a second notice with a 30-day comment period. You may review comments and other related materials that pertain to this information collection beginning on the date of publication of the second notice for this collection by the method set forth in the next bullet.

- *Viewing Comments Electronically:* Go to www.reginfo.gov. Hover over the "Information Collection Review" tab and click on "Information Collection Review" from the drop-down menu. From the "Currently under Review" drop-down menu, select "Department of the Treasury" and then click "submit." This information collection can be located by searching OMB control number "1557-0248" or "Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery." Upon finding the appropriate information collection, click on the related "ICR Reference Number." On the next screen, select "View Supporting Statement and Other Documents" and then click on the link to any comment listed at the bottom of the screen.

- For assistance in navigating www.reginfo.gov, please contact the Regulatory Information Service Center at (202) 482-7340.

FOR FURTHER INFORMATION CONTACT:

Shaquita Merritt, Clearance Officer, (202) 649-5490, Chief Counsel's Office, Office of the Comptroller of the Currency, 400 7th Street SW, Washington, DC 20219. If you are deaf, hard of hearing, or have a speech disability, please dial 7-1-1 to access telecommunications relay services.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501 *et seq.*), Federal agencies must obtain approval from the OMB for each collection of information that they conduct or sponsor.

"Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests or requirements, imposed on ten or more persons, that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of title 44 generally 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, the OCC is publishing notice of the renewal of this collection.

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

OMB Control No.: 1557–0248.

Type of Review: Regular.

Affected Public: Businesses or individuals.

Description: This generic information collection request (ICR) provides the OCC with a means to solicit qualitative stakeholder feedback in an efficient, timely manner, in accordance with the Federal government's commitment to improving service delivery. Qualitative feedback is information that provides useful insights on perceptions and opinions but does not include statistical survey or quantitative results that can be attributed to the surveyed population. This qualitative feedback provides insights into stakeholder perceptions, experiences, and expectations; provides an early warning of issues with service; and/or focuses attention on areas where communication, training, or changes in operations might improve delivery of products or services. It also enables ongoing, collaborative, and actionable communications between the OCC and its stakeholders, while also utilizing feedback to improve program management.

The OCC's solicitations for feedback target areas such as timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues related to service delivery. The OCC uses the responses to inform and plan efforts to improve or maintain the quality of service offered to the public. If the OCC does not collect this information, it will not have access to vital feedback from stakeholders.

Under this generic ICR, the OCC will submit a specific information collection for approval only if the collection meets the following conditions:

- It is voluntary;
- It imposes a low burden on respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and a low cost on both respondents and the Federal government;
- It is non-controversial and does not raise issues of concern to other Federal agencies;
- It is targeted to solicit opinions from respondents who have experience with the program or will have experience with the program in the near future;
- It includes personally identifiable information (PII) only to the extent

necessary, and the OCC does not retain the PII;¹

- It gathers information intended to be used internally only for general service improvement and program management purposes and is not intended for release outside of the OCC;
- It does not gather information to be used for the purpose of substantially informing influential policy decisions;
- It gathers information that will yield qualitative information and will not be designed or expected to yield statistically reliable results or used to reach general conclusions about the surveyed population; and
- Feedback collected provides useful information but does not yield data that can be attributed to the overall population.

If these conditions are not met, the OCC will submit an information collection request to OMB for approval through the normal PRA process.

The OCC will not use this type of generic clearance for the collection of qualitative feedback for any quantitative information collection.

As a general matter, these information collections will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature.

Estimated Burden

Estimated Frequency of Response: On occasion.

Estimated Number of Responses: 22,537.

Estimated Total Annual Burden: 8,850 hours.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on:

- (a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;
- (b) The accuracy of the OCC's estimate of the burden of the collection of information;
- (c) Ways to enhance the quality, utility, and clarity of the information to be collected;
- (d) Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

¹ The OCC may retain PII only in limited circumstances and, if it does so, the OCC must comply with applicable requirements, restrictions, and prohibitions of the Privacy Act of 1974 and other privacy and confidentiality laws that govern the collection, retention, use, and/or disclosure of such PII.

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Eden Gray,

Assistant Director, Office of the Comptroller of the Currency.

[FR Doc. 2025–23792 Filed 12–23–25; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: This action was issued on December 19, 2025. See **SUPPLEMENTARY INFORMATION** section for relevant dates.

FOR FURTHER INFORMATION CONTACT: OFAC: Associate Director for Global Targeting, 202–622–2420; Assistant Director for Sanctions Compliance, 202–622–2490; or <https://ofac.treasury.gov/contact-ofac>.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's website: <https://ofac.treasury.gov>.

Notice of OFAC Action

On December 19, 2025, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authorities listed below.

Individuals:

1. FLORES DE MALPICA, Eloisa, Venezuela; DOB 01 Dec 1948; POB Tinaquillo, Venezuela; nationality Venezuela; Gender Female; Cedula No. 3989591 (Venezuela) (individual) [VENEZUELA–EO13850].

Designated pursuant to section 1(a)(ii) of Executive Order 13850 of November

1, 2018, “Blocking Property of Additional Persons Contributing to the Situation in Venezuela,” 83 FR 55243, 3 CFR, 2018 Comp., p. 881, as amended by Executive Order 13857 of January 25, 2019, “Taking Additional Steps To Address the National Emergency With Respect to Venezuela,” 84 FR 509, 3 CFR 2019 Comp., p. 251 (E.O. 13850) for being responsible for or complicit in, or having directly or indirectly engaged in, any transaction or series of transactions involving deceptive practices or corruption and the Government of Venezuela or projects or programs administered by the Government of Venezuela, or to be an immediate adult family member of such a person.

2. HURTADO PEREZ, Damaris del Carmen, Venezuela; DOB 03 Jul 1975; POB Barinas, Venezuela; nationality Venezuela; Gender Female; Cedula No. 12207076 (Venezuela) (individual) [VENEZUELA–EO13850].

Designated pursuant to section l(a)(ii) of E.O. 13850 for being responsible for or complicit in, or having directly or indirectly engaged in, any transaction or series of transactions involving deceptive practices or corruption and the Government of Venezuela or projects or programs administered by the Government of Venezuela, or to be an immediate adult family member of such a person.

3. MALPICA FLORES, Iriamni, Venezuela; DOB 15 Oct 1975; POB Caracas, Venezuela; nationality Venezuela; Gender Female; Cedula No. 12761280 (Venezuela) (individual) [VENEZUELA–EO13850].

Designated pursuant to section l(a)(ii) of E.O. 13850 for being responsible for or complicit in, or having directly or indirectly engaged in, any transaction or series of transactions involving deceptive practices or corruption and the Government of Venezuela or projects or programs administered by the Government of Venezuela, or to be

an immediate adult family member of such a person.

4. MALPICA HURTADO, Erica Patricia, Venezuela; DOB 14 Jun 2001; POB Valencia, Venezuela; nationality Venezuela; Gender Female; Cedula No. 28331171 (Venezuela) (individual) [VENEZUELA–EO13850].

Designated pursuant to section l(a)(ii) of E.O. 13850 for being responsible for or complicit in, or having directly or indirectly engaged in, any transaction or series of transactions involving deceptive practices or corruption and the Government of Venezuela or projects or programs administered by the Government of Venezuela, or to be an immediate adult family member of such a person.

5. MALPICA TORREALBA, Carlos Evelio, Venezuela; DOB 20 Feb 1947; POB Tinaquillo, Venezuela; nationality Venezuela; Gender Male; Cedula No. 3056173 (Venezuela) (individual) [VENEZUELA–EO13850].

Designated pursuant to section l(a)(ii) of E.O. 13850 for being responsible for or complicit in, or having directly or indirectly engaged in, any transaction or series of transactions involving deceptive practices or corruption and the Government of Venezuela or projects or programs administered by the Government of Venezuela, or to be an immediate adult family member of such a person.

6. CARRETERO NAPOLITANO, Roberto, Panama; DOB 20 Aug 1976; POB Colon, Panama; nationality Panama; Gender Male; Cedula No. 3701218 (Panama) (individual) [VENEZUELA–EO13850].

Designated pursuant to section l(a)(ii) of E.O. 13850 for being responsible for or complicit in, or having directly or indirectly engaged in, any transaction or series of transactions involving deceptive practices or corruption and the Government of Venezuela or projects or programs administered by

the Government of Venezuela, or to be an immediate adult family member of such a person.

7. CARRETERO NAPOLITANO, Vicente Luis, Panama; DOB 06 Oct 1966; POB Colon, Panama; nationality Panama; Gender Male; Cedula No. 3901065 (Panama) (individual) [VENEZUELA–EO13850].

Designated pursuant to section l(a)(ii) of E.O. 13850 for being responsible for or complicit in, or having directly or indirectly engaged in, any transaction or series of transactions involving deceptive practices or corruption and the Government of Venezuela or projects or programs administered by the Government of Venezuela, or to be an immediate adult family member of such a person.

Bradley T. Smith,

Director, Office of Foreign Assets Control.

[FR Doc. 2025–23778 Filed 12–23–25; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF VETERANS AFFAIRS

Advisory Committee Charter Renewals

AGENCY: Department of Veterans Affairs.

ACTION: Notice of Advisory Committee Charter Renewals.

SUMMARY: In accordance with the provisions of the Federal Advisory Committee Act (FACA) and after consultation with the General Services Administration, the Secretary of Veterans Affairs has determined that the following Federal advisory committee is vital to the mission of the Department of Veterans Affairs (VA) and renewing its charter would be in public interest. Consequently, the charter for the following Federal advisory committee is renewed for a two-year period, beginning on the dates listed below:

Committee name	Committee description	Charter renewed on
National Research Advisory Council	Provides advice on the nature and scope of research and development sponsored and/or conducted by the Veterans Health Administration, to include policies and programs of the Office of Research and Development.	August 19, 2025.

The Secretary also determined that the following Federal advisory

committee is vital to VA and reestablished its charter:

Committee name	Committee description	Charter renewed on
Department of Veterans Affairs Voluntary Service National Advisory Committee.	Provides advice on the coordination and promotion of volunteer activities within VA health care facilities, and on other matters relating to volunteerism.	September 16, 2025.

The Secretary has also renewed the charter for the following statutorily authorized Federal advisory committee

for a two-year period, beginning on the date listed below:

Committee name	Committee description	Charter renewed on
Veterans' Advisory Committee on Rehabilitation.	Provides advice on the administration of Veterans' rehabilitation programs under title 38, U.S.C.	May 20, 2024.
Geriatrics and Gerontology Advisory Committee.	Provides advice on all matters pertaining to geriatrics and gerontology. The Committee oversees the recommendations from its 20 Subcommittees located at the Geriatrics Research Education Clinical Centers.	June 20, 2024.
Advisory Committee on Cemeteries and Memorials.	Provides on the administration of VA national cemeteries, Soldiers' lots, and plots, the selection of cemetery sites, the erection of appropriate memorials and the adequacy of Federal burial benefits.	July 24, 2024.
Research Advisory Committee on Gulf War Veterans' Illnesses.	Provides advice on proposed research studies, plans, and strategies related to understanding and treating the health consequences of military service in the Southwest Asia theater of operations during the 1990–1991 Gulf War (Operations Desert Shield and Desert Storm).	January 7, 2025.
Advisory Committee Structural Safety of Department of Veterans Affairs.	Provides advice on all matters of structural safety in the construction and remodeling of VA facilities and recommends standards for use by VA in the construction and alteration of facilities.	April 25, 2025.
Veterans and Community Oversight and Engagement Board.	Coordinates locally with VA to identify the goals of the community and Veteran partnership; provides advice and recommendations to improve services and outcomes for Veterans, members of the Armed Forces, and the families of such Veterans and members; and provides advice and recommendations on the implementation of the Draft Master Plan approved by the Secretary on January 28, 2016, and on the creation and implementation of any other successor master plans.	April 29, 2025.
Veterans' Advisory Committee on Education	Provides advice on the administration of education and training programs for Veterans and Servicepersons, Reservists, Guard personnel, and for dependents of Veterans, including programs under chapters 30, 32, 35, and 36 of title 38, and Chapter 1606 of title 10, U.S.C.	May 5, 2025.
Special Medical Advisory Group	Provides advice on the care and treatment of enrolled Veterans and other matters pertinent to the operations of the Veterans Health Administration.	July 8, 2025.
Advisory Committee on U.S. Outlying Areas and Freely Associated States.	Provides advice to the Secretary on matter relating to covered Veterans residing in American Samoa, Guam, Puerto Rico, The Commonwealth of the Northern Mariana Islands, The Virgin Islands of the United States, The Federated States of Micronesia, The Republic of the Marshall Islands, and The Republic of Palau.	July 24, 2025.
Advisory Committee on Women Veterans	Provides advice on the administration of benefits for women Veterans; reports and studies pertaining to women Veterans; and the needs of women Veterans with respect to health care, rehabilitation benefits, compensation, outreach, and other relevant programs administered by VA.	October 6, 2025.

FOR FURTHER INFORMATION CONTACT:
Jeffrey Moragne, Committee Management Officer, Department of Veterans Affairs, Advisory Committee Management Office (00AC), 810 Vermont Avenue NW, Washington, DC 20420; telephone (202) 714–1578; or email at Jeffrey.Moragne@va.gov. To view a copy of a VA Federal advisory committee charters, please visit <https://department.va.gov/advisory-committee-management/>.

Dated: December 22, 2025.

Jelessa M. Burney,
Federal Advisory Committee Management Officer.
[FR Doc. 2025–23873 Filed 12–23–25; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS
Advisory Committee on the Readjustment of Veterans, Notice of Meeting
The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. Ch. 10., that the Advisory Committee on the Readjustment of Veterans will meet in-person on January 27, 2026–January 28, 2026. The sessions will begin and end as follows:

Dates	Times	Locations	Open session
January 27, 2026	8:00 a.m. to 4:30 p.m. Central Daylight Time (CDT).	Tulsa Vet Center, 6130 E 81st St., #200, Tulsa, OK 74137.	No.
January 28, 2026	8:00 a.m. to 4:30 p.m. CDT	Muscogee Creek Nation Veterans Office, 1006 Bear Ln., Okmulgee, OK 74447.	Yes.

The meeting sessions are open to the public, except during the time the

Committee is participating in focus group discussions or conducting tours

of VA facilities. Tours of VA facilities, clinical discussions, and personal

testimonies are closed to protect Veterans' privacy and personal information, in accordance with 5 U.S.C. 552b(c)(6).

The purpose of the Committee is to advise the VA regarding the provision by VA of benefits and services to assist Veterans in the readjustment to civilian life. The Committee, comprised of 13 subject matter experts, advises the Secretary through the VA Readjustment Counseling Service. In carrying out this duty, the Committee shall take into account the needs of Veterans who served in combat theaters of operation.

On January 27, 2026, and January 28, 2026, the Committee will meet to assemble, review, and assess information relating to the needs of Veterans readjusting to civilian life and the effectiveness of VA services in assisting Veterans in that readjustment. On January 27, 2026, the meeting will take place at the Tulsa Vet Center, located at 6130 E 81st Street, Suite 200, Tulsa, Oklahoma 74137, and will be closed to the public. The meeting will include a tour of the clinical space, and

the duration of the meeting, including clinical discussions and personal testimonies, will take place on-site at the Tulsa Vet Center. Tours of VA facilities, clinical discussions, and personal testimonies are closed to protect the Veterans' privacy in accordance with 5 U.S.C 552b(c)(6).

On January 28, 2026, the meeting will take place at the Muscogee Creek Nation Veterans Office, located at 1006 Bear Lane, Okmulgee, Oklahoma 74447, and will be open to the public. The agenda will consist of presentations and discussions with Muscogee Nation leadership, Native Veterans, representatives from the local VA Medical Center, the Oklahoma Governor's Challenge, as well as a committee discussion and public comment.

Time will be allotted for the public to provide comments starting at 4:00 p.m. CDT and ending no later than 4:30 p.m. CDT on January 28, 2026. The comment period may end sooner if no comments are presented or they are exhausted before the end time. Individuals

interested in providing comments during the public comment period are allowed no more than three minutes for their statements. Additionally, the Committee will accept written comments from interested parties on issues outlined in the meeting agenda or other issues regarding the readjustment of Veterans. Parties should contact Mr. Joshua Mathis via email at Joshua.Mathis@va.gov or by mail at Department of Veterans Affairs, Readjustment Counseling Service (10RCS), 810 Vermont Avenue, Washington, DC 20420.

Any member of the public seeking additional information should contact Mr. Mathis at the email address noted above.

Dated: December 22, 2025.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2025-23836 Filed 12-23-25; 8:45 am]

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Part II

Department of Homeland Security

8 CFR Part 214

Weighted Selection Process for Registrants and Petitioners Seeking To File
Cap-Subject H-1B Petitions; Final Rule

DEPARTMENT OF HOMELAND SECURITY**8 CFR Part 214**

[CIS No. 2847–26; DHS Docket No. USCIS–2025–0040]

RIN 1615–AD01

Weighted Selection Process for Registrants and Petitioners Seeking To File Cap-Subject H–1B Petitions**AGENCY:** U.S. Citizenship and Immigration Services, DHS.**ACTION:** Final rule.

SUMMARY: The U.S. Department of Homeland Security (DHS) is amending its regulations governing the process by which U.S. Citizenship and Immigration Services (USCIS) selects H–1B registrations for unique beneficiaries for filing of H–1B cap-subject petitions (or H–1B petitions for any year in which the registration requirement is suspended). Through this rule, DHS is implementing a weighted selection process that will generally favor the allocation of H–1B visas to higher-skilled and higher-paid aliens, while maintaining the opportunity for employers to secure H–1B workers at all wage levels, to better serve the congressional intent for the H–1B program. This rule will be effective in time for the FY 2027 registration season.

DATES: This final rule is effective February 27, 2026.

FOR FURTHER INFORMATION CONTACT: Business and Foreign Workers Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, U.S. Department of Homeland Security, 5900 Capital Gateway Drive, Camp Springs, MD 20746; telephone (240) 721–3000 (not a toll-free call).

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Table of Abbreviations

AI—Artificial Intelligence
 APA—Administrative Procedure Act
 BLS—U.S. Bureau of Labor Statistics
 CBA—collective bargaining agreement
 CFR—Code of Federal Regulations
 COVID–19—Coronavirus Disease of 2019
 CPI—U—Consumer Price Index for All Urban Consumers
 CRA—Congressional Review Act
 DHS—U.S. Department of Homeland Security
 DOW—U.S. Department of War
 DOL—U.S. Department of Labor
 E.O.—Executive Order
 EPA—U.S. Environmental Protection Agency
 ETA—Employment and Training Administration
 FDNS—Fraud Detection and National Security
 FR—Federal Register
 FY—Fiscal Year
 GDP—gross domestic product
 HHS—U.S. Department of Health and Human Services
 HR—human resources
 HSA—Homeland Security Act of 2002
 IIE—Institute of International Education
 IMG—International Medical Graduate
 INA—Immigration and Nationality Act
 IRFA—Initial Regulatory Flexibility Analysis
 IRS—U.S. Internal Revenue Service
 IT—information technology
 LCA—Labor Condition Application
 MSA—Metropolitan Statistical Area
 NAFSA—National Association of Foreign Student Advisers
 NAICS—North American Industry Classification System
 NEPA—National Environmental Policy Act
 NPRM—notice of proposed rulemaking
 OEWS—Occupational Employment and Wage Statistics
 OFLC—Office of Foreign Labor Certification
 OMB—Office of Management and Budget
 OPQ—Office of Performance and Quality
 OPT—Optional Practical Training
 PRA—Paperwork Reduction Act of 1995
 Pub. L.—Public Law
 PWD—prevailing wage determination
 RFA—Regulatory Flexibility Act of 1980
 RIA—regulatory impact analysis
 SBA—U.S. Small Business Administration

SCA—Service Contract Act
Secretary—Secretary of Homeland Security
SOC—Standard Occupational Classification
STEM—Science, Technology, Engineering,
and Math
SVP—Specific Vocational Preparation
UMRA—Unfunded Mandates Reform Act
1995
U.S.C.—United States Code
USCIS—U.S. Citizenship and Immigration
Services

I. Executive Summary

DHS is amending its regulations governing the H-1B cap selection process. This final rule implements a weighted selection process that will generally favor the allocation of H-1B visas to higher-skilled and higher-paid aliens, while maintaining the opportunity for employers to secure H-1B workers at all wage levels. This final rule follows a notice of proposed rulemaking (NPRM) issued on this topic on September 24, 2025, “Weighted Selection Process for Registrants and Petitioners Seeking to File Cap-Subject H-1B Petitions,” 90 FR 45986 (Sept. 24, 2025).

A. Purpose and Summary of the Regulatory Action

The purpose of this rule is to allow DHS to implement the numerical cap in a way that incentivizes employers to offer higher wages, or to petition for positions requiring higher skills and higher-skilled aliens, that are commensurate with higher wage levels.

This weighted selection process will generally favor the allocation of H-1B visas to higher-skilled and higher-paid aliens, while maintaining the opportunity for employers to secure H-1B workers at all wage levels, to better serve the congressional intent for the H-1B program. Moreover, it will disincentivize abuse of the H-1B program to fill relatively lower-paid, lower-skilled positions, which is a significant problem under the present H-1B program.

Through this rule, DHS is amending the process by which USCIS selects H-1B registrations for unique beneficiaries for filing of H-1B cap-subject petitions (or H-1B petitions for any year in which the registration requirement is suspended) to implement a weighted selection process generally based on each beneficiary’s equivalent wage level. When random selection is required because USCIS receives more registrations (or petitions) than USCIS projects to be needed to meet the numerical allocations, USCIS will conduct a weighted selection among the registrations for unique beneficiaries (or petitions) received generally based on the highest Occupational Employment and Wage Statistics (OEWS) wage level that the beneficiary’s proffered wage will equal or exceed for the relevant Standard Occupational Classification (SOC) code in the area(s) of intended employment. Under this process, registrations for unique beneficiaries or

petitions will be assigned to the relevant OEWS wage level and entered into the selection pool as follows: registrations for unique beneficiaries or petitions assigned wage level IV will be entered into the selection pool four times, those assigned wage level III will be entered into the selection pool three times, those assigned wage level II would be entered into the selection pool two times, and those assigned wage level I will be entered into the selection pool one time. Each unique beneficiary will only be counted once toward the numerical allocation projections, regardless of how many registrations were submitted for that beneficiary or how many times the beneficiary is entered in the selection pool.

As noted in the NPRM, although DHS is not codifying a severability clause in the regulatory text, DHS intends for the provisions of this rule to be severable from one another as well as severable from the registration requirement more broadly and the beneficiary-centric selection methodology. The absence of codified severability language is solely to avoid potential confusion within 8 CFR 214.2, which governs a wide range of nonimmigrant classifications beyond the H-1B program and already contains multiple other severability provisions. *See* 90 FR at 45996.

B. Summary of Costs and Benefits

BILLING CODE 9111–97–P

Table 1.1. Summary of Provisions and Impacts of the Rule			
Final Rule Provisions	Description of the Change to Provisions	Estimated Costs/Transfers of Provisions	Estimated Benefits of Provisions
1. Required Information on the Registration	A registrant will be required to select the box for the highest OEWS wage level that the beneficiary's wage generally equals or exceeds and also will be required to provide the SOC code for the proffered position and the area of intended employment that served as the basis for the OEWS wage level indicated on the registration.	Quantitative: Petitioners - ☐ DHS estimates costs will be \$15 million due to the additional time burden associated with the registration tool. DHS/USCIS - ☐ None Qualitative: Petitioners – ☐ None DHS/USCIS – ☐ None	Quantitative: Petitioners - ☐ None DHS/USCIS - ☐ None Qualitative: Petitioners – ☐ None ☐ DHS/USCIS — Submission of additional wage level information, the SOC code, and area of intended employment on the electronic registration form will allow USCIS to further improve the integrity of the H-1B cap selection processes.
2. Weighting and Selecting Registrations (or petitions if registration is suspended)	DHS implements a wage-based selection process that will operate in conjunction with the existing beneficiary-centric selection process for registrations. When there is random selection USCIS will enter each unique beneficiary (or petition, as applicable) into the selection pool in a weighted manner: a beneficiary (or petition) assigned wage level IV will be entered into the selection pool four times; level III, three times; level II, two times; and level I, one time.	Quantitative: Petitioners - ☐ None DHS/USCIS - ☐ None Qualitative: Petitioners - ☐ None Transfer: H-1B workers ☐ Due to the weighted registration selection process, DHS estimates that \$858 million of wages will be transferred from wage level I H-1B workers to higher wage level H-1B workers in	Quantitative: Petitioners and H-1B Workers- ☐ Total benefits of \$502 million in FY2026, \$1,004 million in FY2027, \$1,506 million in FY2028, \$2,008 million in FY2029, and \$2,510 million in each year from FY2030 through FY2035 estimated in difference of wage paid to the higher wage level H-1B workers.

		FY2026, \$1,717 million in FY2027, \$2,575 million in FY2028, \$3,434 million in FY2029, and \$4,292 million in each year from FY2030 through FY2035. This transfer will be a cost to the wage level I H-1B worker who will lose the wage associated with selected H-1B registrations. This transfer also will be a benefit to the higher wage level H-1B workers who will receive a wage associated with selected H-1B registrations. Petitioners – ☐ There will be an unquantifiable transfer from the petitioners who would have hired wage level I H-1B workers to the petitioners who will hire workers at higher wage levels. This transfer will be a cost in terms of lost producer surplus to the petitioners who registered at wage level I and were not selected due to the changes. This transfer will be an unquantifiable benefit in terms of gained producer surplus to the petitioners who registered at higher wage levels and got their H-1B registrations selected due to the higher probability of getting selected. ☐ There will also be an unquantified transfer and benefit from an increase in state and Federal payroll taxes paid to the government by the petitioner.	DHS/USCIS - ☐ By engaging in a wage-level-based weighting of registrations for unique beneficiaries, DHS will better ensure that initial H-1B visas and status grants will more likely go to the higher-skilled or higher-paid beneficiaries. Facilitating the admission of higher-skilled workers “would benefit the economy and increase the United States’ competitive edge in attracting the ‘best and the brightest’ in the global labor market,” consistent with the goals of the H-1B program. Qualitative: Petitioners - ☐ None DHS/USCIS - ☐ None

		DHS/USCIS – ☐ None	
3. Required Information on the Petition	The information required for the registration process will also be collected on the petition. Petitioners will be required to submit evidence of the basis of the wage level selected on the registration as of the date that the registration underlying the petition was submitted.	Quantitative: Petitioners - ☐ DHS estimates this cost will be \$15 million due to the additional time burden associated with filing the H-1B petition. DHS/USCIS - ☐ None Qualitative: Petitioners – ☐ None DHS/USCIS – ☐ None	Quantitative: Petitioners - ☐ None DHS/USCIS - ☐ None Qualitative: Petitioners – ☐ None DHS/USCIS - ☐ Submission of additional information on the petition form (including wage level information and the SOC code), and evidence of the basis of the wage level selected, will allow USCIS to further improve the integrity of the H-1B cap selection and adjudication processes.
4. Process Integrity	The final rule will require an H-1B petition filed after registration selection to contain and be supported by the same identifying information and position information, including OEWS wage level, SOC code, and area of intended employment provided in the selected registration and indicated on the LCA used to support the petition. The final rule will also allow USCIS to deny a subsequent new or amended petition or revoke an approved petition if USCIS were to determine that the filing of the new or amended petition was part of the petitioner's attempt to unfairly increase odds of selection during the registration selection process.	Quantitative: Petitioners - ☐ None DHS/USCIS - ☐ None Qualitative: Petitioners – ☐ DHS estimates that the final rule could lead to an increase in the number of denials or revocations of H-1B petitions DHS/USCIS – ☐ None	Quantitative: Petitioners - ☐ None DHS/USCIS - ☐ None Qualitative: Petitioners – ☐ None DHS/USCIS – ☐ These changes will lead to improved program integrity for USCIS.

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C. No Changes From the Notice of Proposed Rulemaking

Following consideration of all public comments received on the NPRM, DHS is issuing this final rule as proposed in the NPRM, without modifications to the regulatory text.

D. Implementation

This rule will be effective in time for the FY 2027 registration season. The changes in this final rule will apply to all registrations (or petitions, in the event that registration is suspended), including those for the advanced degree exemption, submitted on or after the effective date of the final rule. The treatment of registrations and petitions filed prior to the effective date of this final rule will be based on the regulatory requirements in place at the time the registration or petition, as applicable, is properly submitted. DHS has determined that this manner of implementation best balances operational considerations with fairness to the public.

II. Background*A. Legal Authority*

The Secretary of Homeland Security (Secretary)'s authority for these regulatory amendments is found in various sections of the Immigration and Nationality Act (INA or the Act), 8 U.S.C. 1101 *et seq.*, and the Homeland Security Act of 2002 (HSA), Public Law 107–296, 116 Stat. 2135, 6 U.S.C. 101 *et seq.* General authority for issuing this final rule is found in section 103(a) of the INA, 8 U.S.C. 1103(a), which authorizes the Secretary to administer and enforce the immigration and nationality laws and establish such regulations as the Secretary deems necessary for carrying out such authority, as well as section 102 of the HSA, 6 U.S.C. 112, which vests all of the functions of DHS in the Secretary and authorizes the Secretary to issue regulations.¹ Further authority for these regulatory amendments is found in:

- Section 101(a)(15)(H)(i)(b) of the INA, 8 U.S.C. 1101(a)(15)(H)(i)(b),

¹ Although several provisions of the INA discussed in this final rule refer exclusively to the “Attorney General,” such provisions are now to be read as referring to the Secretary of Homeland Security by operation of the HSA. *See* 6 U.S.C. 202(3), 251, 271(b), 542 note, 552(d), 557; 8 U.S.C. 1103(a)(1), (g), 1551 note; *Nielsen v. Preap*, 586 U.S. 392, 397 n.2 (2019); *see also* 6 U.S.C. 522 (“Nothing in this chapter, any amendment made by this chapter, or in section 1103 of Title 8, shall be construed to limit judicial deference to regulations, adjudications, interpretations, orders, decisions, judgments, or any other actions of the Secretary of Homeland Security or the Attorney General.”).

which establishes the H–1B nonimmigrant classification;

- Section 214(a)(1) of the INA, 8 U.S.C. 1184(a)(1), which authorizes the Secretary to prescribe, by regulation, the time and conditions of the admission of nonimmigrants;
- Section 214(c)(1) of the INA, 8 U.S.C. 1184(c)(1), which, *inter alia*, authorizes the Secretary to prescribe how an importing employer may petition for nonimmigrant workers, including nonimmigrants described at section 101(a)(15)(H)(i)(b) of the INA, 8 U.S.C. 1101(a)(15)(H)(i)(b), as well as the form of the petition and the information that an importing employer must provide in the petition;
- Section 214(g) of the INA, 8 U.S.C. 1184(g), which, *inter alia*, prescribes the H–1B numerical limitations, various exceptions to those limitations, and the period of authorized admission for H–1B nonimmigrants;
- Section 214(i) of the INA, 8 U.S.C. 1184(i), which sets forth the definition and requirements of a “specialty occupation”;
- Section 235(d)(3) of the INA, 8 U.S.C. 1225(d)(3), which authorizes “any immigration officer . . . to administer oaths and to take and consider evidence of or from any person touching the privilege of any alien or person he believes or suspects to be an alien to enter, reenter, transit through, or reside in the United States or concerning any matter which is material and relevant to the enforcement of [the INA] and the administration of [DHS]”;
- Section 287(b) of the INA, 8 U.S.C. 1357(b), which authorizes the taking and consideration of evidence “concerning any matter which is material or relevant to the enforcement of [the INA] and the administration of [DHS]”;
- Section 101(b)(1)(F) of the HSA, 6 U.S.C. 111(b)(1)(F), which provides that a primary mission of DHS is to “ensure that the overall economic security of the United States is not diminished by efforts, activities, and programs aimed at securing the homeland”;
- Section 402 of the HSA, 6 U.S.C. 202, which charges the Secretary with “[e]stablishing and administering rules . . . governing the granting of visas or other forms of permission . . . to enter the United States” and “[e]stablishing national immigration enforcement

² Section 102(e) of the HSA, 6 U.S.C. 112(e), provides that “the issuance of regulations by the Secretary shall be governed by the provisions of chapter 5 of title 5, except as specifically provided in this chapter, in laws granting regulatory authorities that are transferred by this chapter, and in laws enacted after November 25, 2002.”

policies and priorities”; *see also* HSA sec. 428, 6 U.S.C. 236; and

- Section 451(a)(3) and (b) of the HSA, 6 U.S.C. 271(a)(3) and (b), transferring to USCIS the authority to adjudicate petitions for nonimmigrant status, establish policies for performing that function, and set national immigration services policies and priorities.

B. Background on H–1B Registration

The H–1B visa program allows U.S. employers to temporarily hire foreign workers to perform services in a specialty occupation, services related to a U.S. Department of War (DOW) cooperative research and development project or coproduction project, or services of distinguished merit and ability in the field of fashion modeling. *See* INA sec. 101(a)(15)(H)(i)(b), 8 U.S.C. 1101(a)(15)(H)(i)(b); Immigration Act of 1990, Public Law 101–649, sec. 222(a)(2), 104 Stat. 4978 (Nov. 29, 1990); 8 CFR 214.2(h). A specialty occupation is defined as an occupation that requires the (1) theoretical and practical application of a body of highly specialized knowledge, and (2) attainment of a bachelor’s or higher degree in the specific specialty (or its equivalent) as a minimum qualification for entry into the occupation in the United States. *See* INA sec. 214(i)(1), 8 U.S.C. 1184(i)(1).

Congress has established limits on the number of foreign workers who may be granted initial H–1B nonimmigrant visas or status each fiscal year (FY) (commonly known as the “cap”). *See* INA sec. 214(g), 8 U.S.C. 1184(g). The total number of foreign workers who may be granted initial H–1B nonimmigrant status during any fiscal year may not exceed 65,000. *See* INA sec. 214(g)(1)(A), 8 U.S.C. 1184(g)(1)(A). Certain petitions are exempt from the 65,000 numerical limitation.³ *See* INA

³ Exempt petitions are petitions for (1) employment (or an offer of employment) at an institution of higher education or a related affiliated nonprofit entity, (2) employment (or an offer of employment) at a nonprofit research organization or a government research organization, or (3) H–1B workers who have earned a qualifying U.S. master’s degree or higher degree. Also exempt are those petitions for beneficiaries who have previously been counted under the cap, unless eligible for a full 6-years of authorized admission when the petition is filed, and who seek to change jobs or extend their stay during their 6-year period of authorized admission, and those exempt from the 6-year period of authorized admission limitation based on section 104(c) or 106(a) and (b) of the American Competitiveness in the Twenty-First Century Act (AC21), Public Law 106–313, 114 Stat. 1254 (Oct. 17, 2000), as amended by section 11030A of the 21st Century Department of Justice Appropriations Authorization Act, Public Law 107–273, 116 Stat. 1758 (2002).

secs. 214(g)(5) and (7), 8 U.S.C. 1184(g)(5) and (7). The annual exemption from the 65,000 cap for H-1B workers who have earned a qualifying U.S. master's or higher degree may not exceed 20,000 foreign workers. See INA sec. 214(g)(5)(C), 8 U.S.C. 1184(g)(5)(C).

To manage the annual cap, USCIS used a random selection process in years of high demand to determine which petitions were selected toward the projected number of petitions needed to reach the annual H-1B numerical allocations. In order to better manage the selection process, DHS created a registration requirement for H-1B cap-subject petitions, which was first implemented in 2020 for the FY 2021 cap season. Through issuance of a final rule in 2019, "Registration Requirement for Petitioners Seeking To File H-1B Petitions on Behalf of Cap-Subject Aliens," DHS developed a new way to administer the H-1B cap selection process to streamline processing and provide overall cost savings to employers seeking to file H-1B cap-subject petitions. See 84 FR 888 (Jan. 31, 2019). Under the current registration process, prospective petitioners (also known as registrants) that seek to employ H-1B cap-subject workers must first submit a registration for each requested worker. The H-1B selection process is then run on properly submitted electronic registrations. Only those with valid selected registrations are eligible to file H-1B cap-subject petitions. 8 CFR 214.2(h)(8)(iii)(A)(1).

In February 2024, DHS implemented a beneficiary-centric selection process for H-1B registrations to better ensure each beneficiary will have the same chance of being selected, regardless of the number of registrations submitted on his or her behalf, among other integrity measures. 89 FR 7456 (Feb. 2, 2024). Under this beneficiary-centric selection process, registrations are counted based on the number of unique beneficiaries who are registered. 8 CFR 214.2(h)(8)(iii)(A)(4). Each unique beneficiary is counted once toward the random selection, regardless of how many registrations are submitted for that beneficiary. *Id.* A prospective petitioner whose registration is selected is eligible to file an H-1B cap-subject petition based on the selected registration during the associated filing period. 8 CFR 214.2(h)(8)(iii)(A)(1).

C. Need for Regulatory Reform

Congress provided DHS with the authority to better ensure a fair, orderly, and efficient allocation of H-1B cap numbers based on reasoned decision making, including consideration of the

overall statutory scheme and purpose of the classification: the selection of highly skilled and highly paid nonimmigrants in the United States while protecting the wages, working conditions, and job opportunities of U.S. workers. Congressional intent behind creating the H-1B program was, in part, to help U.S. employers fill labor shortages in positions requiring highly skilled or highly educated workers.⁴ A key goal of the program at its inception was to help U.S. employers obtain the temporary employees they need to meet their business needs to remain competitive in the global economy.⁵ To address legitimate countervailing concerns of the adverse impact foreign workers could have on U.S. workers, Congress enacted a number of measures intended to protect U.S. workers, including the annual numerical limitations. Congress was concerned that a surplus of foreign labor could depress wages for all workers in the long run and recognized the cap as a means of "continuous monitoring of all admissions."⁶

As noted above, USCIS has used a random selection process in years of high demand to determine which registrations (or petitions, as applicable) are selected toward the projected number needed to reach the annual H-1B numerical allocations. While the current random selection of petitions or registrations is reasonable, DHS believes it is neither the optimal, nor the exclusive method of selecting registrations or petitions toward the numerical allocations when more registrations or petitions, as applicable, are simultaneously submitted than projected as needed to reach the numerical allocations. Pure randomization does not serve the ends of the H-1B program or congressional intent to help U.S. employers fill labor shortages in positions requiring highly skilled workers.⁷

⁴ See H.R. Rep. 101-723(I) (1990), as reprinted in 1990 U.S.C.C.A.N. 6710, 6721.

⁵ See Bipartisan Policy Center, *Immigration in Two Acts*, at 7 (Nov. 2015), <https://bipartisanpolicy.org/wp-content/uploads/2019/03/BPC-Immigration-Legislation-Brief.pdf>, citing H.R. Rep. 101-723(I) supra note 10 at 6721 ("At the time [1990], members of Congress were also concerned about U.S. competitiveness in the global economy and sought to use legal immigration as a tool in a larger economic plan, stating that 'it is unlikely that enough U.S. workers will be trained quickly enough to meet legitimate employment needs, and immigration can and should be incorporated into an overall strategy that promotes the creation of the type of workforce needed in an increasingly global economy.'").

⁶ See H.R. Conf. Rep. 101-955, at 126 (1990), as reprinted in 1990 U.S.C.C.A.N. 6784, 6790-91.

⁷ See H.R. Rep. 101-723(I) (1990), as reprinted in 1990 U.S.C.C.A.N. 6710, 6721 (stating "The U.S. labor market is now faced with two problems that immigration policy can help to correct. The first is

DHS believes a better reasoned policy, consistent with the intent of the H-1B statutory scheme, is to utilize the numerical cap in a way that incentivizes a U.S. employer's recruitment of beneficiaries for positions requiring the highest skill levels within the visa classification or otherwise earning the highest wages in an occupational classification and area of intended employment, which generally correlate with higher skill levels. Put simply, because demand for H-1B visas has exceeded the annual supply for more than a decade,⁸ DHS prefers that simultaneously submitted registrations for cap-subject H-1B visas be selected in a manner that favors beneficiaries earning the highest wages relative to their SOC codes and area(s) of intended employment.

While DHS prefers that cap-subject H-1B visas be allocated in a manner that favors beneficiaries earning the highest wages, DHS also recognizes the value in maintaining the opportunity for employers to secure H-1B workers at all wage levels. In this respect, this final rule differs from the wage-based selection rule that DHS proposed and finalized in 2020 and 2021, respectively.⁹ Although the 2021 H-1B Selection Final Rule was subsequently vacated¹⁰ and then withdrawn,¹¹ it would have ranked and selected registrations generally based on the highest equivalent prevailing wage level, as opposed to selecting by unique

the need of American business for highly skilled, specially trained personnel to fill increasingly sophisticated jobs for which domestic personnel cannot be found and the need for other workers to meet specific labor shortages.").

⁸ Total Number of H-1B Cap Registration Submissions and Selections, FY 2021-FY 2025, USCIS Office of Performance and Quality (OPQ), data queried 3/2025, TRK #17518; Total Number of H-1B Cap-Subject Petitions Submitted, FY 2016-FY 2020, USCIS SCOPS, June 2019. See also Jill H. Wilson, Congressional Research Service, *Temporary Professional Foreign Workers: Background, Trends, and Policy Issues* (June 9, 2022), <https://www.congress.gov/crs-product/R47159>.

⁹ See "Modification of Registration Requirement for Petitioners Seeking To File Cap-Subject H-1B Petitions," 85 FR 69236 (Nov. 2, 2020); "Modification of Registration Requirement for Petitioners Seeking To File Cap-Subject H-1B Petitions," 86 FR 1676 (Jan. 8, 2021).

¹⁰ See *Chamber of Commerce of the U.S. v. DHS*, No. 4:20-cv-07331, 2021 WL 4198518 (N.D. Cal. Sept. 15, 2021) (vacating the rule as improperly issued but not reaching the merits of plaintiffs' alternative arguments).

¹¹ Following several months of litigation, on September 15, 2021, the court vacated the rule and remanded the matter to DHS and DHS subsequently withdrew the rule. On December 22, 2021, DHS issued a final rule to withdraw the final rule published on January 8, 2021, because that rule had been vacated by a Federal district court. "Modification of Registration Requirement for Petitioners Seeking To File Cap-Subject H-1B Petitions, Implementation of Vacatur," 86 FR 72516 (Dec. 22, 2021).

beneficiary and assigning a weight to them as in this finalized selection process. The 2021 H-1B Selection Final Rule was expected to result in the likelihood that registrations for level I wages would not be selected, as well as a reduced likelihood that registrations for level II would be selected. 86 FR 1676, 1724 (Jan. 8, 2021). Although DHS believes the selection process finalized under the 2021 H-1B Selection Final Rule was a reasonable approach to facilitate the admission of higher-skilled or higher-paid workers, DHS believes that rule did not capture the optimal approach because it effectively left little or no opportunity for the selection of lower wage level or entry level workers, some of whom may still be highly skilled. Unlike the 2021 H-1B Selection Final Rule, under this final rule, USCIS will assign a weight to—rather than rank and select—registrations for each unique beneficiary generally based on the corresponding OEWS wage level.

By engaging in a wage-level based weighting of registrations for unique beneficiaries, DHS will better ensure that the H-1B cap selection process favors relatively higher-skilled, higher-valued, or higher-paid foreign workers rather than continuing to allow numerically-limited cap numbers to be allocated predominantly to workers in lower skilled or lower paid positions.¹² Ultimately, this final rule will incentivize employers to offer higher

wages or higher skilled positions to H-1B workers and disincentivize the existing widespread use of the H-1B program to fill lower paid or lower skilled positions, without effectively precluding beneficiaries with lower wage levels or entry level positions.¹³ Facilitating the admission of higher-skilled workers “would benefit the economy and increase the United States’ competitive edge in attracting the ‘best and the brightest’ in the global labor market,” consistent with the goals of the H-1B program.¹⁴

This rule is consistent with the Presidential Proclamation 10973 of September 19, 2025, “Restriction on Entry of Certain Nonimmigrant Workers” (“H-1B Proclamation”), which directed the Secretary of Homeland Security to initiate a rulemaking to prioritize the admission as nonimmigrants of high-skilled and high-paid aliens, consistent with INA sections 101, 212, and 214 of the INA, 8 U.S.C. 1101, 1182, and 1184. 90 FR 46027 (Sept. 24, 2025). As noted in the H-1B Proclamation, the H-1B nonimmigrant visa program was created to bring highly skilled temporary workers into the United States, but the program has been deliberately exploited to bring in lower-paid, lower-skilled workers to the detriment of U.S. workers.¹⁵ Further, many employers, particularly employers in certain sectors, have abused the current H-1B framework to artificially suppress wages, resulting in a disadvantageous labor market for U.S. citizens, while at the same time making it more difficult to attract and retain the highest skilled subset of temporary workers.

DHS believes that the current random selection of registrations (or petitions, as applicable) has contributed to the systematic abuse of the H-1B program as described in the H-1B Proclamation. Despite improvements DHS has made over the years to improve the integrity of the H-1B registration process and the

H-1B program overall, companies continue to exploit the current legal framework to obtain a pool of relatively low-wage workers that are detrimental to U.S. workers’ wages, working conditions, and job opportunities. This final rule will help reverse this trend and help the program meet its original goals of attracting highly skilled foreign workers while better protecting the wages, working conditions, and job opportunities of U.S. workers.

III. Response to Public Comments on the Proposed Rule

In response to the proposed rule, DHS received 2,731 comments during the 30-day period for public comments on the NPRM. DHS received additional comments related to the associated information collections during the remainder of the 60-day period for public comments in accordance with the Paperwork Reduction Act.

Commenters included individuals (including U.S. workers), companies, law firms, professional organizations, advocacy groups, nonprofit organizations, universities, healthcare providers, and trade and business associations. Some commenters expressed support for the rule or offered suggestions for improvement. Some expressed general opposition to the rule and some offered alternatives. For some of the public comments, DHS could not ascertain whether the commenter supported or opposed the proposed rule.

DHS has reviewed all of the public comments received in response to the NPRM that were submitted in accordance with the instructions contained in the NPRM during the comment period. In this final rule, DHS has responded to public comments relevant to the NPRM and has addressed the significant issues raised therein. DHS’s responses are grouped by subject area, with a focus on the most common issues and suggestions raised by commenters.

A. Support for the Rule and DHS Justifications

1. General Support for the Rule

Comment: Multiple commenters expressed general support for the rule. Other commenters explained their support in general terms that mentioned: promoting a more merit-based H-1B visa system; expanding employment options for U.S. citizens; promoting a more highly skilled workforce; providing an effective mechanism for weighted selection using wages across different locations; and

¹² See Daniel Costa & Ron Hira, Economic Policy Institute, H-1B Visas and Prevailing Wage Level (May 4, 2020), <https://www.epi.org/publication/h-1b-visas-and-prevailing-wage-levels/> (pointing to data that “all H-1B employers, but especially the largest employers, use the H-1B program either to hire relatively lower-wage workers (relative to the wages paid to other workers in their occupation) who possess ordinary skills or to hire skilled workers and pay them less than the true market value”); George Fishman, Center for Immigration Studies, Elon Musk is Right about H-1Bs (Jan. 9, 2025), <https://cis.org/Report/Elon-Musk-Right-about-H1Bs> (noting the benefit of giving preference to prospective H-1B workers who are “the best and brightest (those promised the highest salaries)”); Norm Matloff, Barron’s, Where are the ‘Best and Brightest?’ (June 8, 2013), <https://www.barrons.com/articles/SB50001424052748703578204578523472393388746> (“The data show that most of the foreign tech workers are ordinary folks doing ordinary work.”); Norman Matloff, Center for Immigration Studies, H-1Bs: Still Not the Best and the Brightest (May 12, 2008), <https://cis.org/Report/H1Bs-Still-Not-Best-and-Brightest> (presenting “data analysis showing that the vast majority of the foreign workers—including those at most major tech firms—are people of just ordinary talent, doing ordinary work.”); Adam Ozimek, Connor O’Brien, & John Lettieri, Economic Innovation Group, Exceptional by Design: How to Fix High-Skilled Immigration to Maximize American Interests (Jan. 2025), <https://eig.org/wp-content/uploads/2025/01/Exceptional-by-Design.pdf> (“Wages are a clear expression of the value firms expect a worker to contribute, yet the H-1B gives no preference to workers with higher salary offers.”).

¹³ See Daniel Costa & Ron Hira, Economic Policy Institute, H-1B Visas and Prevailing Wage Level (May 4, 2020), <https://www.epi.org/publication/h-1b-visas-and-prevailing-wage-levels/>.

¹⁴ See Muzaffar Chishti & Stephen Yale-Loehr, Migration Policy Institute, The Immigration Act of 1990: Unfinished Business a Quarter-Century Later (July 2016), https://www.migrationpolicy.org/sites/default/files/publications/1990-Act_2016_FINAL.pdf (“Sponsors of [the Immigration Act of 1990, which created the H-1B program as it exists today,] believed that facilitating the admission of higher-skilled immigrants would benefit the economy and increase the United States’ competitive edge in attracting the ‘best and the brightest’ in the global labor market.”).

¹⁵ Throughout this rule DHS uses the term “U.S. workers” but notes that the Proclamation uses the term “American workers.” DHS considers these terms synonymous for purposes of this rule.

promoting transparency in selection criteria.

Some commenters said the proposed approach would better align with the H-1B program's purpose by attracting top global talent and/or supporting innovation and economic growth in the United States while also reducing wage-based exploitation. Commenters predicted the new selection process would strengthen the U.S. economy and enhance the United States' competitiveness.

Multiple commenters stated that the new selection process would improve program integrity. Commenters generally noted that the wage-based selection process would improve both the integrity of the registration program and the H-1B program overall. Some commenters praised DHS's efforts to protect the registration selection process against gaming by employers.

Response: DHS agrees that this rule will improve program integrity and will better ensure that the H-1B cap selection process favors relatively higher-skilled, higher-valued, or higher-paid foreign workers, consistent with the congressional intent of helping U.S. employers hire highly skilled aliens to address gaps in the U.S. workforce. DHS agrees with the commenters' statements that the weighted selection process implemented by this rule will expand employment prospects for U.S. citizens, support innovation, encourage skill development, reduce wage-based exploitation, promote integrity and transparency, and help to strengthen the economy. By facilitating the admission of highly skilled, highly paid H-1B workers, this rule helps the United States attract more highly skilled workers in the global labor market, ultimately enhancing U.S. competitiveness.

2. Protecting U.S. Workers and Wages

Comment: Many commenters supported the proposed rule, reasoning that it would address concerns about the current H-1B program's harmful effects on U.S. workers. Commenters criticized the wage undercutting and wage suppression allowed by the current H-1B cap selection process. Some commenters shared their personal observations about how they, their colleagues, or U.S. workers have been harmed by companies that exploit the H-1B program to bring in large numbers of lower-skilled, lower-paid foreign workers.

Multiple commenters predicted that the new H-1B selection process would benefit U.S. workers. Commenters emphasized that the skill- and wage-based selection criteria would promote

fairness; discourage fraudulent practices; encourage prospective beneficiaries to pursue higher-paying, legitimate employment opportunities; and better complement the U.S. labor market. Commenters remarked that the new system would raise wages to more accurately reflect market demand for needed skills. Another noted the rise of artificial intelligence (AI) and the need to protect job opportunities for U.S. workers and graduates. Some commenters remarked that this rule would not only help U.S. citizens, but also lawful permanent residents and legal immigrant workers whose job opportunities have been negatively impacted by low-skill, low-wage H-1B workers.

Many commenters predicted that the new selection process would encourage the hiring of U.S. workers by disincentivizing information technology (IT) staffing companies from hiring cheap, foreign labor. Many commenters said they support efforts to reform the H-1B registration process and expressed concern about IT consulting companies that hire lower-skilled, lower-paid foreign workers who displace U.S. workers. Commenters expressed criticism of the way some IT staffing companies can misuse or abuse the system, whether through loopholes or illegal practices. Some commenters cited data showing that currently 80% of H-1B visas are for workers in wage levels I and II, a statistic they tied to lower wages in affected industries.

Response: DHS agrees that this rule will reduce problems with the H-1B program, which companies have been systematically exploiting to bring in large numbers of lower-skilled, lower-paid foreign workers to the detriment of U.S. workers. In particular, U.S. workers in computer-related fields have been significantly harmed by the prominent manipulation of the H-1B program by IT or outsourcing firms.¹⁶ This rule will incentivize employers to use the H-1B program to primarily fill relatively higher-paid, higher-skilled positions to supplement, rather than replace, U.S. workers. Prioritizing registrations or petitions, as applicable, on the basis of equivalent wage levels will help restore the congressional intent for the program of helping U.S. employers fill labor shortages in positions requiring highly skilled and/or highly educated workers.

DHS agrees that a decrease in the hiring of lower-paid foreign labor will

encourage U.S. employers to hire available and qualified U.S. workers, potentially improving the wages, working conditions, and job opportunities for U.S. workers, particularly for certain positions and industries that have seen wage suppression or stagnation due to lower-paid H-1B workers. The weighted selection process finalized in this rule is expected to result in a marked decrease in registrations (or petitions, as applicable) being selected for workers who will be paid a level I corresponding wage, with a greater percentage of total selected registrations or petitions being for beneficiaries who will be paid a level III or level IV corresponding wage.

DHS also agrees this rule will benefit lawful permanent residents and other legal immigrant workers who have been similarly harmed by lower-paid H-1B workers.

3. Positive Impacts on Entry-Level Workers and Recent Graduates

Comment: Many commenters said that the proposed rule would alleviate competition and provide more entry-level positions for U.S. workers. Citing previously published DHS data indicating that the "number of wage level I petitions will decrease by 10,099 annually," a commenter predicted that this decrease would encourage petitioners to seek out U.S. workers for these entry-level positions. One commenter predicted that the new rule will positively impact early career professionals, both U.S. workers and H-1B nonimmigrants, by raising wages.

Many commenters remarked that this rule would help U.S. college students and other recent graduates, reasoning that the new selection process will help increase their chances of gainful employment and decrease competition against lower-paid foreign workers. Commenters also specifically noted that the proposed weighted selection process would offer some improvements for U.S. graduates in science, technology, engineering, and math (STEM) fields and other U.S. workers who are just starting out their IT careers. Some commenters noted the significant challenges faced by current U.S. graduates seeking work in the IT or STEM fields and stated that this rule would encourage U.S. students to pursue STEM training and positions.

Response: DHS agrees that this rule will help to better protect the wages, working conditions, and job opportunities of U.S. workers, including U.S. college students and recent graduates. Employers that might have petitioned for cap-subject H-1B workers to fill relatively lower-paid, lower-

¹⁶ See "Restriction on Entry of Certain Nonimmigrant Workers," 90 FR 46027 (Sept. 24, 2025). See also Daniel Costa & Ron Hira, Economic Policy Institute, H-1B Visas and Prevailing Wage Level (May 4, 2020), <https://www.epi.org/publication/h-1b-visas-and-prevailing-wage-levels>.

skilled positions may be incentivized to hire available and qualified entry-level U.S. workers for those positions as a result of this rule. DHS also agrees that this rule will offer improvements for U.S. students and graduates in STEM fields. As stated in the H-1B Proclamation, abuse of the H-1B program is creating disincentives for future U.S. workers to choose STEM careers. U.S. college graduates in some STEM fields are facing high unemployment rates as compared to graduates with other majors.¹⁷ 90 FR 46027 (Sept. 24, 2025). Employers have abused the H-1B program to artificially suppress wages, resulting in a disadvantageous labor market for U.S. citizens and other legal workers, particularly in STEM fields. *Id.*

4. Positive Impacts on International Students and New Graduates

Comment: Several commenters expressed appreciation for the proposed rule, stating that it would be greatly beneficial to international students and graduates from U.S. universities who are highly skilled or have job offers at high wage levels. These commenters expressed frustration at not having been selected in several previous H-1B registration seasons despite earning level IV wages, saying that their chances of selection would have been much higher had a wage-based selection process been in place. A commenter similarly noted that a weighted selection will be more merit-based and favorable to students who invested in a U.S. education and have legitimate job offers, compared to the current random selection process which allows “many fake registrations” that “distort the odds.” A commenter said the new rule would benefit international students graduating with master’s degrees and Ph.D.’s.

Response: DHS agrees that this rule will be greatly beneficial to international students who are highly skilled and have job offers with wages that correspond to a higher wage level, as the rule will increase their chances of being selected in any future H-1B lottery relative to their chance in the current randomized selection process. DHS agrees that this rule could be beneficial to aliens who have recently completed a master’s or doctoral program and are seeking to enter the workforce. For these aliens, this rule will further increase their chance of being selected in the H-1B lottery

relative to their chance in the current randomized selection process, to the extent that such aliens secure job offers with salaries that correspond to higher wage levels. It should also be noted that recent graduates with master’s or higher degrees from U.S. institutions of higher education already benefit from the existing advanced degree exemption and cap selection order.

5. Positive Impacts on Companies and the Economy

Comment: Commenters articulated several ways that the proposed rule would benefit U.S. companies and the economy. For example, a commenter expressed support for the proposed rule and suggested it would encourage companies to hire the most qualified person for the job, which in turn helps companies succeed and improves the country’s economy. Commenters stated that foreign professionals earning higher wages, in addition to contributing directly to innovation, may add more to the U.S. economy through gross domestic product (GDP), tax revenue, innovation output per capita, and consumer spending.

Some commenters mentioned ways this rule would help certain types of employers. For instance, a few commenters stated that the proposed rule would help start-ups hire and retain aliens with needed skills, while the current random selection process results in startups losing critical employees because most registrations go to other companies like consulting companies or outsourcing firms. A commenter stated that high-wage positions typically correspond to roles in cutting-edge sectors, such as AI, cybersecurity, semiconductor design, and advanced manufacturing, and stated that this rule would help companies attract and retain top global talent in these fields. A few commenters said the new weighted selection process would promote hiring of U.S. workers in industries key to national security. Another commenter praised the rule for supporting U.S. workers and said the United States should focus on educating and developing doctors from within its own population rather than recruiting doctors from other countries.

Response: DHS agrees that the weighted selection process implemented by this rule will benefit some U.S. companies by facilitating the admission of highly skilled, highly paid workers, attracting the best and brightest in the global labor market. Unlike the current random selection process, which results in a higher proportion of lower wage and lower skilled H-1B workers, this rule will benefit

companies of all types, including startups and those in critical sectors, that are seeking to hire highly skilled workers with wages that correspond to a higher wage level. These workers are more likely to spur innovation and help their employers succeed, ultimately benefiting the U.S. economy, whether directly through taxes paid, consumer spending, and contributions to corporate earnings, or indirectly through promoting growth in key industries, including those related to national security. Finally, DHS agrees that the new weighted selection process will help to better protect the wages, working conditions, and job opportunities for U.S. workers, including those in medicine and health-related fields.

B. Opposition to the Rule and Policy Objections

1. General Opposition to the Rule

Comment: Some commenters opposed the rule based on general policy concerns, stating that the rule would, for example, be unfair, produce uncertainty for businesses, reduce diversity and inclusiveness in the workplace, and “undermine[] the principles of equal opportunity that should guide immigration policy.” Other commenters generally asserted that the rule would weaken American competitiveness or harm innovation in the United States. Other commenters generally described the benefits of the H-1B program (*e.g.*, that it allows companies to invest in domestic facilities, create additional jobs for U.S. employees, fill gaps in technical and scientific areas where shortages exist, and hire foreign workers with specialized skills which complement those of U.S. workers) and claimed that this rule is not needed.

Response: As discussed in greater detail in response to more specific comments later in this preamble, DHS disagrees with these commenters that the rule will result in the asserted harms; moreover, to the extent that harm may occur in any individual case, DHS believes that on balance, this approach is more likely to support the purposes of the H-1B program and the national interest. In addition, DHS disagrees that the rule is not needed, as it is well documented that the H-1B program has been deliberately and systematically exploited. The current random selection process has contributed to the ongoing exploitation of the H-1B program to benefit certain companies in certain sectors, while crowding out other companies and legitimate job seekers who have unsuccessfully sought to participate in

¹⁷ Federal Reserve Bank of New York, The Labor Market for Recent College Graduates, <https://nyfed.org/collegelabor> (last updated Aug. 1, 2025) (data from 2023).

the H-1B program. As noted in the H-1B Proclamation, the H-1B program has been deliberately exploited to replace, rather than supplement, U.S. workers with lower-paid, lower-skilled labor. 90 FR 46027 (Sept. 24, 2025). The large-scale replacement of U.S. workers through systemic abuse of the program has undermined both our economic and national security. 90 FR 46027 (Sept. 24, 2025). These results are contrary to the purpose of the H-1B program.

2. Fairness and Equal Opportunity Concerns

Comment: Many commenters expressed concerns about the fairness and equity of the proposed weighted selection process with some commenters saying the rule goes against U.S. values of opportunity and fairness. Other commenters stated that the current random selection process, though imperfect, provides all qualified applicants with an equal chance regardless of employer size, education level, or industry. The commenters stated that a weighted selection process would favor larger corporations, well-funded petitioners, and candidates with advanced U.S. degrees, unfairly disadvantaging skilled workers with comparable or greater expertise but different academic or geographic backgrounds. Another commenter remarked that one of the most echoed sentiments online is that the wage-weighted rule “only helps the rich get richer” by linking selection chances to salary, which favors those from privileged backgrounds and high-paying industries. Some commenters stated that the proposed rule would create a “pay-to-play” system. Another commenter stated that it is not fair that people with talent but limited resources would be ignored because of this proposal, questioning when money became the main priority over skills and potential. Another commenter remarked that companies may “lowball” their employees in order to control their spending on H-1B visas, leading to more unfair treatment. Another commenter stated that the proposed rule would distort fair competition for labor and would discourage legitimate participation in the H-1B program.

Response: DHS believes that the ongoing exploitation of the H-1B program—to the detriment of U.S. workers and legitimate employers and job seekers who have been crowded out of the program—is contrary to the principles of fairness and equal opportunity. The current random selection process is not fair to U.S. workers whose wages may be adversely affected by an influx of relatively lower-

paid H-1B workers, or to U.S. employers who have sought to petition for foreign workers at higher OEWS prevailing wage levels and are not selected. Regarding the concern about employers “lowballing” their employees to control costs on H-1B visas, DHS believes that as a result of this rule employers may choose to offer a higher wage to a prospective beneficiary whose skill level they value and who they wish to retain. Additionally, this rule may offer highly skilled H-1B workers greater leverage in negotiating for a higher salary, which in turn could encourage competition for labor among petitioners seeking similarly qualified workers.

DHS does not view the weighted selection process as a “pay-to-play” system, but rather a process that attracts the best and the brightest, increases the chance of selection for those who will be paid wages at higher corresponding wage levels, and disincentivizes petitioning employers from offering wages at the lower corresponding wage levels. As stated throughout the NPRM, DHS believes that salary generally is a reasonable proxy for skill level.¹⁸ The purpose of this rule is to implement the numerical cap in a way that will generally favor the allocation of H-1B visas to higher-skilled and higher-paid aliens, while maintaining the opportunity for employers to secure H-1B workers at all wage levels. DHS believes this approach serves congressional intent for the H-1B program more faithfully than the current random selection process. DHS believes that this rule appropriately balances the interests of U.S. workers with the interests of petitioning employers and the alien workers they seek to employ as H-1B nonimmigrants.

Comment: Some commenters expressed concern that the proposed weighted selection process would complicate the registration selection process by creating uncertainty, complexity, and unfair bias. The commenters said that the weighting process would make outcomes harder to understand and undermine trust in the lottery, compared to the current random

lottery which is transparent and simple to understand. A commenter likewise asserted that a “fundamental flaw” with the proposed rule’s approach is that it retains the elements of uncertainty and randomness, such that someone being offered a \$300,000 salary, for example, would have no certainty of winning the weighted lottery. Another commenter said that the rule adds uncertainty and makes workforce planning less predictable, thus making the H-1B program impractical to use.

Response: DHS disagrees with these commenters that the weighted selection process creates uncertainty and unpredictability. To the contrary, this rule will increase certainty and predictability by increasing the chances that a registration for a highly skilled, highly paid alien will be selected in the selection process. Under the current system, the chance that any particular beneficiary is selected in the lottery is just under 30 percent, regardless of how highly skilled that beneficiary may be. These low chances of selection increase uncertainty for all beneficiaries. In contrast, under this final rule the chances of selection for a beneficiary weighted at a level IV wage will increase to over 61 percent and a beneficiary weighted at a level III wage will increase to over 45 percent.

While the final rule retains some degree of uncertainty because it retains an element of randomness, DHS believes it is important to retain these aspects of the lottery. As stated in the NPRM, DHS believes it is optimal to increase the chances of selection for highly skilled aliens while maintaining the opportunity for employers to secure H-1B workers at all wage levels.

DHS disagrees that the weighted selection process finalized in this rule will complicate the H-1B registration selection process or make outcomes harder to understand. USCIS is fully prepared to implement the weighted selection process from an operational and technical perspective in time for the upcoming H-1B cap season. DHS believes that the public has received sufficient notice of the weighted selection process and that the parameters of the process have been made clear.

Finally, DHS disagrees that the weighted selection process undermines trust in the H-1B cap selection process. As previously described, the prevalent and systematic abuse of the current H-1B program undermines public trust. DHS believes that the new weighted selection process will restore trust in the H-1B program by returning the program to its original intended purpose of helping U.S. employers fill labor

¹⁸ See “Wage Methodology for the Temporary Non-Agricultural Employment H-2B Program,” 76 FR 3452, 3453 (Jan. 19, 2011) (it is a “largely self-evident proposition that workers in occupations that require sophisticated skills and training receive higher wages based on those skills.”); Daniel Costa & Ron Hira, Economic Policy Institute, H-1B Visas and Prevailing Wage Level (May 4, 2020), <https://www.epi.org/publication/h-1b-visas-and-prevailing-wage-levels/> (“Specialized skills should command high wages; such skills are typically a function of inherent capability, education level, and experience. It would be reasonable to expect that these workers should receive wages higher than the median wage.”).

shortages in positions requiring highly skilled or highly educated workers while protecting the wages, working conditions, and job opportunities of U.S. workers, rather than allowing the continued abuse of the H-1B program to displace and otherwise harm U.S. workers.

3. Negative Impacts on Companies, the Workforce, and the Economy

Comment: Several commenters asserted that H-1B professionals drive innovation, productivity growth, and entrepreneurship. Some commenters addressed the contributions of international students to innovation and economic growth and said that limiting their job opportunities would undermine such growth. Other commenters specified that startups and small businesses are significant drivers of innovation and economic growth in the United States, and limiting their access to international talent could stifle such innovation and entrepreneurship. Other commenters said that innovation and breakthroughs often come from early-career professionals, startups, and research institutions that typically cannot compete with the salaries of larger, established companies. Another commenter stated that startups rely on the H-1B program to attract talented workers who possess “niche expertise,” and that this rule will make the H-1B program more expensive and difficult to use, and ultimately limit the growth of U.S. tech innovation and global leadership.

Response: DHS disagrees that the rule will stifle innovation, economic growth, and global leadership. Rather than limiting access to international talent, DHS believes that this rule will facilitate employers of all types and sizes to attract and retain highly skilled and highly paid aliens. This rule will help the United States to attract the best and brightest workers by increasing the chance of selection for highly skilled, highly paid aliens who are more likely to spur innovation and make significant contributions to their employers and industry, while also better protecting the wages, working conditions, and job opportunities of U.S. workers.

Additionally, this rule does not treat people who work for startups or small-sized entities differently than those who work for other larger companies. While DHS recognizes that some startups and small businesses may operate on smaller margins compared to other companies, if an employer values a beneficiary's work and the unique qualities the beneficiary possesses, the employer could offer a higher wage than required by the prevailing wage level to reflect

that value. DHS recognizes that this could result in increased costs for a business, however, DHS believes that the tradeoff of having a greater chance to recruit or retain talented employees may offset these increased costs. If a company is unable to pay an employee a higher wage for a greater chance of selection, they could then try to find a substitute U.S. worker. This rule, by weighting selection, allows employers seeking workers at any wage level to have an opportunity for selection, such that they are not precluded from participating in the program solely because they are unable to pay a wage that corresponds to a higher wage level.

Comment: Commenters claimed that this rule would result in companies outsourcing more work overseas, directly contrary to the intent of this rule. Commenters remarked that employers who depend on entry-level talent would either cut back on hiring or outsource jobs abroad, reducing job creation within the United States. Some commenters specifically stated that the proposed rule would result in IT companies replacing onsite H-1B workers with lower-paid offshore resources, with some commenters remarking that this would be an additional way to undercut U.S. workers' wages by paying significantly lower salaries to offshore employees. A manufacturing association stated that in industries that cannot meet their labor force needs domestically, if companies cannot use the H-1B program to address shortages, employers may be incentivized to move production and workforce positions offshore. Another commenter noted that their industry will be unable to substitute lost global talent with U.S. workers who still need training and education, meaning that changes to the H-1B program will leave critical positions unfilled, slowing innovation and overall job growth. This same commenter went on to state that research from the Economic Innovation Group and George Mason University shows that restrictions on H-1B visas drives companies to offshore work or expand operations abroad, undermining the goal of supporting U.S. workers.

Response: DHS disagrees that this rule will cause employers to outsource more jobs or move operations to other countries. While DHS acknowledges this rule may impose some costs to individual employers, the commenters do not address the countervailing impact on those employers benefited by this rule, including those U.S. employers offering level III and IV wages that will have higher chances of selection, or U.S. employers that have historically been squeezed out of the H-

1B lottery that will likely see an increased chance to participate in the H-1B program. DHS believes that this rule, instead, will facilitate the admission of higher-skilled workers, which will benefit the economy and increase the United States' competitive edge in attracting the best and the brightest in the global labor market, consistent with the goals of the H-1B program.

DHS is not persuaded that U.S. companies would rather incur the time and expense to move their operations abroad instead of increasing their hiring of U.S. workers, particularly for entry level positions where U.S. workers have been replaced with lower-paid, lower-skilled foreign labor. DHS believes that U.S. employers are more likely to change their hiring practices in the United States, rather than offshoring work abroad, as evidenced by news articles highlighting how more and more companies have signaled their intent to increase their investment in America and hire more U.S. workers rather than to rely on foreign workers.¹⁹ Likewise, DHS is not persuaded by the research cited by a commenter concluding that H-1B “visa restrictions lead to offshoring.”²⁰ This analysis primarily discussed “visa restrictions” in terms of companies unable to hire H-1B workers due to the statutory 65,000 visa cap and not because they were not selected “by pure ‘luck’ of the H-1B lottery process.” However, this rule does not restrict the number of H-1B visas available under the statutory cap, nor does it preclude any company from selection in the H-1B cap selection process.

Comment: Several commenters said large IT companies or outsourcing firms

¹⁹ See, e.g., The White House, TRUMP EFFECT: A Running List of New U.S. Investment in President Trump's Second Term (Aug. 15, 2025), <https://www.whitehouse.gov/articles/2025/08/trump-effect-a-running-list-of-new-u-s-investment-in-president-trumps-second-term/>; Forbes, International Companies Bet Big On America: A New Wave Of US Jobs (Mar. 31, 2025), <https://www.forbes.com/sites/jackkelly/2025/03/31/international-companies-bet-big-on-america-a-new-wave-of-us-jobs/>; Praveen Paramasivam, Reuters, India's Tata Tech to hire more locals in US as Trump cracks down on immigration (Oct. 22, 2025), <https://www.reuters.com/world/india/indias-tata-tech-hire-more-locals-us-trump-cracks-down-immigration-2025-10-23/>; Craig Hale, Techradar Pro, Meta says it wants to invest \$600 billion in US infrastructure and jobs by 2028 (Nov. 10, 2025), <https://www.techradar.com/pro/meta-says-it-wants-to-invest-usd600-billion-in-us-infrastructure-and-jobs-by-2028>.

²⁰ DHS reviewed the research cited by the commenter from the Economic Innovation Group and George Mason University entitled, Unintended Consequences of Restrictions on H-1B Visas (Jan. 28, 2021), <https://www.mercatus.org/research/policy-briefs/unintended-consequences-restrictions-h-1b-visas>.

would disproportionately benefit from this rule, as they are more likely to pay higher wages and could exploit the proposed rule to their advantage, contrary to the intent of this rule. Commenters remarked that this approach would unfairly favor large, established corporations that are able to pay higher salaries, including the large tech companies that are the predominant users of the H-1B program, with one commenter claiming that this weighted lottery system “would exaggerate their dominance of the program.” A commenter remarked that IT companies may end up profiting even more under the proposed rule, while others said that outsourcing companies would be “rewarded” by this rule and fill positions in areas of “less critical need.” A few commenters claimed that the rule will actually increase the number of large IT outsourcing companies selected in the lottery, as these companies generally certify at levels II and III. For instance, a commenter claimed that “large IT outsourcing would be awarded 7.4 percent more visas under the proposed rule than under current policy” while other commenters cited an analysis indicating that large IT outsourcing firms would receive 8 percent more visas under the rule.

In addition to benefitting large outsourcing companies, a commenter said that the proposed system would also benefit other H-1B-dependent employers, even though they pay less than other companies. The commenter explained that large outsourcers and other H-1B-dependent employers pay less than other H-1B employers, but they get certified at higher wage levels because they use H-1Bs for workers in lower-skilled, lower-paid occupations, and provided an analysis to support this contention.²¹ This analysis indicated that the rule would increase the share of selected registrations for H-1B dependent companies by 4 percent.

Response: DHS disagrees with the assertion that the weighted selection process will disproportionately benefit large IT or outsourcing companies and H-1B-dependent employers that use the H-1B program to fill lower-skilled, lower-paid occupations. Under the new selection process, registrations or petitions for positions with salaries that correspond to lower wage levels will have a lower chance of selection than those with salaries that correspond to higher wage levels. This will incentivize

all H-1B cap-subject employers, including outsourcing companies and H-1B dependent employers, to offer higher wages to increase their chances of selection, thereby aligning with the program’s goal of prioritizing highly skilled and highly paid workers.

DHS acknowledges the analysis cited by some commenters that this rule will likely increase the share of selected registrations from large IT outsourcers and, to a lesser extent, H-1B dependent employers. However, this analysis appears to misunderstand the nature of the weighting process which is generally based on the highest wage level that the proffered salary would equal or exceed and is not based purely on Department of Labor (DOL) wage levels. For instance, commenters cited to a report that says: “On the surface, this seems like a merit-based reform: higher wages should mean higher skills. In reality, DOL’s Wage Levels are very different from actual wages. The Wage Level framework was never designed to compare wages across occupations because it measures relative seniority within a job category, not actual pay. There are many workers paid at the highest DOL Wage Level but making below the median American wage, while some at the lowest DOL Wage Level are among the best-paid in the economy.”²² This statement does not acknowledge that the weighted registration process accounts for the actual salary proffered by employers, which could correspond to a higher wage level. For registration purposes, the requirements of the position corresponding to the DOL wage level would only be relevant if OEWS wage data is not available. But even if this analysis were reliable, DHS reiterates that the weighted selection process is not intended to treat any companies or industries better or worse than others. Again, the goal of this rule is to implement a weighted selection process that would generally favor the allocation of H-1B visas to higher-skilled and higher-paid aliens, regardless of company type or industry.

Comment: Commenters wrote that the proposed rule would have a negative impact on the workforce and U.S. economy. Some commenters stated that the proposed rule would negatively impact the United States’ ability to maintain key talent pipelines, asserting that entry-level positions are crucial for developing the future workforce and that removing early-career talent from

the workforce pipeline would harm long-term economic growth. Another commenter remarked that the United States relies on the contributions of global talent for innovation, economic growth, and competitiveness.

A few commenters remarked that new or growing companies, which often hire foreign talent and would be disadvantaged by this rule, create most new U.S. jobs. One commenter asserted that in the technology industry, each H-1B request is associated with an increase of approximately five jobs, while another said that unemployment in technology fields declined from 3.4 percent to 3 percent over the past year, even as the number of H-1B workers remained significant. A commenter pointed out that studies have shown that “high-skilled immigration causes large increases in productivity and economic growth in the United States” and that U.S. firms employing highly skilled international graduates are more likely to expand business, research, and development. Other commenters suggested that high-skilled immigration generates additional domestic employment opportunities, reduces unemployment in certain occupations, and complements U.S. workers rather than replacing them.

Some commenters stated that by making it difficult to hire recent graduates, the rules would interfere with investment and innovation in industries that rely on highly skilled entry-level workers to fill critical roles that cannot be met by the U.S. labor market alone. Similarly, a commenter said that limiting access to H-1B visas for early-career professionals would reduce the flow of new ideas, constrain entrepreneurship, and slow wage growth in high-productivity sectors. Another commenter stated that the proposed rule would reduce the diversity of specialty occupations in the U.S. workforce and weaken innovation. A commenter wrote that instead of benefiting U.S. workers, the rule would “hit entry- and mid-level workers the hardest, blocking young Americans” from certain jobs.

Response: The goal of this rule is to favor the allocation of H-1B visas to higher-skilled and higher-paid aliens. DHS believes the weighted selection process implemented through this rule will best achieve this goal and disagrees that this rule will have a net negative impact on the workforce and the U.S. economy. Instead, DHS believes this rule will incentivize employers to proffer higher wages, or to petition for positions requiring higher skills and higher-skilled aliens that are commensurate with higher wage levels,

²¹ Jeremy Neufeld, The ‘Wage Level’ Mirage: How DHS’s H-1B Proposal Could Help Outsourcers and Hurt U.S.-Trained Talent, Inst. for Progress (Sept. 24, 2025), <https://ifp.org/the-wage-level-mirage/>.

²² Jeremy Neufeld, “The ‘Wage Level’ Mirage: How DHS’s H-1B Proposal Could Help Outsourcers and Hurt U.S.-Trained Talent,” Inst. for Progress (Sept. 24, 2025), <https://ifp.org/the-wage-level-mirage/>.

thereby attracting the best and the brightest employees and promoting innovation across all industries and occupations. DHS further believes that increasing the chance of selection for higher-skilled, higher-paid aliens will encourage competition and better protect the wages, working conditions, and job opportunities of U.S. workers.

Regarding the studies and benefits of high-skilled immigration mentioned by some commenters, DHS acknowledges that high-skilled immigration *in general* can be beneficial to companies, the workforce, and the economy at large. However, these studies and commenters do not acknowledge the specific problem that this rule addresses, which is the abuse of the H-1B program to bring in lower-skilled workers in lower-paid positions. Further, this rule favors the allocation to higher-skilled aliens but does not alter the numerical limitations, such that higher-skilled aliens who are selected and ultimately granted H-1B status may still provide the general benefits that the commenter alludes to, while better protecting the wages, working conditions and job opportunities of U.S. workers. DHS does not agree that the rule will ‘hit entry and mid-level U.S. workers the hardest’ or ‘block young Americans’ from jobs. The commenter offers no data connecting the weighted selection process to reduced job opportunities for U.S. workers. The rule does not change the number of H-1B cap-subject visas. It does not eliminate lower-wage jobs or employers’ ability to hire or train entry-level workers. Employers must comply with statutory and regulatory requirements ensuring that H-1B workers do not adversely affect the wages and working conditions of U.S. workers. The purpose of the rule is not to raise H-1B wages at the expense of U.S. workers. Instead, by improving the probability that higher-wage H-1B positions are selected, the weighted selection process may reduce reliance on lower wage filings and can help preserve more entry- and mid-level employment opportunities for U.S. workers.

Comment: Some commenters remarked that negative impacts to U.S. industries would affect U.S. citizens and young Americans, stating that: losing access to educators would lead to fewer learning opportunities for American students; fewer international engineers would impact mid-sized manufacturers, slowing innovation and hurting U.S. workers who rely on these jobs; fewer international doctors would impact healthcare for Americans; disadvantaging startups reduces opportunities for Americans;

disadvantaging justice and public interest firms that rely on international workers could create inequities in the justice system, ultimately harming U.S. citizens; disadvantaging engineers and architects would shut out mid-sized construction companies, which would slow projects and drive up costs for American homeowners; and disadvantaging companies involved in supply chain operations can increase delivery costs and create delays that would impact American consumers. Another commenter noted that as a U.S. citizen, they may see fewer employment opportunities if research labs that depend on international workers downsize because of the proposed rule. A commenter claimed that the rule would result in costs to the U.S. economy in terms of U.S. employers not having access to necessary skills, which would delay productivity and innovation, disrupt delivery of essential services to the American public, and cause employers to abandon projects or move the projects overseas. The commenter concluded that these costs outweigh the benefits of this rule.

Response: DHS disagrees with the commenters’ assertions that this rule will negatively impact U.S. industries, U.S. citizens, and young Americans. As explained in the other responses throughout this rule, the weighted selection process would likely have little effect on certain occupations, such as professors and doctors, since these occupations are usually cap-exempt or have other immigration pathways for employment in the United States (such as J-1 or the Conrad 30 program for doctors). Regarding small and mid-size companies and startups, these employers will be treated the same as all other employers and have the option to pay any highly sought after beneficiary a higher wage for a better chance at selection. As for opportunities for U.S. citizens, DHS disagrees that they will see fewer employment opportunities at research labs if these labs are not able to hire as many international workers. Rather, DHS anticipates that if these companies hire fewer international workers, they may look to fill such roles with U.S. workers, thereby improving job prospects for U.S. workers.

With respect to the commenter’s assertion that the asserted economic costs of the rule outweigh the benefits, DHS disagrees with this commenter. The commenter did not provide data to support the claimed costs of this rule on the U.S. economy. In addition, this commenter did not consider the costs to U.S. workers who have been displaced or denied employment opportunities, or whose wages have been suppressed, due

to the abuse of the H-1B program. Incentivizing employers to proffer higher wages to aliens seeking H-1B status to increase their chance of selection would indirectly benefit the wages, working conditions, and job opportunities of U.S. workers and mitigate the claimed costs to the U.S. economy that the commenter described.

Comment: Some commenters warned that the proposed rule would create artificial wage inflation, which harms U.S. workers. The commenters claimed that the rule would encourage employers to inflate wages and overpay foreign workers compared to U.S. workers, creating inequity for U.S. workers performing the same work who are paid less.

Response: This rule does not mandate what wages employers must pay their employees and does not mandate employers to pay more for their H-1B workers. Rather, this rule fills in a statutory gap regarding how to administer the H-1B numerical allocations in years of excess demand and does so in a manner that will incentivize employers to employ highly paid, highly skilled workers. Rather than overpaying foreign workers as compared to U.S. workers, DHS believes that U.S. employers that might have petitioned for cap-subject H-1B workers to fill relatively lower-paid, lower-skilled positions may be incentivized to hire available and qualified U.S. workers for those positions. DHS also believes that an employer who offers a higher wage than required by the prevailing wage level only would do so if it was in their economic interest to do so based on the beneficiary’s skill level and relative value to the employer.

Comment: Many commenters said that the proposed rule would negatively affect the United States’ ability to compete for global talent. A commenter said that America’s competitors focus on attracting young talent and the proposed rule would limit the United States’ ability to do the same. Several commenters stated that the proposed rule may cause a “brain drain” or “talent migration” away from the United States, including from certain industries. Some commenters expressed concern that the proposed rule, when viewed alongside other recent immigration policy changes, will negatively impact U.S. companies’ ability to access, retain, and move talent needed for global competition, which they said will diminish the country’s economic security, contrary to DHS’s statutory mission under the Homeland Security Act. Some commenters said that the proposed rule could lead

companies to deprioritize roles in key fields, such as STEM and AI research.

Response: DHS does not agree that this rule will weaken America's competitiveness, harm innovation and entrepreneurship, or lead to "brain drain." On the contrary, DHS believes this rule will strengthen America's competitiveness and innovation by incentivizing and facilitating the admission and retention of higher-paid, higher-skilled foreign workers, including those in key fields, such as STEM and AI research. Under this rule, U.S. employers will have increased access to more talented, higher-paid foreign workers, thus increasing innovation and productivity for these employers and contributing to American competitiveness.

DHS disagrees with the claims that this rule will diminish the country's economic security and is contrary to DHS's statutory mission under the Homeland Security Act. As already discussed earlier in this preamble, the large-scale replacement of U.S. workers through systemic abuse of the program has undermined both the United States' economic and national security. By addressing these abuses, this rule supports the nation's economic and national security and is consistent with DHS's statutory mission under the Homeland Security Act to "ensure that the overall economic security of the United States is not diminished by efforts, activities, and programs aimed at securing the homeland." HSA sec. 101(b)(1)(F), 6 U.S.C. 111(b)(1)(F).

4. Negative Impacts on National Security

Comment: Some commenters expressed opposition to the proposed rule on the basis of national security and strategic interests. A commenter stated that international students account for over half of graduate enrollments in computer science and engineering in U.S. universities, fields that directly contribute to advances in AI, cybersecurity, biotechnology, and semiconductor design—all areas identified by the Departments of War and Commerce as critical to U.S. national security and economic resilience. Other commenters stated that the proposed rule will undermine the global competitiveness of U.S. businesses and negatively impact the overall economic security of the United States. One commenter said that international students in key technical and scientific fields at U.S. universities will be more likely to find post-graduate employment outside the United States if this rule is passed, noting that "competitor countries that recognize the

value of attracting these highly sought-after professionals are strengthening their analogous programs." Another commenter similarly emphasized the importance of retaining foreign students that pursue in-demand degrees at U.S. universities, asserting that it is in the national interest that foreign students completing U.S. graduate degrees apply their skills to advancing U.S. interests, rather than seeking opportunities in their home country or another country with more flexible early-career immigration pathways.

Response: DHS does not believe this rule will disadvantage prospective beneficiaries contributing to advancements that strengthen national security or innovation in critical sectors, and the commenters have not provided evidence that this is likely to occur. A general correlation between degrees obtained by international students and fields that contribute to national security does not demonstrate that this rule will negatively impact critical industries or undermine national security. Rather, DHS believes this rule will incentivize employers to proffer higher wages, or to petition for positions requiring higher skills and higher-skilled aliens that are commensurate with higher wage levels, thereby attracting the best and the brightest employees and promoting advancements and innovation across all industries, including those that are important to national security.

Further, as noted in the H-1B Proclamation, abuses of the H-1B program present a national security threat by discouraging Americans from pursuing careers in science and technology, risking American leadership in these fields. 90 FR 46027 (Sept. 24, 2025). This rule will help reverse this trend of abuse and help strengthen national security.

5. Negative Impacts on Entry-Level Workers and Recent Graduates

Comment: Many commenters expressed concern that the proposed weighted selection process would disproportionately disadvantage recent graduates and entry-level workers, reducing or eliminating their chance of selection. One commenter said that the proposed weighted selection process will penalize early-career, U.S.-educated international talent because the wage levels measure seniority within an occupation and most international students are hired at level I or level II wages, and provided an analysis to support this contention.²³ Commenters

remarked that most new graduates typically start their careers at level I wages due to their limited work experience, but many soon become valuable contributors and leaders and the rule would harm these graduates' ability to be employed, undermine the "education-to-employment pipeline," and harm companies' ability to attract qualified talent in the future. Similarly, some commenters remarked that talent or value is not always correlated with wage level or years of experience, but the proposed rule would create a system that rewards seniority or wage level rather than merit, pushing out the next generation of early-career innovators and harming the companies that employ them. One commenter stated it does not make sense to prioritize older, higher-paid workers who have fewer years left in their career. Commenters also noted that international graduates already have difficulty securing an entry-level role due to lack of U.S. work experience, and the proposed rule would present an additional challenge that is unfair for aliens who had studied in the United States legally and would limit career opportunities for these aliens.

Other commenters wrote that entry-level positions are important and legitimate roles, not examples of program abuse, and represent the natural starting point for professional growth. Commenters reasoned that "blocking" level I beneficiaries from the H-1B program undermines upward mobility and creates an artificial barrier to career development. Some commenters stated that under the current system, level I applicants already face low selection odds of approximately 10–15%, and the proposed weighted system would reduce these chances to "nearly zero," effectively creating what some described as a "de facto ban" on early-career professionals. One commenter said that the probability of a level I applicant being selected would be reduced by 48 percent, and another commenter said the probability of a level I or II applicant being selected could decrease to 15 percent.

Some commenters stated that while their companies' starting salaries for recent graduates are competitive, they cannot compare to big corporations that can offer high salaries. A commenter stated that certain industries generate essential public and economic benefits, but tend to pay less, which does not reflect a lack of skill or potential. Commenters said that the emphasis on wage-based selection could harm the

²³ Jeremy Neufeld, The 'Wage Level' Mirage: How DHS's H-1B Proposal Could Help Outsourcers and

Hurt U.S.-Trained Talent, Inst. for Progress (Sept. 24, 2025), <https://ifp.org/the-wage-level-mirage/>.

nation's long-term interests, and that the U.S. economy benefits from attracting and retaining individuals at all career levels. Another commenter also emphasized that wage level is not dispositive of an employee's contribution value and remarked that limiting the amount of level I and II professionals is not sound economic policy and would lead to negative impacts greater than any benefit derived from higher wages paid to level III and IV employees.

Response: DHS disagrees that this rule would be “blocking” or amount to a “de facto ban” on all entry-level workers or early-career professionals, or that their chances of selection would be “nearly zero.” As stated in the NPRM, DHS recognizes the value in maintaining the opportunity for employers to secure H-1B workers at all wage levels. In this respect, this rule differs from the selection process in the 2021 H-1B Selection Final Rule, through which USCIS would have ranked and selected registrations generally based on the highest equivalent OEWS wage level that the proffered wage equaled or exceeded for the relevant SOC code and area(s) of intended employment, beginning with level IV and proceeding in descending order with levels III, II, and I. The 2021 rule was expected to result in the likelihood that registrations for level I wages would not be selected, as well as a reduced likelihood that registrations for level II would be selected. Conversely, as noted in Table 13 of the NPRM, DHS projects that through the weighted selection process implemented by this rule, those with a level I registration (or petition, as applicable) will have a 15.29-percent probability of being selected to file a cap-subject petition, and those with a level II registration (or petition, as applicable) will have an increased chance of selection as compared to the current random selection process (30.58% up from 29.59%, respectively). DHS believes commenters' claims that this rule would result in a de facto ban or block on early-career professionals are inaccurate and overstated. For instance, prior to implementation of the beneficiary-centric selection process, 780,884 total registrations for 85,000 statutorily capped H-1B visas allocated randomly in cap fiscal year 2024 yielded a mere 10.9-percent probability that a foreign student educated in the United States would ultimately be able to obtain an H-1B cap-subject visa.²⁴

DHS acknowledges that, under this rule, in years of excess demand, relatively lower-paid or lower-skilled positions will have a reduced chance of selection. However, this rule maintains the opportunity for employers to secure H-1B workers at all levels, including recent graduates or those who are just starting out in their professions. Additionally, if an employer chooses to offer a recent foreign graduate a wage that equals or exceeds a particular wage level, the registration will be weighted accordingly, regardless of the beneficiary's experience level or the requirements of the position. In fact, this rule will benefit talented international graduates who are offered wages at higher levels, as they will have a higher chance of selection compared to the current random selection process. DHS notes that this rule does not require any employer to offer higher wages. Rational employers will not offer wages exceeding the expected value of the employee's work. To the extent an employer chooses to offer a higher wage, they are doing so because that higher wage is a clear reflection of the beneficiary's value to the employer.

With respect to the analysis provided by a commenter about the “wage level mirage,” this article appears to misunderstand the nature of the weighted selection process. The weighting process is generally based on the beneficiary's *equivalent* wage level, that is, the highest wage level that the proffered salary would equal or exceed. The weighting process specifically allows for consideration of the proffered salary. Thus, even if a job offer would otherwise be classified as level I under the OEWS wage level structure for Labor Condition Application (LCA) purposes based on the requirements of the position, the beneficiary could still be assigned to a higher equivalent wage level based on a high salary for registration purposes. Furthermore, the analysis grouped firms that registered more than 2,000 H-1Bs in FYs 2021, 2022, 2023, or 2024 together as “outsourcers” to argue that “other companies” with fewer than 2,000 registrations are disadvantaged by this rule because they generally register more level I positions despite paying generally higher salaries. This overlooks the direct impact of the rule on lottery outcomes of those employers of more than 2,000 H-1Bs who, like all other companies, will see fewer level I registrations selected and more level II, III and IV registrations selected. The comment presents no evidence that

these “outsourcers” are more likely to register positions for workers educated outside the United States and neither the comment nor analysis acknowledges that the referenced cap fiscal years 2021–2024 saw exponential growth of eligible registrations for beneficiaries with multiple eligible registrations. Thus, DHS does not find this analysis persuasive.

To the extent that this rule may disadvantage recent graduates and entry level alien workers seeking positions corresponding to a lower wage level, these positions may instead be made available to U.S. graduates and workers starting out in their careers. This result would be consistent with the purpose of the H-1B program, which is to help employers fill labor shortages with highly skilled workers, rather than as a program for employers to use to replace U.S. workers with lower-paid, lower-skilled labor. As noted in the H-1B Proclamation, exploitation of the H-1B program to replace, rather than supplement, U.S. workers with lower-paid, lower-skilled labor has resulted in a disadvantageous labor market for U.S. citizens and especially for U.S. college graduates who are facing higher unemployment rates.²⁵ 90 FR 46027 (Sept. 24, 2025).

Lastly, DHS disagrees that the rule is not sound economic policy. This rule will help the United States attract the best and brightest workers by increasing the chance of selection for highly skilled, highly paid aliens who are more likely to make significant contributions to their employers and industry, while also better protecting the wages, working conditions, and job opportunities of U.S. workers.

Comment: Some commenters stated that this rule would make it more difficult for foreign students, recent graduates, trainees, postdoctoral fellows, and specialists seeking to transition from F-1 to H-1B status through Optional Practical Training (OPT) or STEM OPT extensions so that they can enter the workforce and launch their professional careers. Some commenters stated the proposed rule would limit career paths available in the United States for recent graduates and early-career professionals and would disrupt the F-1 to H-1B pipeline, potentially causing employers to stop hiring students and terminate OPT participants. A commenter remarked that the uncertainty of H-1B selection is already a source of instability for these

²⁴ See Historical Data Table from USCIS H-1B Electronic Registration Process at [https://www.uscis.gov/working-in-the-united-states/temporary-workers/h-1b-specialty-occupations/h-](https://www.uscis.gov/working-in-the-united-states/temporary-workers/h-1b-specialty-occupations/h-1b-electronic-registration-process)

[1b-electronic-registration-process](https://www.uscis.gov/working-in-the-united-states/temporary-workers/h-1b-specialty-occupations/h-1b-electronic-registration-process) (last updated July 18, 2025).

²⁵ Federal Reserve Bank of New York, The Labor Market for Recent College Graduates, <https://nyfed.org/collegelabor> (last updated Aug. 1, 2025) (data from 2023).

individuals and their employers, and the proposed weighted selection process would further disadvantage those in entry-level and research positions. A different commenter noted that OPT is a temporary transitional program and should not be viewed as guaranteed employment for international students, and without a bridge to H-1B status, international students would be “forced to leave” the United States despite years of education and contribution. Another commenter noted that this rule likewise negatively impacts companies who are already employing aliens as part of the F-1 program, but will not be able to transition them to the H-1B program. At least one commenter cited an analysis that found that the proposed selection process would reduce H-1B visas awarded to F-1 graduates by 7 percent despite these graduates earning higher salaries on average than other H-1B workers.²⁶

Response: DHS disagrees. This rule will not preclude F-1 students in the United States from transitioning from OPT to employment under the H-1B visa or “force” such students to leave. As stated in the NPRM, DHS recognizes the value in maintaining the opportunity for employers to secure H-1B workers at all wage levels, including those employers seeking to hire workers in F-1 status. While this rule generally may reduce the chance of selection for relatively lower-paid or lower-skilled positions, it does not create a barrier to being selected in the H-1B lottery.

Further, this rule has no impact on OPT. To the extent that F-1 students are talented and obtain job offers corresponding to high wage levels, this rule may facilitate their ability to transition to the H-1B program.

DHS disagrees with the analysis cited by some commenters about the impact on international students because this article misunderstands the nature of the weighted selection process that generally weights registrations (or petitions, if applicable) based on the highest wage level that the proffered wage will equal or exceed. For example, one commenter cites to data showing that “F-1 students entering the H-1B process earned higher salaries on average than non-F-1 workers, but they were far more likely to be placed at the lowest Wage Levels.”²⁷ Under the

weighted process finalized by this rule, F-1 students who earn relatively high salaries may be ranked at higher wage levels (the wage level that their proffered wage equals or exceeds, if OEWS wage level data is available for that occupation and area of employment) and would not be constrained to the “lowest wage levels” for registration purposes.

Finally, to the extent that this rule does make it more difficult for some F-1 students seeking lower-skilled, lower-paid positions to transition to an H-1B visa, it is important to note that the purpose of the H-1B visa program is not to serve as an early career transition program for foreign students. Instead, the H-1B program was created to help U.S. employers fill labor shortages in positions requiring highly skilled or highly educated workers while protecting the wages, working conditions, and job opportunities of U.S. workers. The entry-level or other lower-skilled, lower-paid positions that these F-1 students may have filled could instead be made available to American students and recent graduates. DHS believes that this rule appropriately balances the interests of U.S. workers with the interests of petitioning employers and the alien workers they seek to employ as H-1B nonimmigrants.

6. Negative Impacts on Mid-Level Workers

Comment: In addition to negatively impacting entry-level professionals, some commenters claimed that this rule would also negatively impact mid-level professionals seeking H-1B visas or status. For instance, a commenter claimed that a mid-wage level employee would be disadvantaged by this rule because they would have a lower chance of selection. A commenter provided an example of a level II professional who is “uniquely qualified to lead a critical project involving cutting-edge technology” and claimed that the level II wage does not diminish the employee’s value. The commenter concluded that “limiting employers’ access to foreign talent at the two lower levels is not sound economic policy.”

Response: DHS disagrees with the assertion that the rule would disadvantage mid-level professionals earning wages corresponding to wage levels II and III. Under the weighted selection process, level II and level III registrations or petitions will still have a reasonable chance of selection, as outlined in the NPRM. Specifically, as noted in Table 13 of the NPRM, DHS projects that these groups will have an increased probability of selection

compared to the current random selection process, with the probability of selection increasing by 3 percent for level II and by 55 percent for level III. As noted previously, the weighted selection process is designed to incentivize employers to offer higher wages, which generally correlate with higher skill levels, while maintaining opportunities for employers to secure H-1B workers at all wage levels. This approach strikes a balance between prioritizing highly skilled and highly paid workers and preserving access to foreign talent across all wage levels.

Comment: A commenter claimed that the proposed rule makes it more likely that U.S. companies could shift their talent acquisition policy to favor foreign mid-career to senior-level professionals rather than focusing on hiring recent international graduates from U.S. universities.

Response: As noted, the goal of this rule is to incentivize employers to offer higher wages, or to petition for positions requiring higher skills and higher-skilled aliens, that are commensurate with higher wage levels. A U.S. company shifting their talent acquisition policy to use the H-1B program only for higher-skilled aliens more advanced in their careers aligns with that goal. If a U.S. company wishes to focus its talent acquisition policies on hiring recent graduates, it may focus its search among American graduates.

7. Negative Impacts on International Students

Comment: Many commenters expressed concern about the negative impact the proposed rule would have on international students who are studying at U.S. universities. Commenters stated that these students invest significant time and financial resources to obtain U.S. degrees, often paying substantially higher tuition than domestic students. Some commenters stated that the proposed rule would make it more difficult for these students to secure employment in the United States after graduation, effectively wasting their investment in U.S. education or sending the message that their investment and contributions mean little if they are not also high earners. Another commenter remarked on the many benefits that recent graduates bring, which help global companies.

Many commenters stated that the proposed rule may cause international graduates who studied in the United States to relocate to other countries that actively welcome skilled workers, ultimately harming the U.S. economy and innovation. Some commenters remarked that this rule sends a

²⁶ For the survey cited by the commenters, see Jeremy Neufeld, The ‘Wage Level’ Mirage: How DHS’s H-1B Proposal Could Help Outsourcers and Hurt U.S.-Trained Talent, Inst. for Progress (Sept. 24, 2025), <https://ifp.org/the-wage-level-mirage/>.

²⁷ See Jeremy Neufeld, “The ‘Wage Level’ Mirage: How DHS’s H-1B Proposal Could Help Outsourcers and Hurt U.S.-Trained Talent,” Inst. for Progress (Sept. 24, 2025), <https://ifp.org/the-wage-level-mirage/>.

discouraging signal to prospective international students, who may choose to study in other countries with clearer pathways to employment and immigration. Some commenters noted that because the rule applies to the 20,000 advanced degree exemption, it will deprive the workforce of graduates in high-demand fields.

Another commenter said that tighter H-1B policies will cause the academic profile of international applicants to U.S. schools to worsen, in that the best students are the ones most likely to be discouraged from coming to the United States. This commenter also noted that despite being disproportionately at relatively low wage levels, international students currently appear to have higher average salaries than other H-1B visa holders. The commenter noted that the difference reflects, at least in part, the concentration of petitions for international students in relatively high-wage occupations and areas.

Response: DHS disagrees that this rule will significantly harm international students. First, this rule will not impact the ability of international students to study in the United States, which is the basis of their admission to the United States in student status. While the prospect of future H-1B employment may be a factor in deciding whether to study in the United States, the reputation of the academic institutions themselves is also an important factor for students choosing to study in the United States. DHS also disagrees that this rule will worsen the profile of international students. Conversely, DHS believes this rule will help attract the best and brightest international students, to the extent that they will earn relatively high wages, as they will see their chances of being selected in the H-1B lottery increase compared to the current random selection process. As a commenter pointed out, international students appear to have higher average salaries than other H-1B nonimmigrants, which seems to suggest that international students will generally benefit from this rule, contrary to the commenter's claims.

DHS disagrees that this rule will lead U.S.-educated international students to relocate to other countries. On the contrary, DHS believes this rule will incentivize and facilitate the admission and retention of the best and brightest international students. Facilitating the admission of higher-skilled foreign workers, as indicated by their earning of wages that equal or exceed higher prevailing wage levels, will increase the United States' competitive edge in attracting the "best and the brightest" students in the global labor market,

consistent with the goals of the H-1B program. DHS also reiterates that recent graduates with master's or higher degrees from U.S. institutions of higher education already benefit from the existing advanced degree exemption and cap selection order.

Comment: Some commenters stated that the proposed rule would discourage foreign students from studying in the United States, citing a survey of international graduate students in the United States conducted by the Institute for Progress and National Association of Foreign Student Advisers (NAFSA): Association of International Educators.²⁸ Specifically, commenters cited the survey results finding that 53 percent of international graduate student respondents would not have enrolled in U.S. universities if "access to H-1B visas was determined by wage levels." The same survey also found that 48 percent of master's students, 52 percent of Ph.D. students, and 38 percent of postdoctoral respondents, who said they are currently likely to try to obtain another visa under current rules, would not do so if access to H-1B visas was determined by wage levels.

Response: DHS reviewed the survey results and does not find them convincing.²⁹ In pertinent part, the survey concluded that "53% of respondents said they would not have enrolled in the first place if access to H-1B was determined by Wage Levels." However, this rule will not result in "access to H-1B [being] determined by Wage Levels." Again, this final weighted selection process will maintain the opportunity for employers to secure H-1B workers at all wage levels and thus does not preclude "access" to the H-1B program. While selection will be weighted generally based on corresponding wage level, it will not be "determined" by wage levels. This final rule also does not affect H-1B petitioners who are exempt from the H-1B cap. Similarly, the relevant survey question asked: "Think back to your decision to enroll in a US program. If eligibility to work for a for-profit employer after graduation were out of reach unless you are compensated at the highest levels and above the median wage for all Americans working in your occupation, including those

most experienced, how likely would you have been to enroll in a degree-granting program in the US?" The survey question itself was inaccurate. This wage-based selection rule does not impact eligibility for H-1B classification. It also does not make selection in the H-1B registration "out of reach" as this rule does not create a barrier to getting an entry level job and being selected in the registration.

Comment: Some commenters discussed how the proposed rule would have a negative impact on businesses supported by foreign students and faculty who provide important economic contributions. Some commenters pointed to data indicating that international students contribute billions to the U.S. economy through direct spending and support hundreds of thousands of jobs, stating the rule would be a setback for those contributions. Some commenters similarly remarked that lower enrollment of foreign students would mean losing the boost to local economic activity and jobs that they bring, and would have "ripple" or "cascading" effects on businesses that support colleges and universities, including service providers, such as restaurants and retail stores. One such commenter cited Institute of International Education (IIE) Open Doors data estimating the contribution of foreign students to the United States economy to be \$44.7 billion from 2018–2019. Another commenter suggested that in 2026, a 40 percent plunge to approximately 657,000 students would eviscerate \$17.5 billion and 151,000 jobs. A different commenter similarly expressed that NAFSA reports that international students contribute \$43.8 billion to the U.S. economy and create or support 378,175 jobs.

A commenter said that new international graduates also support the local economies by paying rent, shopping in local stores, and volunteering. A different commenter remarked that the proposed rule will remove the ability of international graduates of U.S. universities to transition into the workforce, and asserted that the resulting loss in innovation output, startup formation, and tax generation would be staggering. The commenter suggested that the cumulative impact could exceed \$1–2 trillion in lost economic productivity. The commenter expressed that declining international enrollment would create a chain reaction, causing a collapse in university revenues, layoffs and program closures, local economic contraction, reduced tax bases, and weakened national

²⁸ The commenters cited the September 15, 2025, survey, "Surveys on International Talent Pipeline" conducted by the Institute for Progress and NAFSA: Association of International Educators.

²⁹ DHS reviewed the survey results available at Institute for Progress and NAFSA: Association of International Educators, Surveys on International Talent Pipelines (Sept. 15, 2025), <https://ifp.org/wp-content/uploads/2025-Surveys-on-International-Talent-Pipelines-1.pdf>.

competitiveness. Some commenters stated that new international graduates often are employed outside of major metropolitan areas, and that businesses in these areas rely on new graduates to support development, technical workflows, and business growth. Some commenters remarked that concentrating international students in major cities would strain infrastructure and increase housing costs.

Response: DHS disagrees with these commenters. Since this rule does not impact the ability of international students to study in the United States, it does not take away the economic and other benefits these international students provide for their local economies and communities. In addition, DHS disagrees that this rule removes the ability of international graduates to enter the workforce. While this rule may disadvantage some recent graduates to the extent that they have job offers with salaries at relatively lower wage levels, this rule does not prevent recent graduates on F-1 status from transitioning to H-1B status. Rather, the rule will generally favor the allocation of H-1B visas to higher-skilled and higher-paid aliens while maintaining the opportunity for employers to secure H-1B workers at all wage levels, without disadvantaging employment opportunities for recent American graduates in the same or similar fields.

Further, this rule will facilitate the admission of higher-skilled workers. Facilitating the admission of higher-skilled foreign workers, as indicated by their earning of wages that equal or exceed higher prevailing wage levels, is expected to increase the United States' competitive edge in attracting the "best and the brightest" in the global labor market and benefit the economy. H-1B workers earning higher wages as a direct result of this rule are likely to increase, not decrease, many of the economic impacts that were described by commenters, such as housing or shopping in local stores.

Comments citing Open Doors data and NAFSA analysis provided no evidence or rationale for their own beliefs that the rule would result in reduced enrollment and dire cascading effects. DHS again emphasizes that the weighted-selection mechanism preserves the possibility that level I registrations will be selected. Open Doors' data on enrollment trends show total number of international students has grown every year since 2004/2005 with the exception of temporary declines in 2019/2020 and 2020/2021

due to COVID-19.³⁰ DHS notes that this growth in international students occurred despite decades of generally diminishing probability of obtaining an H-1B cap-subject visa.³¹ Open Doors data affirm international students' motivations for studying in the United States are complex and unlikely to exhibit the sensitivity commenters speculated would lead to a collapse of this talent and innovation pipeline.³²

8. Negative Impacts on STEM Fields

Comment: Multiple commenters remarked on negative impacts on international graduates and workers with degrees in STEM fields as well as on their employers that depend on them. Many commenters remarked that recent graduates often bring the most current knowledge in rapidly evolving fields like AI, clean energy, climate science, public health, machine learning, semiconductors, bioinformatics, and biotechnology, and that they play indispensable roles on their teams. Commenters stated that the rule would lock out entry-level STEM graduates trained in U.S. universities, wasting U.S. educational investment, and preventing those graduates from contributing to the U.S. economy. Commenters remarked that the United States competes for a global talent pipeline, especially in areas, such as STEM, biotechnology, AI, data infrastructure, cybersecurity, semiconductors, quantum computing, advanced manufacturing, and

healthcare, and that this rule would undermine the talent pipeline in these fields. A commenter cited data that foreign nationals comprise a significant percentage of U.S. college graduates in STEM fields, and noted that "U.S. employers aggressively recruit the top students from U.S. colleges and universities to fill early career positions that leverage their skills." This commenter similarly concluded that the rule would erode the pipeline of "highly educated and talented professionals, of which foreign students are a critical component pipeline." Similarly, another commenter cited data showing that foreign students represent the majority of STEM masters and Ph.D. graduates in the United States, many of which are entering the labor market for the first time.

Commenters also specifically addressed the proposed rule's negative impact on science and technology more generally, including in AI, robotics, machine learning, quantum computing, cybersecurity, electronics design and manufacturing, semiconductor manufacturing, biotechnology, digital health, automation, and data analytics fields or industries.

The commenters expressed that their companies and industries rely on access to global talent through the H-1B program, and that they will be harmed without access to this talent. Some commenters claimed that there is not sufficient domestic talent in STEM fields, which is why they need continued access to the H-1B program. A commenter claimed that this rule would go against President Trump's efforts to increase investments in the U.S. semiconductor industry.

Response: DHS disagrees with these commenters. This rule will not preclude early-career STEM graduates from being selected in the H-1B lottery. While this rule generally may reduce the chance of selection for an early-career STEM graduate who is relatively lower-paid, it does not create a barrier to getting an entry level job and being selected in the H-1B cap selection process. Additionally, this rule incentivizes employers to offer a wage that equals or exceeds a higher wage level for a beneficiary with desirable skills, regardless of the beneficiary's experience level or the requirements of the position, in order to increase a beneficiary's chance of selection in the H-1B lottery. Thus, contrary to commenters' claims, DHS believes this rule will facilitate the admission and retention of the best and brightest international students and enhance the talent pipeline in STEM fields.

³⁰ See IIE Open Doors, International Students, Enrollment Trends <https://opendoorsdata.org/data/international-students/enrollment-trends/> (last visited Nov. 24, 2025).

³¹ In general, the number of H-1B cap-subject petitions received in the years before registration, and the number of registrations submitted in the years before the beneficiary centric selection process, has trended upwards each year whereas the statutory cap has remained the same at 85,000 per year. See, e.g., USCIS, H-1B Registration Process (last updated July 18, 2025), <https://www.uscis.gov/working-in-the-united-states/temporary-workers/h-1b-specialty-occupations/h-1b-electronic-registration-process> (showing the increasing number of registrations from cap years FY2021 through FY2024 prior to the beneficiary centric process); "Registration Requirement for Petitioners Seeking to File H-1B Petitions on Behalf of Cap-Subject Aliens" 84 FR 888, 928 (Jan. 31, 2019) (table 6 showing the generally increasing numbers of H-1B cap-subject petitions received from cap years FY2013 through FY2017).

³² See Daniel Obst & Joanne Forster, IIE, Country Report: USA, Perceptions of European Higher Education in Third Countries (2007), <https://www.iie.org/wp-content/uploads/2022/12/International-Students-in-the-US.pdf>. Table 10 shows improving chances for an international career is a strong motivation, but not the only motivation for studying in the United States. Table 17 shows that complicated visa procedures/strict requirements were an obstacle to foreign students planning to remain in the United States, but many other obstacles are not related to an expectation of H-1B employment after college.

To the extent that this rule will disincentivize U.S. companies to hire fewer low-skilled, low-wage foreign STEM workers, DHS views this as an overall benefit to U.S. workers. First, these companies could instead be incentivized to hire qualified U.S. workers to fill STEM positions, including those U.S. workers who have STEM degrees but are currently unemployed or underemployed.³³ As highlighted in the H-1B Proclamation, a recent study indicated that in 2023, unemployment among recent computer science and computer engineering graduates was high as compared to graduates with other majors.³⁴ 90 FR 46027 (Sept. 24, 2025). Notably, the abuse of the H-1B visa program has made it even more challenging for college graduates trying to find IT jobs, allowing employers to hire foreign workers at a significant discount to U.S. workers. 90 FR 46027 (Sept. 24, 2025). Observers have written that there are plenty of qualified U.S. workers with STEM degrees or pursuing such degrees who are seeking employment in these fields.³⁵

³³ See, e.g., Adam Hardy, Money, Recent College Grads are Discovering That a STEM Degree Doesn't Guarantee a Stable Job (May 30, 2025), <https://money.com/college-grads-stem-degrees-unemployed/> (citing data from the Federal Reserve Bank of New York and separate data from the National Association of Colleges and Employers (NACE) reflecting declining career prospects for U.S. graduates with bachelor's degrees in certain STEM majors, including computer/information sciences and mathematics/statistics); Andrew Mark Miller, Fox News, '3 headed monster': Expert reveals how H-1B visa program is crushing American college graduates (Oct. 27, 2025), <https://www.foxnews.com/politics/expert-reveals-3-headed-monster-crushing-american-college-graduates-as-trump-makes-strikes-on-h1b-visas> ("unemployment rate for college graduates with those degrees is significantly higher than the average for all college graduates and there is a "concerning" level of unemployment with college graduates in IT.").

³⁴ Federal Reserve Bank of New York, The Labor Market for Recent College Graduates, <https://nyfed.org/collegelabor> (last updated Aug. 1, 2025) (data from 2023).

³⁵ See, e.g., Ron Hira, Is There Really a STEM Workforce Shortage? Issues in Science and Technology (Summer 2022), <https://issues.org/stem-workforce-shortage-data-hira/> (Unemployment rates for computer occupations indicates that "there are too many educated, experienced STEM workers who are trying to find a job; there is not a shortage of them."); Rachel Rosenthal, Bloomberg, Tech Companies Want You to Believe America Has a Skills Gap But what they really want is a steady supply of cheap, dependent IT workers (Aug. 4, 2020), <https://www.bloomberg.com/opinion/articles/2020-08-04/big-tech-wants-you-to-believe-america-has-a-skills-gap> ("The IT industry is 'awash with supply' and citing data that "U.S. students are both interested and capable of doing this kind of work"); Steven Camarota, Center for Immigration Studies, New data show no STEM worker shortage (Sept. 17, 2024), <https://cis.org/Oped/New-data-show-no-STEM-worker-shortage>.

Second, companies that have historically relied on a steady pool of lower-skilled, lower-wage foreign STEM workers could instead be incentivized to hire highly skilled foreign workers who would be more likely to supplement, rather than replace, U.S. workers. Many of these companies are the same companies that have laid off their U.S. workers and replaced them with low-paid H-1B workers. Again, as highlighted in the H-1B Proclamation, reports indicate that many U.S. tech companies have laid off their qualified and highly skilled U.S. workers and simultaneously hired thousands of H-1B workers.³⁶ 90 FR 46027 (Sept. 24, 2025). Information technology firms, in particular, have prominently manipulated the H-1B system, significantly harming U.S. workers in computer-related fields. The high numbers of relatively low-wage workers in the H-1B program undercut the integrity of the program and are detrimental to U.S. workers' wages and labor opportunities, especially at the entry level, in industries where such low-paid H-1B workers are concentrated. In fact, workers in computer related fields have seen virtually no real wage growth in decades; and real wages for all types of engineers as well as several other STEM occupations, including software developers, have stagnated or even declined in the past decades.³⁷

³⁶ See, e.g., Crunchbase, The Crunchbase Tech Layoffs Tracker (last updated Nov. 19, 2025), <https://news.crunchbase.com/startups/tech-layoffs/>; Daniel Costa & Ron Hira, Tech and outsourcing companies continue to exploit the H-1B visa program at a time of mass layoffs (Apr. 11, 2023), <https://www.epi.org/blog/tech-and-outsourcing-companies-continue-to-exploit-the-h-1b-visa-program-at-a-time-of-mass-layoffs-the-top-30-h-1b-employers-hired-34000-new-h-1b-workers-in-2022-and-laid-off-at-least-85000-workers/>; Reuters, Lawmakers seek answers from major US firms over H-1B visa use amid layoffs (Sept. 25, 2025), <https://www.reuters.com/business/finance/us-lawmakers-scrutinize-tech-firms-over-h-1b-visa-use-amid-other-job-layoffs-wsj-2025-09-25/>.

³⁷ See, e.g., Ron Hira, Is There Really a STEM Workforce Shortage? Issues in Science and Technology, (Summer 2022), <https://issues.org/stem-workforce-shortage-data-hira/> ("After accounting for inflation, real wage growth was minimal or negative: real wages for computer and mathematical occupations declined by 0.4% over the five-year period [between 2016 and 2021]."); Hal Salzman, Daniel Kuehn, & B. Lindsay Lowell, Economic Policy Institute, Guestworkers in the high-skill U.S. labor market (Apr. 24, 2013), <https://www.epi.org/publication/bp359-guestworkers-high-skill-labor-market-analysis/> ("Wages have remained flat, with real wages hovering around their late 1990s levels" and concluding that "the United States has more than a sufficient supply of workers available to work in STEM occupations.").

9. Negative Impacts on Academic Institutions

Comment: Some commenters expressed concern that the proposed weighted H-1B selection process would negatively impact U.S. universities and higher education institutions. Commenters stated that the rule would reduce the attractiveness of U.S. universities for international students and undermine the competitiveness of U.S. higher educational institutions. Commenters stated that international students provide essential tuition revenue for U.S. universities, which this rule would threaten. At least one commenter claimed that international students essentially subsidize domestic students at U.S. colleges and universities, making it cheaper for U.S.-born students to receive higher education and cushioning public universities' budgets in the face of declining state appropriations. Some commenters acknowledged that U.S. institutions of higher education are exempt from the H-1B cap, but that the proposed changes to the H-1B selection process would still have negative, and potentially long-term, effects on U.S. higher education. A commenter mentioned that the U.S. higher education system would be destabilized by the proposed rule as it recovers from low enrollment and financial strain due to the Coronavirus Disease of 2019 (COVID-19) pandemic. Commenters also noted that international students provide other types of benefits to educational institutions and their surrounding communities, including exposure to new ideas and cultures.

A commenter referenced a survey conducted by NAFSA estimating a possible 30 to 40 percent drop in foreign student enrollment for the 2025–2026 academic year, which could have a significant impact on the U.S. economy.

Response: DHS does not believe that this rule will have a significant negative impact on the ability of U.S. colleges and universities to recruit talented international students. To the contrary, DHS believes this rule is more likely to enhance an academic institution's ability to attract the best and brightest international students through offering them an increased chance of H-1B employment if they secure a job offer at a salary that corresponds to a higher wage level. To the extent that this change will negatively affect the ability of some colleges and universities to recruit lower-skilled or less-experienced international students, DHS believes that any such harm will be outweighed by the benefits of better ensuring that initial H-1B visas and status grants

would more likely go to higher-paid, higher-skilled beneficiaries. Facilitating the admission of higher-skilled foreign workers, as indicated by their earning of wages that equal or exceed higher prevailing wage levels, would benefit the economy and increase the United States' competitive edge in attracting the "best and the brightest" in the global labor market, consistent with the goals of the H-1B program discussed in the NPRM. Concerning the survey the commenter referenced, the commenter did not indicate that there was a correlation between the potential change in international student enrollment and this rule.³⁸ Further, DHS expects this rule to have a positive effect on the economy, which could counteract any negative economic effects caused by a potential drop in enrollment. Regarding the cultural benefits that international students provide, DHS reiterates that this rule will not ban international students from coming to or remaining in the United States, so this aspect is unlikely to be affected.

Comment: Commenters remarked that this rule would negatively impact U.S. universities to attract the best students because many students select the United States for the opportunity to work in the United States following graduation. Some of these commenters specifically addressed the OPT program and the possibility of F-1 students transitioning to an H-1B visa. The commenters stated that this rule risks deterring international students who wish to study in the United States specifically because of the prospect of OPT employment. Some commenters stated that the proposed rule would create a policy contradiction: the government issues student visas, allows OPT, and promotes U.S. degrees as a pathway to opportunity, but then erects a barrier to getting the first job.

Response: DHS does not believe that this rule creates a policy contradiction or threatens the pipeline of students who wish to study in the United States. This rule will not impact the ability of international students to study in the United States, which is the basis of their admission to the United States in F-1

nonimmigrant status. Further, this rule has no impact on OPT. While this rule generally may reduce the chance of selection for relatively lower-paid or lower-skilled positions, it does not create a barrier to getting a job on OPT or transitioning to H-1B nonimmigrant status. Rather, as explained previously, for international students who are offered jobs with a salary that corresponds to a higher wage level, this rule increases their chance for selection in the H-1B cap selection process as compared to their chances in the current random selection process.

Comment: Some commenters opposed the proposal because they reasoned it would harm research, stating that universities and research labs depend on international students and graduates. For instance, a commenter stated that entry-level graduates are essential to the future of the U.S. workforce as they often work in research labs, develop new technologies, and fill important roles. Another commenter said master's and Ph.D. graduates perform a disproportionate share of research labor and contribute to Federal grant deliverables, and denying them equitable access to H-1B visas reduces the return on public and private educational spending. A different commenter noted that research labs depend on international workers, and that if research labs cannot obtain the foreign workers they need, then this rule could also harm U.S. students who wish to work in research labs after graduation. Similarly, a commenter wrote that the large population of international students in STEM doctoral programs and federally funded labs generate patents, publications, and breakthroughs, significantly contributing to U.S. scientific discovery. The commenter stated discoveries in labs can emerge from researchers who begin in wage level I positions and eliminating these positions through the proposed rule would lead to fewer advancements, and reduced U.S. influence in global research.

Response: DHS disagrees with the assertions that this rule will harm research or research facilities. The weighted selection process implemented through this rule impacts the probability of selection towards the H-1B cap. H-1B petitions for aliens who are employed by, or have received offers of employment at, U.S. institutions of higher education, nonprofit entities related to or affiliated with U.S. institutions of higher education, or nonprofit research organizations or governmental research organizations are exempt from the H-1B cap. See INA sec. 214(g)(5), 8 U.S.C.

1184(g)(5). Many employers and aliens described by these commenters would be cap-exempt and therefore not impacted by this rule. In FY 2025 alone, USCIS approved over 49,000 petitions that qualified under one of these cap exemptions.³⁹ In the scenarios where researchers are not cap-exempt, DHS believes this rule will have a positive impact by increasing the chance of selection for highly paid, highly skilled foreign researchers and encouraging employers to hire American graduates for research positions instead of lower-paid aliens. Additionally, DHS disagrees with the concern that level I positions will be eliminated by this rule. The weighted selection implemented through this rule favors the allocation of H-1B visas to higher-skilled and higher-paid aliens while maintaining the opportunity for employers to secure H-1B workers at all wage levels.

Comment: Some commenters said the rule would decrease U.S. universities' access to or ability to recruit international faculty. One commenter asserted that wage-based weighting could exacerbate dental faculty shortages at schools accredited by the Commission on Dental Accreditation and could thereby limit access to dental education.

Response: DHS disagrees that this rule will decrease the ability of academic institutions to recruit or retain international faculty. Again, this rule will increase the chance of selection for those who will be paid a wage that corresponds to higher wage levels and thus is more likely to facilitate the selection of higher paid, higher skilled international faculty for cap-subject H-1B status.

Also, many petitions for U.S. universities and other academic institutions of higher learning will likely not be affected by this rule. Congress already exempted from the annual H-1B cap aliens who are employed by, or have received offers of employment at, U.S. institutions of higher education, nonprofit entities

³⁸ The commenter cited to a Fall 2025 International Student Enrollment Outlook and Economic Impact survey conducted by NAFSA: Association of International Educators (Aug. 8, 2025), <https://www.nafsa.org/fall-2025-international-student-enrollment-outlook-and-economic-impact>. DHS reviewed the survey. The survey listed four factors as driving the claimed decline in international student enrollment: visa interview suspension, limited appointment availability, visa issuance trends, and visa bans. All four factors specifically relate to visa issues, not the H-1B registration process.

³⁹ DHS, USCIS, OPQ, CLAIMS 3 and ELIS, queried 10/2025, PAER0019172. Approvals of Petitions from Cap Exempt Employers, By Cap Exemption and New Employment and Renewal/Amendment Filings, October 2025. This data shows the following breakdown for total cap-exempt H-1B approvals in FY25: 24,835 for institutions of higher education; 19,866 for affiliated or related nonprofit entities; 5,654 for nonprofit research organizations or governmental research organizations; and 3,634 for beneficiaries employed at a qualifying cap exempt entity. This data further shows total cap-exempt approvals in the above categories as follows: 25,452 for New Employment and 23,901 for Renewals/Amendments. Some petitioners selected "Yes" on multiple questions, which is why the totals are higher than the sum of the individual categories.

related to or affiliated with U.S. institutions of higher education, and nonprofit research organizations or government research organizations. *See* INA sec. 214(g)(5), 8 U.S.C. 1184(g)(5). In FY 2025 alone, USCIS approved over 24,000 petitions for petitioners who were cap exempt as an institution of higher education.⁴⁰

Comment: Some commenters expressed concern that the proposed weighted selection process would negatively impact public and private schools that are already experiencing difficulties recruiting qualified K–12 teachers in certain areas, such as STEM subjects. Some of these commenters specifically noted the difficulties faced by public schools, particularly in rural, low income, or other underserved communities. These commenters stated that the rule would harm such schools, leaving them without critical staff. Another commenter, expressing concern over the rule's impact on public schools, stated that public school districts cannot adjust salaries to compete for higher wage levels, because teacher compensation is determined by state or district salary schedules which are established through statute or collective bargaining. The commenter emphasized the importance of prioritizing all qualified educators, including those at entry or mid-career level likely to be at level I or level II wage levels.

Response: Some public schools may be exempt from the H–1B cap based on their affiliation with U.S. institutions of higher education. For those public or private schools that are not cap-exempt and are unable to proffer wages that equal or exceed prevailing wage levels with greater chances of selection, including those with compensation levels outside of the employer's control, they may be able to find available and qualified workers outside of the H–1B program, including U.S. workers.

10. Negative Impacts on the Healthcare Sector

Comment: Multiple commenters said the proposed rule would have a negative impact on the healthcare sector. A commenter stated that International Medical Graduates (IMGs)⁴¹ account for

significant portions of healthcare personnel, with others noting that H–1Bs are heavily utilized in the field. Some commenters stated that when hospitals face staffing shortages, in specialized areas and generally, international medical professionals help fill gaps in the workforce and that a weighted selection would limit access to qualified healthcare workers. Some commenters cited a U.S. Department of Health and Human Services statistic estimating a shortfall of around 187,000 physicians by 2037. Another commenter also noted that the proposed rule could encourage highly qualified, early-career physicians to practice in other countries. A commenter noted that international doctors were critical during COVID–19 and, without them, public health crises would be harder to manage.

Numerous commenters remarked that critical fields, such as healthcare, may offer lower starting salaries compared to other sectors and said that the proposed rule would “restrict access to international experts” who rely on H–1B visas to work in these sectors. Another commenter, expressing concern about eliminating a healthcare talent pipeline, wrote that healthcare professionals in their required training period are in level I or level II positions and that level I wages reflect the cost structure of supervised practice. Another commenter, using the healthcare industry as an example of industries whose wage structures are incompatible with the proposed rule, wrote that medical residents and fellows, despite being some of the most highly educated workers in the United States, earn wages that would typically be categorized as level I, leading to a reduced probability of being granted H–1B status and an exacerbation of the physician shortage.

More than one commenter wrote that hospitals and healthcare systems cannot easily meet higher wage levels or absorb compliance costs, particularly small to mid-sized healthcare providers. Another commenter remarked that the OEWS system under the proposed rule does not reflect healthcare compensation schemes, which often use standardized pay scales determined by facility budgets and Medicare reimbursement. One commenter predicted that adoption

of the final rule would lead to consolidation in the healthcare field and higher costs for patients. Another commenter suggested that non-profit hospitals, even in urban areas, would be at a disadvantage compared to for-profit corporations, creating disparities within the same city.

A commenter noted that wages for physicians vary by medical specialty. The commenter expressed concern about the impacts of the rule on primary care physicians, stating that primary care physicians' wages tend to be lower than the wages of procedure-oriented specialists. The commenter stated the rule could incentivize IMGs to apply for higher paying subspecialty positions to increase their chance of selection, which would further exacerbate shortages in lower paying specialties. The commenter stated that the rule will exacerbate shortages in nephrologists and thus lead to an increase in mortality for people burdened by kidney disease.

Similarly, another commenter expressed concern that the new rule would disproportionately disadvantage dentists serving in community health centers and public hospitals and could worsen access to dental care for vulnerable populations, including in underserved and rural areas. The commenter stated that many federally qualified health centers that employ H–1B dentists operate on fixed budgets and cannot match salaries offered by private or technology sectors.

Response: DHS disagrees that this rule will negatively affect the healthcare sector. Many H–1B petitions for healthcare workers are cap-exempt. From FY 2020 through FY 2025, more than 94 percent of H–1B petitions approved for initial employment for physicians, surgeons, and dentists were cap-exempt and thus not subject to the H–1B cap selection process.⁴² In addition, Congress has established programs meant to encourage certain recent foreign medical graduates to serve in the United States as H–1B nonimmigrants. These programs are exempt from the annual H–1B cap and unaffected by this rule. Certain J–1 exchange visitors are subject to a 2-year

⁴⁰ DHS, USCIS, OPQ, CLAIMS 3 and ELIS, queried 10/2025, PAER0019172. Approvals of Petitions from Cap Exempt Employers, By Cap Exemption and New Employment and Renewal/Amendment Filings, October 2025.

⁴¹ DHS notes that some commenters use the term International Medical Graduate (IMG) when addressing this rule. DHS further notes that, as stated in a study cited by a commenter, the term IMG may refer to the location of a physician's medical school, rather than citizenship, and as such IMGs may include U.S. citizens and other aliens not seeking H–1B status. *See* Awad Ahmed, Wei-Ting

Hwang, & Charles R. Thomas Jr., Deville C. Jr., “International Medical Graduates in the US Physician Workforce and Graduate Medical Education: Current and Historical Trends,” *Journal of Graduate Medical Education* (Apr. 1, 2018), <https://jgme.kglmeridian.com/view/journals/jgme/10/2/article-p214.xml>. Regardless, DHS believes responses in this rule sufficiently address commenters' concerns.

⁴² DHS, USCIS, OPQ, Approvals for New Employment with a DOT Code of 070, 071, 072 Listed by Whether Cap Exempt, Receipt Fiscal year 2020 through 2025. CLAIMS3, ELIS, queried 10/2025, PAER0019171, showing that, from FY 2020 through FY 2025, on average more than 94 percent of H–1B petitions approved for initial employment for physicians, surgeons, and dentists were cap-exempt and not subject to the H–1B cap selection process). *See also* 86 FR 1676, 1682 (Jan. 8, 2021) (“Importantly, according to DHS data, in FY 2019, more than 93 percent of H–1B petitions approved for initial employment for physicians, surgeons, and dentists were cap-exempt and thus not subject to the H–1B cap selection process.”).

foreign residence requirement under INA sec. 212(e), 8 U.S.C. 1182(e), which requires them to return to their country of nationality or country of last residence for at least two years in the aggregate prior to being eligible to apply for an immigrant visa; adjustment of status; or certain nonimmigrant visas, including H–1B visas (with limited exceptions). See INA sec. 212(e), 8 U.S.C. 1182(e); INA sec. 248, 8 U.S.C. 1258. However, INA sec. 214(l), 8 U.S.C. 1184(l), contains provisions authorizing waivers of the 2-year foreign residence requirement for certain aliens, including foreign medical graduates who agree to work full-time (at least 40 hours per week) in H–1B classification for not less than three years in a shortage area designated by the U.S. Department of Health and Human Services (HHS) with a request from an interested Federal Government agency or state agency of public health or its equivalent, or with the U.S. Department of Veterans Affairs. See INA sec. 214(l), 8 U.S.C. 1184(l). See also 8 CFR 212.7(c)(9). The petition requesting a change to H–1B nonimmigrant status for these physicians is not subject to the numerical limitations contained in INA sec. 214(g)(1)(A), 8 U.S.C. 1184(g)(1)(A). See INA sec. 214(l)(2)(A), 8 U.S.C. 1184(l)(2)(A). While participation in the Conrad 30 program (relating to waivers based on requests from a state agency of public health or its equivalent for service in an HHS-designated shortage area) is limited to 30 participants per eligible jurisdiction annually, the other programs have no limits on the number of participants. See INA sec. 214(l)(1)(B), 8 U.S.C. 1184(l)(1)(B).

In the scenarios where they are not cap-exempt, DHS believes this rule may have a positive impact for some highly skilled, highly paid aliens. DHS notes that shortages of medical professionals are multi-causal and beyond the scope of one visa category to address. With respect to the ability to offer increased wages generally, DHS acknowledges that healthcare institutions, like employers in all industries, are impacted by a variety of factors in determining employee salary. For employers unable to proffer wages that equal or exceed prevailing wage levels with greater chances of selection, they may be able to find available and qualified workers outside of the H–1B program, including U.S. workers. Additionally, it is possible that aliens filling the positions described by these commenters would be eligible for alternate immigrant or nonimmigrant classifications offering employment authorization.

Further, DHS disagrees with the comment that this rule may unfairly discriminate against primary care physicians who typically have lower annual salaries than certain specialty physicians. In general, family physicians or other primary care physicians have different SOC codes than specialty physicians. As DOL prevailing wage level calculations generally differ by SOC codes, when wage data is available, the corresponding wage level would necessarily account for the different occupational classification for primary care physicians as opposed to other types of physicians. When such wage level data is unavailable, wage level weighting will be based on the skill, education, and experience requirements for the position, again taking into account the particulars of the relevant occupational classification, such that registrations or petitions for primary care physicians will be weighted in comparison to the normal requirements for primary care physicians and not in comparison to other types of physicians. As such, DHS does not believe that this rule will disadvantage registrations or petitions for primary care physicians or any other subset of physicians.

Comment: Some commenters identified other employers and professionals in the healthcare field who would be negatively impacted by this rule, including nurses; pharmacists; laboratory technologists; healthcare IT professionals working in data security, analytics, and telehealth systems who are protecting patient data and furthering innovation; and therapists and counselors providing mental health and other services. Some commenters noted that those in emergency preparedness fields who partner with healthcare workers will be negatively impacted by this rule. These commenters generally stated that the rule would make it financially and logistically difficult for healthcare-related employers to recruit and retain essential staff.

Response: Overall, DHS believes this rule will have a positive impact by increasing the chance of selection for the most highly skilled, highly paid aliens within each SOC code and encouraging companies to hire U.S. workers. For employers unable to proffer wages that equal or exceed prevailing wage levels with greater chances of selection, they may be able to find available and qualified workers outside of the H–1B program, including U.S. workers. DHS notes that shortages in the number, distribution, and specialties of medical professionals are multi-causal and beyond the scope of

one visa category to address. DHS believes that this rule will promote the interests of U.S. workers—and those students and trainees who are future workers—in line with administration priorities. Additionally, it is possible that aliens filling the positions described by these commenters would be eligible for alternate immigrant or nonimmigrant classifications offering employment authorization.

11. Negative Impacts on Rural or Underserved Communities

Comment: Multiple commenters stated that the proposed rule would have a particularly negative impact on healthcare in rural and underserved areas with one commenter noting the unique and complex challenges faced by patients in rural areas. A commenter stated that in falsely assuming high-skilled workers are paid a higher wage, the rule devalues high-skilled physicians in underserved areas and could lead to the consolidation of physicians in larger healthcare organizations, leading to greater costs for patients. Some commenters expressed specific concerns that underserved or rural areas that are reliant on international doctors would face difficulties with or lose healthcare access, with one commenter noting such areas could potentially face facility closure. Without citing specific data, a commenter remarked that IMGs are more likely to serve in rural and underserved areas compared to their U.S. counterparts. The commenter said that the proposed rule disincentivizes entering specialty programs with lower wages, further exacerbating primary care shortages in rural and underserved areas. Another commenter similarly opined that because U.S. medical graduates typically apply for and locate in urban and higher-income areas, when non-urban medical facilities lose access to IMGs because of the proposed rule, they would struggle to find alternative healthcare worker options. The commenter reasoned that the result would be the closure of emergency rooms, obstetric services, and specialty care, creating “medical deserts” that require rural residents to travel hours for basic medical care.

Response: DHS acknowledges the important role that foreign physicians may play in providing healthcare in rural and/or underserved communities, including early career and entry level physicians. As explained in response to the previous comments, Congress has established programs meant to direct foreign medical graduates to those communities.

As noted previously, physicians whose nonimmigrant status is changed to H-1B through their participation in any of the three waiver programs in INA sec. 214(l), 8 U.S.C. 1184(l), are not subject to the annual H-1B caps. The Conrad 30 program (relating to waivers based on requests from a state agency of public health or its equivalent for service in an HHS-designated shortage area) is limited to 30 participants per eligible jurisdiction annually. *See* INA sec. 214(l)(1)(B), 8 U.S.C. 1184(l)(1)(B). However, there are no annual limits on the number of aliens who can obtain a waiver through service in an HHS-designated shortage area based on the request of an interested Federal Government agency. Since these programs are not subject to the annual H-1B caps, they will not be affected by this rule and the programs will continue to provide a pipeline for these physicians to serve in HHS-designated shortage areas.

Congress has established a similar statute in the immigrant context, which also channels physicians to serve in HHS-designated shortage areas, commonly known as the Physician National Interest Waiver Program. *See* INA sec. 203(b)(2)(B)(ii)(I), 8 U.S.C. 1153(b)(2)(B)(ii). That program has no limits on the number of physicians who can participate in a given fiscal year, though there are numerical limitations on the number of employment-based immigrant visas that can be allocated annually. This program is unaffected by this rule and will continue to provide a pipeline for an unlimited number of physicians to serve in HHS-designated shortage areas.

DHS acknowledges that some alien physicians seeking to serve in rural or underserved areas would be subject to H-1B numerical limitations. DHS is aware that medical institutions in rural or underserved areas may not be U.S. institutions of higher education, related or affiliated non-profit entities, or non-profit research organizations or governmental research organizations and, as a result, aliens who are employed by or who have received an offer of employment from such medical institutions may not be exempt from the annual H-1B numerical limitations under INA sec. 214(g)(5), 8 U.S.C. 1184(g)(5). DHS also acknowledges that not all alien physicians who serve in rural or underserved areas as H-1B nonimmigrants are participating in the waiver programs of INA sec. 214(l), 8 U.S.C. 1184(l). However, some medical institutions in rural or underserved areas do meet the requirements to be cap-exempt, and their employees will not be subject to the numerical

limitations.⁴³ To the extent these physicians are subject to H-1B numerical limitations, DHS believes this rule will have a positive impact by increasing the chance of selection for highly skilled, highly paid aliens. Additionally, it is possible physicians may avail themselves of alternative pathways to serve in these areas.

Further, as with all other registrations, DHS will weigh and select registrations for these positions generally according to the highest OEWS prevailing wage level that the proffered wage equals or exceeds, which necessarily takes into account the area of intended employment when such wage level data is available. Where there is no current OEWS prevailing wage information for the proffered position, which DHS recognizes is the case for some physician positions based on limitations in OEWS data, the registrant would follow DOL guidance on prevailing wage determinations to determine which OEWS wage level to select on the registration. The determination of the appropriate wage level in those instances would be based on the skill, education, and experience requirements of the position, and generally does not take into consideration the area of intended employment. Therefore, DHS does not believe that this rule necessarily will disadvantage rural and/or underserved communities relative to registrations or petitions based on offers of employment in other areas.

Comment: Expressing concern about the impact of the rule on rural healthcare, a commenter pointed specifically to the impact on nurses in H-1B status, stating that in fiscal year 2025, 34 out of the 367 nurses they hired were on H-1B visas. The commenter interpreted data presented in the NPRM as stating that nurses will be treated as a level I position, disadvantaging them as compared to certain other SOC codes.

Response: DHS disagrees with the commenter's blanket assumption that nurses will be treated as a level I position or will be disadvantaged compared to other SOC codes. DHS aims to incentivize employers to offer higher wages, or to petition for positions requiring higher skills and higher skilled aliens that are commensurate with higher wage levels, across all

occupations. Under this rule, registrations (or petitions, as applicable) will be weighted generally based on the highest OEWS wage level that the prospective beneficiary's proffered wage equals or exceeds for the relevant SOC code in the area(s) of intended employment. Employers may choose to offer a higher wage to a prospective beneficiary whose skill level they value and who they wish to retain to increase that beneficiary's chances of selection.

12. Negative Impact on Small Businesses, Startups, and Nonprofits

Comment: Several commenters said the proposed rule would have a negative impact on small businesses, startups, and nonprofits. Multiple commenters stated that smaller entities, startups, and nonprofits cannot afford to pay higher wage levels compared to large corporations and often rely on international talent or new graduates to support their business. A commenter said that small businesses and startups will not be able to afford such wage premiums, as they frequently operate with limited capital while offering alternative incentives like equity ownership, stock options, or future profit participation, which would not be recognized under the proposed weighted-lottery selection process. Similarly, commenters wrote that small companies typically lack financial resources or legal staff compared to large corporations with more resources. One commenter did an analysis to show that small businesses would be disproportionately adversely affected by the proposed weighting scheme. This analysis showed that since small businesses disproportionately have petitions at wage levels I and II, their projected share of H-1B visas would fall.

A few commenters specified that the burden of increased compliance, including documenting wage levels, SOC codes, and matching registration and petition data, may disproportionately strain small companies with fewer resources and often without in-house legal or human resources (HR) compliance teams.

One commenter remarked that the proposed rule may deter talented workers who are seeking opportunities at small businesses or startups that typically offer lower wages. Another commenter stated that although the proposed weighted selection process will disadvantage all U.S. companies that have talent needs that are not met by the domestic labor market, the problem will be worse for smaller-sized employers, and especially for small non-profit employers that are not cap-

⁴³ DHS, USCIS, OPQ, Approvals for New Employment with a DOT Code of 070, 071, 072 Listed by Whether Cap Exempt, Receipt Fiscal year 2020 through 2025. CLAIMS3, ELIS, queried 10/2025, PAER0019171, showing that, from FY 2020 through FY 2025, on average more than 94 percent of H-1B petitions approved for initial employment for physicians, surgeons, and dentists were cap-exempt and not subject to the H-1B cap selection process).

exempt. Numerous commenters suggested that the proposed rule would disadvantage veteran-owned businesses that are often small and benefit from specialized international workers. Some commenters remarked that nonprofits help underserved communities and without international experts, vulnerable populations could suffer without support.

Response: This rule does not treat people who work for small businesses, startups, non-profits, or other small-sized entities (including veteran-owned businesses) differently than those who work for large, established companies. While DHS recognizes that some small-sized entities may operate on smaller margins than larger companies, if an employer values a beneficiary's work and the unique qualities the beneficiary possesses, the employer could offer a higher wage than required by the prevailing wage level to reflect that value. This rule will benefit those small entities that are applying for relatively higher-paid employees, as they will have a greater chance of their employees being selected compared to the current random selection process. If a small-sized entity is unable to pay a beneficiary at a higher wage level for a greater chance of selection, they could try to find a U.S. worker. U.S. employers, including small-sized entities, could also consider hiring recent American graduates to meet their business needs while playing an integral part in the U.S. worker's career growth.

DHS acknowledges that this final rule will have an economic impact on small businesses, startups, or other small-sized entities that can only offer a level I wage, as those registrations will have a lesser chance of selection than under the current random selection process. However, as explained in the NPRM, DHS conducted an initial regulatory flexibility analysis and found no other alternatives that achieved the stated objectives with less burden to small entities. 90 FR 45986, 46016 (Sept. 24, 2025). Given that 76 percent of unique cap-subject H-1B filers are small entities, and 47 percent of H-1B cap petitions in FY 2024 were filed by small entities, any alternative process that provides a different, preferential weighting scheme for small entities would undermine the overall utility of this rule, which is to generally favor the allocation of H-1B visas to higher-skilled and higher-paid aliens. And as mentioned previously, it is possible that any alternative that imposes a lower burden on small entities generally could also reduce those employers' chance of selection for higher wage level workers.

DHS also disagrees that the burden of complying with the rule will disproportionately affect smaller employers. As stated in the NPRM, DHS estimates that the changes implemented in this rule would increase the time burden by 20 minutes for each registration and by 15 minutes for each petition, whether completed by an HR specialist, in-house lawyer, or outsourced lawyer. If a smaller employer is using an outsourced specialist for H-1B work in general, the additional paperwork burden associated with this rule is unlikely to be substantial in most cases.

Finally, DHS does not believe this rule will have a significant negative impact on nonprofit organizations. Congress already exempted from the H-1B cap any alien who is employed or has received an offer of employment at a U.S. institution of higher education, a non-profit entity related or affiliated with a U.S. institution of higher education, or a non-profit research organization or a governmental research organization. See INA sec. 214(g)(5), 8 U.S.C. 1184(g)(5); 8 CFR 214.2(h)(8)(iii)(F). Thus, many petitions for nonprofits will not be affected by this rule. For those nonprofit entities that are not cap-exempt and are unable to proffer wages that equal or exceed prevailing wage levels with greater chances of selection, they may be able to find available and qualified U.S. workers.

13. Industry and Occupational Disparities

Comment: Some commenters expressed concern that the proposed rule would disproportionately favor certain industries and occupations over others, as some sectors have more financial resources and are more readily able to absorb the costs associated with offering higher wages. Some commenters said that industries with naturally higher wage structures, such as technology and finance, would have an advantage over sectors with lower prevailing wages, regardless of the importance or skill level of the positions.

Other commenters asserted that the rule would put some industries at a competitive disadvantage. Many commenters said that wage-based selection would privilege existing high-income sectors and reinforce barriers for professionals working in critical lower-paying fields, positions that are often hard to fill and vital to U.S. long-term competitiveness. Some commenters remarked that the proposed rule may have a negative effect on the arts and other creative and recreational

endeavors in the United States. One commenter said that the rule will harm educators, health care workers, and nonprofit professionals. A commenter said that a wage-based selection system is biased against certain professions, particularly lower-paying professions like research, healthcare, urban planning, and civil engineering. This commenter asserted that the additional financial burden of offering higher wages would eliminate some industries' abilities to use the H-1B program. Other commenters wrote that the rule creates a significant bias towards large multinational technology corporations and disfavors the engineering industry, which is already facing a critical labor shortage. One commenter said that architecture, engineering, and construction industries would be disadvantaged under the proposed rule's weighting system, and another commenter suggested that every engineering hire should be in a bracket based on the specific industry, rather than all competing against software engineers. A few other commenters discussed the rule's perceived disproportionate harm on manufacturers, particularly on small- and medium-sized manufacturers and manufacturers in the electro-industry, stating that many jobs in the manufacturing industry fall into lower wage levels. A different commenter suggested that employers, such as universities, hospitals, regional service firms, and manufacturers that maintain distributed or hybrid operations would be penalized. A commenter said that the proposed rule unfairly disadvantages essential infrastructure and public-interest professions—such as civil, structural, environmental, and transportation engineering—whose wages are tied to public-sector pay scales and regional cost-of-living differences rather than individual skill or value to the nation. Citing data on median salaries per wage level, another commenter stated that the proposed H-1B cap selection process disadvantages innovative technology companies that pay significantly higher wages even at lower wage levels, and remarked that the proposed rule fails to fulfill President Trump's directive to prioritize high-paid nonimmigrants, as it does not account for the substantial wage differences between industries and employers at the same wage level.

Other commenters expressed concern that the wage-based weighting system would create a system that prioritizes "roles less important to U.S. interests." The commenters stated that, due to the complex nature of wage level

calculations, there are scenarios where individuals assigned a high wage level in an occupation that the commenter considered less important to national interests would receive more entries in the H-1B lottery than an individual assigned a lower wage level in a more important occupation. The commenter provided examples of how a landscape architect and acupuncturist with higher wage level salaries would have higher chances of selection than an AI researcher, surgeon, or startup executive.

Response: This rule does not, and is not intended to, treat any industries better or worse than others. Nor does this rule seek to prioritize “roles less important to U.S. interests.” DHS acknowledges that, as stated in the NPRM, this rule will likely impact the number of selected registrations for certain SOC codes, with some occupations possibly seeing a decrease in selected H-1B registrations while others seeing an increase. 90 FR 45986, 46008–09 (Sept. 24, 2025). However, the goal of this rule is to implement a weighted selection process that would generally favor the allocation of H-1B visas to higher-skilled and higher-paid aliens, while ensuring meaningful opportunities for selection regardless of industry or profession. An employer could offer a higher wage than required by the prevailing wage level to reflect the value of the prospective employee; an employer that chooses not to do so, or cannot do so, may still enter a registration that would potentially be selected. DHS believes this rule will benefit the best and brightest workers in all professions and industries.

14. Geographic and Regional Disparities

Comment: Some commenters said that the weighted selection process fails to account for regional differences in wage levels, creating geographic inequities and favoring employers in high-wage metropolitan areas while disadvantaging those in regions with lower costs of living and correspondingly lower prevailing wages. Some commenters remarked that talent would concentrate in high-cost regions, such as Silicon Valley and the Bay Area, noting that wages differ substantially by location due to regional cost-of-living variation, not worker skill. Conversely, other commenters claimed that the proposed weighted selection process would benefit companies in lower-cost areas while hurting startups and other tech companies in high-cost hubs like Silicon Valley, with one commenter stating that pushing talent away from such hubs would make these regions less globally competitive.

Some commenters wrote that the rule would exacerbate existing regional economic imbalances by concentrating talent in a few major metropolitan areas and leaving rural areas with talent shortages. Multiple commenters said companies in rural areas providing competitive wages for their location are disadvantaged against employers in high-cost metropolitan areas that can offer higher wages. Some commenters also remarked that the proposed rule would leave rural areas underserved and exacerbate economic inequality. A commenter wrote that the proposed rule would undermine the “billions of dollars” the United States has invested into encouraging regional development in smaller cities. Another commenter said that the proposed rule would create severe economic disruptions in regions that have built their economies around industries that depend on international talent by restricting the flow of such talent.

Response: DHS does not believe that this rule will necessarily disadvantage certain geographic regions as compared with others. As with all other cap-subject H-1B registrations (or petitions), DHS will weight registrations for these positions generally according to the highest OEWS prevailing wage level that the proffered wage equals or exceeds, which necessarily takes into account the area of intended employment. In other words, under this rule, registrations corresponding to the same wage level will be weighted the same regardless of whether their proffered wages are different owing to their areas of intended employment. This final rule neutralizes geographic differences in salary amounts by taking into account the area of intended employment when weighting registrations. DHS therefore does not agree that this rule would disadvantage certain geographic regions, exacerbate existing regional economic imbalances, or undermine regional development. With respect to the commenter’s concern about regions with economies built around specific industries that depend on international talent, DHS disagrees that this rule would restrict the flow of such talent. Instead, the rule will generally favor the allocation of H-1B visas to higher-skilled and higher-paid aliens, while maintaining the opportunity for employers to secure H-1B workers at all wage levels.

15. Negative Impacts on Mixed Compensation Models

Comment: Commenters expressed concern that a wage-based selection process does not consider all aspects of compensation. A commenter pointed

out that while the OEWS data takes into account a range of other types of pay (such as commission, cost-of-living allowance, hazard pay, incentive pay, piece rate, production bonus, and tips,) employers are only allowed to use the base wages when complying with wage requirements in the H-1B program.

Commenters wrote that an employee’s pay can go beyond base pay and can include: bonuses, equity, benefits, commission, cost-of-living allowance, deadheading pay, guaranteed pay, hazard pay, incentive pay, longevity pay, over-the-road pay, piece rate, portal-to-portal pay, production bonus, and tips, with some commenters noting that such incentives may vary by industry. Other commenters expressed concern that small businesses and startups, which often rely on equity compensation, future profit participation, or stock options rather than high salaries, would be particularly disadvantaged. Some commenters said that if only base salary is considered, it would not provide a standardized comparison and could distort the H-1B selection process.

Some commenters remarked that employers relying on equity-based pay may appear to offer lower wages despite competitive packages and cautioned that these employers could inflate base salaries without improving total compensation, potentially distorting the system. Similarly, a commenter remarked that the proposed rule would overlook the challenge of adjudicating disputes about compensation packages that include bonuses, equity, or other non-cash benefits. The commenter stated that because the system privileges base salary alone, employers will be incentivized to overstate base pay on paper while cutting back on other components of total compensation. The commenter expressed concern that this creates enforcement disputes that USCIS is ill-equipped to resolve at scale.

Some commenters suggested that DHS could improve the system by incorporating total compensation, including the cash value of stock and bonuses. A commenter suggested that if wages are considered, it would make sense to consider past Internal Revenue Service (IRS) transcripts of candidates to get a more complete picture of compensation.

Response: DHS recognizes that companies may offer various forms of pay and benefits provided as compensation for services, such as cash bonuses, stock options, paid insurance, retirement and savings plans, and profit-sharing plans. While cash bonuses may, in limited circumstances, be counted towards the annual salary (see 20 CFR

655.731(c)(2)), other forms of benefits, such as stock options, profit sharing plans, and flexible work schedules may not be readily quantifiable or guaranteed, which means that they cannot reliably be calculated into proffered wages. While this may affect some petitioners and beneficiaries negatively, DHS does not believe there is a viable alternative that could consider all of the various forms of compensation that companies may offer that could be implemented in an uncomplicated and predictable way. Additionally, DOL regulations define payment of wages for purposes of satisfying the H-1B required wage. *See* 20 CFR 655.731(c)(2). This rule does not change how wages are defined or measured. Regarding the suggestion to consider past IRS transcripts of candidates, DHS notes that proffered wages at the time of registration and petition filing generally relate to future employment, so it is unclear what purpose transcripts or other IRS documentation of prospective employees would serve.

16. General Concerns on Wage-Based Selection

Comment: Many commenters said that wage is not a proxy for experience, skill, or education and that the rule erroneously assumes those who earn more contribute more to the economy or society. Other commenters stated the proposed rule would significantly reduce the chances of obtaining an H-1B visa in entrepreneurial, academic, and research spaces which would restrict access to international workers with specialized skills in these areas. Other commenters said that the new system would disadvantage top earners, as a highly paid individual with a level I wage in a high-earning field would be ranked lower than someone who earns far less as a level IV in a lower-earning field. Commenters also stated that the proposed rule would favor only experienced, high-paid workers and big firms, while shutting out early-career professionals and the startups, healthcare institutions, and research sectors that rely on them. One commenter said that by conflating wage level with skill and innovation potential, DHS would systematically disadvantage the early-career talent pipeline that drives technological breakthroughs. Another commenter stated that the proposed weighted selection process does not account for a level IV H-1B employee who may be laid off and may need to accept a bridge job at level II or III, putting their status in jeopardy.

Response: DHS disagrees with these comments and believes that salary generally is a reasonable proxy for skill level.⁴⁴ DHS believes that an employer who offers a higher wage than required by the prevailing wage level does so because that higher wage is a clear reflection of the beneficiary's value to the employer, which reflects the unique qualities the beneficiary possesses. DHS does not believe this rule will favor certain high paying professions or companies, because the rule takes into account wage level relative to the SOC code when weighting registrations (or petitions). Additionally, DHS recognizes that this rule will decrease the chance of H-1B cap selection for jobs with a proffered wage that corresponds to a level I wage, but it does not shut out early-career professionals. As stated in the NPRM and throughout this final rule, DHS recognizes the value in maintaining the opportunity for employers to secure H-1B workers at all wage levels. DHS also disagrees with the concern that wage levels are inadequate to compare workers across occupations as this rule is designed to generally favor the allocation of H-1B visas to higher-skilled and higher-paid aliens, while ensuring meaningful opportunities for selection regardless of industry or profession.

DHS also does not believe that this rule will disadvantage particular industries or employers based on geography, size, or other factors. Wage levels already account for these factors by taking into account the area of intended employment and SOC code. While the weighted selection process may not account for every scenario, such as a laid-off worker taking a temporary lower paying job, DHS believes that this is a rare scenario and is unable to provide for every possible scenario when implementing a weighting process that is uncomplicated and predictable for prospective petitioners. Further, DHS believes that the advantages of the new selection

process and the benefits it will bring to the economy overall outweigh any possible disadvantages that may occur in rare cases.

17. Concerns With the OEWS Program

Comment: Several commenters expressed concern with using the OEWS program. For instance, a commenter noted that the rule relied on faulty wage level assumptions in using the OEWS data and said that the OEWS wage survey, on which H-1B wage levels are based, was never intended to measure skill or productivity. The commenter explained that its purpose is to represent mean and percentile wage distributions within occupational codes, and it makes no adjustment for the employer's industry, business model, or regional cost factors. The commenter said that the proposed rule's assumption that positions commanding a wage that corresponds to a level IV wage represent the "most skilled" workers ignores the structural wage differentials that exist across industries. The commenter notes that DOL's OEWS data aggregate wages across all employers within an occupation, without adjusting for the profit structure, funding model, or public versus private character of the employer, and that the wage levels are based primarily on statistical percentiles of pay, not individualized measures of experience. As a result, the proposed weighted selection process risks granting preferential treatment to junior employees in lucrative markets over experienced professionals in essential but lower-paying fields, such as education, public health, and infrastructure engineering. Similarly, several commenters stated that wage levels are inadequate to compare workers across occupations.

A commenter also expressed concern with wage inflation, noting that it reflects market conditions rather than skill increases. The commenter noted that some areas, such as technology, finance, and law have seen wage inflation in recent years, where compensation has escalated due to market competition rather than measurable increases in skill and the proposed weighted selection process would reward industries that can inflate salaries fastest, not those that develop or employ the most capable workers. Other commenters stated that the selection process artificially inflates the chances of roles requiring less training, experience, or responsibility.

Response: DHS appreciates these concerns but maintains that salary generally is a reasonable proxy for skill

⁴⁴ *See* DOL, Educational Level and Pay, <https://www.dol.gov/general/topic/wages/educational> (last visited Nov. 24, 2025) ("Generally speaking, jobs that require high levels of education and skill pay higher wages than jobs that require few skills and little education."). *See also* "Wage Methodology for the Temporary Non-Agricultural Employment H-2B Program," 76 FR 3452, 3453 (Jan. 19, 2011) (it is a "largely self-evident proposition that workers in occupations that require sophisticated skills and training receive higher wages based on those skills."); Daniel Costa & Ron Hira, Economic Policy Institute, H-1B Visas and Prevailing Wage Level (May 4, 2020), <https://www.epi.org/publication/h-1b-visas-and-prevailing-wage-levels>. ("Specialized skills should command high wages; such skills are typically a function of inherent capability, education level, and experience. It would be reasonable to expect that these workers should receive wages higher than the median wage.")

level.⁴⁵ While DHS is aware that some structural wage differentials may exist across industries, DHS is not aware of an efficient and uncomplicated way to incorporate such differentials into the OEWS wage system or to otherwise account for these differentials when weighting and selecting registrations or petitions. Similarly, DHS is not aware of an alternate program (other than OEWS) that would consider such unique factors as individualized experience and wage inflation. While no data set is perfect, the OEWS data represents the best available resource for this purpose. DHS favors using the OEWS wage level system because it is already used in the H-1B program, widely recognized, publicly available, and updated annually by DOL. DHS intentionally chose a selection methodology that used information and resources already familiar to most petitioners and stakeholders. Utilizing OEWS wage levels allows USCIS to leverage employers' existing knowledge of the wage levels in order to implement the weighted selection process. Employers are already required to complete LCAs and access OEWS wage information or alternative wage sources. This rule simply requires that the employer will look at the wage they are offering the alien and, when OEWS wage level is available, select the wage level that corresponds to that offered wage for the offered position's SOC codes and metropolitan statistical area (MSA). Although OEWS does not collect information on skill or experience levels, DHS believes it is reasonable to use features of the OEWS wage distribution as a proxy for those variables. If OEWS wage level is unavailable, the employer determines the wage level using the DOL guidance that the employer would otherwise follow when determining the relevant wage level to select on the LCA.

Comment: A commenter expressed concern that the rule would create confusion between the wage level

offered for USCIS purposes and the wage level required under DOL rules. The commenter noted that if a petitioner decides to pay a beneficiary a higher wage level than what is required under DOL rules for a better chance at selection (such as a level IV wage), then the prevailing wage level indicated in its registration submitted to USCIS will not match the prevailing wage level indicated on its LCA submitted with the petition (which may have been a level I wage). The commenter stated that at minimum, USCIS should refine 8 CFR 214.2(h)(8)(iii)(D)(1) to make clear that the actual LCA submitted with an H-1B petition should still calculate the prevailing wage based upon existing DOL rules, and the offered wage listed in the registration is to be used solely for determining the weighting of the lottery entry.

Response: As clearly stated in the NPRM, a registrant is required to select the box for the highest OEWS wage level ("wage level IV," "wage level III," "wage level II," or "wage level I") that the beneficiary's proffered wage generally equals or exceeds for the relevant SOC code in the area(s) of intended employment. 90 FR 45986, 45992 (Sept. 24, 2025). DHS does not agree that this is confusing. Conversely, DHS believes it would be confusing to add language in 8 CFR 214.2(h)(8)(iii)(D)(1) that discusses how to calculate the prevailing wage under DOL rules since this provision is about filing procedures with USCIS.

18. Other Opposition

Comment: A commenter expressed concern that the rule allows the government to manipulate market-based wages through the use of immigration policy, saying this rule establishes "dangerous precedents for government wage determination." The commenter claimed that this represents "a fundamental departure from how the United States has historically approached labor markets," and noted that in the labor market, wages are primarily determined through negotiations between employers and workers. While the commenter acknowledged that the government is justified in ensuring fair wages for U.S. workers and H-1B workers, the commenter concluded that the proposed weighted selection system goes beyond these legitimate interests into government intervention in market-based wages.

Response: DHS disagrees with this commenter. This rule merely fills in a statutory gap regarding how to administer the H-1B numerical allocations in years of excess demand,

consistent with DHS's statutory authority to determine the form and manner of submitting H-1B petitions and the administration of the H-1B numerical allocations. *See* INA secs. 103(a) and 214(c)(1), 8 U.S.C. 1103(a) and 1184(c)(1). This rule does not constitute government intervention in market-based wages. Through this rule, DHS is not mandating what wages employers must pay their employees. Employers that wish to participate in the H-1B program may be incentivized to offer higher wages to their prospective H-1B workers in order to increase their chances of selection under the cap, but they remain free to determine what wages they want to offer prospective H-1B employees. Employers also remain free to choose not to participate in the H-1B program.

Further, this rule does not represent "government intervention" in the labor market nor a "fundamental departure from how the United States has historically approached labor markets," as the commenter claimed. In order to participate in the H-1B program, employers have always had to meet certain wage requirements, including prevailing wage requirements as determined by DOL and other generally applicable Federal and state wage requirements. *See* 20 CFR 655.40. It is therefore unclear what the commenter means by claiming that this rule would establish "dangerous precedents for government wage determination" when various government agencies routinely regulate an employer's wage obligations and given that this rule does not mandate what wages employers must pay their employees.

Comment: A few commenters discussed how the proposed rule would unfairly and disproportionately harm certain minority groups. Some of these commenters specifically noted the disproportionate impact on Asian and Pacific Islander groups, pointing out that Asian workers account for the majority of H-1B workers in the United States. Another commenter said that the rule would have a disparate impact on Hispanic groups, claiming that the rule would deepen existing racial wealth disparities.

Response: DHS disagrees that this rule will unfairly impact certain minority groups or deepen racial wealth disparities. This rule does not target or favor any particular minority group. This rule merely increases the chance of selection for aliens who will be paid a wage that corresponds to a higher wage level, regardless of their race, ethnicity, or country of origin.

⁴⁵ *See* DOL, Educational Level and Pay, <https://www.dol.gov/general/topic/wages/educational> (last visited Nov. 24, 2025) ("Generally speaking, jobs that require high levels of education and skill pay higher wages than jobs that require few skills and little education."). *See also* "Wage Methodology for the Temporary Non-Agricultural Employment H-2B Program," 76 FR 3452, 3453 (Jan. 19, 2011) (it is a "largely self-evident proposition that workers in occupations that require sophisticated skills and training receive higher wages based on those skills."); Daniel Costa & Ron Hira, Economic Policy Institute, H-1B Visas and Prevailing Wage Level (May 4, 2020), <https://www.epi.org/publication/h-1b-visas-and-prevailing-wage-levels>. ("Specialized skills should command high wages; such skills are typically a function of inherent capability, education level, and experience. It would be reasonable to expect that these workers should receive wages higher than the median wage.").

C. Legal Authority, Basis, and Background

1. Statutory Authority

Comment: Several commenters supported the rule, saying that the changes to H-1B selection are consistent with statutory language. Commenters stated that the statutory language is ambiguous and silent as to how visas should be allocated if they cannot be issued in the order that they were filed, and that the proposed wage level weighting scheme is reasonable and within DHS's authority. Some commenters agreed that DHS has the authority to determine how the government selects H-1B petitions when they receive more petitions than available visas.

Response: DHS agrees that the statute is silent as to how USCIS must select H-1B petitions, or registrations, to be filed toward the numerical allocations in years of excess demand; the term "filed" as used in INA sec. 214(g)(3), 8 U.S.C. 1184(g)(3), is ambiguous;⁴⁶ and these changes are reasonable and within DHS's general authority. See INA secs. 103(a), 214(a), and (c)(1), 8 U.S.C. 1103(a), 1184(a), and (c)(1).

Comment: Some commenters said the proposed rule would violate the INA, which prioritizes the selection of H-1B cap-subject petitions in the "order in which they are filed," and that USCIS lacks the statutory authority for the proposed weighted selection process. Some commenters stated that the INA says that DHS "shall" issue visas in the order in which they are filed, underscoring that this is a statutory mandate not subject to DHS's discretion. Commenters stated that, while the random lottery is permissible, there is nothing in the statute allowing for wage-based prioritization and thus the proposed rule exceeds DHS's statutory authority. Commenters remarked that INA sec. 214(g) is silent on allocation methods beyond random selection, and that USCIS cannot use the statute's silence as an invitation to adopt wage- or skill-based criteria. Echoing other commenters' concerns about DHS's lack of statutory authority for the rule, some commenters added that an executive action like the one proposed in the NPRM would require legislative action or approval by Congress. Commenters stated that the Executive Branch does not have "plenary authority" and there are processes in place to amend laws.

A commenter said the rule is ultra vires because it improperly changes the process and adds new requirements to

the selection order for H-1B cap subject petitions that exceed what is clearly stated in the INA. The commenter cited INA sec. 214(g)(3), which states:

Individuals subject to H-1B numerical limitations ". . . shall be issued visas (or otherwise provided nonimmigrant status) in the order in which petitions are filed for such visas or status."

Pointing out that Congress did not change this section when it amended it through the H-1B Visa Reform Act of 2004, the commenter asserted that the proposal to add the wage level element violates clear congressional intent. The commenter added that the well-established principle of law remains that an agency cannot modify a statute by regulation, and that since the statute is neither ambiguous nor silent, Congress did not leave a gap for USCIS interpretation via regulation. The commenter added that it is particularly telling that the agency previously evaluated this very issue in January 2019 and concluded that the INA is clear and does not permit the type of prioritization it proposes here.⁴⁷ The commenter asserted that USCIS cites no congressional intent relating to the H-1B numerical cap and its justification and reasoning lacks analysis from official research or studies by government agencies.

Several other commenters also noted that DHS previously determined in its 2019 rule, Registration Requirement for Petitioners Seeking to File H-1B Petitions on Behalf of Cap-Subject Aliens, that prioritization based on salary would require statutory changes. Some commenters said that senators introduced bipartisan legislation four days after the publication of this proposed rule to authorize DHS to process H-1B petitions on proffered wages, and commented that Congress would not be legislating on this exact issue if it thought DHS could implement these changes to the H-1B program on its own.

Some commenters wrote that the Supreme Court's 2024 overruling of the *Chevron* framework eliminated the judicial deference to agencies in Administrative Procedure Act (APA) rulemaking. A commenter noted that since the 2024 Supreme Court decision

⁴⁷ See "Registration Requirement for Petitioners Seeking To File H-1B Petitions on Behalf of Cap Subject Aliens," 84 FR 888, 913 (Jan. 31, 2019) (noting that "DHS believes that reversing the cap selection order to prioritize beneficiaries with a master's or higher degree from a U.S. institution of higher education is a permissible interpretation of the existing statute, as explained in detail in response to other comments in this preamble. DHS believes, however, that prioritization of selection on other bases such as those suggested by the commenters would require statutory changes.").

in *Loper Bright Enterprises v. Raimondo*, *Chevron* deference has been overturned, "thereby removing the power of administrative agencies to interpret ambiguous statutes."

Similarly, another commenter stated that the proposed rule would go beyond the discretion afforded by Congress and that USCIS discretion is constrained by *Loper Bright* such that USCIS may not simply use its preferred interpretation of "filing" under that statute, but instead must use "the best" interpretation, as any other interpretation is impermissible. The same commenter indicated support for the Administration's goal of prioritizing high-skilled immigration, but stated that USCIS' obligation to administer the INA does not give USCIS the flexibility to select applicants in the manner proposed by this rule.

Response: DHS disagrees with the commenters' assertions that the weighted selection process would violate the INA or that DHS lacks the statutory authority to implement a weighted selection process. The statute is silent as to how USCIS must select H-1B petitions, or registrations, to be filed toward the numerical allocations in years of excess demand; the term "filed" as used in INA sec. 214(g)(3), 8 U.S.C. 1184(g)(3), is ambiguous;⁴⁸ and these changes are reasonable and within DHS's general authority. See INA secs. 103(a), 214(a), and (c)(1), 8 U.S.C. 1103(a), 1184(a), and (c)(1).

Excess demand for numerically limited H-1B cap numbers created a rush of simultaneous submissions at the beginning of each H-1B cap petition period, preventing application of the numerical limitations based solely on the order in which the petitions are received by USCIS. See *Liu v. Mayorkas*, 588 F. Supp. 3d 43, 48 (D.D.C. 2022) (discussing the high demand for H-1B visas, the operational challenges USCIS faced administering the H-1B cap because of the high demand, and the creation of the registration requirement).

DHS acknowledges that Congress directed DHS to process earlier-filed petitions before later-filed petitions, see INA sec. 214(g)(3), 8 U.S.C. 1184(g)(3) (stating that aliens who are subject to the numerical limitations will be "issued visas (or otherwise provided nonimmigrant status) in the order in which the petitions are filed"),⁴⁹ but

⁴⁸ See *Walker Macy LLC v. USCIS*, 243 F. Supp. 3d 1156, 1170 (D. Or. 2017).

⁴⁹ See also "Registration Requirement for Petitioners Seeking to File H-1B Petitions on Behalf of Cap-Subject Aliens," 84 FR 888, 896 (Jan. 31, 2019) (noting that "a literal application of this statutory language [to issue visas or otherwise provide H-1B status in the order in which the

⁴⁶ See *Walker Macy LLC v. USCIS*, 243 F. Supp. 3d 1156, 1170 (D. Or. 2017).

Congress did not define what it means to “file” a petition, or how to order petitions that are filed during the same timeframe.

The Secretary has broad authority to administer and enforce the INA, establish such regulations as the Secretary deems necessary for carrying out such authority, and to prescribe the time and conditions under which an alien may be admitted to the United States as a nonimmigrant and how an importing employer may petition for nonimmigrant workers. *See* INA secs. 103(a), 214(a)(1), and 214(c)(1), 8 U.S.C. 1103(a), 1184(a)(1), and (c)(1). Such authority includes prescribing rules to fill statutory gaps.⁵⁰

DHS has leveraged these authorities to make significant improvements to the H–1B selection process over the years in response to the high demand, consistent with the purpose and structure of the annual numerical limitations. The registration process, for instance, selects among “registrations submitted electronically over a designated period of time to ensure the fair and orderly administration of the numerical allocations.” 84 FR 896 (Jan. 31, 2019).⁵¹

petitions are filed, down to the second] would lead to an absurd result” because “[s]uch a literal application would necessarily mean that processing delays pertaining to a petition earlier in the petition filing order would preclude issuance of a visa or provision of status to all other H–1B petitions later in the petition filing order.” Therefore, USCIS’ “longstanding approach to implementing the numerical limitation has been to project the number of petitions needed to reach the numerical limitation. . . .”).

⁵⁰ *See Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 395 (2024) (explaining that a statute’s meaning may be that the agency is authorized to exercise a degree of discretion and empowered to prescribe rules to fill in statutory gaps based on “reasoned decision making”); *see also Liu v. Mayorkas*, 588 F. Supp. 3d 43, 55 (D.D.C. 2022) (finding that the registration requirement does not violate the INA, is not ultra vires, and that registration is merely “an antecedent procedural step to be eligible to file an H–1B cap[subject] petition”); *Walker Macy LLC v. USCIS*, 243 F. Supp. 3d 1156 (D. Or. 2017).

⁵¹ DHS notes that the registration process, like the petition process that applies when registration is suspended, faithfully implements INA sec. 214(g)(3), 8 U.S.C. 1184(g)(3) by, among other things, ensuring that earlier-filed registrations and petitions receive priority over later ones. For instance, in addition to allowing for a more efficient administration of the annual numerical allocations, the process accounts for the possibility that DHS will receive an insufficient number of simultaneously submitted registrations during the initial registration to meet the H–1B regular cap; in such a circumstance, registration will remain open until USCIS has received a sufficient number of registrations for unique beneficiaries to meet the cap. *See* 8 CFR 214.2(h)(8)(iii)(A)(5)(i); *see also* 84 FR 896 (Jan. 31, 2019) (explaining that, where an insufficient number of registrations have been received during the initial registration period, USCIS would select all of the registrations properly submitted during the initial registration period, and that registrations submitted after the initial registration would continue to be selected on a

DHS’s random selection process is a similar type of gap-filling measure. When this process was previously challenged, DHS prevailed.⁵² The court observed that “[i]t is not difficult to envision a scenario where many more petitions arrive on the final receipt date than are needed to fill the statutory cap, and processing them ‘in order’ . . . may also be random and arbitrary.”⁵³ This court importantly held that “Congress left to the discretion of USCIS how to handle simultaneous submissions” and “USCIS has discretion to decide how best to order those petitions.”⁵⁴ In short, DHS has authority to engage in reasoned decision making with regard to how to administer the H–1B petitioning process (including whether to require a registration process as an antecedent procedural step to be eligible to file an H–1B cap-subject petition), and how to best select among simultaneously submitted H–1B registrations or petitions.⁵⁵ Congress provided DHS with the authority to better ensure a fair, orderly, and efficient allocation of H–1B cap numbers based on reasoned decision making, including consideration of the overall statutory scheme and purpose of the classification: the selection of highly skilled and highly paid nonimmigrants in the United States while protecting the wages, working conditions and job opportunities of U.S. workers.

DHS acknowledges that it has implemented regulations over the years that provide for a random selection from all petitions or registrations that occur within a certain timeframe. *See, e.g.*, 70 FR 23775 (May 5, 2005), 84 FR 888 (Jan. 31, 2019). However, while the current random selection of petitions or registrations is reasonable, DHS believes it is neither the optimal, nor the exclusive method of selecting registrations or petitions toward the numerical allocations when more registrations or petitions, as applicable, are simultaneously submitted than projected as needed to reach the numerical allocations. Pure

rolling basis until such time as a sufficient number of registrations have been received).

⁵² *See Walker Macy LLC v. USCIS*, 243 F. Supp. 3d 1156 (D. Or. 2017).

⁵³ *Id.* at 1174.

⁵⁴ *Id.* at 1176.

⁵⁵ *See Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 395 (2024) (explaining that a statute’s meaning may be that the agency is authorized to exercise a degree of discretion and empowered to prescribe rules to fill in statutory gaps based on “reasoned decision making”); *see also Liu v. Mayorkas*, 588 F. Supp. 3d 43, 55 (D.D.C. 2022) (finding that the registration requirement does not violate the INA, is not ultra vires, and that registration is merely “an antecedent procedural step to be eligible to file an H–1B cap[subject] petition”); *Walker Macy LLC v. USCIS*, 243 F. Supp. 3d 1156 (D. Or. 2017).

randomization does not serve the ends of the H–1B program or congressional intent to help U.S. employers fill labor shortages in positions requiring highly skilled workers.⁵⁶ Under the current random selection process, in every fiscal year from FY 2019 through FY 2024, petitions for beneficiaries at wage level III and wage level IV were the least represented among all wage levels in cap-subject H–1B filings, both under the regular cap and the advanced-degree exemption.⁵⁷

Regarding the comments that referenced recently proposed legislation to support assertions that this rule exceeds DHS’s authority, DHS notes that proposed legislation that is not enacted is not a reliable indicator of congressional intent, particularly as it pertains to previously enacted legislation. *See Red Lion Broadcasting v. FCC*, 395 U.S. 367, 381 n.11 (1969) (“unsuccessful attempts at legislation are not the best of guides to legislative intent.”).

Regarding commenters’ assertions that the statute is neither ambiguous nor silent on allocation methods beyond random selection, DHS observes that the statute does not expressly refer to allocation by random selection or address how the numerical allocations should be administered when demand exceeds the available supply of H–1B visa numbers. Rather, that is the silence that DHS permissibly filled in prior rules providing for random selection, and is the same silence that DHS is permissibly filling in this final rule by implementing a reasonable selection process, consistent with a key goal of the program: protecting the wages, working conditions, and job opportunities of U.S. workers.

DHS recognizes that it considered the issue of cap selection by wage level in 2019 and concluded at that time that prioritization by wage level or other bases would require statutory change. DHS acknowledged that prior statement in footnote 20 in the preamble to the proposed rule. 90 FR 45986, 45990 (Sept. 24, 2025). DHS reconsidered the analysis as far back as 2020, and again

⁵⁶ *See* H.R. Rep. 101–723(I) (1990), as reprinted in 1990 U.S.C.C.A.N. 6710, 6721 (stating “The U.S. labor market is now faced with two problems that immigration policy can help to correct. The first is the need of American business for highly skilled, specially trained personnel to fill increasingly sophisticated jobs for which domestic personnel cannot be found and the need for other workers to meet specific labor shortages.”).

⁵⁷ USCIS OPQ, CLAIMS3 and ELIS, queried 3/2025, TRK #17265. LCA data from DOL. Disclosure Files for LCA Programs (H–1B, H–1B1, E–3), FY–2018–FY–2024. DOL data downloaded from <https://www.dol.gov/agencies/eta/foreign-labor/performance> (last visited Nov. 24, 2025).

in the context of this rulemaking, and determined that selection by wage level is consistent with its broad statutory authority and fills a statutory gap in a way that is consistent with a key goal of the program.

2. Congressional Intent

Comment: Commenters stated that the wage-based system is reasonable because it is consistent with the intent of the H-1B program, which is to help U.S. businesses obtain highly skilled foreign workers to supplement the domestic workforce. Some commenters said that a weighted, wage-based selection process would better reflect the statutory intent to admit “highly skilled” workers and help mitigate negative labor market impacts.

Response: DHS agrees with these comments that the rule is consistent with congressional intent and statutory language; the statute is silent as to how USCIS must select H-1B petitions, or registrations, to be filed toward the numerical allocations in years of excess demand; the term “filed” as used in INA sec. 214(g)(3), 8 U.S.C. 1184(g)(3), is ambiguous; and these changes are reasonable and within DHS’s general authority. DHS, therefore, is relying on its general statutory authority to implement an H-1B cap selection process that prioritizes selection generally based on the highest prevailing wage level that a proffered wage equals or exceeds. *See* INA secs. 103(a), 214(a), and (c)(1), 8 U.S.C. 1103(a), 1184(a), and (c)(1).

Comment: Some commenters wrote that the proposed weighted selection process would violate the clear congressional intent of the H-1B program—to fill existing gaps in the U.S. labor supply in specialized fields. One commenter said Congress deliberately chose prescriptive statutory language that forecloses the type of “executive branch creativity” proposed in this rule. Another commenter said that the rule’s weighted selection process would transform the congressionally established H-1B program into a wage-based preference system, for which there is no basis in the text of the INA.

Some commenters wrote that Congress designed the H-1B program to be accessible across wage levels, and that the current random lottery reflects congressional intent for fairness and equal opportunity. A comment from multiple organizations stated that Congress and DOL designed the system to ensure wage parity within an occupation and within a local labor market, not to stack-rank different workers. Some commenters said that the

H-1B program was created to give U.S. employers access to specialized workers across all experience levels, and that the NPRM would undermine that purpose. Another commenter wrote that the INA requires USCIS to implement a “fair” selection process when petitions exceed the visa cap, and suggested that the proposed selection process would fail to meet this requirement by disproportionately disfavoring early-career workers. A commenter wrote that the H-1B program has “drifted far from its congressional intent” and fundamental reforms are needed to ensure the visa holders are not used to replace U.S. workers with “cheaper foreign labor.”

Some commenters wrote that DHS’s proposed weighting toward more skilled workers directly conflicts with the statutory definition of “specialty occupation,” which is defined in terms of a minimum requirement of a bachelor’s degree for entry into the occupation, and does not depend on an experience requirement. One of the commenters said that DHS has no authority to enact its policy preference for admitting H-1B workers based on their experience as a deciding factor in selecting their registrations as it is contrary to the statutory definition.

Another commenter wrote that the NPRM is “unjustified” in its citation to 6 U.S.C. 111(b)(1)(E) as one of its legal bases. The commenter asserted that this provision was intended as a constraint on DHS’s regulatory power, and that it obligates DHS “to avoid initiatives that would weaken economic stability or burden lawful sectors of American commerce.” The commenter suggested that the proposed rule conflicts with this limitation by diminishing, rather than safeguarding, the nation’s overall economic security. The commenter stated that because the rule “constrains U.S. employers’ ability to access specialized talent,” it undermines the statutory mission Congress assigned to DHS.

Response: DHS disagrees with the commenters’ assertions that the weighted selection process would violate the INA or that DHS lacks the statutory authority to implement a weighted selection process. The statute is silent as to how USCIS must select H-1B petitions, or registrations, to be filed toward the numerical allocations in years of excess demand; the term “filed” as used in INA sec. 214(g)(3), 8 U.S.C. 1184(g)(3), is ambiguous;⁵⁸ and these changes are reasonable and within DHS’s general authority. *See* INA secs.

103(a), 214(a), and (c)(1), 8 U.S.C. 1103(a), 1184(a), and (c)(1).

While the current random selection of petitions or registrations is reasonable, DHS believes it is neither the optimal, nor the exclusive method of selecting registrations or petitions toward the numerical allocations when more registrations or petitions, as applicable, are simultaneously submitted than projected as needed to reach the numerical allocations. Pure randomization does not serve the ends of the H-1B program or congressional intent to help U.S. employers fill labor shortages in positions requiring highly skilled workers.⁵⁹ Under the current random selection process, in every fiscal year from FY 2019 through FY 2024, petitions for beneficiaries at wage level III and wage level IV were the least represented among all wage levels in cap-subject H-1B filings, both under the regular cap and the advanced-degree exemption.⁶⁰

Contrary to commenters’ assertions, the weighted selection process does not preclude access to skilled workers at the lower wage levels or diminish, rather than safeguard, the nation’s overall economic security. Congress imposed an annual numerical limitation on the number of foreign workers who may be issued an initial H-1B visa or otherwise provided initial H-1B status. *See* INA sec. 214(g)(1)(A), 8 U.S.C. 1184(g)(1)(A). Congress, however, “left to the discretion of USCIS how to handle simultaneous submissions” and “USCIS has discretion to decide how best to order those petitions.”⁶¹ As DHS explained in the preamble to the proposed rule (90 FR 45991 (Sept. 24, 2025)), by engaging in a wage-level-based weighting of registrations for unique beneficiaries, DHS will better ensure that initial H-1B visas and status grants would more likely go to the highest skilled or highest paid beneficiaries, while not effectively precluding those at lower wage levels. Facilitating the admission of higher-skilled workers “would benefit the economy and increase the United States’

⁵⁹ *See* H.R. Rep. 101–723(I) (1990), as reprinted in 1990 U.S.C.C.A.N. 6710, 6721 (stating “The U.S. labor market is now faced with two problems that immigration policy can help to correct. The first is the need of American business for highly skilled, specially trained personnel to fill increasingly sophisticated jobs for which domestic personnel cannot be found and the need for other workers to meet specific labor shortages.”).

⁶⁰ USCIS, OPQ, CLAIMS3 and ELIS, queried 3/2025, TRK #17265. LCA data from DOL. Disclosure Files for LCA Programs (H-1B, H-1B1, E-3), FY–2018–FY–2024. DOL data downloaded from <https://www.dol.gov/agencies/eta/foreign-labor/performance> (last visited Nov. 24, 2025).

⁵⁸ *See Walker Macy LLC v. USCIS*, 243 F. Supp. 3d 1156, 1170 (D. Or. 2017).

⁶¹ *See Walker Macy LLC v. USCIS*, 243 F. Supp. 3d 1156, 1176 (D. Or. 2017).

competitive edge in attracting the ‘best and the brightest’ in the global labor market,” consistent with the goals of the H–1B program and will help to safeguard the nation’s overall economic security.⁶²

3. Previous H–1B Rulemakings and Related Court Cases

Comment: A commenter wrote that DHS attempted to make a similar change in 2021 and it was vacated by a Federal court in *Chamber of Commerce v. DHS*, No. 4:20–cv–07331, 2021 WL 4198518 (N.D. Cal. Sept. 15, 2021), adding that DHS has not explained how the approach described in the NPRM would avoid the same legal defects of that previous rule. Another commenter similarly stated that wage-based selection policies have faced legal challenges in the past, raising significant questions about the statutory authority for such a weighted selection process. Commenters stated that this rule would similarly likely face legal challenges. One commenter said that DHS should withdraw the rule to avoid litigation.

Some commenters wrote that while the *Walker Macy* court decision upheld USCIS’ use of a random lottery for simultaneously submitted petitions, it does not support introducing wage-based preference as a new requirement to determine eligibility or priority. Some commenters wrote that the proposed rule improperly cites *Liu v. Mayorkas*.⁶³ One of these commenters asserted that *Liu* “does not support the agency’s proposed imposition of a thumb-on-the-scale lottery system based on wage levels,” and in any case cannot be relied upon because it is a single, nonbinding district court decision and not controlling law. The commenter added that the court described the lottery as an antecedent measure that did not replace the statutory requirement of chronological allocation; rather, it was a preliminary step taken before the chronological allocation process begins. Another commenter reasoned that *Liu v. Mayorkas* only addressed the narrow challenge to online registration system implementation and the prevention of multiple filings, and therefore that using

Liu to justify the significant shift to an unequal, wage-based weighted lottery expands beyond precedent and what the INA mandates. The commenter added that *Liu* specifically warned that agency discretion must adhere to statutory language and purpose.

One commenter asserted that this rulemaking represents a “premature departure” from the 2024 final rule. 89 FR 7456 (Feb. 2, 2024). The commenter noted that the 2024 final rule was designed to reduce “gaming” the system to ensure that each beneficiary has the same chance of selection and said that it is premature to change that framework before evaluating outcomes across the FY 2025 and FY 2026 cycles.

Response: DHS notes that the court in *Chamber of Commerce v. DHS*, No. 4:20–cv–07331, 2021 WL 4198518 (N.D. Cal. Sept. 15, 2021), did not reach the issue of DHS’s statutory interpretation and the substantive merits of the 2021 H–1B Selection Final Rule. Because the court did not reach the substantive merits of that rulemaking, DHS disagrees with the commenter’s assertion that the 2021 H–1B Selection Final Rule was inconsistent with DHS’s statutory authority or that DHS has not sufficiently explained how this current rulemaking is consistent with DHS’s statutory authority.

DHS also disagrees with the commenters’ assertions that the weighted selection process would violate the INA or that DHS lacks the statutory authority to implement a weighted selection process. The statute is silent as to how USCIS must select H–1B petitions, or registrations, to be filed toward the numerical allocations in years of excess demand; the term “filed” as used in INA sec. 214(g)(3), 8 U.S.C. 1184(g)(3), is ambiguous;⁶⁴ and these changes are reasonable and within DHS’s general authority. See INA secs. 103(a), 214(a), and (c)(1), 8 U.S.C. 1103(a), 1184(a), and (c)(1).

The Secretary has broad authority to administer and enforce the INA, establish such regulations as the Secretary deems necessary for carrying out such authority, and to prescribe the time and conditions under which an alien may be admitted to the United States as a nonimmigrant and how an importing employer may petition for nonimmigrant workers. See INA secs. 103(a), 214(a)(1), and (c)(1), 8 U.S.C. 1103(a), 1184(a)(1), and (c)(1). Such authority includes prescribing rules to fill statutory gaps.⁶⁵

⁶⁴ See *Walker Macy LLC v. USCIS*, 243 F. Supp. 3d 1156, 1170 (D. Or. 2017).

⁶⁵ See *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 395 (2024) (explaining that a statute’s meaning

DHS disagrees with the commenters’ assertion that *Liu* was improperly cited in the proposed rule. The *Liu* decision, while not a binding precedential decision, is persuasive authority pertaining to DHS’s authority to fill the statutory silence and implement a registration requirement.⁶⁶ The court in *Liu* correctly recognized that registration is not a petition, but rather an antecedent procedural step.⁶⁷ Creation of an antecedent registration requirement, and random selection of registrations or petitions, as applicable, are reasonable gap filling regulations just as the current rulemaking is a reasonable gap filling regulation consistent with the Secretary’s broad statutory authority.

DHS also disagrees with the commenter’s assertion that it is premature to implement a new selection process before at least a couple of years have passed since the implementation of the beneficiary-centric selection process. DHS notes that this final rule builds on, and does not replace, the changes made by the final rule implementing the beneficiary-centric selection process.⁶⁸ DHS also notes that the gaming addressed by the final rule implementing the beneficiary-centric selection process was the submission of multiple registrations for the same beneficiary by companies that were working together to unfairly increase a beneficiary’s chance of selection. That is a different issue than what this final rule will address. This final rule builds on the 2024 final rule to continue selecting beneficiaries, such that the selection process remains beneficiary-centric rather than registration-centric, but weights each unique beneficiary in

may be that the agency is authorized to exercise a degree of discretion and empowered to prescribe rules to fill in statutory gaps based on “reasoned decision making”); see also *Liu v. Mayorkas*, 588 F. Supp. 3d 43, 55 (D.D.C. 2022) (finding that the registration requirement does not violate the INA, is not ultra vires, and that registration is merely “an antecedent procedural step to be eligible to file an H–1B cap[subject] petition”); *Walker Macy LLC v. USCIS*, 243 F. Supp. 3d 1156 (D. Or. 2017).

⁶⁶ See *Liu v. Mayorkas*, 588 F. Supp. 3d 43, 55 (D.D.C. 2022) (explaining that the registration requirement “makes sense, is inherently reasonable, and saves the agency and employers time and money.”).

⁶⁷ *Id.* (finding that the registration requirement does not violate the INA, is not ultra vires, and that registration is merely “an antecedent procedural step to be eligible to file an H–1B cap[subject] petition”).

⁶⁸ See 90 FR at 45993 (“With regard to selection of unique beneficiaries and the registrations submitted on their behalf, because the beneficiary-centric selection process is needed to prevent unscrupulous actors from unfairly increasing the odds that a beneficiary would be selected, DHS proposes to implement a wage-based selection process that would operate in conjunction with the existing beneficiary-centric selection process.”).

⁶² See Muzaffar Chishti & Stephen Yale-Loehr, Migration Policy Institute, The Immigration Act of 1990: Unfinished Business a Quarter-Century Later (July 2016), https://www.migrationpolicy.org/sites/default/files/publications/1990-Act_2016_FINAL.pdf (“Sponsors of [the Immigration Act of 1990, which created the H–1B program as it exists today,] believed that facilitating the admission of higher-skilled immigrants would benefit the economy and increase the United States’ competitive edge in attracting the ‘best and the brightest’ in the global labor market.”).

⁶³ 588 F. Supp. 3d 43 (D.D.C. 2022).

the registration selection process generally based on the corresponding wage level that the proffered wage equals or exceeds. Because this final rule builds on the 2024 final rule, DHS disagrees with the commenter's assertion that DHS should have waited longer before making additional changes to the H-1B cap selection process.

4. DHS Background and Justification for the Rule

Comment: Some commenters expressed support for DHS's justifications for the proposed rule and reasoned that the H-1B program does not bring in high-skilled workers and is instead used to replace U.S. workers at lower costs. A commenter similarly expressed support for DHS's justifications, concluding that the current random lottery allows for program abuse and has become the primary mechanism through which the H-1B program fails to meet its core mission. Another commenter acknowledged that given the high volume of H-1B applications USCIS simultaneously receives exceeding the cap, it is impossible to determine the order in which they were filed. The commenter stated that because the original statute cannot be adhered to, DHS's rationale in proposing an updated selection process is reasonable.

Response: As noted in the H-1B Proclamation, the H-1B program has been deliberately exploited to replace, rather than supplement, U.S. workers with lower-paid, lower-skilled labor. 90 FR 46027 (Sept. 24, 2025). The large-scale replacement of U.S. workers through systemic abuse of the program has undermined both our economic and national security. 90 FR 46027 (Sept. 24, 2025). The current random selection process has contributed to the ongoing exploitation of the H-1B program to benefit certain companies in certain sectors, while crowding out other companies and legitimate job seekers. For this primary reason, DHS is implementing a weighted selection process that would generally favor the allocation of H-1B visas to higher-skilled and higher-paid aliens, while maintaining the opportunity for employers to secure H-1B workers at all wage levels, to better serve the congressional intent for the H-1B program.

Comment: Some commenters opposed the rule, claiming that the proposed rule is based on the false premise that foreign workers displace or take away job opportunities from U.S. workers and depress wages. For instance, some commenters cited statistics highlighting the positive impacts H-1B workers

make to the economy and showing that H-1B workers make wages above the median for U.S. workers. Likewise, a commenter said that the NPRM ignores studies that convincingly show that workers with H-1B visas earn more than similarly situated U.S. workers. The commenter added that the proposed rule fails to show why it is necessary to prioritize more-senior workers given that the average H-1B visa holder is already earning more than similar U.S. workers, particularly if doing so risks eroding many of the economic benefits of the H-1B program. Another commenter said that entry level roles are not displacing U.S. workers and that removing international graduates from the applicant pool simply excludes equally qualified candidates.

Response: DHS disagrees with the commenters. As an initial matter, DHS does not dispute the general premise that H-1B workers can make positive contributions to the U.S. economy. DHS sees the value that highly skilled H-1B workers can bring to the economy, provided that the H-1B program functions as originally intended, which is to help employers bring temporary workers into the United States to perform additive, high-skilled functions to supplement the U.S. workforce and to help the U.S. economy.

However, the H-1B program is not functioning as intended. Instead, it is being exploited on a large scale to bring in lower-paid, lower-skilled workers. As noted in the H-1B Proclamation the H-1B program has been deliberately exploited to replace, rather than supplement, U.S. workers with lower-paid, lower-skilled labor. 90 FR 46027 (Sept. 24, 2025). The H-1B Proclamation also indicated that many U.S. tech companies have laid off their qualified and highly skilled U.S. workers and simultaneously hired thousands of H-1B workers, and some even forced their U.S. workers to train the foreign workers. 90 FR 46027 (Sept. 24, 2025). Further, unemployment among recent computer science and computer engineering graduates has reached some of the highest levels in the country and has been exacerbated by abuse of the H-1B visa program. 90 FR 46027 (Sept. 24, 2025). This rule is an important step to reversing the abuse of the H-1B program. This rule will disincentivize the existing widespread use of the H-1B program to fill lower paid or lower skilled positions. Instead, U.S. employers that might have petitioned for cap-subject H-1B workers to fill relatively lower-paid, lower-skilled positions, may be incentivized to hire available and qualified U.S. workers for those positions.

Comment: Many commenters disputed the premise that wage is a proxy for experience, skill, or education. Several commenters stated that the proposed rule is based on the false premise that salary alone equates with value and individuals who earn more in their profession contribute more to the economy. Some commenters said that DHS failed to provide empirical support for its core assumptions—that higher wage levels reliably correlate with higher skills, productivity, or greater economic benefit to the United States, or that some industries paying higher wages are more valuable to the economy and society than other industries that offer more modest salaries. Commenters emphasized that wage levels do not accurately reflect skill, innovation, potential, economic contributions, contributions to underserved communities, or other contributions. One commenter noted that wage levels do not necessarily reflect skill or economic contribution and cited multiple studies that demonstrate that using wage level as a proxy for skill level lacks empirical evidence and may harm both employers and workers. Some commenters remarked that wages are impacted by a variety of factors not taken into account in the rule, including different industries, market, employer size, or geography, and it is an unreliable proxy for skill and professional level.

A commenter said level I reflects standard entry-level positions and that removing the level would contradict “the government’s own system and unfairly redefines “specialty occupation” as something only senior employees can fill.” Another commenter voiced concern that the proposed rule would significantly skew H-1B lottery outcomes and urged DHS to reconsider its impact on lower-wage applicants.

Response: DHS disagrees with these comments and believes that salary generally is a reasonable proxy for skill level. As stated in the NPRM, in most cases where the proffered wage equals or exceeds the prevailing wage, a prevailing wage rate reflecting a higher wage level is a reasonable proxy for the higher level of skill required for the position, based on the way prevailing wage determinations are made. DHS believes that an employer who offers a higher wage than required by the prevailing wage level does so because that higher wage is a clear reflection of the beneficiary's value to the employer, which, even if not related to the position's skill level *per se*, reflects the unique qualities the beneficiary possesses. DHS believes that the rule

will incentivize an employer to proffer a higher wage to increase their chances of selection, but that the employer only would do so if it was in their economic interest to do so based on the beneficiary's skill level and relative value to the employer.

DHS acknowledges that aliens may be offered salaries at level I prevailing wages to work in specialty occupations and may be eligible for H-1B status. DHS is not removing the possibility of selection for registrations for positions paid at level I wages through this rulemaking. However, DHS also believes that, in years of demand exceeding the annual limits for initial H-1B visas or status grants subject to the numerical allocations, the current process of purely random selection does not optimally serve Congress' purpose for the H-1B program. Instead, in years of excess demand, selection of H-1B cap-subject petitions generally on the basis of the OEWS prevailing wage level that the proffered wage equals or exceeds, which generally correlates to higher skills, is more consistent with the purpose of the H-1B program and with the administration's goal of improving policies such that H-1B classification is more likely to be awarded to petitioners seeking to employ higher-skilled and higher-paid beneficiaries. The purpose of this rule is to implement a weighted selection process that will generally favor the allocation of H-1B visas to higher-skilled and higher-paid aliens, while maintaining the opportunity for employers to secure H-1B workers at all wage levels.

Comment: Multiple commenters stated that wage levels are inadequate to compare workers across occupations and that wage levels are intended to ensure fair pay within occupation and area of intended employment. Some commenters stated that wage levels are based on experience, education, and supervisory level within a given occupation and geographic location, while other commenters stated that wage levels are more reflective of seniority and career progression rather than skill. A commenter similarly indicated that the prevailing wage levels were not intended to be used in this way, but rather meant to ensure that employing foreign workers does not adversely impact the wages and working conditions of U.S. workers, and are used by DOL to characterize career progression.

Some commenters stated opposition to the rule, reasoning that it would favor lower-skilled and lower-paid positions, contrary to its stated goal of prioritizing higher-skilled, higher-paid workers. A commenter referenced how prevailing

wage levels are calculated based on the average wage for similarly employed workers in a specific occupation and location, which could advantage occupations with lower entry-level requirements. Similarly, a commenter stated that the use of wage levels would prioritize lower-skilled, lower-paid workers, undermining the purpose of the rule, which is to prioritize top talent with scarce and in-demand skills. Additionally, the commenter stated that while wage levels correlate well with wages within a specific occupation, wages between occupations can vary significantly, which was not taken into account in the proposed rule, and provided several examples to illustrate this point. Some commenters stated the proposed selection process could favor seniority in lower-paid occupations over high-wage, high-skill roles in other fields, and is not supported by underlying statute, DOL regulations, guidance, or "the government's own data."

While voicing concern about the use of prevailing wage levels in the proposed weighted selection process, a commenter stated that applying wage levels across industries was "inappropriate," as DOL's prevailing wage system accounts for factors, such as job duties, education, experience, and location, which vary significantly by occupation. The commenter remarked that high-skilled roles—such as physicians, lawyers, and professors—may still fall under level I wages due to standard entry requirements, while other occupations with lower educational thresholds could qualify for higher wage levels. The commenter reasoned that this mismatch could lead to inequitable outcomes, where individuals in lower-paid occupations might receive more chances in the lottery than those in higher-skilled, higher-paid roles.

Multiple commenters discussed concerns in associating lower wage levels with low skill work, noting that more advanced occupations with more rigorous job requirements may be assigned lower wage levels compared to less advanced occupations with lower job requirements. For example, some commenters said that a specialized surgeon earning \$300,000 would be certified as a level I and a Ph.D. working at a high tech company earning \$280,000 would be certified at a level II, whereas an acupuncturist earning \$41,600 is considered level III and a landscape architect with a \$36,000 salary is certified as level IV. Another commenter noted that a Master's degree requirement for a Job Zone 4 occupation can result in a level II wage while the

same requirement for a Job Zone 5 occupation can result in a level I wage, despite the Job Zone 5 position being more advanced. Another commenter similarly noted that employees in occupations with a higher Specific Vocational Preparation (SVP) and higher levels of compensation may be assigned lower prevailing wage levels than occupations with a lower SVP and said that a position requiring a doctorate and 2–4 years of experience may have a prevailing wage level I that is set at \$200,000 per year, whereas a position in an occupation that has an entry level requirement of a Bachelor's degree and 0–2 years of experience may yield a salary of \$150,000 per year at prevailing wage level 3. Another commenter noted the different wage levels resulting from differing job requirements of cardiologists as compared to civil engineers.

Response: DHS disagrees that wage levels are inadequate to compare workers across occupations. DHS is aware that different occupational classifications carry differing position and wage requirements and that wage levels reflect a comparison within an occupation, rather than across occupations. DHS also recognizes that higher wage levels may correspond with seniority, but this does not negate the fact that they also reflect higher skills required for the position.

As noted in the NPRM, DHS believes that salary generally is a reasonable proxy for skill level.⁶⁹ DHS data shows a correlation between higher salaries and higher skill and wage levels.⁷⁰ 90 FR 45986, 45990 (Sept. 24, 2025). As a position's required skill level increases relative to the occupation, so, too, may the wage, and necessarily, the

⁶⁹ See DOL, ETA, "Wage Methodology for the Temporary Non-Agricultural Employment H-2B Program," 76 FR 3452, 3453 (Jan. 19, 2011) (it is a "largely self-evident proposition that workers in occupations that require sophisticated skills and training receive higher wages based on those skills."); Daniel Costa & Ron Hira, Economic Policy Institute, "H-1B Visas and Prevailing Wage Level" (May 4, 2020), <https://www.epi.org/publication/h-1b-visas-and-prevailing-wage-levels>. ("Specialized skills should command high wages; such skills are typically a function of inherent capability, education level, and experience. It would be reasonable to expect that these workers should receive wages higher than the median wage.")

⁷⁰ For example, in Computer and Mathematical Occupations, the FY 2024 national median salary of H-1B workers for Level I was \$89,253; for Level II was \$106,000; for Level III was \$140,000; and for Level IV was \$163,257. USCIS OPQ, SAS PME C3 Consolidated, VIBE, DOL OFLC TLC Disclosure Data, queried 4/2025, TRK #17347. This example illustrates that median wages generally increase with the increase to the LCA wage level. As LCA wage levels increase to account for a higher-than-usual skill or other job requirements, the data show the correlation between higher median wages and higher skill and wage levels.

corresponding prevailing wage.⁷¹ A proffered wage that corresponds to the prevailing wage rate reflecting a higher wage level is generally a reasonable proxy for the higher level of skill of the alien or value placed by the employer on the alien's value to the employer. DHS recognizes, however, that some employers may choose to offer a higher proffered wage to a certain beneficiary to be more competitive in the H-1B selection process.

Regarding the occupational examples provided by commenters, DHS notes that the purpose of this rule is not to prioritize certain occupations or industries over others. The purpose of this rule is to implement the numerical cap in a manner that generally favors the allocation of H-1B visas to higher-skilled and higher-paid aliens, while maintaining the opportunity for employers to secure H-1B workers at all wage levels and in all eligible occupations.

Comment: Some commenters criticized the proposed rule as lacking clarity and justification, specifically stating that the rule does not clearly explain how “wages” will be defined or measured, whether future positions are considered, how wage amendments after approval will be handled, how wage levels will be set or updated, or how part-time versus full-time work will be treated. A commenter stated that the rule lacks necessary specificity, as it fails to define key terms (e.g., how “wage” is computed for remote work and for split worksites), and it offers no credible description of enforcement mechanisms to prevent wage manipulation, post-selection wage reductions, or worksite misreporting. The commenter concluded that this vagueness would invite both litigation and systemic abuse.

Response: DHS disagrees with these commenters' assertions that the rule lacks clarity and justification and disputes the claims made by these commenters. DOL regulations define payment of wages for purposes of satisfying the H-1B required wage. See 20 CFR 655.731(c)(2). This rule does not change how wages are defined or measured, including how wages are computed for remote work and split worksites. It is unclear what the commenter is referring to when stating that the rule does not clearly explain

“whether future positions are considered,” but notes that at the time a registration is submitted, each prospective petitioner is required to sign an attestation, under penalty of perjury, that the registration reflects a legitimate job offer (among other attestations). Regarding the comment claiming a lack of clarity around how wage amendments after approval will be handled, DHS refers to new 8 CFR 214.2(h)(10)(iii), finalized in this rule, which allows USCIS to deny a subsequent new or amended petition filed by the petitioner, or a related entity, on behalf of the same beneficiary if USCIS were to determine that the filing of the new or amended petition is part of the petitioner's attempt to unfairly increase the odds of selection during the registration (or petition, if applicable) selection process, such as by reducing the proffered wage to an amount that would be equivalent to a lower wage level than that indicated on the original registration or petition. Furthermore, DHS does not set or update wage levels and did not propose to do so through this rule. Finally, the adjudication of part-time employment is not relevant in the selection process.

5. Concerns the Rule Is Arbitrary and Capricious

Comment: Some commenters raised concerns that the proposed weighted selection process's core assumption—that higher salaries correlate with economic value, innovation potential, and long-term contributions to U.S. competitiveness—is arbitrary and capricious. A commenter stated that treating salary as a universal proxy for skill across occupations and regions is insufficiently substantiated. The commenter said the change effectively converts a beneficiary-centric lottery into a salary screen, raising “arbitrary and capricious” risk and disregarding reliance interests of diverse stakeholders. A commenter stated that every agency has a constitutional duty under the Administrative Procedure Act (APA) to act in good faith, to prevent arbitrary discrimination, and to uphold the rule of law, and this rule fails all three tests. Another commenter noted that OEWS updates trail the market, so similar offers can receive different weights based on timing alone. The commenter concluded that elevating salary to the “decisive lever,” without robust evidence that it consistently tracks skill across occupations and regions, raises serious APA concerns.

One commenter said that the proposed rule is arbitrary and capricious because it overlooks the impact on H-1B petitions for essential

roles in healthcare, education, and other sectors reliant on early-career professionals. Citing *Motor Vehicle Mfrs. Ass'n v. State Farm*, the commenter said DHS failed to consider a key aspect of the issue, resulting in a policy that harms U.S. businesses and contradicts the Administration's goals. Other commenters stated that the proposed rule was arbitrary and capricious because it failed to address the impact on small and mid-sized employers.

Response: Based on its comprehensive review of the submitted comments and available evidence, DHS has concluded that, by changing the selection process from a purely random lottery selection to a weighted selection process generally based on the OEWS prevailing wage level that the proffered wage equals or exceeds, DHS will implement the statute more faithfully to its dominant legislative purpose. DHS disagrees with the claim that this rule is arbitrary or capricious, or that it fails to account for potential negative impacts on certain types of H-1B positions and industries. First, DHS reiterates that the new weighted selection process will neither exclude nor “effectively exclude” H-1B visa petitions for level I wages. Second, DHS has determined, after considering possible negative impacts, that pure randomization does not serve the ends of the H-1B program or congressional intent to help U.S. employers fill labor shortages in positions requiring highly skilled workers. DHS believes that the potential costs of engaging in a wage-level-based weighting of registrations for unique beneficiaries are outweighed by the benefits of better ensuring that initial H-1B visas and status grants would more likely go to the highest skilled or highest paid beneficiaries, while not effectively precluding those at lower wage levels.

Comment: A commenter said that the proposed rule “represents a substantial policy shift” from when the agency said in 2019 that prioritizing H-1B petitions beyond degree-based criteria “would require statutory change.” The commenter noted that under the APA, agencies are expected to provide a reasoned explanation when changing interpretations. The commenter claimed DHS did not do so, and that DHS's change in interpretation is “[w]ithout a compelling factual record or new statutory mandate” and risks being found arbitrary and capricious. Another commenter said that the proposed rule disregards established reliance interests for certain industries and fails to provide a rational basis for its changes, rendering it legally unsupported and arbitrary.

⁷¹ DOL, ETA, Prevailing Wage Determination Policy Guidance: Nonagricultural Immigration Programs (last modified Nov. 2009), https://www.dol.gov/sites/dolgov/files/ETA/oflc/pdfs/NPWHC_Guidance_Revised_11_2009.pdf (noting that a wage level increase may be warranted if a position's requirements indicate skills that are beyond those of an entry level worker).

Response: DHS recognizes that it considered the issue of cap selection by wage level in 2019 and concluded at that time that prioritization by wage level or other bases would require statutory change. DHS acknowledged that prior statement in footnote 20 in the preamble to the proposed rule. *See* 90 FR 45986, 45990 (Sept. 24, 2025). DHS reconsidered the analysis as far back as 2020, and again in the context of this rulemaking, and determined that selection by wage level is consistent with its broad statutory authority and fills a statutory gap in a way that is consistent with a key goal of the program.

DHS recognizes that some employers may have relied on a random selection process to prepare for the possibility that the beneficiary(ies) the employer registered for might be selected. DHS, however, disagrees with any assertion that a purely random selection process engenders strong reliance interests or that such reliance interests outweigh the benefit of a weighted selection process that better protects the wages, working conditions, and job opportunities of U.S. workers.

DHS disagrees with the assertion that it did not provide a rational basis for the rule. As explained in the preamble to the proposed rule, while the current random selection of petitions or registrations is reasonable, DHS believes it is neither the optimal, nor the exclusive method of selecting registrations or petitions toward the numerical allocations when more registrations or petitions, as applicable, are simultaneously submitted than projected as needed to reach the numerical allocations. *See* 90 FR 45986, 45990 (Sept. 24, 2025). Pure randomization does not serve the ends of the H-1B program or congressional intent to help U.S. employers fill labor shortages in positions requiring highly skilled workers.⁷² Under the current random selection process, in every fiscal year from FY 2019 through FY 2024, petitions for beneficiaries at wage level III and wage level IV were the least represented among all wage levels in cap-subject H-1B filings, both under the regular cap and the advanced-degree exemption.⁷³

⁷² *See* H.R. Rep. 101–723(I) (1990), as reprinted in 1990 U.S.C.C.A.N. 6710, 6721 (stating “The U.S. labor market is now faced with two problems that immigration policy can help to correct. The first is the need of American business for highly skilled, specially trained personnel to fill increasingly sophisticated jobs for which domestic personnel cannot be found and the need for other workers to meet specific labor shortages.”).

⁷³ USCIS OPQ, CLAIMS3 and ELIS, queried 3/2025, TRK #17265. LCA data from DOL. Disclosure Files for LCA Programs (H-1B, H-1B1, E-3), FY–

As DHS explained in the preamble to the proposed rule, by engaging in a wage-level-based weighting of registrations for unique beneficiaries, DHS will better ensure that initial H-1B visas and status grants would more likely go to the highest skilled or highest paid beneficiaries, while not effectively precluding those at lower wage levels. *See* 90 FR 45986, 45991 (Sept. 24, 2025). Facilitating the admission of higher skilled workers “would benefit the economy and increase the United States’ competitive edge in attracting the ‘best and the brightest’ in the global labor market,” consistent with the goals of the H-1B program and will help to safeguard the nation’s overall economic security.⁷⁴

Comment: A commenter alleged that USCIS failed to explain why it is changing direction based on its previous findings that foreign nationals employed in STEM fields are important for businesses and the economic development of the United States. *See* 81 FR 13040, 13047–48 (Mar. 11, 2016) (cap gap STEM OPT rule). The commenter concluded that USCIS failed to explain or justify the reasons for its “reverse in course” in light of those prior findings and policy determinations. The commenter also claimed that DHS failed to consider the related reliance interests of employers in employing recent international student graduates. *See Dep’t of Homeland Sec. v. Regents of the Univ. of Cal.*, 591 U.S. 1, 30 (2020).

Response: DHS disagrees with the commenter’s assertion that statements made nearly one decade ago in the context of a rulemaking pertaining to F-1 nonimmigrants indicate a change of course in the H-1B nonimmigrant context. DHS notes that this final rule, which pertains to the selection of beneficiaries in the H-1B cap selection process, does not preclude employers from registering H-1B beneficiaries with STEM degrees in the H-1B cap and, if selected, from filing a petition on their behalf.

As DHS explained in the preamble to the proposed rule, by engaging in a

2018–FY–2024. DOL data downloaded from <https://www.dol.gov/agencies/eta/foreign-labor/performance> (last visited Nov. 24, 2025).

⁷⁴ *See* Muzaffar Chishti & Stephen Yale-Loehr, Migration Policy Institute, The Immigration Act of 1990: Unfinished Business a Quarter-Century Later (July 2016), https://www.migrationpolicy.org/sites/default/files/publications/1990-Act_2016_FINAL.pdf (“Sponsors of [the Immigration Act of 1990, which created the H-1B program as it exists today,] believed that facilitating the admission of higher-skilled immigrants would benefit the economy and increase the United States’ competitive edge in attracting the ‘best and the brightest’ in the global labor market.”).

wage-level-based weighting of registrations for unique beneficiaries, DHS will better ensure that initial H-1B visas and status grants would more likely go to the highest skilled or highest paid beneficiaries, while not effectively precluding those at lower wage levels. *See* 90 FR 45986, 45991 (Sept. 24, 2025). As explained previously in response to other comments, pure randomization does not serve the ends of the H-1B program or congressional intent to help U.S. employers fill labor shortages in positions requiring highly skilled workers, regardless of whether those positions are in STEM related fields. DHS recognizes that some employers may have relied on a purely random selection process to prepare for the possibility that the beneficiary(ies) the employer registered for might be selected. DHS, however, disagrees with any assertion that a purely random selection process engenders strong reliance interests or that such reliance interests outweigh the benefit of a weighted selection process that better protects the wages, working conditions, and job opportunities of U.S. workers, including those in STEM related positions.

6. Other Legal Comments

Comment: Some commenters wrote that terminating or changing the lottery system has broad political and economic consequences that implicates the major questions doctrine, so clear congressional authority is required to change the system. Another commenter said that the rule implicates the major questions doctrine, explaining that when an agency claims authority to make decisions of “vast economic and political significance,” courts require clear congressional authorization *West Virginia v. EPA*, 597 U.S. 697, 723–4 (2022). The commenter added that fundamentally restructuring how H-1B visas are allocated constitutes a major question and that the INA’s directive that visas be issued “in the order” petitions are filed does not clearly authorize DHS to create a wage-based preference system.

Response: The major questions doctrine, as articulated in *West Virginia v. EPA*, applies in “extraordinary cases” where an agency claims a “transformative expansion” of its regulatory authority without clear congressional authorization. However, the selection process detailed in this rule does not trigger the major questions doctrine.

This rule deals with the Secretary’s administration and enforcement of the H-1B numerical allocations—a topic that DHS has long regulated, including

via the random selection process that this rule will replace. Specifically, and as discussed elsewhere in this rule, the Secretary has broad authority to administer and enforce the INA, establish such regulations as the Secretary deems necessary for carrying out such authority, and to prescribe the time and conditions under which an alien may be admitted to the United States as a nonimmigrant and how an importing employer may petition for nonimmigrant workers. See INA secs. 103(a), 214(a)(1), and (c)(1), 8 U.S.C. 1103(a), 1184(a)(1), and (c)(1). Such authority includes prescribing rules to fill statutory gaps, which DHS has done for years.⁷⁵

In *West Virginia v. EPA*, the Court found that the U.S. Environmental Protection Agency (EPA) lacked clear congressional authorization to implement a generation-shifting approach to regulating power plant emissions under the Clean Air Act. By contrast, DHS's authority under the INA and the HSA is broad and clear and falls under DHS's traditional role. Unlike the EPA's Clean Power Plan, which sought to restructure the nation's energy grid—a task far outside the EPA's traditional role—DHS's wage-based selection process is well within its traditional role of administering and regulating the H-1B visa program. DHS has long exercised authority over the selection process for H-1B petitions, and this rule simply refines the selection methodology to prioritize higher paid and higher skilled workers. This is not a novel or transformative assertion of authority but rather a refinement of an existing regulatory function.

In addition, in *West Virginia v. EPA*, the Court emphasized that the major questions doctrine applies when an agency's action is inconsistent with Congress's broader design. Here, the wage-based weighted selection process aligns with Congress's intent in the INA to protect the wages, working conditions, and job opportunities of U.S. workers by ensuring that H-1B workers are not used to undercut domestic wages. See INA sec. 212(n), 8 U.S.C. 1182(n). The INA explicitly ties H-1B eligibility to wage requirements contained in the LCA process, which

requires employers to pay the greater of the actual or the prevailing wage to H-1B workers. The INA also mandates the computation of prevailing wage levels. See INA sec. 212(p), 8 U.S.C. 1182(p). This rule builds on this statutory framework by prioritizing higher-wage workers in the selection process, thereby furthering Congress's goal of protecting the wages, working conditions, and job opportunities of U.S. workers.

The Court in *West Virginia* was concerned with the EPA's assertion of authority to “substantially restructure the American energy market” under a “long-extant statute.” The wage-based H-1B weighted selection process does not involve a comparable expansion of DHS's authority. DHS is not asserting new or unheralded powers; it is merely adjusting the methodology for selecting H-1B registrations (or petitions) in a way that is consistent with its statutory mandate and historical practice. The rule does not create a new regulatory regime or fundamentally alter the structure of the H-1B program.

The majority in *West Virginia* identified several factors that might trigger the major questions doctrine, including whether the agency action involves a matter of “vast economic and political significance” or represents an “unheralded power.” None of those factors apply here. The wage-based weighted selection process does not have vast economic or political significance; it affects only the method by which DHS selects H-1B registrations (or petitions) under the statutory cap. While the rule may be significant to those U.S. workers who have had to compete with lower-paid H-1B workers who have dominated the current random selection process, and will help to attract the “best and brightest” to the United States by increasing the chance of selection for higher-skilled, higher-paid aliens, the rule's overall economic impact is not vast. And this rule does not assert a new power; DHS has long exercised authority over the H-1B selection process and has previously modified that process through rulemakings.

While the wage-based H-1B selection process is economically significant under Executive Order (E.O.) 12866, it does not rise to the level of “vast economic and political significance” required to trigger the major questions doctrine. The threshold for economic significance under E.O. 12866 is relatively low (\$100 million annual impact), whereas the major questions doctrine requires a much higher level of economic and political impact. In *West Virginia v. EPA*, the Court applied the

doctrine to the EPA's Clean Power Plan because it sought to restructure the entire energy grid—a matter of extraordinary economic and political significance. By contrast, DHS's wage-based H-1B weighted selection process does not involve a comparable restructuring of the economy or labor market. The rule affects only the selection methodology for H-1B registrations (or petitions), a discrete regulatory function within DHS's traditional authority. The wage-based weighted selection process is narrowly tailored to incentivize employers seeking initial classification of H-1B cap-subject aliens to offer higher wages, or to petition for positions requiring higher skills and higher-skilled aliens, that are commensurate with higher wage levels. It affects the odds of selection for a program that has long been oversubscribed and under which selection was previously random and never guaranteed. It does not fundamentally alter the structure of the H-1B program or the broader labor market. While the rule may shift the composition of H-1B workers toward higher-wage positions, it does not impose new substantive requirements on employers or workers beyond the existing statutory framework.

Comment: A commenter wrote that DHS has not demonstrated that it has considered and ruled out alternative methods to accomplish its goals, which is required by the APA. The commenter wrote that “[t]he only other means DHS appears to have considered is the ‘ranking’ model the agency pursued in 2020, which would have had even more drastic impacts on early-career talent, and was vacated in court and later withdrawn.”

Some commenters expressed concern that the proposed rule could make the program more susceptible to legal challenges. One commenter stated that legal challenges regarding statutory authority for the weighted selection approach would be likely, and litigation would leave employers with lingering uncertainty about whether the process might “change midstream.” The commenter wrote that “[e]mployers begin planning months in advance of the H-1B registration window, and it is critical for businesses to be able to fulfill talent needs in their operations with confidence that the rules will not change midstream. Expected litigation could cause companies to lose global talent to other countries, especially in the midst of competition for dominance in AI and other critical technologies.”

Response: DHS agrees that it discussed in the preamble to the NPRM the alternative of proposing the

⁷⁵ See *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 395 (2024) (explaining that a statute's meaning may be that the agency is authorized to exercise a degree of discretion and empowered to prescribe rules to fill in statutory gaps based on “reasoned decision making”); see also *Liu v. Mayorkas*, 588 F. Supp. 3d 43, 55 (D.D.C. 2022) (finding that the registration requirement does not violate the INA, is not ultra vires, and that registration is merely “an antecedent procedural step to be eligible to file an H-1B cap-subject petition”); *Walker Macy LLC v. USCIS*, 243 F. Supp. 3d 1156 (D. Or. 2017).

methodology from the 2020 H-1B Selection NPRM and explained why it instead chose to propose a weighted selection process. See 90 FR 45986, 46013 (Sept. 24, 2025). DHS also requested potential alternatives to the proposed weighted selection process. 90 FR at 46013. The commenter, however, did not identify alternatives for DHS to consider and instead asserted that the statute is unambiguous and that DHS is not permitted to establish a prioritization scheme through rulemaking. (See subsequent Section III F.1 *Alternatives to the Proposed Weighted Selection Process* for DHS' consideration of alternatives suggested by other commenters.)

DHS disagrees with the commenter's assertion that DHS should not finalize the rule because it may lead to litigation challenging the rule and uncertainty as to the cap selection process while litigation is pending. DHS does not believe that the threat of future litigation, and speculation as to the ultimate outcome of any future litigation pertaining to the final rule, is a reasonable basis not to finalize a rule that will improve the administration of the H-1B cap selection process and better protect the wages, working conditions, and job opportunities of U.S. workers.

D. Proposed Changes to the Registration Process for H-1B Cap-Subject Petitions

1. Proposed Weighted Selection Process

Comment: Some commenters expressed their support for the proposed weighted selection process. For instance, a commenter stated their support for maintaining opportunities across all wage levels. The commenter remarked that while the proposed rule prioritizes higher wage levels, it still would allow employers offering positions at wage levels I and II to participate in the H-1B program. The commenter concluded that this approach would help ensure the program remains accessible to a wide range of employers and industries that require specialized knowledge but may not offer top-tier wages. Another commenter stated support for the weighted selection process and particularly commented on the use of OEWS wage levels for a SOC code within a particular area of intended employment as an effective mechanism for wage and geographic normalization. The commenter explained that this "astutely avoids an unfair advantage" for employers in certain areas.

Response: DHS agrees that the weighted selection approach will help ensure the program remains accessible

to a wide range of employers and industries. The purpose of this rule is to implement a weighted selection process that will generally favor the allocation of H-1B visas to higher skilled and higher-paid aliens, while maintaining the opportunity for employers to secure H-1B workers at all wage levels. DHS also agrees that the use of OEWS wage levels is effective for wage and geographic normalization.

Comment: Some commenters asserted that the proposed weighting (four times chance for level IV, three times chance for level III, two times chance for level II, and one times chance for level I) is arbitrary. One commenter said the weighting appears to simply reflect the numbers assigned to the four wage levels, not workers' relative salaries, skill levels, or economic value. Another such commenter added that the usage of 4x, 3x, 2x, and 1x weighting lacks evidence demonstrating that the multiples would meet the H-1B program's goals, address integrity gaps left unresolved by previous reform, and protect U.S. workers.

Response: DHS disagrees that the proposed weights are arbitrary. The multiples of 4 times, 3 times, and 2 times, correspond to wage levels IV, III, and II, respectively, as selected on the registration form (or petition if registration is suspended). It is reasonable to tie the probability of an alien's chances of selection in the lottery to the highest OEWS wage level that the proffered salary equals or exceeds because salary is generally a reasonable proxy for skill level.⁷⁶ DHS data show a correlation between higher salaries and higher skill and wage levels.⁷⁷ As a position's required skill level increases relative to the occupation, so too, may the wage level, and necessarily, the corresponding prevailing wage. A proffered wage that

corresponds to the prevailing wage rate reflecting a higher wage level is generally a reasonable proxy for the higher level of skill required for the position. The proposed weighting scheme was chosen because it would achieve the policy goals of increasing the average skill level of the H-1B worker, thus better protecting U.S. workers, while balancing that goal with the competing policy goal of ensuring that U.S. employers who are unable to pay a proffered wage that corresponds to a higher wage level are not precluded from the opportunity to obtain H-1B workers if otherwise eligible. DHS believes that this rule appropriately balances the interests of U.S. workers with the interests of petitioning employers and the alien workers they seek to employ as H-1B nonimmigrants.

2. Required Information From Petitioners

a. OEWS Wage Level

Comment: A commenter asked about the timing of the wage level "lock-in." Specifically, the commenter said that the rule requires that "the OEWS wage level selected on the petition must reflect the corresponding OEWS wage level as of the date that the registration underlying the petition was submitted." See 90 FR 45986, 45993 (Sept. 24, 2025). The commenter asked DHS to clarify which data controls if OEWS wage data is updated between registration and petition filing, which can be 90 or more days apart. The commenter also asked how registrants should account for this uncertainty when making initial wage level selections.

A few commenters expressed concerns about potential consequences if OEWS prevailing wage data were to change in between the time of registration submission and petition filing. A commenter stated that OEWS updates can lag, which could result in identical job offers that straddle release cycles to receive different weights for reasons unrelated to skill, producing arbitrary outcomes. Another commenter discussed annual wage appreciation that is effective for their position each May, which could affect the wage level selected, but would not be anticipated or reflected in their March petition. The commenter expressed concerns about being penalized if they submit lower or higher wage estimate of their future wage. The commenter suggested more flexible prevailing wage levels, rather than a fixed wage level. A commenter expressed that requiring employers to commit to specific wage levels during registration, then verifying that petition wages match registration wages months

⁷⁶ See DOL, ETA, "Wage Methodology for the Temporary Non-Agricultural Employment H-2B Program," 76 FR 3452, 3453 (Jan. 19, 2011) (it is a "largely self-evident proposition that workers in occupations that require sophisticated skills and training receive higher wages based on those skills."); Daniel Costa & Ron Hira, Economic Policy Institute, "H-1B Visas and Prevailing Wage Level" (May 4, 2020), <https://www.epi.org/publication/h-1b-visas-and-prevailing-wage-levels>. ("Specialized skills should command high wages; such skills are typically a function of inherent capability, education level, and experience. It would be reasonable to expect that these workers should receive wages higher than the median wage.").

⁷⁷ DHS provided the following example in the NPRM: in Computer and Mathematical Occupations, the FY 2024 national median salary of H-1B workers for Level I was \$89,253; for Level II was \$106,000; for Level III was \$140,000; and for Level IV was \$163,257. USCIS OPQ, SAS PME C3 Consolidated, VIBE, DOL OFLC TLC Disclosure Data, queried 4/2025, TRK #17347. See 90 FR 45986, 45990 (Sept. 24, 2025).

later, would create multiple opportunities for technical violations that have nothing to do with fraud or abuse but reflect the reality of how hiring processes work in practice.

Response: The OEWS wage level selected on the petition must reflect the corresponding OEWS wage level as of the date that the underlying registration was submitted, unless registration is suspended. In other words, in years that registration is required, the OEWS wage data used to determine the wage level on the registration is “locked in” as of the date of the registration. As clearly stated in the NPRM 90 FR 45986, 45993 (Sept. 24, 2025) and finalized at new 8 CFR 214.2(h)(8)(iii)(D)(1), petitioners must submit evidence of the basis of the wage level selected on the registration *as of the date that the registration underlying the petition was submitted* (emphasis added).

Specifically, as finalized, the revisions to Form I-129 direct petitioners to follow the form instructions to select the appropriate wage level box in response to question 2, Section 3.⁷⁸ The revisions to the Form I-129 instructions list the following as required initial evidence if filing for an H-1B cap petition in a year that registration is required: “Evidence of the basis of the wage level selected on the registration. Such evidence could include, but is not limited to, a printout from the DOL [Office of Foreign Labor Certification] (OFLC) Wage Search website for the beneficiary’s SOC code and area(s) of intended employment *as of the date of registration*” (emphasis added). The revisions to the Form I-129 instructions further state: “The OEWS wage level selected must reflect the corresponding OEWS wage level *as of the date that the registration underlying the petition was submitted*” (emphasis added). However, if the registration process is suspended, the OEWS wage level selected must reflect the corresponding OEWS wage level as of the date that the petition is submitted.” Thus, DHS believes it is sufficiently clear that the appropriate wage level selected in response to Section 3, question 2 pertains to OEWS wage data that was current as of the date of registration. Even if OEWS wage data changes in between the registration and the petition filing, the Form I-129 petition (*i.e.*, the appropriate wage level box selected on question 2, Section 3) should still reflect information that was current as of the time of registration. For

example, if the proffered wage at the time of registration corresponded to a level IV wage, but a subsequent change in OEWS wage data resulted in the same proffered wage corresponding to a level III wage at the time of filing the petition, the petitioner would select the level IV wage box in response to Section 3, question 2, on the Form I-129 petition. However, the petitioner may wish to submit an explanation of any relevant changes in OEWS wage data with the petition.

Regarding the commenters’ concerns about committing to the OEWS wage level at the time of registration and the suggestion for more flexible prevailing wage levels, DHS must collect the wage information at the time of registration, prior to petition filing in April, in order to weight and select registrations. DHS does not see another viable solution for collecting wage information at a later date or allowing flexible wage levels. Additionally, under the current registration process, registrants must attest that the registration reflects a legitimate job offer. Through this rule making, DHS is modifying this language to require registrants certify that the registration reflects a bona fide job offer and codifying that “a valid registration must represent a bona fide job offer” at new 8 CFR 214.2(h)(10)(ii).⁷⁹ A bona fide job offer is one that exists as described on the registration and petition and in which the employer intends to employ the beneficiary. As such, DHS believes that registrants (or petitioners) should be able to accurately reflect the corresponding wage level at the time of registration.

Comment: A commenter stated that it is unclear whether DHS will rely on the wage level reflected on the LCA or the OEWS level that the offered wage equals or exceeds. The commenter requested DHS confirm this point.

Response: DHS disagrees that the rule is unclear on which wage level will be the basis for weighting in the selection process. The rule clearly states that, on the registration (or petition, in the event of suspended registration), the registrant (or petitioner, if applicable) must select the highest OEWS wage level that the beneficiary’s proffered wage equals or exceeds for the relevant SOC code in the area(s) of intended employment.

The wage level selected on the LCA may differ from the appropriate wage

level selected on the registration as a result of this rule allowing registrants to choose the highest OEWS wage level that the beneficiary’s proffered wage generally equals or exceeds for the relevant SOC code in the area(s) of intended employment. It is important to distinguish the appropriate wage level selected for purposes of the registration with the wage level selected for purposes of the LCA. The wage level and prevailing wage requirements are part of the LCA process regulated by DOL. A petitioner is required to file an LCA with DOL attesting that H-1B nonimmigrants will be paid either the actual wage paid by the employer to all other individuals with similar experience and qualifications for the specific employment in question or the prevailing wage for the occupational classification in the area of intended employment, whichever is greater. *See* INA secs. 212(n)(1)(A)(i) through (ii), 8 U.S.C. 1182(n)(1)(A)(i) through (ii); 20 CFR part 655, subpart H. Petitioners must follow DOL instructions to specify the appropriate wage level for the requirements of the offered position for purposes of the LCA.⁸⁰

Comment: A commenter stated that allowing employers to interpret key factors that determine the prevailing wage (*e.g.*, employers interpreting the occupation and wage level differently and granting employers substantial front-end discretion over choices when they have conflicts of interest) introduces errors. The commenter claimed that this can be remedied with stronger back-end enforcement. The commenter provided examples of H-1B data from two large H-1B employers that they state demonstrate the failure of prevailing wage regulations in achieving their goal of protecting workers, labor standards, and labor market integrity.

Response: DHS recognizes that allowing employers to select the factors (*i.e.*, the SOC code, wage level, and location) that determine prevailing wage may introduce some errors. However, DHS does not see another viable solution for allowing petitioners to self-select such factors at the registration stage. DHS notes that, as part of the DOL process, petitioners already select the factors determining the prevailing wage and include such information on the LCA. DOL must certify the application within 7 days unless the application is incomplete or contains obvious inaccuracies. *See* INA sec. 212(n)(1), 8

⁷⁸ All supporting documents to the NPRM, including the proposed revisions to the form instructions, are available in the docket at: <https://www.regulations.gov/docket/USCIS-2025-0040/document>.

⁷⁹ As stated in the NPRM, in this context, a “legitimate job offer” and a “bona fide job offer” mean the same thing. DHS is finalizing the phrase “bona fide job offer” to more closely align with the definition of a “United States employer” at 8 CFR 214.2(h)(4)(ii), which requires that the employer have “a bona fide job offer for the beneficiary to work within the United States.”

⁸⁰ *See* DOL, Labor Condition Application for H-1B, H-1B1 and E-3 Nonimmigrant Workers, Form ETA-9035CP—General Instructions for the 9035 & 9035E, <https://www.dol.gov/sites/dolgov/files/ETA/oflc/pdfs/Form%20ETA-9035CP%20Instructions-exp.%2010.31.2027.pdf> (expires Oct. 31, 2027).

U.S.C. 1182(n)(1). If the LCA is certified, the petitioner may file a petition with USCIS based on the certified LCA. See INA sec. 101(a)(15)(H)(i)(b), 8 U.S.C. 1101(a)(15)(H)(i)(b). Further, both DOL and DHS already have several integrity measures in place to ensure that employers follow the prevailing wage regulations and make truthful attestations on the LCA, registration, and petition. See 20 CFR 655.705(b); 8 CFR 214.2(h)(4)(i)(B)(1)(ii); 8 CFR 214.2(h)(10)(ii) and (11)(iii)(A)(2).

DHS agrees with the need for stronger back-end enforcement. This rule finalizes new integrity measures to guard against petitioners intentionally misclassifying the occupation, for example, by requiring the H-1B petition filed after registration selection to contain and be supported by the same position information and contain a proffered wage that equals or exceeds the prevailing wage for the corresponding OEWS wage level in the registration for the SOC code in the area(s) of intended employment. See new 8 CFR 214.2(h)(8)(iii)(D)(1). The rule also finalizes a provision allowing USCIS to deny a subsequent new or amended petition in certain circumstances suggesting an attempt to unfairly increase the odds of selection. See new 8 CFR 214.2(h)(10)(iii). These new provisions will complement existing integrity provisions and enhance DHS's back-end enforcement.

i. Prevailing Wage Not Based on OEWS or No Current OEWS Prevailing Wage Information Available

Comment: A few commenters stated that the rule would have a negative impact on petitioners using alternative wage sources, such as private wage surveys, collective bargaining agreements (CBAs), Service Contract Act (SCA) wage determinations, or other legitimate sources. For instance, a commenter stated that where employers rely on CBAs or legitimate private surveys, if the proffered wage falls below OEWS level I, the registration is forced into level I—reducing selection weight even for highly specialized jobs. The commenter said this punishes lawful, collectively bargained structures and sectors with atypical wage curves. A different commenter similarly expressed concerns that the rule does not treat wages arising out of alternative sources on equal footing. Another commenter wrote that the proposed rule conflicts with the DOL's regulations defining prevailing wages based on collective bargaining agreements and SCA wage determinations because it would render those wage determinations “disadvantageous when

they are correlated with a level I or level II OEWS wage rate under the corresponding SOC-listed occupation. As a result, USCIS' proposed rule undercuts those prevailing wage rates and deems them detrimental for employers seeking to employ H-1B workers whose wages are subject to collective bargaining or SCA wage rates.”

Response: When determining how to rank and select registrations (or petitions, as applicable) by wage level, DHS decided to use OEWS prevailing wage levels because they are the most comprehensive and objective source for comparing wages. The OEWS program produces employment and wage estimates annually for approximately 830 occupations.⁸¹ Additionally, most registrants and petitioners are familiar with the OEWS wage levels since they are used by DOL and have been used in the foreign labor certification process since 1997.⁸²

OEWS prevailing wage level data is publicly available through DOL's Foreign Labor Application Gateway (FLAG) system. Wages based on alternate sources, such as private wage surveys, collective bargaining agreements, and SCA wage determinations, are not always publicly available and do not always have four wage levels.

DHS disagrees with the assertions that petitioners that use non-OEWS wage sources would be disadvantaged by the rule. Petitioners may continue to use private wage surveys and other alternative wage sources, if they choose to do so, to establish that they will be paying the beneficiary a required wage. This rule, however, will weight registrations (or petitions, as applicable) generally based on the highest OEWS wage level that the proffered wage equals or exceeds as OEWS wage data is the most comprehensive and objective source for comparing wages.⁸³

⁸¹ BLS, DOL, Occupational Employment and Wage Statistics, <https://www.bls.gov/oes/> (last visited Nov. 24, 2025).

⁸² See Prevailing Wage Policy for Nonagricultural Immigration Programs, General Administration Letter No. 2-98 (GAL 2-98) (Oct. 31, 1997), available at <https://www.dol.gov/agencies/eta/advisories/general-administration-letter-no-2-98>, https://www.dol.gov/sites/dolgov/files/ETA/advisories/GAL/1997/GAL2-98_attach.pdf.

⁸³ BLS, DOL, Occupational Employment and Wage Statistics, Frequently Asked Questions, https://www.bls.gov/oes/oes_ques.htm#:~:text=The%20OEWS%20program%20produces%20employment,nonmetropolitan%20areas%20in%20each%20State (“The OEWS program is the only comprehensive source of regularly produced occupational employment and wage rate information for the U.S. economy, as well as States, the District of Columbia, Guam, Puerto Rico, the U.S. Virgin Islands, and all metropolitan

Petitioners that use a private wage survey may choose to increase the proffered wages of their prospective beneficiaries in order to increase their chances of selection.

To help avoid disadvantaging prospective petitioners that rely on a private wage survey or other alternative sources to determine the required wage level for the proffered position for registration purposes, new 8 CFR 214.2(h)(8)(iii)(A)(4)(i) states that registrants relying on a prevailing wage that is not based on the OEWS survey would select the “wage level I” box on the registration form if the proffered wage were less than the corresponding level I OEWS wage. DHS expects that all petitioners offering a wage lower than the OEWS wage level I wage will be using another legitimate source other than the OEWS survey. However, DHS deliberately chose to group these registrations together with level I registrations so that petitioners relying on non-OEWS sources would have a better chance of selection than if there were an additional category below level I and these registrations would have been weighted below level I registrations.

Comment: A commenter stated that although 8 CFR 214.2(h)(8)(iii)(A)(4)(i) requires registrants to follow DOL guidance on prevailing wage determinations (PWDs) when no OEWS prevailing wage information is available, the rule does not specify which version of the guidance applies.

Response: As indicated in the NPRM, in the limited instance where there is no current OEWS prevailing wage information for the proffered position, the registrant would follow DOL guidance on PWDs to determine which OEWS wage level to select on the registration. 90 FR 45986, 45993 (Sept. 24, 2025). The sentence included a footnote to the proper guidance in effect as of the time of publication of the NPRM: DOL, Employment and Training Administration (ETA), Prevailing Wage Determination Policy Guidance: Nonagricultural Immigration Programs (last modified Nov. 2009), https://www.dol.gov/sites/dolgov/files/ETA/oflc/pdfs/NPWHC_Guidance_Revised_11_2009.pdf. As of the time of publication of this final rule, this is still the guidance in effect that registrants should use, however, in the event DOL updates their guidance in the future, registrants should use any updated version of the Prevailing Wage Determination guidance published by DOL.

and nonmetropolitan areas in each State.”) (last visited Dec. 11, 2025).

ii. Supporting Evidence of Basis of Wage Level

Comment: A commenter requested clarification on the requirement to “submit evidence of the basis of the wage level selected on the registration as of the date that the registration underlying the petition was submitted.” The commenter asked what specific evidence would be accepted, asking for example if a printout from the DOL OFLC Wage Search website would suffice in all cases, and asking how petitioners should document determinations made using alternative methodologies when OEWS data is unavailable.

Response: Petitioners must submit evidence of the basis of the wage level selected on the registration as of the date that the registration underlying the petition was submitted. *See* new 8 CFR 214.2(h)(8)(iii)(D)(1). As noted in the NPRM, such evidence could include, but is not limited to, a printout from the DOL OFLC Wage Search website for the beneficiary’s SOC code and area(s) of intended employment as of the relevant date. 90 FR 45986, 45993 (Sept. 24, 2025). Where an alternate wage source is used, a petitioner should submit evidence that is appropriate for that source, such as a private wage source or collective bargaining agreement.

iii. Lowest Equivalent OEWS Wage Level When Beneficiary Would Work in Multiple Locations or Positions

Comment: A commenter expressed support for the proposals to use the lowest applicable wage or location for multi-site roles, and to treat multiple registrations for the same beneficiary by the lowest wage level, saying these proposals will address abuse patterns. Conversely, a commenter stated that the proposal directing employers to choose the lowest level of multiple locations that the proffered wage meets or exceeds undermines the policy objective of rewarding higher wages and skills.

Response: DHS agrees with the commenter that said using the lowest applicable wage level if the beneficiary will work in multiple locations makes the most sense to preserve program integrity. DHS disagrees with the commenter that said that this requirement undermines the policy objective of the rule. As noted in the NPRM, this requirement removes a potential incentive to inflate wage levels through strategic location or position choices and helps ensure integrity of the selection process. 90 FR 45986, 45993 (Sept. 24, 2025). While a major policy objective of the rule is to favor the allocation of H–1B visas to higher-

skilled and higher-paid aliens, it is also important that DHS not jeopardize program integrity.

Comment: Regarding agents placing beneficiaries in multiple positions, a commenter asked how they should calculate and document the “lowest corresponding OEWS wage level” when positions may have different SOC codes, different locations, and different wage structures.

Response: As indicated in the NPRM, if the beneficiary will work in multiple locations, or in multiple positions if the petitioner is an agent, the petitioner must select the lowest corresponding OEWS wage level that the beneficiary’s proffered wage will equal or exceed. 90 FR 45986, 45992–93 (Sept. 24, 2025). Petitioners must submit evidence of the basis of the wage level selected on the registration as of the date that the registration underlying the petition was submitted. *See* new 8 CFR 214.2(h)(8)(iii)(D)(1). As noted in the NPRM, such evidence could include, but is not limited to, a printout from the DOL OFLC Wage Search website for the beneficiary’s SOC code and area(s) of intended employment as of the relevant date. 90 FR 45986, 45993 (Sept. 24, 2025). Such evidence may also include a separate print-out for each location, and each position if there are multiple positions. USCIS will consider all submitted evidence, in addition to the information contained in the registration, LCA, and petition, to determine if the registrant indeed selected the lowest corresponding OEWS wage level among the multiple locations or positions.

iv. Lowest OEWS Wage Level Among All of the Registrations Submitted on a Beneficiary’s Behalf (if the Registrations Have Different Wage Levels)

Comment: Expressing concern about “loopholes” in the rule, a commenter recommended, in cases where multiple employers petition on behalf of the same individual, only the petitions at the highest wage level should be considered, and to require beneficiaries to remain at the same position title and receive at least the same wages as shown in their application for the duration of their visa.

Conversely, a commenter stated that the proposal for USCIS to assign a wage level to a beneficiary based on the lowest OEWS wage level among all registrations for a beneficiary will erase legitimate higher wage offers and give controlling significance to the lowest bid. Another commenter said that this approach would penalize a legitimate employer with a level IV wage, and requested that DHS consider the highest

OEWS wage level among the registrations to avoid the “cascading effect that would otherwise allow one lower-wage registration to dilute the merit-based weighting for all employers associated with the same worker.” Another commenter discussed the situation where multiple entries are created for registrants who file H–1B petitions at wage level II and the resulting dilution of any advantage of higher wage level registrants. Further, the commenter discussed handling of beneficiaries with multiple offers and where the lower-level offer will determine the lottery positioning of all of that beneficiary’s petitions. Another commenter said that the rule creates inequity for multi-location employers, pointing to proposed 8 CFR 214.2(h)(8)(iii)(A)(4)(i), which says that if a position involves multiple worksites, the employer must base the registration on the lowest applicable wage level across all sites. The commenter explained that a software engineer dividing time between Atlanta (level III) and Birmingham (level II) must therefore be registered at level II. The commenter said that this “lowest-common-denominator” rule penalizes universities, hospitals, regional service firms, and manufacturers that maintain distributed or hybrid operations, forcing them into lower-weighted categories and further reducing selection odds.

Response: DHS is aware that multiple employers may register or petition on behalf of the same individual at various corresponding wage levels. However, rather than assign the highest wage level among multiple registrations as the commenters suggest, DHS believes that assigning the lowest wage level is preferable because it would create less of an incentive for unscrupulous employers to try to game the system. In this scenario, a beneficiary for whom a level I registration and a level IV registration have been submitted will be assigned to wage level I for the purpose of weighted selection. The proposal to assign the beneficiary to the lowest OEWS wage level among all of the registrations submitted on his or her behalf is intended to remove an incentive for multiple registrants to submit frivolous registrations with artificially high wage levels in an attempt to unfairly increase a beneficiary’s chances of selection.

DHS is aware of the potential that a registration with a wage corresponding to a lower wage level would negatively impact other registrations for the same beneficiary at higher wage levels, including a legitimate employer’s registration for a beneficiary with a level IV wage. However, it is expected that

registrants will communicate with beneficiaries to make informed decisions regarding whether other companies have submitted registrations on their behalf, and under which corresponding wage level.

Regarding multi-location employers, DHS does not agree that this rule will generally penalize the list of employer types that the commenter indicated. Employers should be aware that, if they are placing beneficiaries at multiple locations, DHS will assign the registration the lowest corresponding wage level for selection purposes. DHS does not believe that this is a common enough scenario that it is worth leaving open a loophole for unscrupulous employers to try to game the system.

v. Other Comments Related to OEWS Wage Data

Comment: Some commenters expressed other concerns about perceived inadequacies of OEWS data and survey methodology. One commenter raised concerns about relying solely on OEWS data to determine wage levels, noting it could lack detail for emerging, specialized, or hybrid roles. Another commenter raised concerns about OEWS survey methodology, saying that urban respondents outnumber rural respondents, artificially inflating wages for many positions. The commenter also said that the voluntary nature of DOL's wage survey makes it highly unlikely that there will be an accurate depiction of physician wage levels across all specialties and all geographic areas. A different commenter wrote that the prevailing wage system concentrates opportunities in lower-wage localities or remote arrangements, disadvantaging large cities that serve as innovation hubs. This commenter wrote that a prevailing wage framework should better align level I wages "to the true entry level percentile for the occupation and locality" and should allow alternative wage sources when OEWS data for a locality are skewed by senior level concentrations.

Response: DHS recognizes that the OEWS system has certain data limitations but disagrees that an alternative method of calculating wages is necessary to implement a fair and efficient weighted H-1B cap selection process. DHS notes that DOL guidance on prevailing wage determinations provides for use of the OEWS survey.⁸⁴ Additionally, DHS believes that OEWS

provides the most comprehensive and objective publicly available source for obtaining prevailing wage information and, thus, is still the best available option to serve the overarching goal of this rule. Further, DHS believes that incorporating non-OEWS wage sources into the registration selection process would add unnecessary complexity into the process and frustrate the goal of administering the cap selection process in an efficient and effective manner.

vi. SOC Code of Proffered Position

Comment: A commenter said the proposed rule assumes that SOC codes can serve as a precise proxy for labor market value and skill differentiation, but in practice SOC codes are broad occupational groupings developed for statistical tracking, not for making nuanced distinctions in immigration benefit allocation. For example, the commenter wrote that the SOC classification "Attorney" encompasses all practice areas regardless of specialization, meaning a newly licensed attorney in a small firm and a highly experienced attorney in a specialized practice are treated identically, which would create distortions when wage-based weighting is applied without regard to function or expertise.

Another commenter wrote that there are significant ambiguities in choosing SOC codes, as many positions fall between two or three SOC codes, and beneficiaries often have interdisciplinary educational backgrounds, which could create inconsistencies in how wage levels and lottery weights are applied. Similarly, a commenter stated that because multiple roles can map to multiple plausible SOC codes with different wage ladders, the SOC choice will directly affect selection odds, which increases the stakes and the chance of misclassification disputes. A couple of commenters discussed inconsistencies between how employers classify occupations using SOC codes. A commenter stated that the proposed wage level construct is misleading because it does not allow for effective comparison or ordering for, or among, specific or detailed occupations.

Response: While DHS understands that SOC codes sometimes provide broad occupational groupings that may not allow for nuances in certain occupations, DHS does not see a viable alternative for sorting and classifying occupations for the purpose of this rule. Employers already must select the appropriate SOC code when submitting an LCA and when filing an H-1B petition, and this rule relies on that longstanding practice to implement a

process to efficiently and effectively determine the corresponding wage level for purpose of weighting registrations or petitions, as applicable. DHS disagrees with the commenter's assertion that a newly experienced attorney would be treated the same as a specialized and experienced attorney. DHS believes that employers will offer a wage commensurate with the difference in experience and specialization, such that it is more likely that an experienced, specialized attorney would be paid a wage that corresponds to a higher wage level than a newly experienced attorney and have a greater chance of selection based on this final rule.

b. Area of Intended Employment

Comment: Multiple commenters stated that wage levels based on geographic location could lead to inconsistent outcomes, where the same salary places applicants in different wage levels depending on the region. A commenter stated that there is a risk of introducing inequitable geographic and sectoral consequences because prevailing wage data are inconsistent across metropolitan areas and occupational codes, causing firms in lower-cost regions to potentially face artificially lower selection odds than when offering competitive wages relative to local market.

Some commenters claimed that the proposed rule would disproportionately disadvantage applicants in high-cost areas, even when their compensation and skill level are equivalent to those in lower-cost regions. Some commenters said that cost-of-living differences across regions create structural bias where employers in high-cost metropolitan areas struggle to meet wage thresholds while those in lower-cost regions can more easily offer higher wage levels for similar roles. Similarly, a commenter stated that a salary-based weighting system would benefit outsourcing firms in lower-cost areas while hurting start-ups and other tech companies in high-cost hubs like Silicon Valley. One commenter stated that the proposed wage weighting would punish "agglomeration centers" and reward lower-cost regions, "skewing outcomes away from where spillovers and mentorship are largest." Another commenter suggested that the proposed weighting could penalize applicants in "innovation-driven regions," such as San Francisco and Seattle where employees earn higher wages due to living costs and competitive markets.

In contrast, a few commenters stated that the proposed rule would favor companies in high-cost areas, where

⁸⁴ DOL, ETA, Prevailing Wage Determination Policy Guidance: Nonagricultural Immigration Programs (last modified Nov. 2009), https://www.dol.gov/sites/dolgov/files/ETA/oflc/pdfs/NPWHC_Guidance_Revised_11_2009.pdf.

higher salaries are more common, over those in lower-cost areas. A commenter expressed concern that a pure wage-based model would unfairly penalize employers in States with lower costs of living, even if they are paying fair, market-competitive salaries locally. A commenter expressed concern that the proposed rule could create geographic bias by favoring workers in high-cost metropolitan areas over those in rural or lower-cost regions, potentially undermining national economic development goals. A commenter said this geographic distortion could lead to inequities and make the program appear arbitrary.

Response: DHS disagrees that this rule will disproportionately disadvantage or advantage registrants in certain geographic areas. The rule neutralizes geographic differences in salary amounts by taking into account the area of intended employment when weighting registrations. Particularly, USCIS will select H-1B registrations generally based on the highest OEWS prevailing wage level that the proffered wage equals or exceeds for the relevant SOC code and area(s) of intended employment. In weighting according to the equivalent wage level, which already considers the area(s) of intended employment, the final rule makes it so that registrations for the same wage level will be weighted the same regardless of whether their proffered wages are different owing to their areas of intended employment.

Comment: A commenter expressed concern that the prevailing wage system would set entry-level thresholds too high in certain regions, creating barriers for junior international workers and misaligning wages with real cost-of-living. Another commenter said that while they support the wage level concept, they are concerned it could disadvantage workers at mid-sized companies who perform similar work as those at larger firms but receive lower pay due to location-based constraints, potentially leading to unfair outcomes in visa eligibility. Another commenter said that current wage tiers are too low to reflect market conditions, especially in certain regions. Another commenter stated that the NPRM does not provide supporting analysis of economic or regional impacts across metropolitan and nonmetropolitan areas. The commenter predicted the proposed wage-level weighting system would affect different occupations and geographic regions in different ways due to inequities that arise from local wage variations. The commenter stated the inequities in wage variations would impact lower nominal wage industries

like healthcare, nonprofit research, and early-stage innovation, and would reduce the industry diversity and geographic reach of the H-1B program.

Response: DHS disagrees that this rule will favor companies in certain areas since the rule neutralizes geographic differences in salary amounts by taking into account the area of intended employment when weighting registrations. The OEWS prevailing wage inherently accounts for wage variations by location, as such data is broken down by occupational classification in an area of employment. DHS agrees that some wage levels are below market rate, which is part of the reason DHS sees the need for this rulemaking. One of the goals of this rule is to better ensure that the H-1B cap selection process favors relatively higher-skilled, higher-valued, or higher-paid foreign workers rather than continuing to allow numerically limited cap numbers to be allocated predominantly to workers in lower skilled or lower paid positions. While DHS did not conduct an in-depth analysis to measure regional impacts across metropolitan and nonmetropolitan areas, DHS notes that the rule neutralizes geographic differences in salary amounts by taking into account the area of intended employment when weighting registrations.

c. Other Comments Related to Required Information

Comment: Some commenters discussed how certain staffing or contracting companies are deliberately altering or misrepresenting a beneficiary's passport number so as to enter an individual multiple times in the registration. To avoid this problem, a commenter said that DHS must ensure that each registration must be accompanied by a scanned copy of the beneficiary's passport with clearly identifiable information.

Response: DHS does not believe requiring a scanned copy of the beneficiary's passport with the registration is necessary, as the current regulations already require the petitioner to provide the beneficiary's passport or travel document information at the time of registration. *See* 8 CFR 214.2(h)(8)(iii)(A)(4)(i). Further, on the registration form the registrant must certify under penalty of perjury that the registration represents a bona fide job offer and that the organization(s) on whose behalf this registration is being submitted intends to file an H-1B petition on behalf of the beneficiary named in each registration if the beneficiary is selected.

Petitioners are also required to submit evidence of the passport or travel document used at the time of registration to identify the beneficiary at the time of filing. *See* 8 CFR 214.2(h)(8)(iii)(D)(1). The H-1B petition filed on behalf of a beneficiary must contain and be supported by the same identifying information, and if the passport numbers do not match, USCIS may deny or revoke the petition. USCIS may also deny or revoke a petition if the statement of facts contained on the registration or petition submission was inaccurate, fraudulent, materially misrepresents any fact, or was not true and correct. Additionally, USCIS may refer an individual or entity to appropriate Federal law enforcement agencies for investigation and further action, as appropriate.

E. Process Integrity

1. Certifying the Contents of the Registration and Consequences

Comment: A commenter asked what documents must be provided at registration to demonstrate that the registration represents a bona fide job offer.

Response: On the registration form, the registrant must certify under penalty of perjury, among other things, that the registration represents a bona fide job offer and that the organization(s) on whose behalf this registration is being submitted intends to file an H-1B petition on behalf of the beneficiary named in each registration, if the beneficiary is selected. Aside from the requisite certification, documentation is not required to be provided at the time of registration because USCIS does not adjudicate the registration. Registration is merely an antecedent procedural step to efficiently administer the H-1B cap selection process and determine eligibility to file an H-1B cap petition in years of excess demand.

If USCIS has reason to believe that the certifications made during registration are not true and correct, it will investigate the parties in question, including examining evidence of collusion and patterns of non-filing of petitions. If USCIS finds that a certification was not true and correct, USCIS will find the registration to not be properly submitted. The prospective petitioner would not be eligible to file a petition based on that registration, and USCIS may deny a petition, or revoke a petition approval, based on an invalid registration that contained a false certification. *New* 8 CFR 214.2(h)(10)(ii). USCIS may make findings of fraud or willful material misrepresentation against petitioners, if

the facts of the case support such findings. USCIS may also refer the individual or entity who submitted a false certification to appropriate Federal law enforcement agencies for investigation and further action, as appropriate.

2. Potential Employer Wage Manipulation

Comment: Numerous commenters said the proposed rule would incentivize employer wage manipulation at the registration stage. Multiple commenters reasoned that employers might inflate wages to increase their chances in the lottery without actually paying the stated wages. Many commenters also remarked that job titles or descriptions for a beneficiary could be inflated to increase the salary level and chance of selection.

Some commenters discussed how companies could engage in fraudulent payroll practices by inflating paychecks to increase chances in the lottery. Commenters stated that companies may issue inflated paychecks to meet wage requirements on paper, but in reality pay employees much less. A commenter characterized the rule as a “half-measure,” writing that employers will inflate proffered wages on paper, then bench workers or dodge pay via loopholes like phantom bonuses—fueling abuse by outsourcers who undercut U.S. wage rates. One commenter discussed that small companies could inflate paychecks to meet wage requirements, sometimes reclaiming the excess amount from employees through unofficial means, even when there is no actual job. Another commenter suggested that companies could collude in determining which level of wage to offer to increase the chance of selection.

A commenter said the rule may inadvertently encourage wage manipulation, such as by employers: artificially increasing wages to reach higher tiers without genuine job changes; cutting benefits or other compensation to offset inflated base pay; clustering wages just above OEWS thresholds (“bunching”); or narrowing job roles to maintain appearance of high pay. Other commenters suggested that a self-sponsored H–1B could claim they make a salary that would allow them to gain an advantage in the lottery.

A commenter also raised concerns about employers manipulating salary timing to meet H–1B requirements, such as paying low wages for most of the year and increasing pay shortly before submitting a petition, thereby USCIS only seeing the higher recent pay on submitted paystubs. The commenter

recommended requiring all paystubs or income tax records to verify consistent compensation. The commenter further cautioned that advances in AI could make it easier to falsify documents, urging USCIS to take greater care in validating submitted materials.

Some commenters also expressed doubts about USCIS’ ability to enforce the proposed wage-based selection process and verify that employers pay the wages promised. A commenter said that the proposed rule does not address how companies will be prevented from inflating wages for the lottery and reducing them later. Another commenter recommended that employers report any changes to wage or position in real-time to USCIS, and that penalties for violations be significant enough to deter gaming the system, including fines and potential disqualification from future H–1B filings. Some commenters provided suggestions to detect and deter employer wage manipulation, including ensuring:

- Employers provide supporting documentation that demonstrates the offered wage is appropriate for the position and location, such as internal compensation policies or comparable industry data.
- Companies demonstrate real ability to pay the stated wage;
- The occupational classification aligns with actual job duties;
- The selected wage be paid for a minimum of 12 months after the H–1B start date;
- Payroll records verify consistent compensation;
- The employer provides a signed attestation confirming the wage commitment;
- Penalties for violations or misclassification, including repayment of the difference and potential bans on future H–1B filings;
- Tie the wage level used for weighting to the certified LCA at filing;
- Require attestations under penalty of perjury;
- Run post-selection audits against DOL OEWS and LCA data; and
- Set meaningful penalties for misclassification.

Response: DHS is also concerned about wage manipulation and program integrity, but this rule and existing regulations contain provisions to sufficiently address these concerns. This rule will require an H–1B petition filed after registration selection to contain and be supported by the same identifying information and position information, including SOC code, provided in the selected registration and indicated on the LCA used to support

the petition. *See* new 8 CFR 214.2(h)(8)(iii)(D)(1). The petition must also include a proffered wage that equals or exceeds the prevailing wage for the corresponding OEWS wage level in the registration for the SOC code in the area(s) of intended employment as described in 8 CFR 214.2(h)(8)(iii)(A)(4)(i). *See* new 8 CFR 214.2(h)(8)(iii)(D)(1). In addition, USCIS may deny a subsequent petition by the employer if USCIS determines that the filing of the new or amended petition is part of the petitioner’s attempt to unfairly increase the chance of selection during the registration or petition selection process, as applicable, such as by changing the proffered wage in a subsequent new or amended petition to an amount that would be equivalent to a lower wage level than that indicated on the registration. *See* new 8 CFR 214.2(h)(10)(iii).

These new requirements will work in conjunction with existing H–1B regulations to prevent unscrupulous actors from entering information at the registration stage to increase their chance of selection without intending to employ the beneficiary under the same terms indicated at registration. Both the submitted registrations and filed petitions are signed under penalty of perjury that the information on the registration or petition is true and correct and that both the registration and petition represent the offer of a legitimate or bona fide job. USCIS may deny a petition or, if approved, revoke the approval of a petition, if the statement of facts contained on the registration form is inaccurate, fraudulent, misrepresents any material fact, or is not true and correct. *See* 8 CFR 214.2(h)(10)(ii) and (11)(iii)(A)(2). Employers must also attest on the registration submission, under penalty of perjury, that they have not colluded to increase their chances of selection.

DHS likewise agrees that petitioners misrepresenting the salary (including salary timing) in order to inflate the odds of selection, while not actually paying the beneficiary that salary, is an important integrity concern. DHS acknowledges these concerns but does not agree that the weighted selection framework will produce the harm described. Existing DHS and DOL regulations clearly require the petitioner to meet the obligations of the LCA and the petition, including the proffered wage requirements. *See* 8 CFR 214.2(h)(4)(iii)(B), 20 CFR 655.705(c)(1), and 655.731. This rule does not address or change DOL regulations regarding the petitioner’s wage obligations. Employers cannot inflate wages on paper to obtain higher wage levels because prevailing

wage classifications are based on job requirements and location, and employers are legally required to pay the actual or prevailing wage, whichever is higher. *See* INA sec. 212(n)(1), 8 U.S.C. 1182(n)(1). Failure to pay at least the required wage is illegal and the rule does not change these obligations or create incentives for wage misclassification. Similarly, existing H-1B rules already prohibit unpaid benching and require employers to pay the required wage during nonproductive time. These protections remain fully in place under the weighted-selection process.

Additionally, DHS⁸⁵ and DOL⁸⁶ have mechanisms in place to report concerns of fraud or misrepresentation in the H-1B process. If DOL finds that an employer has violated the LCA attestations and wage obligations, DOL may impose administrative sanctions and notify USCIS that the employer shall be disqualified from approval of petitions filed by the employer for a designated period of time, depending on the nature of the violations. *See* 20 CFR 655.800. Moreover, as noted previously, if USCIS discovers that a petitioner is violating the terms and conditions of the petition, including not paying the beneficiary the required wage, USCIS may revoke the petition approval on notice. *See* 8 CFR 214.2(h)(11)(iii). During the adjudication of any petition based on a selected registration, USCIS will confirm that the OEWS wage level and LCA information support the submitted registration and petition.

DHS notes that these regulations apply to all registrations, including those submitted by beneficiary owners. If a beneficiary owner submits a registration with a wage level that is higher than that which corresponds to what the offered position actually pays, the petition would be denied. If the beneficiary owner instead misrepresents the salary on the LCA or petition, the petition will be denied or the approval revoked because the information contained in the LCA or petition was not true and correct. *See* 8 CFR 214.2(h)(10)(ii) and (11)(iii)(A)(2).

DHS declines to add additional evidentiary requirements to verify salary at the registration stage through this rulemaking, such as requiring all paystubs or income tax records, as USCIS does not adjudicate registrations.

Further, requiring such documents as initial evidence during the petition stage may not be feasible, as many registrations are for prospective jobs such that this evidence would not be available at the time of filing. Moreover, USCIS already requires such evidence to determine whether the beneficiary maintained status when adjudicating an extension petition. USCIS also uses a compliance review program as an additional way to verify information in certain visa petitions.⁸⁷ Under this program, USCIS Fraud Detection and National Security (FDNS) officers make unannounced site visits to collect information as part of a compliance review. A compliance review verifies whether petitioners and beneficiaries are following the immigration laws and regulations that are applicable in a particular case. During a compliance review, FDNS officers may assess whether the beneficiary is being paid the wage as stated on the petition and consistent with the wage level marked on the registration. Therefore, DHS believes this rule and existing regulations are sufficient to address these issues.

Concerning the comments on existing integrity issues, such as bad actors claiming to employ or pay beneficiaries when in reality the job does not actually exist and the beneficiary is then paying their “wage” back to the company, DHS continues to explore ways to improve the integrity of the H-1B petition process. However, as this concern is not a result of the proposed weighted selection process, it is beyond the scope of this narrowly tailored rule. Similarly, the suggestions that DHS pursue additional enforcement mechanisms, such as “penalties” for violations or misclassification, or potential bans from the registration, are also out of scope of this rulemaking. USCIS may, however, refer an individual or entity who submitted a false certification to appropriate Federal law enforcement agencies for investigation and further action, as appropriate.

a. Part-Time Employment Concerns

Comment: Several commenters expressed concerns about the possibility of abuse by companies that would offer part-time positions at greater hourly wages, but would reduce overall working hours, to increase their chance of selection. Other commenters expressed similar concerns about

potential abuse of part-time positions or ways to manipulate work hours to artificially inflate the salary used as the basis for the registration. Commenters proposed that USCIS should only count the annual salary for lottery purposes, or require full-time employment.

Response: DHS appreciates these concerns but believes they are adequately addressed by existing regulations and the provisions finalized by this rule. USCIS may already deny a petition or, if approved, revoke the approval of a petition, if the statement of facts contained on the registration form is inaccurate, fraudulent, misrepresents any material fact, or is not true and correct. *See* 8 CFR 214.2(h)(10)(ii) and (11)(iii)(A)(2). This final rule authorizes USCIS to deny or revoke approval of a subsequent new or amended petition filed by the petitioner, or a related entity, on behalf of the same beneficiary, if USCIS determines that the filing of the new or amended petition is part of the petitioner’s attempt to unfairly decrease the proffered wage to an amount that would be equivalent to a lower wage level, after listing a higher wage level on the registration to increase the odds of selection. *See* new CFR 214.2(h)(10)(iii) and (11)(iii)(A)(8). Thus, if USCIS finds that an employer misrepresented the part-time or full-time nature of a position, the number of hours the beneficiary would work, or the proffered salary, then USCIS could deny the petition or revoke the petition approval. *See* 8 CFR 214.2(h)(10)(ii) and (11)(iii)(A)(2). The ability to deny or revoke approval of an H-1B petition in this context will militate against registrants and petitioners attempting to abuse the H-1B cap selection process through misrepresentation.

b. Domestic vs. Consular Petitions

Comment: Some commenters mentioned that employers who file petitions for consular processing can offer higher wages yet avoid paying those wages until the worker enters the United States, allowing them to gain selection process advantages without financial commitment. The commenters noted that this creates asymmetry between petitioners who must pay wages immediately for workers inside of the United States and those who delay activating their workers located abroad.

Response: DHS declines to make any changes to address this perceived advantage or asymmetry. By the commenters’ logic, a petitioner requesting a one-year validity period would have an unfair advantage over a petitioner requesting a three-year validity period because they would not

⁸⁵ *See* the ICE Tip Form for reporting suspected immigration benefit fraud and abuse, <https://www.ice.gov/webform/ice-tip-form>.

⁸⁶ *See* 20 CFR 655.710(a) for procedures for filing a complaint concerning misrepresentation in the labor condition application or failure of the employer to meet a condition specified in the application.

⁸⁷ *See* USCIS, Administrative Site Visit and Verification Program, <https://www.uscis.gov/about-us/organization/directorates-and-program-offices/fraud-detection-and-national-security-directorate/administrative-site-visit-and-verification-program> (last modified May 13, 2025).

have to pay the employee the stated wage for as long. However, the timing of wage obligations is governed by DOL regulations and is not being addressed or changed with this rule. DHS further notes that the petitioner must still be offering a bona fide job to the alien with the intent that the alien will enter the United States to perform the offered work. Employers are obligated to pay aliens in H-1B status in compliance with DOL regulations. Additionally, as noted previously, if the company or related entity were to file an amended petition in an attempt to later lower the proffered wage after using a higher wage level to gain an unfair advantage in registration, USCIS could deny that petition. *See* new CFR 214.2(h)(10)(iii).

3. Consistency Between the Registration and the Petition

Comment: A commenter discussed the need for consistency of requirements between the registration and the petition stating that (1) a “zero-tolerance policy for bait-and-switch tactics” should be adopted and any discrepancy between a petition and registration result in an automatic denial; and (2) a cross-agency data verification (e.g., H-1B registration, DOL LCA filing, and Form I-129 petition) should be used to flag inconsistencies in wage and position data for immediate manual review.

Response: As noted in the NPRM, this rule will require an H-1B petition filed after registration selection to contain and be supported by the same identifying information and position information, including SOC code, provided in the selected registration and indicated on the LCA used to support the petition. *See* new 8 CFR 214.2(h)(8)(iii)(D)(1). 90 FR 45986, 45995 (Sept. 24, 2025). This is necessary to prevent unscrupulous actors from entering information at the registration stage to increase their chance of selection without intending to employ the beneficiary under the same terms indicated at registration. USCIS will utilize available USCIS and DOL systems to ensure that the information on the LCA supports, and is consistent with, the registration and petition.

4. Potential SOC Code Manipulation

Comment: Some commenters reasoned the proposed rule would create opportunities for the SOC codes to be exploited to boost selection odds and manipulated to exaggerate job complexity. Another commenter said that the standards for assigning wage levels are not strict enough. Expanding on this same point, another commenter said that explicitly prioritizing wage levels will encourage employers to

manipulate them, which they can achieve without actually raising salaries. The commenter explained that the largest new incentive will be to reclassify a job into an occupational category with a lower prevailing wage so that they will get more lottery entries for the same salary.

One commenter provided an example of how two managerial roles could be classified under the Industrial Engineer SOC code (primary duties include technical process improvement, metrics analysis, and workflow optimization) to achieve a higher wage level, even though the position is effectively a managerial role. Some commenters also remarked that job titles or descriptions for a beneficiary could be manipulated to support selection of an SOC code where the proffered wage would place the beneficiary into a higher wage level rather than the true SOC code, which would put the beneficiary in a lower wage level, thereby inflating the beneficiary’s selection chances.

Commenters also stated that lower-skilled job codes could be selected that have higher prevailing wages because the SOC framework permits multiple plausible classifications for a given role and not all specialized occupations have a perfectly matching SOC code.

Response: All petitioners are required to identify the appropriate SOC code for the proffered position on the LCA. During the adjudication process, USCIS “will determine whether the labor condition application involves a specialty occupation as defined in section 214(i)(1) of the Act and properly corresponds with the petition.” *See* 8 CFR 214.2(h)(4)(i)(B). If USCIS has reason to question whether the SOC code selected by the petitioner properly corresponds with the petition, USCIS will comply with 8 CFR 103.2(b)(8) and may provide the petitioner an opportunity to explain the selected SOC code, as applicable. If USCIS determines that the petitioner failed to meet its burden of proof in establishing that it selected the appropriate SOC code for the position, USCIS may deny the petition. *See* new 8 CFR 214.2(h)(10)(ii). Further, a petition will be denied if USCIS determines “that the statements on the petition, H-1B registration (if applicable), the application for a temporary labor certification, or the labor condition application, were inaccurate, fraudulent, or misrepresented a material fact, including if the attestations on the registration are determined to be false.” *See* 8 CFR 214.2(h)(10)(ii). As such, a petitioner’s misrepresentation of the offered position on the LCA, registration, or petition is already

grounds for denial of the petition. Additionally, if USCIS discovers that the petitioner is violating the terms and conditions of the petition (for example, employing the beneficiary in a position that does not align with the SOC code and position described in the petition, registration, or on the LCA), USCIS may revoke the petition approval on notice. *See* 8 CFR 214.2(h)(11)(iii). DHS believes that USCIS’ ability to verify that the LCA, including the SOC code on the LCA, properly corresponds with the petition will help to prevent possible abuse, such as choosing an inaccurate SOC code to increase the chance of selection.

5. Potential Job Location Manipulation

Comment: Several commenters expressed concerns that employers could manipulate job locations to meet specific salary thresholds, thereby improving an applicant’s chances of selection. Some commenters discussed how companies could choose a low-cost location with a level IV wage as the work location when entering the location, but after a brief period of stay, move the individual to the actual work location. Conversely, multiple commenters said employers could also promise a high-cost city wage level far above what they intend to pay and shift workers to lower-cost regions after activation where pay is significantly lower. A commenter noted that the proposed rule would effectively encourage companies to reposition jobs toward cheaper regions to gain lottery advantage, because the same job may be treated as “high level” in a smaller city and “low level” in a metropolitan hub. Commenters expressed concern that outsourcing firms could exploit the rule by relocating operations to smaller cities with lower wages. Citing examples of multiple office locations with the same wage package in different regions, a commenter asked how employee-preferred relocation to a position in a low-cost area (where the position would have a higher wage level) for a better chance in the lottery would be treated in terms of compliance. Some commenters questioned how USCIS will distinguish between permissible disclosure of multiple locations versus impermissible gaming of the wage level selection.

Response: As noted in the NPRM, this rule will require an H-1B cap-subject petition filed after registration selection to contain and be supported by the same identifying information and position information, including SOC code, provided in the selected registration and indicated on the LCA used to support the petition. *See* new 8 CFR

214.2(h)(8)(iii)(D)(1). 90 FR 45986, 45995 (Sept. 24, 2025). Such petition must also include a proffered wage that equals or exceeds the prevailing wage for the corresponding OEWS wage level in the registration for the SOC code in the area(s) of intended employment as described in 8 CFR

214.2(h)(8)(iii)(A)(4)(i). See new 8 CFR 214.2(h)(8)(iii)(D)(1). These requirements are necessary to prevent unscrupulous actors from entering information at the registration stage to increase their chance of selection without intending to employ the beneficiary under the same terms indicated at registration. DHS also expects that the area of intended employment provided at registration will be reflected as a worksite in the subsequently filed petition, such that the petition continues to support the requirement that the registration was based on a bona fide job offer. See new 8 CFR 214.2(h)(8)(iii)(D)(1). While the registration will require the registrant to list only one work location—specifically, the work location corresponding to the lowest equivalent wage level as the area of intended employment if the beneficiary will work in multiple locations—the petition will have to list all addresses where the beneficiary is expected to work.

The final rule will also allow USCIS to deny a subsequent new or amended petition filed by the petitioner, or a related entity, on behalf of the same beneficiary if USCIS were to determine that the filing of the new or amended petition was part of the petitioner's attempt to unfairly increase the odds of selection during the registration (or petition, if applicable) selection process, such as by reducing the proffered wage to an amount that would be equivalent to a lower wage level than that indicated on the original registration or petition. See new 8 CFR 214.2(h)(10)(iii). If the new or amended petition included the same proffered wage but changed the work location such that the proffered wage now corresponded to a lower OEWS wage level for the new location than the level indicated on the registration, USCIS will consider that change in determining whether the new or amended petition was part of the petitioner's attempt to unfairly increase the odds of selection. These regulations will apply regardless of the reason for relocation and whether it was employer or employee driven.

This rule does not prevent employers from making business decisions about the location or relocation of their operations and the terms of employment for their employees. If an employer chooses to move a position to a low-cost

area while retaining a salary commensurate with a high-cost location, such that the salary would result in a higher wage level designation in the low-cost area, that is in the purview of the business. This would be permissible under this rule as long as the employer is offering a bona fide position at that location and the beneficiary will in fact work in that location. However, attempts to then move the beneficiary back to a high-cost location would be heavily scrutinized and the petition could be denied if USCIS finds that the employer did not meet its burden of proof to show that the move was not made to unfairly increase the chances of selection. See new 8 CFR 214.2(h)(10)(iii).

In regard to questions about how USCIS will distinguish between legitimate multiple locations and impermissible gaming, the proposed rule makes clear that the position, as described on the LCA and registration, must be bona fide and if the offered position involved work in multiple locations, the employer must submit a registration corresponding to the lowest wage level associated with the locations. See new 8 CFR 214.1(h)(8)(iii)(A)(5)(i). For example, if a job involves work in two different MSAs, one where the proffered salary equals a level I wage and one where the proffered salary equals a level II wage, the employer must submit a registration at level I. Failure to do so will result in denial of the petition. Whether a change represents "impermissible gaming" is case specific based on the facts presented. USCIS will examine the registration and the petition, which includes the LCA, to compare the offered positions, SOC codes, locations, and wage levels, along with the totality of the circumstances to determine whether the petitioner has established that the change in employment is not part of an attempt to game the selection process and increase the chance of selection.

a. Remote Work Considerations

Comment: Many commenters specifically addressed remote work considerations in the context of gaining an unfair advantage in the weighted selection process. A commenter said that the proposed rule contemplates the possibility of someone working at two different locations (onsite work plus remote work, the hybrid model) but does not address the possibility of someone working entirely remotely. A commenter discussed how an employer could apply for a low-cost-of-living location and an occupational category having a lower wage level to increase

chances in the lottery, but have the beneficiary work remotely in a high-cost-of-living location. Similarly, another commenter reasoned that an employer could list fully remote positions in low-wage areas in order to claim a level IV wage in a rural nonmetropolitan area, thereby offering a lower wage but higher chance for the beneficiary to be selected. The commenter added they could foresee a "wave" of H-1B registrations claiming level IV wages, not because a job requires high-level skills or offers truly high compensation, but because artificial work locations give a statistical edge. A commenter said USCIS should clarify how remote workers are to be treated under the weighted selection process, including guidance on relocations, wage determination, and weight eligibility. Another commenter suggested that to prevent gaming of the system, wage levels must be binding once selected, and remote work should default to the primary worksite for prevailing wage purposes, and misrepresentation should incur strict penalties.

Response: Regardless of whether the work will be performed at an office or remotely, the registrant must provide the appropriate SOC code of the proffered position and the area of intended employment that served as the basis for the OEWS wage level indicated on the registration, in addition to any other information required on the electronic registration form (and on the H-1B petition) as specified in form instructions. See new 8 CFR 214.2(h)(8)(iii)(A)(4)(i). The registrant must also certify, under penalty of perjury, that all of the information contained in the registration is true and correct. Importantly, if the beneficiary will work in multiple locations, the registrant must select the lowest corresponding OEWS wage level that the beneficiary's proffered wage will equal or exceed. *Id.* This provision removes a potential incentive to inflate wage levels through strategic location choices, including through remote work, to help ensure integrity of the selection process.

The rule also allows USCIS to deny a subsequent new or amended petition filed by the petitioner, or a related entity, on behalf of the same beneficiary if USCIS were to determine that the filing of the new or amended petition was part of the petitioner's attempt to unfairly increase the odds of selection during the registration selection process, such as by reducing the proffered wage to an amount that would be equivalent to a lower wage level than that indicated on the original registration or petition.

See new 8 CFR 214.2(h)(10)(iii). Further, USCIS will deny a petition if it determines “that the statements on the petition, H–1B registration (if applicable), the application for a temporary labor certification, or the labor condition application, were inaccurate, fraudulent, or misrepresented a material fact, including if the attestations on the registration are determined to be false.” See 8 CFR 214.2(h)(10)(ii). As such, a petitioner’s misrepresentation of the offered position’s location on the LCA, registration, or petition is already grounds for denial of the petition.⁸⁸ Additionally, if USCIS discovers that a petitioner is violating the terms and conditions of the petition (for example, employing the beneficiary in a location that does not align with the location described in the petition, registration, or on the LCA), USCIS may revoke the petition approval on notice. See 8 CFR 214.2(h)(11)(iii).

6. Multiple Registrations

Comment: Some commenters stated that companies could submit multiple registrations using shell companies or subsidiaries to game the weighted selection process. Another commenter reasoned that employers could “manufacture” job positions to game the system by submitting for multiple job applicants, even though there is only one position available.

Response: DHS disagrees that the weighted selection process will allow companies to submit multiple registrations on behalf of an individual alien through subsidiaries or shell companies to increase their chance of selection. Importantly, the weighted selection process is built on the beneficiary centric registration selection process. All registrations submitted on behalf of each unique individual will be identified and grouped together. If more than one registration is submitted for a beneficiary, USCIS will use the lowest equivalent wage level provided in any of the registrations submitted on that individual’s behalf when determining the weight to be accorded to that beneficiary in the weighted selection process. The number of registrations submitted on an alien’s behalf does not impact the chance of selection. Further, the existing registration attestation requires an employer to certify that the registration reflects a legitimate job offer. Through this rule making, DHS is also adding that “a valid registration

must represent a bona fide job offer” to the regulatory language. See new 8 CFR 214.2(h)(10)(ii). A bona fide job offer is one that exists as described on the registration and petition and in which the employer intends to employ the beneficiary. If the employer is submitting registrations for different individuals for the same job opportunity, those registrations do not represent a bona fide job offer. As such, petitions filed based on these registrations would be subject to denial or revocation of the petition’s approval. See 8 CFR 214.2(h)(10)(ii) and (11)(iii).

7. Related Entities

Comment: A commenter remarked that the proposed rule references “related entity” at proposed 8 CFR 214.2(h)(10)(iii) and (11)(iii)(A)(8) but provides only general factors (familial ties, proximity, leadership structure), and questioned how USCIS would make these determinations and if there would be guidance or precedent decisions published to provide predictability. Another commenter expressed similar concern, adding that USCIS should revise 8 CFR 214.2(h)(2)(i)(G) to codify a clear, enforceable definition for the term “legitimate business need” and that it should explicitly operate pursuant to the objectives of the INA.

Response: The proposed regulations at 8 CFR 214.2(h)(10)(iii) and (11)(iii)(A)(8) use the term “related entity” as it has been understood and applied in the H–1B program for many years. The term is not new and USCIS issued policy guidance on this term in *Matter of S- Inc.*, Adopted Decision 2018–02 (AAO Mar. 23, 2018). Therefore, proposed 8 CFR 214.2(h)(10)(iii) and (11)(iii)(A)(8) will be finalized without change. DHS did not propose to amend the regulation at 8 CFR 214.2(h)(2)(i)(G) and DHS will not modify that provision in the final rule. Like the term “related entity,” the term “legitimate business need” is not new and was likewise explained in USCIS-issued policy guidance *Matter of S- Inc.*, Adopted Decision 2018–02 (AAO Mar. 23, 2018).

8. Other Comments Related to Process Integrity

Comment: A commenter referenced proposed 8 CFR 214.2(h)(10)(iii), stating the proposed rule only provides one example of attempting to “unfairly increase the odds of selection” (reducing the proffered wage to a lower wage level). The commenter questioned what other scenarios would trigger this provision, and how USCIS would provide notice and opportunity to respond before making such

determinations. A commenter expressed that the proposed rule’s integrity provisions would create particularly severe problems by allowing USCIS to deny or revoke petitions based on subjective determinations about whether changes between registration and petition represent attempts to “unfairly increase the odds of selection.” The commenter added that the proposed rule provides limited guidance about what types of changes would be permissible versus impermissible. A different commenter suggested that the proposed rule would allow USCIS to deny a petition or revoke a petition approval if it appears the petitioner made a subsequent change to wage level after selection as evidence of inconsistency, even when ordinary business conditions may explain the adjustment.

Response: Whether an employer has attempted to unfairly increase the odds of selection is a case specific determination based on the facts in the record. USCIS will examine the registration, the original petition, and any subsequent petition to compare the offered positions, SOC codes, locations, and wage levels, along with the totality of the circumstances to determine whether the petitioner has established that the change in employment is not part of an attempt to game the selection process and increase the chance of selection.

As explained in the proposed rule, the petition must contain and be supported by the same identifying information and position information, including SOC code, provided in the selected registration and indicated on the LCA used to support the petition. See new 8 CFR 214.2(h)(8)(iii)(D)(1). The petition must also include a proffered wage that equals or exceeds the prevailing wage for the corresponding OEWS wage level in the registration for the SOC code in the area(s) of intended employment. See new 8 CFR 214.2(h)(8)(iii)(D)(1). USCIS may deny or revoke the approval of an H–1B petition that does not meet these requirements. However, in its discretion, USCIS may find that a change in the area(s) of intended employment between registration submission and petition filing is permissible, provided such change is consistent with the requirement of a bona fide job offer at the time of registration.

For changes between an initial petition and subsequent new or amended petitions filed by the petitioner or a related entity, if the petition would lower the wage level that would have been selected in registration, USCIS would scrutinize

⁸⁸ Nothing in this rule changes the Department of Labor’s administration and enforcement of statutory and regulatory requirements related to labor condition applications.

whether the original offered position that was the basis of the registration and original petition was in fact bona fide or the employer was attempting to unfairly increase the odds of selection. In accordance with existing regulations, before denying a petition under 8 CFR 214.2(h)(10)(iii), the petitioner would be given notice of the issue(s) through a notice of intent to deny.

Comment: Numerous commenters expressed concerns regarding fraud and system abuse in the H-1B program as it relates to this rule. A few commenters remarked that the existing random, beneficiary-centric lottery, while imperfect, treats all registrants equally and avoids inequities and potential loopholes. Many commenters expressed concern that the proposed weighted selection process would do nothing to fix the systemic fraud and abuse issues in the H-1B program.

A commenter stated that USCIS has already established mechanisms for guarding against fraud and misrepresentation, and that the proposed rule would provide minimal benefit regarding program integrity, while disproportionately increasing the risk of penalizing employers for unavoidable discrepancies. Another commenter voiced opposition to the proposed rule and expressed that the proposed rule is a “half measure” to fix a system that harms U.S. workers’ careers by prioritizing foreign labor. Another commenter suggested that without modernizing the visa cap and improving administrative efficiency, a wage-based selection process will only deepen existing challenges.

A commenter voiced concern about whether the proposed rule would adequately address fraud and enforcement, stating that vague provisions around wage calculation and job tracking could enable manipulation. Another commenter questioned whether the rule provides sufficient procedural clarity, remarking on the lack of detail on wage enforcement, worksite transfers, and post-approval wage amendments. A commenter expressed general concern about fraud in the H-1B program and questioned whether USCIS could effectively manage this issue. Similarly, another commenter said that USCIS and DOL lack the capacity to verify beneficiary qualifications and that the proposed rule could increase financial incentives to exploit the program through falsified credentials and kickback schemes.

Response: DHS agrees that enhancing the integrity of the H-1B program is important. This narrowly scoped rule seeks to build on the success of the beneficiary-centric registration selection

process to reduce registration fraud while at the same time achieving the policy goal of incentivizing employers to use the H-1B program to employ highly paid, highly skilled workers. The rule includes provisions to prevent gaming of the weighted selection process as detailed previously, including provisions governing changes in wage, location, and position, as well as provisions addressing changes in amended petitions. Additionally, existing regulations also allow USCIS to address fraud or misrepresentation in the registration, LCA, or petition process through denial or approval revocation. Further, where USCIS determines that an employer is attempting to subvert the weighted selection process and has submitted false attestations, USCIS may refer the individual or entity who submitted a false attestation to appropriate Federal law enforcement agencies for investigation and further action, as appropriate. Although DHS declines to add additional anti-fraud provisions to this narrowly scoped rule, DHS will continue to look for ways to improve the H-1B program and to protect the interests of U.S. workers.

Comment: A commenter remarked that a result of the proposed rule could be the increased use of alternative visa categories and employment structures to avoid H-1B restrictions. The commenter suggested, for example, that employers unable to secure H-1B workers at desired wage levels might increase use of L-1 intracompany transferee visas, O-1 extraordinary ability visas, or other categories not subject to the numerical cap or wage-based selection.

Response: DHS is focused on ensuring the integrity of all the employment-based classifications and will continue to carefully adjudicate all benefit requests. Although DHS is aware of employers and individuals filing frivolous petitions for which they are not qualified, it is possible that an alien and his or her employer would qualify under more than one nonimmigrant classification. Moreover, the goal of this rule is to enhance the H-1B cap selection process, not to prevent aliens from seeking other classifications for which they may be eligible.

F. Other Issues Relating to the Rule

1. Alternatives to the Proposed Weighted Selection Process

a. Recommendations To Weight Wage Levels More Heavily

Comment: Some commenters expressed a preference for the wage-based approach that DHS finalized in 2021. Under that approach, DHS would adopt a selection process that would be

fully determined by wage level, starting with selecting all level IV registrations and proceeding sequentially to levels III, II, and I only if the cap were not met. If, at any wage level, the number of applicants exceeds the remaining cap, then a random lottery should be conducted only among that wage level. Some commenters asserted that, while the proposed weighted approach would still be a notable improvement from the status quo, it would be less effective at protecting the interests of U.S. and foreign workers than the approach described in the 2021 final rule. Another commenter advocated for a “wage-based allocation system” modelled on the 2021 rule stating that that system would advantage direct-hire employers, including start-ups and small businesses, and more effectively improve the H-1B visa allocation process in comparison to the proposed weighted selection. A different commenter stated that the proposed rule is insufficient to address the issues caused by the random lottery and provided several reasons why it preferred the 2021 rule, including: this rule still retains the element of randomness while the 2021 rule created more certainty; this rule will only minimally raise the median salary of H-1B workers compared to the 2021 rule; this rule still allows outsourcing firms to benefit; and the 2021 rule provided more benefits to U.S. early-career workers who would face reduced competition from H-1B workers.

Response: While the approach in the 2021 final rule was reasonable to facilitate the admission of higher-skilled or higher-paid workers, that rule did not capture the optimal approach. DHS believes that the weighted selection process as proposed in the NPRM and being finalized in this rule is the optimal approach because it increases the chance of selection for beneficiaries who will be paid a wage that corresponds to a higher wage level while not excluding those at lower wage levels, unlike the 2021 final rule. While DHS prefers that cap-subject H-1B visas be allocated in a manner that favors higher-paid, higher-skilled beneficiaries, DHS also recognizes the value in maintaining the opportunity for employers to secure H-1B workers at all wage levels. DHS believes that this rule appropriately balances the interests of U.S. workers with the interests of petitioning employers and the alien workers they seek to employ as H-1B nonimmigrants.

Comment: Commenters provided various alternatives that would prioritize registrations for higher level wages while giving less weight to

registrations for lower wage levels than proposed. These commenters generally reasoned that level I and II workers have fewer skills, are more likely used by consulting companies to replace higher-paid U.S. employees, and that prioritizing level IV registrations would be truer to the original purpose of the H-1B program since workers at higher wage levels better reflect Congress' intended recipients of H-1B visas as high-skilled, high-wage workers, among other reasons. For example, many commenters recommended that level IV registrations should have much higher chances of selection than just four times, whereas level I and II registrations should have much lower chances. Others recommended an allocation framework involving "pools" or "caps" for each wage level, wherein the allocation for level IV registrations would be the highest and would decrease in order of the remaining wage levels.

Response: DHS appreciates these suggestions but believes that the weighted selection process proposed in the NPRM and finalized in this rule is a reasonable approach because it increases the chance of selection for beneficiaries who will be paid a wage that corresponds to a higher wage level while not entirely excluding those at lower wage levels. With regard to the asserted benefits of the proposed alternatives, DHS believes the approach in this final rule similarly offers these benefits with respect to incentivizing higher wages, mitigating unfair competition to U.S. workers, and providing greater access to visas for higher-paid, higher-skilled beneficiaries.

Comment: A couple of commenters suggested that DHS should ensure 100% selection or guarantee "approval" of all level IV registrations. Likewise, some commenters recommended guaranteeing selection for levels III and IV, while excluding levels I and/or II entirely.

Response: It is unclear whether the commenters were suggesting guaranteed petition approval or guaranteed selection in the registration process for aliens at higher wage levels. In either case, DHS declines to adopt this suggestion. USCIS does not adjudicate registrations. Additionally, DHS declines to ensure 100% petition approval or guaranteed work visas to all aliens at certain wage levels. It is possible that the number of prospective alien H-1B beneficiaries at levels III and IV could exceed congressionally established numerical limitations. Additionally, USCIS adjudicates every petition to ensure eligibility and does not offer blanket guaranteed approvals, regardless of proffered wage or wage

level. DHS believes the proposed approach of weighting registrations (or petitions, as applicable) for selection based on a beneficiary's equivalent wage levels meets the goal of favoring higher-skilled and higher-paid aliens, while still ensuring the integrity of the registration process (or petition filing process, as applicable).

Regarding the commenters' suggestions to entirely exclude lower wage levels from the selection process, DHS prefers a weighted selection process that does not effectively eliminate the odds of selection for wage levels I and II. DHS reiterates that this rule strikes an appropriate balance between prioritizing high wage levels while also recognizing the value in maintaining the opportunity for employers to secure H-1B workers at all wage levels. This rule also preserves the opportunity for employers utilizing non-OEWS wage sources to be selected. DHS recognizes that there may be some occupations or geographic areas for which OEWS wage data is not available, or positions for which a private wage survey or CBA may be used to determine the required wage. In these cases, the registration might be assigned a level I wage and as such would be effectively precluded if registrations at lower wage levels were excluded. DHS believes that the weighted selection process finalized in this rule is optimal because it increases the chance of selection for those with wages that correspond to higher wage levels but does not effectively preclude beneficiaries from being selected solely because of variables, including OEWS data limitations. DHS believes that this rule appropriately balances the interests of U.S. workers with the interests of petitioning employers and the alien workers they seek to employ as H-1B nonimmigrants.

Comment: A commenter stated that DHS must cap the number of level I registrations, or else the weighted registration system would continue to have issues. The commenter reasoned that employers could still "manufacture" job positions to game the system by submitting for multiple beneficiaries at low wage levels, therefore making it even less likely that higher wage levels would be selected.

Response: DHS appreciates the commenter's concern for potential gaming in the manner described. It is theoretically possible that all registrants will collude with each other to submit only level I registrations, such that this rule would not have the intended impact of incentivizing employers to hire higher-skilled H-1B workers. However, DHS does not believe this

scenario to be likely. Further, under the existing registration process, all registrants must certify that: each registration represents a legitimate job offer; all of the information contained in the submission is complete, true and correct; and that they have not worked with or agreed to work with another registrant, petitioner, agent, or other individual or entity to submit a registration to unfairly increase a beneficiary's chances of selection. If DHS discovers that any of these certifications are not true, DHS may deny or revoke the petition based on the underlying registration and potentially pursue other appropriate action. Through this rulemaking, DHS is also adding that "a valid registration must represent a bona fide job offer" to the regulatory language (see new 8 CFR 214.2(h)(10)(ii)) and updating the registration attestation regarding a legitimate job offer to attest to a "bona fide job offer." These provisions should further deter any registrant from colluding with other registrants to manipulate wage levels during the registration stage, thus rendering a cap on the number of level I registrations unnecessary.

b. Recommendations To Select or Weight by Highest Salary, Not Wage Level

Comment: Many commenters recommended allocating all H-1B visas by the highest offered salaries rather than wage levels. Allocating by salary would guarantee that the highest offered salaries would be selected, without any random lottery elements. The commenters generally explained that this alternative would ensure that the rule better advances the objectives DHS laid out in the NPRM of increasing the share of H-1Bs going to high-skilled, high-paid workers, and better aligns with the program's intent to fill specialized positions while ensuring fair compensation that does not undercut domestic wages, among other reasons. A commenter similarly wrote that a wage-based system would provide greater employer certainty, incentivize competitive wages, advantage direct-hire employers over outsourcing firms, and increase opportunities for international graduates from U.S. institutions. Another commenter explained that allocating visas according to wage would yield a more precise reflection of current market demand and better reward petitioners who pay compensation that reflects market demand. Some commenters stated that actual salary is a better measure of skill rather than wage level, and cited research that, according to the

commenters, showed that the proposed rule would increase median H-1B salary by 3 percent, while a compensation-based system could lead to a 52 percent increase. A commenter stated that ranking by salary would alleviate uncertainty and decrease the likelihood of fraud by companies miscoding or misclassifying their sponsored workers.

Conversely, another commenter expressed opposition to other commenters' proposals for a selection method based solely on salary. The commenter stated that under the pure salary-based allocation system, they would expect a greater share of H-1B visas being allocated to computer and engineering occupations in high cost-of-living urban and coastal areas. The commenter reasoned that this would undermine the H-1B program's goals, since such occupations are not experiencing labor shortages. Furthermore, the commenter remarked that this kind of salary-based allocation system would be clearly inconsistent with the statute, and that since all occupations have value, the H-1B program should not use an allocation system that would mostly award visas to tech companies.

Response: DHS declines the suggestions to select registrations purely based on the highest salary. DHS believes that selecting registrations or petitions, as applicable, solely based on the highest salary would unfairly favor certain professions, industries, or geographic locations, such as computer and engineering occupations in high cost-of-living urban areas as mentioned by a commenter. DHS believes that prioritizing generally based on the highest OEWS wage level that the proffered wage equals or exceeds for the relevant SOC code and in the area of intended employment is the better alternative. While DHS appreciates the commenter's concerns about the need to alleviate uncertainty for employers, DHS also needs to balance this with the countervailing interest H-1B employers have in maintaining the opportunity to secure workers at all wage levels in all eligible occupations, and without introducing unintended preference for geographical locations.

DHS is also concerned about miscoding or misclassifying through SOC code manipulation but believes it has sufficient enforcement mechanisms in place to deter and penalize such behavior. DHS must also balance the concerns for SOC code manipulation with the concerns of potentially shutting out entire professions, industries, or geographic locations that happen to be lower paying.

Regarding the comments that this rule would not sufficiently increase the median H-1B salary, DHS appreciates these concerns but notes that the primary goal of this rule is to generally favor the allocation of H-1B visas to higher-skilled and higher-paid aliens, while maintaining the opportunity for employers to secure H-1B workers at all wage levels, to better serve the congressional intent for the H-1B program. Moving to a weighted selection process is expected to increase the number and share of equivalent level IV wage selections, resulting in higher average offered wages among selected H-1B cap-subject workers. While the expected increase to average H-1B wages may not be as much as the increase that might result from the compensation-based selection system advocated by these commenters, DHS considered the disadvantages of such an alternative, *e.g.*, unfairly favoring certain professions, industries, or geographic locations, to outweigh the benefits.

c. Recommendations To Account for Geographic Differences

Comment: Commenters provided various recommendations to adjust wages or wage levels to account for geographic differences. These recommendations included: considering national benchmarks or adjusted weighting to avoid disadvantaging beneficiaries in major metro areas; apply a nationally uniform wage-level standard to better reflect the value of high-skilled labor; set wage limits based on the highest wage levels in the State where a business operates (with the example that entry-level programmer salaries in states like California or Washington are typically at least 30 percent higher than in Midwestern states, such as Michigan); normalize wage levels across regions; adjust wage levels based on local statistical areas; normalize wages for cost-of-living or purchasing power parity; and incorporate cost-of-living or regional adjustments into the weighting model so the rule is consistent for high-skilled workers in all U.S. regions.

Response: DHS declines to adopt these alternatives. This final rule neutralizes geographic differences in salary amounts by taking into account the area of intended employment when weighting registrations. DHS disagrees that additional adjustments for national benchmarks or a nationwide wage-level standard would improve the proposed weighted selection process, or that it is necessary to set wage limits based on the State where the business operates. Similarly, DHS does not believe that

normalizing wages across regions, or adjusting wages based on local statistical areas is necessary, and such recommendations related to the prevailing wage system go beyond DHS's expertise. While DHS appreciates the additional recommendations, DHS does not believe that they are necessary or feasible to incorporate into a weighted selection process that is efficient to administer in a fair and effective way.

d. Recommendations To Account for Multiple Factors

Comment: A few commenters suggested that DHS could make adjustments to salary to account for various factors. A commenter said that if directly weighting salaries, DHS could adjust for various factors, including: age and experience to ensure that workers who are early in their careers (who may earn less, but are likely to make larger economic contributions over their careers), are still able to get H-1B visas, or alternatively, to prioritize workers with higher skill levels by assigning weights based on applicants' highest degree and major field, with larger weights for advanced degree holders in science and engineering majors. One commenter stated that a salary-based selection could be adjusted to select high-earning, high-value workers by projecting earnings over a lifetime, for example, through adjusting for age by taking the net present value of the discounted future earnings stream. A different commenter recommended using actual wages paid rather than wage levels as the selection metric, potentially adjusted for geography and age. The commenter provided analysis that they characterized as showing that this approach would decrease H-1B outsourcing while increasing the share going to F-1 students, especially Ph.D.s. The commenter added that such a system would be harder to game than wage levels and better achieve the agency's goals. A commenter suggested normalizing wages nationally by adjusting for cost of living and region, calculating an adjusted "national equivalent" wage percentile to ensure fairness across geographic regions. Another commenter similarly requested that DHS recognize regional differences in wage structures so that businesses outside major cities are not unfairly excluded. Some commenters recommended tying H-1B pay scales to inflation. Another commenter suggested prioritizing by wages while also implementing weighted adjustments for designated critical shortage occupations—such as healthcare providers in medically underserved

communities, teachers in low-income school districts, and national security-relevant technical occupations in lower-cost regions—determined in coordination with certain government agencies.

Response: DHS believes that selecting registrations (or petitions, as applicable) based on the highest salary would unfairly favor certain professions, industries, or geographic locations. DHS believes that prioritizing generally based on the highest OEWS wage level that the proffered wage equals or exceeds for the relevant SOC code and in the area of intended employment is the better alternative.

DHS also believes that combining and weighing multiple factors is not feasible, as such an approach could be overly complicated, unpredictable, and subjective. DHS believes that incorporating adjustments based on multiple factors, such as the geographic area, cost of living, the beneficiary's age, projected earnings over a lifetime, and inflation would add unnecessary complexity into the process and frustrate the goal of administering the cap selection process in an efficient and effective manner. Some of these factors could change over time or may be subjective, which increases the chance of unpredictability and undermines some of the commenters' concerns about the need for predictability. Therefore, DHS prefers to use the OEWS wage level system that is already used in the H-1B program, publicly accessible, and updated annually by DOL. DHS further notes that the OEWS prevailing wage already takes into consideration variations in wages due to different occupations and geographic locations.

Regarding the suggestion to reserve visas or otherwise adjust weighting for critical shortage occupations in the healthcare industry, DHS believes that employers should be able to utilize the H-1B program within a broad range of occupations and industries. Further, DHS reiterates that H-1B petitions for aliens who are employed by, or have received offers of employment at, U.S. institutions of higher education, nonprofit entities related to or affiliated with U.S. institutions of higher education, or nonprofit research organizations or governmental research organizations are exempt from the H-1B cap. See INA sec. 214(g)(5), 8 U.S.C. 1184(g)(5). Many employers and aliens in the healthcare industry described by this commenter would be cap-exempt and therefore not impacted by this rule. In the scenarios where such aliens are not cap-exempt, DHS believes this rule will have a positive impact by increasing the chance of selection for

higher-paid, higher-skilled foreign workers for employers in all industries and encouraging employers to hire U.S. workers.

Comment: A commenter suggested that DHS should weight by the OEWS wage level that corresponds to the requirements of the position, rather than focusing on the salary being paid. The commenter said that this method would ensure that the most highly skilled and talented employees have the highest odds of selection, rather than incentivizing employers to artificially increase wages regardless of the skill requirements of the position.

Response: DHS continues to believe that salary, as demonstrated by the equivalent OEWS wage level, remains the better proxy for skill. Relying only on the OEWS wage level for each petition, as determined by the education, skill and responsibility required for each position, would only reflect the requirements for a position and would not necessarily benefit an employer seeking to hire the most talented candidate for a position, which undermines the primary purpose of this rule.

e. Recommendations To Preserve Opportunity for Lower Wage Levels

Comment: A few commenters expressed the need to preserve opportunity for all wage levels to be selected, claiming that the rule will disproportionately advantage level IV registrations. The commenters provided various alternatives intended to mitigate the risk of overconcentration and preserve fair competition across wage levels, including: capping the number of weighted entries assigned to higher wage positions; setting a maximum selection weight to avoid giving higher wage levels an “overwhelming” advantage; setting a proportional selection floor or tiered quota that would ensure opportunity for all wage levels; reserving a proportion of H-1B visas for recent graduates as level I and II applicants, or at each wage level; and increasing the selection chances for level II applicants to ensure equitable access for talented professionals across all wage levels.

Response: DHS declines to adopt these suggestions, as the goal of this rule is to implement a weighted selection process that would generally favor the allocation of H-1B visas to higher-skilled and higher-paid aliens. Further, this rule already preserves the chance that registrations with wages corresponding to any one of the four wage levels may be selected. As stated in Table 13 of the NPRM and the analysis accompanying this final rule,

this rule is expected to provide an estimated 89,911 level I registrations a 15.29% chance of selection and an estimated 177,216 level II registrations a 30.58% chance of selection based on a simple weighted-probability calculation. While the Monte Carlo simulation may be more difficult for some commenters to interpret, the results presented in row F of Table 13 show an estimated 15,330 selected registrants out of 89,911 for level I, reflecting a slightly higher probability than the calculated 15.29%. Because the Monte Carlo simulation accounts for non-replacement in the selection process, the probabilities will be closer to the simple weighted probability but not exact. DHS believes this result, summarized in row F of Table 13, is sufficient to address the commenters' concerns about ensuring opportunity for all corresponding wage levels.

f. Recommendations To Set Minimum Salaries for Each Wage Level

Comment: Numerous commenters proposed setting various minimum salaries for each wage level. The commenters' suggestions varied widely, requesting DHS to set the level I minimum salary as low as \$120,000 per year to as high as \$175,000 per year, and the level IV minimum salary to be as low as \$250,000 per year to as high as \$800,000 per year.

Response: DHS declines the suggestions to set minimum salaries for each wage level. The weighted selection process will use the OEWS wage levels, which is already used in the H-1B program, publicly accessible, and updated annually. Importantly, OEWS prevailing wages and wage levels are set by DOL. DHS does not have the expertise nor manpower to create an entirely new prevailing wage system that would need to be regularly updated, so this is not a feasible alternative.

g. Recommendations Regarding SOC Codes

Comment: Some commenters cautioned that weighting by wages could unfairly weight identical SOC codes differently based on location. The commenters recommended DHS weight offers by SOC codes and “local SOC percentile” so that offers that are equally competitive for their respective location receive the same lottery weight, regardless of location. Likewise, a commenter noted that the proposed weighting approach could unfairly disadvantage professionals in certain occupations and locations; this commenter recommended that USCIS

weight wages within each occupation rather than across all fields.

Response: DHS believes that the weighted selection process proposed in the NPRM and finalized in this rule addresses the concerns raised by these commenters. Wage levels are based on the OEWS survey wage distribution for a specific occupation and location, with wage level I currently set at approximately the 17th percentile of the OEWS wage distribution for the relevant occupation in the relevant location, wage level II set at approximately the 34th percentile, wage level III set at approximately the 50th percentile, and wage level IV set at approximately the 67th percentile. 90 FR 45986, 45990 (Sept. 24, 2025). Accordingly, by using wage levels, the weighted selection process takes into consideration variations in wages due to different occupations and geographic locations and avoids favoring particular occupations or locations.

h. Recommendation Regarding Four-Digit SOC Codes

Comment: In order to mitigate the adverse effects of occupational misclassification during registration, a commenter recommended that employers use a four-digit, instead of a six-digit, SOC code to identify the wage level for registration purposes. According to this commenter, employers would select the six-digit occupation with the highest median wage within its four-digit SOC family, and then map their proffered wage to the corresponding wage level. For example, applications with any computer occupation (15–12XX) would map their wage levels to 15–1221, Computer and Information Research Scientists. The commenter concluded that correcting occupational misclassification this way is analogous to the proposed rule's handling of multiple worksite locations and would prevent gaming of the weighted selection process through the selection of favorable SOC codes.

Response: DHS is also concerned with employers gaming the system through SOC codes and appreciates this suggestion. However, selecting the six-digit occupation with the highest median wage within its four-digit SOC family code—rather than the six-digit SOC code corresponding to the nature of the job offer—could cause confusion for stakeholders as it deviates from long-standing DOL prevailing wage guidance on how to choose the correct SOC code and wage level for the employer's job

opportunity.⁸⁹ DHS believes there are sufficient provisions to detect and deter occupational misclassification during registration and declines this suggestion.

i. Recommendations Related to U.S. Education

Comment: Commenters provided various suggestions on how to prioritize registrations based on a prospective beneficiary's U.S. education or degree. Some commenters suggested prioritizing graduates from U.S. universities regardless of their starting salary level. To retain talent at all levels, several commenters suggested giving additional weight or preference to graduates of U.S. institutions, with some commenters suggesting extra consideration for graduates of top-tier schools, graduates completing U.S. master's or higher degrees, or graduates of highly ranked U.S. universities. These commenters reasoned that the selection process should reward individuals who are already invested in U.S. institutions, and have paid high amounts of tuition and undergone a rigorous admission process, and successfully assimilated into U.S. culture and values. Some commenters specifically recommended that DHS give priority to individuals who have completed OPT in the United States or who are in F–1 status.

Some commenters recommended exempting registrations towards the master's degree cap from the proposed wage-based weighting. Other commenters wrote that only beneficiaries with Ph.D.s should be admitted, or that beneficiaries with Ph.D.s should automatically be assigned to level IV in the registration. A commenter proposed a qualification-based allocation system that would assign higher selection priority to Ph.D. holders, followed by master's degree holders, and then bachelor's degree holders.

Some commenters suggested prioritizing applicants with U.S. degrees in STEM fields. A commenter recommended, as one potential alternative to the proposed wage-weighted selection process, that DHS apply weighting by education level with higher weights for advanced degrees, particularly in STEM fields, to prioritize beneficiaries whose skills most closely align with U.S. economic needs, reasoning that this would avoid distortions inherent to a percentile-based OEWS wage level weighting.

More specifically, another commenter recommended awarding one additional registration chance to U.S.-educated applicants who submit a registration within 12 months of graduation, with a second additional chance for graduates in critical STEM fields identified by the administration. Some commenters recommended exempting or otherwise prioritizing STEM Ph.D.s, to ensure intelligent individuals, invested in the U.S. education system, are able to contribute to the United States, even if they have low wages.

Response: DHS declines these suggestions to further prioritize registrations based on a prospective beneficiary's U.S. education or degree. Registrations or petitions, as applicable, submitted for beneficiaries who have earned a master's or higher degree from a U.S. institution of higher education already have a higher chance of selection through the administration of the selection process. DHS has already reversed the order in which USCIS selects registrations or petitions, as applicable, which resulted in an increase in the number of H–1B beneficiaries with a master's degree or higher from a U.S. institution of higher education selected.⁹⁰

DHS declines to adopt the suggestion to give every F–1 graduate an equal entry-level opportunity, as this goes against the stated goal of the rule, which is to generally favor the allocation of H–1B visas to higher-skilled and higher-paid aliens. DHS also declines to ensure that U.S.-educated recent graduates, including those in critical fields, are given increased weighting in the selection process. The weighted selection process discussed in the NPRM is intended to incentivize employers to pay a higher proffered wage to a certain beneficiary to be more competitive in the H–1B selection process. 90 FR 45986, 45990 (Sept. 24, 2025). This process also maintains the opportunity for employers to secure H–1B workers at all wage levels, thus it will not completely leave out aliens in entry-level positions. Similarly, DHS declines to give priority to aliens who completed OPT in the United States.

DHS believes that prioritizing an alien based on their degree field, including whether their degree is from a STEM field, is not necessary. The purpose of this rule is not to prioritize the admission of foreign STEM workers. Further, DHS generally notes that prioritizing registrations on multiple

⁸⁹ DOL, ETA, Prevailing Wage Determination Policy Guidance: Nonagricultural Immigration Programs (last modified Nov. 2009), https://www.dol.gov/sites/dolgov/files/eta/oflc/pdfs/npwgc_guidance_revised_11_2009.pdf.

⁹⁰ “Registration Requirement for Petitioners Seeking To File H–1B Petitions on Behalf of Cap Subject Aliens,” H–1B Registration Final Rule, 84 FR 888, 890 (Jan. 31, 2019).

characteristics—for example, a STEM degree plus an advanced degree—is not feasible, as such an approach could be overly complicated, unpredictable, and subjective. Therefore, DHS declines to adopt the commenters' suggestions.

Comment: Some commenters recommended exempting international students who have graduated from U.S. institutions from the visa cap or wage selection requirements, or both. Another commenter recommended using a lottery system for graduates already in the United States and only applying wage-based selection to beneficiaries outside the United States. One commenter stated support for expanding and preserving the advanced degree exemption selection.

Response: DHS did not propose exempting students who have graduated from U.S. institutions from the cap or granting this group a carve-out from the proposed rule and declines to do so now. However, many students may already qualify for the annual, numerically limited exemption from the 65,000 cap for H-1B workers who have earned a qualifying U.S. master's or higher degree. *See* INA sec. 214(g)(5)(C), 8 U.S.C. 1184(g)(5)(C). DHS does not have the authority to expand this congressionally created, numerically limited exemption.

j. Recommendations Related to Particular Industries, Occupations, and Employer Sizes

Comment: Commenters expressed concerns that the wage-based approach does not account for wage variations across various industries and sectors. For example, some commenters recommended that DHS consider additional weighting for registrations in "critical sectors" or "essential industries" such as AI, quantum computing, semiconductors, cybersecurity, aerospace, and healthcare. Other commenters proposed implementing industry carve-outs or quotas for "critical sectors" to ensure that these roles are prioritized over others.

Some commenters requested alternatives specific to the tech industry. For example, a commenter said the proposed weighting approach should only apply to the tech industry where employers can afford high wages, while registrations from all other industries should be weighted as level IV by default. Other commenters recommended disallowing level I or II registrations from tech industry companies, and some commenters recommended revising the rule to ensure that it does not unfairly favor the IT industry.

Several commenters noted that certain industries like manufacturing or some engineering fields generally pay lower salaries compared to other industries, such as the tech industry, and recommended that H-1B visa slots be allocated by industry, rather than through a general pool. A commenter urged USCIS to adapt the proposed rule to mitigate negative effects on the manufacturing sector, particularly by reserving a portion of the cap or enhancing selection odds for lottery registrations for small and medium-sized manufacturers applying for H-1B visas for engineering and similar roles.

Other commenters expressed concern that the proposed rule disadvantages employers in lower paying, non-tech sectors, and recommended various measures, such as bonus weighting or special carve-outs. Commenters said the proposed approach may unfairly disadvantage public sector and local government functions where wages are typically lower. A commenter expressed concern about the proposed rule's effect on school districts' ability to address staffing shortages amid a national teacher shortage and recommended DHS prioritize K-12 teaching as a priority occupation eligible for additional weighting. A commenter suggested prioritizing teachers, especially in areas of shortage, such as math and science. Other commenters suggested various alternatives for universities, nonprofits, and research institutions, as well as for small employers and startups. These commenters indicated that these alternative weighting methods would help ensure employers are not disadvantaged solely because they are unable to pay high salaries compared to other employers.

Commenters suggested exceptions for their industry, such as exempting all alien physicians from the rule's weighted selection process, or weighting all healthcare workers at wage level IV. Another commenter generally recommended exempting all doctors and nurses from the proposed rule. Several commenters requested special consideration for healthcare professionals in underserved and rural areas. For example, a commenter recommended implementing exceptions for physicians practicing in shortage areas and in lower-paying but needed specialties like primary care. Another commenter suggested that DHS consider special weighting or exemption for healthcare occupations designated by DOL as shortage occupations or listed on Schedule A. A different commenter recommended adjusting the weighting formula for occupations where supervised clinical training is required,

including for occupational and physical therapists, noting that the healthcare field depends on a structured, supervised clinical hierarchy that by definition are wage levels I or II. Another commenter recommended that the rule exclude the legal industry, stating that big law firms already pay high salaries and thus would be unfairly advantaged in the weighted lottery.

Response: DHS declines to adopt special carve outs for certain industries or sectors or give additional weighting for registrations in "critical sectors" or "essential industries." Similarly, DHS declines to provide exemptions, weighting, or other special treatment for small businesses, non-profits, the public sector, startups, or other specific occupations or fields from the rule. While DHS appreciates the challenges faced by certain sectors, industries, and types or sizes of employers, carving out exceptions for some would be highly problematic. DHS believes that such an approach would be overly complicated, unpredictable, and subjective. For example, DHS recognizes that there are many occupations that can be considered "critical" or "essential" now but could change in the future. Making these types of determinations is not feasible for efficiently conducting the registration selection process on an annual basis. Therefore, DHS declines to adopt these commenters' suggestions.

k. Recommendations To Weight Other "Merit-Based" Factors Related to the Petitioner

Comment: Expressing concern that the proposed rule would not achieve its goals, multiple commenters recommended that DHS consider alternatives that incorporate a more "merit-based" approach that would weight multiple factors. Commenters provided various suggestions for factors that are specific to the petitioning employer, such as, but not limited to: the petitioner's industry and whether such industry is critical, essential, or important to the national interest; company type and size; occupational and labor-market shortages; industry or occupational need; employer demand or need for the position; the nature of the job duties, including the level of complexity or rarity of the job; societal impact; employer credibility and compliance history; whether the petitioner is in a "high-unemployment commuting zones and for occupations with plentiful domestic supply"; the employer's percentage of "local" or U.S. workers; or whether the hiring of the foreign worker displaces a U.S. worker. The commenters generally claimed that weighting various factors would make

the lottery process more fair and balanced, as the proposed rule's approach of using salary as a proxy for skill may be skewed towards certain types of employers.

Response: DHS declines to adopt the commenters' suggestions. As previously discussed, DHS believes that identifying and weighing multiple factors is not feasible, as such an approach could be overly complicated, unpredictable, and subjective. Incorporating multiple factors would add unnecessary complexity into the process and frustrate the goal of administering the cap selection processing in an efficient and effective manner. Further, some of these additional factors, such as high unemployment commuting zones or whether the employer recently conducted layoffs, are not feasible for efficiently conducting the selection process on an annual basis and may involve determinations that are beyond DHS's expertise.

Furthermore, the goal of this rulemaking is not to favor employers with certain characteristics in the allocation of H-1B visas. Rather, the goal of this rule is to efficiently and effectively implement a weighted selection process that would generally favor the allocation of H-1B visas to higher-skilled and higher-paid aliens.

l. Recommendations To Weight Other "Merit-Based" Factors Related to the Beneficiary

Comment: Numerous commenters requested DHS consider various factors that are specific to the individual beneficiary. These factors include, but are not limited to, the beneficiary's: degree field; industry certification; entrepreneurial promise; whether the beneficiary is a "founder" of a bona fide startup or is an owner of the petitioner; U.S. work history and professional experience; seniority; professional tenure; patents, research contributions; personal references; commitment to professional development; demonstrated expertise in critical technology or STEM fields; whether the beneficiary has completed or are still studying under OPT; length of legal residence in the United States; IQ; and English proficiency. The commenters generally claimed that weighing various factors would make the lottery process more fair and balanced, as the proposed rule's approach of using salary as a proxy for skill does not capture all indicators of a beneficiary's value, including his or her talent, potential, and contributions to an employer.

Some commenters suggested giving higher weight to beneficiaries based on the number of prior H-1B registration

attempts, such that a person in their second or third attempt would get a higher priority. Another commenter made a similar recommendation, but added that for candidates that are selected but do not apply, their chances should be reduced if they enter the lottery again. Other commenters suggested providing "last-chance" priority (e.g., +1 weight or guarantee minimum selection) for students transitioning from F-1/OPT to H-1B. Another commenter said the rule should grandfather current F-1/OPT cohorts and phase-in changes, so current students are not suddenly trapped.

Response: DHS declines to adopt the commenters' suggestions. As previously discussed, DHS believes that identifying and weighing multiple factors is not feasible, as such an approach could be overly complicated, unpredictable, and subjective. DHS acknowledges that salary is a proxy for skill, but maintains that this approach is reasonable and optimal because it provides ease of implementation, predictability, and objectivity that would not be found in a multi-factor approach, and accomplishes the policy goal of increasing the chance of selection for beneficiaries who will be paid a wage that corresponds to a higher wage level.

Regarding the suggestions to specifically consider a beneficiary's prior H-1B registration attempts or time left in F-1 status, DHS does not believe these factors are relevant to a beneficiary's skill level. As explained in the NPRM, the purpose of the weighted selection process is to generally favor the allocation of H-1B visas to higher-skilled and higher-paid aliens. Facilitating the admission of higher-skilled workers would benefit the U.S. economy and increase the United States' competitive edge in attracting the "best and the brightest." 90 FR 45986, 46011 (Sept. 24, 2025). Giving priority to F-1 students or beneficiaries solely because they have made several unsuccessful attempts to obtain an H-1B visa would not achieve this purpose.

Comment: A commenter recommended that USCIS allow companies to purchase additional chances in the lottery for particular candidates, reasoning that this would increase the likelihood of selection for priority candidates while remaining consistent with the lottery system's intent and avoiding wage discrimination against U.S. employees. Citing two articles, another commenter said that a better way is to prioritize workers with greater economic value by "auctioning" to employers the right to hire a foreign worker through the H-1B program.

Response: DHS declines to allow companies to "purchase" or create an "auction" as suggested. Similar to DHS's concerns with a selection method based purely on the highest salary, DHS believes that auctioning registrations to the highest bidders would favor large corporations with more resources. Further, with respect to the concerns about wage discrimination against U.S. employees, as explained elsewhere, DHS does not agree that the rule would result in or encourage such discrimination. The rule does not mandate what wages employers must pay their employees and does not require employers to artificially raise wages. DHS believes businesses are unlikely to offer higher wages if the employee's skills do not justify the cost. DHS expects that companies will continue to make business decisions that align with their operational and financial interests.

m. Other Recommendations Regarding the Registration Process

Comment: Commenters suggested that the proposed weighted selection process could still be gamed unless DHS restricts the maximum number of registrations that may be submitted by a single company or its affiliated entities.

Response: While DHS appreciates the concerns the commenters raised, the intent of the weighted selection process is to generally favor the allocation of H-1B visas to higher-skilled and higher-paid aliens, while maintaining the opportunity for employers to secure H-1B workers at all wage levels. It is unclear that limiting the maximum number of registrations a company or related entity may submit in a fiscal year would accomplish this goal. Further, it would not be possible to determine at the registration stage whether a registrant is affiliated with or related to another registrant, as USCIS does not adjudicate the registration. Therefore, DHS declines this suggestion.

Comment: A commenter suggested, without further elaboration, "integrating a beneficiary-centric appeal process" for workers to report occurrence of wage reduction or misrepresentation.

Response: DHS is unclear what a "beneficiary-centric appeal process" means. Regardless, DHS encourages individuals to report instances of wage reduction or misrepresentation to DOL or USCIS, depending on the specific facts, through existing channels. DHS maintains a tip form where individuals can report these and other issues of

compliance and fraud.⁹¹ When investigating tips received, USCIS also works with Immigration and Customs Enforcement and DOL, referring cases as needed to those agencies.

n. Recommendations To Strengthen Enforcement Actions

Comment: Many commenters stated that DHS should strengthen its enforcement actions against bad actors and fraudulent companies and provided alternative anti-fraud measures that DHS could pursue instead of broadly changing the registration system. Some of these commenters stated that targeted or more effective enforcement is preferable to broadly changing the entire registration system which could impact bona fide employers and prospective beneficiaries. Some commenters similarly reasoned that instead of adding burdens on all applicants, USCIS should focus on tracking, auditing, and penalizing the bad actors or fraudulent agencies thereby not risking harming the entire system when only a minority of players are responsible for abuses. The commenters' various anti-fraud recommendations included:

- Increased targeted audits and compliance checks, background checks;
- Post-approval and post-activation audits to verify that employers follow through on wage and job commitments;
- Run post-selection audits against DOL OEWS and LCA data;
- Annual compliance reporting to monitor whether wage commitments are being honored;
- Mandatory post-selection wage verification to confirm that promised wages are actually paid;
- Verified reporting of work hours and actual worksite locations to ensure compliance with labor conditions;
- Stricter oversight of remote work arrangements to prevent misrepresentation of job locations;
- Upfront scrutiny of SOC code classifications to reduce manipulation of job categories;
- Increased penalties for fraudulent registrations, violators, and those who have misrepresented facts.
- Closer scrutiny of certain types of companies; and
- Bans or caps on registrations from firms with patterns of overuse;
- Bans on outsourcing companies or third-party placements.

These commenters said that targeted enforcement would better protect program integrity while preserving fairness for bona fide petitioners.

Response: While DHS agrees with the commenters that stronger measures against fraud and abuse of the H-1B program are necessary, DHS disagrees that the weighted selection process is unnecessary. The changes finalized in this rule generally favor the allocation of H-1B visas to higher-skilled and higher-paid aliens, while maintaining the opportunity for employers to secure H-1B workers at all wage levels, to better serve the congressional intent for the H-1B program. This rule represents an important step the agency is taking towards improving the integrity of the overall H-1B program.

With respect to the suggestions to increase post-selection verification efforts, USCIS officers are trained to appropriately scrutinize each petition to ensure eligibility during the adjudication process, including scrutinizing the wage level, SOC code, and area of intended employment selected on the LCA to determine that the LCA properly corresponds to the petition, and ensuring that the petition includes the same identifying and position information. If USCIS were to determine that the statement of facts contained on the registration or petition submission was inaccurate, fraudulent, materially misrepresents any fact, or was not true and correct, USCIS would deny the petition or, if approved, would revoke the petition approval. See 8 CFR 214.2(h)(10)(ii) and (11)(iii)(A)(2). In addition, USCIS would deny (or revoke, if approved) an H-1B cap-subject petition if it were not based on a valid selected registration for the beneficiary named or identified in the petition. See 8 CFR 214.2(h)(10)(ii) and (11)(iii)(A)(6).

Regarding comments about increasing upfront scrutiny at the registration stage, USCIS does not adjudicate registrations. Because registration is not intended to replace the petition adjudication process or to assess eligibility, USCIS cannot feasibly determine at the time of registration selection whether a registrant has manipulated SOC codes.

Finally, it is noted that commenters provided various other suggestions about increasing enforcement or anti-fraud activities. Although DHS is concerned about preventing fraud and abuse in the H-1B program, this rule is narrowly focused on governing the process by which USCIS selects H-1B registrations for unique beneficiaries for filing H-1B cap-subject petitions. Therefore, DHS considers those comments out of scope. However, DHS may consider ways to improve the integrity of the H-1B program through future rulemakings and policy.

o. Recommendations for Pilot Program

Comment: Some commenters generally recommended starting with a pilot program to assess the proposed changes on a smaller scale, rather than finalizing the rule as proposed. Other commenters recommended that DHS proceed with a pilot program, using a multi-factor model, including weights for occupational shortages, role complexity, and employer size, with wages normalized to localities and published transparently, accompanied by a rigorous impact analysis.

Response: DHS declines to adopt these recommendations and will finalize the rule as proposed. As previously noted, DHS believes that identifying and weighing multiple factors is not feasible, as such an approach could be overly complicated, unpredictable, and subjective.

p. Recommendations for Staggered Filing

Comment: A commenter who supported the proposed rule recommended having staggered filing deadlines for petitions by wage levels as an alternative in case the proposed rule is met with legal challenges. Under this alternative, USCIS could have a first filing period, where only petitions with jobs paying level IV are considered. Once all the level IV petitions are submitted and approved, then a second filing period at a later date could be set to receive only petitions with jobs paying level III wages. After those are collected and approved, if there are any visas remaining under the H-1B cap, then a filing period for level II wages would be next, and finally a filing period for level I. This way, all of the petitions would not be submitted at once, thereby still allowing USCIS to adjudicate and allocate petitions "in the order in which" they were filed, as the statute requires. If there were more petitions than available H-1B slots at a particular wage level, there could be a "mini-lottery" within that wage level. Another commenter similarly stated that the proposed weighted selection scheme is lawful but additionally suggested amending the proposed process to "more closely align with the statute." Specifically, the commenter suggested that USCIS create different "application windows" for each wage level starting with wage level IV and proceeding in descending order such that when USCIS selects a level IV petition it will have been received before any petition with a lower wage level, consistent with INA sec. 214(g)(3). The commenter asserted that this process would offer increased

⁹¹ See the ICE Tip Form for reporting suspected immigration benefit fraud and abuse, <https://www.ice.gov/webform/ice-tip-form>.

predictability and would better withstand legal challenges.

Response: DHS declines the suggestions to use staggered filing deadlines or petition filing windows by wage levels. DHS believes these suggestions are not necessary because, as explained above, this rule is consistent with and permissible under DHS's general statutory authority provided in INA secs. 103(a), 214(a), and (c); 8 U.S.C. 1103(a), 1184(a), and (c); and HSA sec. 102, 6 U.S.C. 112.

2. Effective Date and Implementation

Comment: Some commenters who supported the rule urged DHS to implement the changes immediately before the next H-1B registration season.

Response: This rule will be effective in time for the upcoming FY 2027 registration period, which is set to begin in March 2026.

Comment: Some commenters who disagreed with the proposed rule said that, if USCIS were to finalize the proposed rule, it should refrain from implementing the proposed rule for the FY 2027 H-1B registration season because changes so late in the year would adversely impact U.S. employers, immigration lawyers, and individuals. The commenters explained that hiring decisions and filing processes and procedures have already begun based on the existing registration system, so delaying implementation until after the FY 2027 cap filing season would give the regulated community time to adapt to the new process. A commenter stated that a phased-in implementation approach would be consistent with principles of regulatory fairness and would allow stakeholders to adjust hiring strategies and educational planning accordingly. Likewise, a commenter suggested that implementation should be delayed until at least the FY 2028 H-1B cap filing season. The commenter stated that USCIS should provide a minimum of six months in advance of any H-1B registration period, as U.S. employers need time to adapt their recruitment procedures, hiring process, and filing process to the new selection process. Another commenter suggested withdrawing or delaying the implementation of the rule by two years. A different commenter suggested implementing the weighting gradually, with transparent data collection and public reporting on effects by wage level, employer size, and geographic area. A few commenters urged USCIS to engage directly with stakeholders before finalizing any wage selection rule.

Response: DHS is not delaying the implementation of this rule. DHS believes that this rule is being published with sufficient time to allow employers to plan appropriately prior to the start of the registration period for FY 2027. While some petitioners may benefit from additional time to adjust to the new weighted selection process, DHS does not believe that petitioners will face significant adverse impacts with the implementation of this change in the selection process and believes that employers have sufficient time to make any decisions they believe are needed as a result of this rule, such as increasing proffered wages to increase the odds of selection. In addition, DHS believes that it is important to implement the rule as soon as possible to prevent further adverse impacts on U.S. workers who are competing with lower paid H-1B workers.

3. Processing Time Outlook

Comment: Some commenters remarked that the current system is already difficult for people to navigate, and the proposed rule would make the system more confusing and add unnecessary complexity and burden. Other commenters similarly noted that the proposed weighted selection process would be far more complex, resource intensive, and lead to adjudication delays, inconsistent adjudications, and possibly filing errors or erroneous rejections. A commenter expressed concern that the new, complex weighted process would increase the risk of technical system errors and unfair rejections due to factors outside of the petitioner's control, which could lead to delays and add on to what some commenters described are already lengthy processing times. Some commenters stated that increased complexity and bureaucracy would lead to more costs for the government, petitioners, and taxpayers.

Response: DHS does not agree that the weighted selection process implemented through this rule adds unnecessary complexity or confusion for stakeholders. DHS also does not agree that the weighted selection process would lead to lengthy adjudication or processing times. First, DHS notes that USCIS does not adjudicate the registration. If commenters were referring to the petition adjudication process, DHS acknowledges there may be some added complexity to the adjudication, for which DHS will need to train officers, and USCIS adjudicators will need additional time to review newly required information during the adjudication of the petition. However,

DHS does not anticipate any unnecessary delays and believes that any additional adjudicative burden will be outweighed by the overall benefits of the weighted selection system. With respect to the commenters' concerns about increased costs to the government, this rule does not impact current H-1B filing or registration fees. In general, USCIS reviews the fees for its services on a biennial basis. If the review determines the current fees are inadequate to recover costs, or that they otherwise need to be adjusted, then the fee schedule adjustment would be determined at USCIS' next comprehensive biennial fee review.⁹² It is unclear what other costs to the government the commenters contemplated. Regarding the claim that this rule would increase costs to taxpayers, DHS disagrees and finds these comments unclear as to how or why this rule would impact taxpayers in general as USCIS is primarily a fee-funded agency and is not dependent on taxpayer dollars.⁹³

With respect to technical errors, USCIS is confident that the new system and process will be operable in time for the FY 2027 registration and cap filing season. In the unlikely event that USCIS discovers that the new weighted selection process is inoperable in time for the FY 2027 season, USCIS would take remedial measures at that time.

4. Data and Transparency

Comment: A commenter recommended publishing the exact weighting scheme in advance, including any caps, so employers and schools can plan accordingly. The commenter requested DHS publish "final technical guidance" and "selection outcomes by wage level, degree type, employer size, North American Industry Classification System code, and geography," adding that transparency will let DHS validate that the system is meeting program goals without unintended effects. Another commenter requested clear guidance on how geographic wage differences will be handled. A different commenter suggested publishing annual,

⁹² See USCIS, USCIS Policy Manual, Volume 1, Part B, Chapter 3—Fees, <https://www.uscis.gov/policy-manual/volume-1-part-b-chapter-3> (last modified Nov. 3, 2025) (explaining that USCIS reviews the fees for its services on a biennial basis, at which time it reviews to determine if current fees are inadequate to recover costs or otherwise need to be adjusted).

⁹³ See USCIS, USCIS Policy Manual, Volume 1, Part B, Chapter 3—Fees, <https://www.uscis.gov/policy-manual/volume-1-part-b-chapter-3> (last modified Nov. 3, 2025) ("Unlike most government agencies, U.S. Citizenship and Immigration Services (USCIS) is not dependent on taxpayer dollars . . . USCIS receives 96 percent of its funding from filing fees and not from congressional appropriations.").

anonymized statistics on weighting outcomes by wage level, SOC code, and metro area to allow labor markets to adjust and deter misuse.

Response: DHS believes that the regulations finalized by this rule sufficiently detail the weighted selection process for the H-1B cap. As described in the NPRM and codified at new 8 CFR 214.2(h)(8)(iii)(A)(4)(ii) and (5)(ii), a beneficiary assigned wage level IV will be entered into the selection pool four times, a beneficiary assigned wage level III will be entered into the selection pool three times, a beneficiary assigned wage level II will be entered into the selection pool two times, and a beneficiary assigned wage level I will be entered into the selection pool one time. It is unclear what “caps” the commenter is referring to, as DHS is not implementing caps of any particular wage level or otherwise altering the existing H-1B cap.

Regarding the request to publish data on selection outcomes, DHS notes that it is not legally required to publish such information. However, DHS already makes certain information about H-1B beneficiaries public on an annual basis. Specifically, pursuant to Section 416(c)(2) of the American Competitiveness and Workforce Improvement Act of 1998 (ACWIA),⁹⁴ DHS submits information on the countries of origin and occupations of, educational levels attained by, and compensation paid to, aliens who were issued H-1B visas or otherwise provided H-1B nonimmigrant status during the previous fiscal year to the Committees on the Judiciary of the United States House of Representatives and the Senate on an annual basis.⁹⁵ DHS plans to closely monitor the impacts of weighting under this rulemaking and will consider what information, if any, it may be appropriate to make publicly available beyond what USCIS already provides through the annual report to Congress and the H-1B Data Hub.⁹⁶

Comment: A commenter said the need for the proposed weighting approach is premature because DHS has not yet published a transparent assessment of FY 2025–FY 2026 outcomes under the

beneficiary-centric rule, which was designed to reduce gaming and ensure each beneficiary has the same chance of selection. The commenter further said that DHS must first provide evidence that “material integrity gaps persist” that the beneficiary-centric changes did not solve but that wage weighting would. Another commenter said that the proposed rule does not account for the recently implemented H-1B Modernization Rule and the beneficiary-centric registration system, which have significantly strengthened the integrity of the H-1B program.

Response: DHS disagrees with these commenters. Beneficiary-centric selection and weighted selection serve different, though complementary, policy goals. It is therefore appropriate to have both beneficiary-centric selection and weighted selection. In February 2024, DHS amended its regulations to implement a beneficiary-centric selection process for H-1B registration to ensure each beneficiary would have the same chance of being selected, regardless of the number of registrations submitted on his or her behalf, among other integrity measures. 89 FR 7456 (Feb. 2, 2024). The beneficiary-centric selection process is needed to prevent unscrupulous actors from unfairly increasing the odds that a beneficiary will be selected, thus it is important to keep the beneficiary-centric selection process in place. The goal of this rule is to implement a selection process that builds on the beneficiary-centric selection process and favors the allocation of H-1B visas to higher-skilled and higher-paid workers. Even with the weighted selection process, the need to prevent unscrupulous actors from unfairly increasing the odds of selection remains. Therefore, the wage-based selection process finalized in this rule will operate in conjunction with the existing beneficiary-centric selection process and there is no reason to delay this rule. Similarly, the commenters have failed to explain how they believe the integrity measures in the final rule “Modernizing H-1B Requirements, Providing Flexibility in the F-1 Program, and Program Improvements Affecting Other Nonimmigrant Workers” impact the weighted selection process. While the integrity measures in that rule have value, they did not implement a weighted selection process to favor the allocation of H-1B visas to higher-skilled and higher-paid aliens. The weighted selection process will build upon improvements made in prior rules, and the commenters provided nothing to suggest otherwise.

5. Comments Related to Presidential Proclamation 10973, Restriction on Entry of Certain Nonimmigrant Workers (September 19, 2025)

Comment: Some commenters who opposed the rule stated that the impact of the proposed rule must be considered in combination with the \$100,000 fee. For instance, commenters noted that certain businesses, such as small and mid-sized businesses, startups, nonprofits, and universities, would essentially be priced out of the H-1B program. Other commenters remarked that the combination of the new fee plus the weighted registration would deter skilled international students and workers from choosing to work and study in the United States. A few commenters further argued that the fee would be cost-prohibitive and thus employers in less geographically-desirable locations will have even more difficulty filling open positions. Another commenter noted that the new fee along with a new weighted lottery system introduces two significant procedural changes which will likely cause investment uncertainty and risk for companies that utilize H-1B visas, which will harm U.S. companies and not help U.S. workers.

Response: DHS disagrees with these commenters. In the H-1B Proclamation, President Trump noted that the H-1B program “has been deliberately exploited to replace, rather than supplement, American workers with lower-paid, lower-skilled labor.” 90 FR 46027 (Sept. 19, 2025). The President concluded that it was, therefore, “necessary to impose higher costs on companies seeking to use the H-1B program in order to address the abuse of that program while still permitting companies to hire the best of the best temporary foreign workers.” 90 FR 46027 (Sept. 19, 2025). The President, in the H-1B Proclamation, also directed the Secretary of Homeland Security to “initiate a rulemaking to prioritize the admission as nonimmigrants of high-skilled and high-paid aliens.” 90 FR 46027 (Sept. 19, 2025). This rule is consistent with the President’s policy direction and is an important component of the effort to favor the allocation of H-1B visas to higher-skilled and higher-paid aliens. That is, even where the H-1B Proclamation applies, this rule is needed to help ensure the allocation of H-1B visas to higher-skilled and higher-paid aliens, while maintaining the opportunity for employers to secure H-1B workers at all wage levels.

Further, DHS notes that the \$100,000 payment required by the H-1B

⁹⁴ Public Law 105–277, div. C, tit. IV, 112 Stat. 2681.

⁹⁵ See, e.g., USCIS, Characteristics of H-1B Specialty Occupation Workers: Fiscal Year 2024 Annual Report to Congress; October 1, 2023–September 30, 2024 (Apr. 29, 2025).

⁹⁶ USCIS, H-1B Employer Data Hub, <https://www.uscis.gov/tools/reports-and-studies/h-1b-employer-data-hub#:~:text=The%20H%2D1B%20Employer%20Data%20Hub%20contains%20data,query%2Dspecific%20data%20in%20Excel%20or%20.csv%20format> (last visited Dec. 5, 2025).

Proclamation does not apply to all H-1B petitions. For example, USCIS has clarified that the H-1B Proclamation “does not apply to a petition filed at or after 12:01 a.m. eastern daylight time on September 21, 2025, that is requesting an amendment, change of status, or extension of stay for an alien inside the United States where the alien is granted such amendment, change, or extension.”⁹⁷ In addition, exceptions to the \$100,000 payment may be granted by the Secretary of Homeland Security to any individual alien, all aliens working for a company, or all aliens working in an industry. Finally, the H-1B Proclamation will expire, absent extension, 12 months from its effective date. This rule, in contrast, will continue indefinitely.

For these reasons, DHS believes that this rule remains necessary to better ensure that initial H-1B visas and status grants would more likely go to the highest-skilled or highest-paid beneficiaries. While DHS recognizes that this could result in increased costs for a business, and that the combined effect of the two policies could further disadvantage businesses that lack the resources to pay the \$100,000 fee and higher wages, DHS believes that having a greater chance to recruit or retain talented employees may offset these increased costs. If a company is unable to pay an alien a higher wage for a greater chance of selection, they could alternatively try to find and hire a U.S. worker.

Comment: A few commenters noted the combined impact of the \$100,000 fee with the proposed rule. A commenter stated that the \$100,000 fee represents a substantial enough surcharge such that it already limits H-1B petitions to beneficiaries who are “very valuable to the company and America.” The commenter suggested that DHS should first allow more time to measure the impact of these recent changes on the H-1B program without further complicating it with a weighted selection process. Another commenter said that the new \$100,000 fee helps to ensure that only genuine and serious H-1B filings will be submitted and will address issues of registration abuse. This commenter concluded that the new fee renders a weighted lottery “unnecessary and redundant.”

Response: DHS disagrees with these commenters. As previously explained, the weighted selection process implemented in this rulemaking complements the stated goals of the H-

1B Proclamation, in that it seeks to “prioritize the admission as nonimmigrants of high-skilled and high-paid aliens.” 90 FR 46027 (Sept. 19, 2025). Further, the H-1B Proclamation applies to a subset of petitions, whereas this rule applies to all cap-subject petitions, and the H-1B Proclamation has an expiration date, whereas this rule does not. DHS therefore believes that this rule remains necessary, and that there is no need to allow more time for the implementation of this final rule.

G. Statutory and Regulatory Requirements

1. Administrative Procedure Act (APA)

a. Request for 30-Day Extension

Comment: Some commenters requested that USCIS extend the comment period by 30 days, stating that given the complexity and impact of the proposed changes the current 30-day window is insufficient for meaningful public input on a rule of this scope. For example, one such commenter cited the rule’s economic significance, technical detail, and broad impact across sectors, and said that a longer period would support informed public participation, strengthen the administrative record, and align with established practices under the APA and Executive Order 12866.

Commenters stated that E.O.s 12866 and 13563 recommend a minimum 60-day comment period for economically significant regulatory actions and wrote that DHS’s delay in publishing the rule undermines the urgency argument. The commenters also said that the government shutdown on October 1, 2025, disrupted normal operations since it resulted in the cessation of operations of National Archives and Records Administration (NARA), which controls the **Federal Register**. The commenters said that although public comments can still be submitted during the shutdown, NARA noted on the **Federal Register** page that it will not provide any technical assistance. The commenter did not explain what technical assistance they may have required in this regard.

The commenters expressed concern over the lack of prior notice about the rule and cited past DHS statements and court decisions that questioned the legality of prioritizing H-1B petitions based on wages. Several commenters requested more time to conduct economic and legal analysis, collect data, and to propose viable alternatives, asserting that DHS should provide a full 60-day period to allow employers time to analyze the rule, prepare feedback,

and adjust operations to reduce unintended negative impacts.

Response: While DHS acknowledges that E.O.s 12866 and 13563 indicate that agencies generally should provide 60 days for public comment, DHS believes that the 30-day comment period was sufficient in this case given: (1) the narrow scope of the rulemaking (*i.e.*, addressing the selection process, which is a discrete aspect of the H-1B program), and (2) the history of rulemaking on this topic. In addition, DHS has a compelling policy interest, as well as a rulemaking directive from the President to propose a rule that prioritizes the admission of high skilled and high paid aliens. 90 FR 46027 (Sept. 19, 2025). Therefore, DHS did not extend the comment period. Given the narrow scope of this rulemaking, and the fact that DHS had previously proposed a similar, though not identical, concept of wage-based selection, DHS believes that 30 days was sufficient time for the public to determine the impacts of the proposed rule and to prepare and submit comments. The sufficiency of the 30-day comment period is demonstrated by the number of high-quality comments received from the public, including individuals, attorneys, employers, and organizations.

Comment: Some commenters discussed perceived shortcomings of the NPRM and urged DHS to reconsider the proposal and, as necessary, to publish a supplemental NPRM addressing these shortcomings and requesting public comment. Some commenters discussed such perceived shortcomings and requested that DHS at a minimum delay implementation of the rule until the following (FY 2028) cap season. Among other issues, commenters stated that the proposal to tie selection to wage levels could deter employers from filling hard-to-fill roles or result in employers pushing work offshore, and that DHS failed to consider variable compensation factors, provide exemptions for roles tied to critical infrastructure, or clarify ambiguities regarding situations involving relocations, multiple office locations, SOC code classification flexibility, and lottery allocation uncertainty. Commenters wrote that these issues must be addressed to ensure fairness, predictability, and transparency in the H-1B process.

Other commenters advised DHS to take into consideration other factors to prioritize selection, such as age, tenure, performance, and long-term contribution potential and issue an updated proposal or not implement changes until the FY 2028 cap season, particularly “[g]iven that many

⁹⁷ USCIS, H-1B Specialty Occupations, <https://www.uscis.gov/working-in-the-united-states/h-1b-specialty-occupations> (last modified Oct. 20, 2025).

international workers cannot even access their official wage level data during this public comment period, proceeding now would be premature.”

Response: DHS declines to delay the implementation of this final rule until the FY 2028 cap season. DHS has addressed proposed alternatives to the wage selection methodology elsewhere in this rule but believes that the weighted methodology strikes a balance between addressing policy goals of selecting higher-paid and higher-skilled beneficiaries in a fair manner and creating a methodology that is administrable in the context of the H-1B registration process, as well as the H-1B petition process, in the event the registration process is ever suspended.

With respect to commenters who said they could not access wage-level data during the comment period, it is unclear what they were referencing. However, DHS does not believe that a temporary inability to access wage-level data prevents the commenters from understanding the weighted selection methodology included in this rule. DHS also notes that wage-level data changes from year to year based on adjustments to the OEWS. As discussed elsewhere in this rule, DHS believes that it has compelling reasons to move expeditiously to implement the wage-level-based selection for the upcoming FY 2027 cap season.

2. Regulatory Impact Analysis and Benefits (E.O.s 12866 and 13563)

Comment: A commenter stated that the Regulatory Impact Analysis (RIA) failed to fully address the impacts of the proposed selection process on the broader economy. The commenter cited DHS analysis that showed that 76 percent of H-1B petitioners are small business owners, and that the proposed regulation would impose significant financial burdens on a substantial number of small entities, with many facing cost increases greater than 1–5 percent of their revenue. However, the commenter claimed that DHS failed to address the fact that small businesses are the primary drivers of job creation and innovation in the United States. The commenter further claimed that imposing heavy costs or pricing small businesses out of the global talent market undermines national interests by impeding their ability to hire and innovate. The commenter concluded that, ultimately, these burdens could lead to higher costs or reduced services for American communities.

An industry group commented that using LCA wage data as a proxy for registration wage data leaves considerable ambiguity on the projected

impact of the rule, because the LCA is not currently required to be submitted at registration. The commenter encouraged USCIS to conduct a comprehensive impact assessment that quantifies potential effects on critical industries.

One commenter said that DHS has not “adequately quantified and considered the distortions of this proposal, including potential disparate impacts on the economies of different geographic areas.” A commenter highlighted the need for DHS to estimate the number of affected small entities, detail compliance burdens, consider significant alternatives, and therefore reopen comments to allow meaningful input from small businesses.

A commenter said that DHS failed to adequately address the negative impacts on particular employers, such as those in critical infrastructure sectors. The commenter further stated that DHS acknowledged a significant reduction in H-1B selections for civil engineers and architects yet failed to provide a comprehensive economic assessment of the resulting labor shortages.

Response: DHS acknowledges the importance of small businesses to the U.S. economy and that the rule may have a significant economic impact on a substantial number of small entities. DHS notes that these impacts primarily reflect distributional outcomes inherent in administering a fixed statutory cap, rather than new compliance costs created by the rule. Establishing different standards or preferential treatment for small businesses would be inconsistent with the policy objective of facilitating the admission of higher-skilled alien workers for employers and would undermine fairness and program integrity. Prioritizing registrations by higher wage level equivalencies aligns with the policy objective to allocate limited H-1B visas to positions that reflect higher skill and pay and supports innovation and competitiveness by increasing the chance of selection for higher-paid, higher-skilled beneficiaries.

DHS recognizes that an LCA is not required at registration and, therefore, DHS does not have data on the number of registrations by wage level. For analytical purposes, DHS assumes that the distribution of wage levels observed in cap-subject petitions (from LCA data) reasonably approximates the distribution of wage levels in registrations. To the extent proffered wages exceed the wage levels indicated on the LCA, the projections presented here should be viewed as an upper bound of the rule’s impact. Because DHS cannot estimate how many registrants would select a higher wage level than required on the LCA, DHS

uses LCA wage data as a reasonable proxy for registration wage data. DHS did not receive any alternative data sources from commenters that would allow for a more reasonable proxy for registration data or that could appropriately substitute for the petition data used in the analysis.

LCA wage data are based on the Bureau of Labor Statistics’ OEWS wage survey which is derived from employer compensation data and produces estimates by occupation and geographic area, reflecting national patterns and regional labor-market conditions. The LCA wage levels are adjusted to correspond to progressively higher degrees of skill, experience, and responsibility within an occupation, and using them in the selection process helps normalize comparisons across local labor markets.

DHS declines to establish carve-outs for particular employers or occupations, and such carve-outs would be impractical within the H-1B framework. Accordingly, DHS applied a consistent allocation method while ensuring that all employers—including small entities and those in essential occupations—retain meaningful opportunities for selection under the same criteria.

In the Initial Regulatory Flexibility Analysis (IRFA) accompanying the NPRM, DHS carefully addressed the number of affected small entities and the estimation methods, the principal North American Industry Classification System (NAICS) sectors among filers, wage-level distributions by entity size, the direct economic impacts and counts of impacted entities, projected reporting, recordkeeping, and other compliance requirements, and the significant alternatives considered. Accordingly, DHS has determined that reopening the comment period is not warranted to obtain additional meaningful input from small entities.

DHS declines to include an economic assessment on separate occupation-specific labor shortages. The new weighted selection process is not designed to project occupational demand, nor does DHS seek to set occupation-specific priorities, guarantees, or reserved allocations. The H-1B program is a general specialty occupation visa category, not a targeted labor shortage program. The weighted selection process applies uniformly and neutrally across all SOC codes and industries. DHS’s goal is to fairly and efficiently administer the H-1B cap selection process whenever registrations (or petitions, as applicable) exceed the annual numerical limitations. It is not DHS’s goal to ensure a certain number

of workers in specific sectors are selected each year.

DHS appreciates the commenter's concerns regarding the potential broader economic impacts of the proposed selection process, particularly on small businesses and their role in job creation and innovation. However, the RFA does not require agencies to assess indirect or secondary effects, such as broader economic impacts or downstream consequences on the economy as a whole. The IRFA and Final Regulatory Flexibility Analysis (FRFA) prepared for this rule focus on the direct economic impacts on small entities that are subject to the proposed selection process. While DHS recognizes the importance of small businesses to the U.S. economy and innovation, the broader economic considerations raised by the commenter are not part of the RFA's requirements.

3. Methodology and Adequacy of the Cost-Benefit Analysis

Some commenters stated that the cost-benefit analysis conducted by DHS is flawed. Specific issues that were raised are addressed below.

a. Quantifying the Impacts

Comment: A commenter stated that given the availability of multi-year DHS data on registrations, selections, and petition approvals, the cost-benefit analysis should have simulated how the proposed weighted selection process would affect selections by wage level, employer size, occupation, and geography, as well as to estimate expected changes in labor market outcomes. Without such quantitative analysis, the regulatory impact analysis is incomplete.

Response: DHS disagrees with this comment. The RIA quantified expected impacts by wage level using DOL LCA data, which is the best available dataset aligned with the rule's use of LCA wage levels. Because the LCA process generally relies on OEWS prevailing wages that are specific to occupation and geographic area, the wage-level analysis inherently reflects occupational and regional labor market differences. The IRFA accompanying the NPRM also addressed employer size, including the number of affected small entities, the principal NAICS sectors among petitioners, and wage-level distributions by entity size. Accordingly, the RIA provided rigorous quantification where data permitted and qualitative assessment where measurement constraints exist.

Comment: A commenter stated that the NPRM did not adequately model or quantify the broader economic costs of

reducing access to high-skilled foreign talent. The commenter argued that wage level is not the same as skill, and the NPRM does not convincingly show that the new process will actually raise skill or pay levels.

Response: DHS disagrees with these comments. The rule does not alter the eligibility criteria, numerical cap limits, or availability of H-1B visas, nor does it affect the availability of foreign students' enrollment and post completion OPT. Accordingly, DHS does not expect direct effects on the foreign talent pipeline. DHS believes that wages reflect market valuation of skills and productivity. OEWS wage levels, derived from employer compensation data, provide occupation- and geography-specific estimates that capture national and regional conditions and the higher wage levels are a reasonable proxy for progressively higher skill.

DHS also disagrees with the comment that the NPRM does not convincingly show that the new process will actually raise skill or pay levels. As shown in Table 12 of the NPRM, over a five-year period, the wage-level distribution of cap-subject petition receipts was approximately 28 percent (level I), 55 percent (level II), 12% (level III), and 5% (level IV). Because receipts are concentrated in levels I and II, a purely random selection would mirror that distribution. The rule's shift from random to weighted selection is intended to encourage employers to offer higher wages to higher-skilled H-1B workers to increase their chance of selection and to reduce incentives to use the program for relatively lower-paid, lower-skilled workers. As discussed in the RIA, moving to a weighted selection process is expected to increase the number and share of selected registrations with wages that correspond to a level IV, resulting in higher average offered wages among selected H-1B cap-subject workers.

b. Calculation Error

Comment: A commenter identified what he or she characterized as a calculation error in DHS's analysis that led the agency to understate the negative impact on workers at level I and overstate the benefits for those at levels III and IV. After correcting the error, the commenter found that individuals at level I would receive 11,518 fewer H-1B selections, more than DHS's estimate, while those at level IV would receive 4,426 more selections, and level III and II would also see increased selections. Another commenter raised the same issue, stating that there were calculation errors

in the NPRM's tables (specifically Table 13), where the method for estimating the number of petitions by wage level is unclear or incorrect. The commenter claimed that this issue affected subsequent estimates of how the rule would change the distribution of petitions by wage level.

Response: DHS clarifies that the final line in Table 13 is not an error; it is the simulation result rather than the product of the number of petitions and the suggested weighted probability. In this final rule, further explanation is added in the notes to Table 13, explaining why DHS presented simulation results rather than using a weighted probability. Since unique beneficiaries can be selected only once, the selection process is conducted without replacement. However, multiplying the number of petitions by the selection probability assumes a with-replacement lottery (e.g., for a wage level IV registrant, four entries are placed into the lottery. If one of the beneficiary's registrations is selected, the remaining three registrations for that beneficiary would still have an equal chance of selection. However, under the USCIS selection process, the remaining three registrations would be removed once the first registration was selected). In practice, selections are made without replacement, so this calculation overstates the number of selected beneficiaries and the estimated impact under the proposed rule. Also, calculating the weighted probability without replacement is intractable to compute explicitly, so DHS used a Monte Carlo simulation method to estimate line F in Table 13.

Comment: A commenter said the NPRM relies on petitions (winners) rather than registrations (all submissions) and fails to align its analysis with the "unique beneficiary" selection process. The commenter wrote that DHS's calculations in the NPRM were based on FY 2020–FY 2024 lotteries among registrations instead of unique beneficiaries, even though USCIS shifted to beneficiary-centric selection for the FY 2025 cap season. The commenter also wrote that the NPRM incorrectly stated that implementation occurred in FY 2024, which creates confusion, and the analysis should be conducted under the current unique beneficiary process. Moreover, the commenter stated that DHS presumably has the information necessary to merge registrations with LCA data, but the NPRM did not merge registrations with LCAs to obtain wage levels for all submissions, and relying only on petition winners may bias

estimates and overstate shifts to higher wage levels under weighting.

Response: To clarify the timeline, the beneficiary-centric process applied to the FY 2025 cap season, and the operational work for that season occurred during FY 2024. Stating that the beneficiary-centric process was implemented in FY 2024 refers to when USCIS operationalized the change, not the cap year label. The timing does not affect the analytical framework, and an explanatory note was included in Table 3 in the NPRM.

Contrary to the commenter's assumption, DHS does not have the information necessary to merge registrations with LCA data. LCAs are not required for registrations. Registrations currently do not include verified wage level information. Wage levels are verified at the petition stage via the associated LCA. Also, not every registration can be cleanly merged with an LCA by employer and position, and a substantial share of registrations never mature into petitions. For those reasons, wage distributions derived by merging registrations and LCAs by employer and position would be noisy and potentially misleading. DHS acknowledges the limitation of using petition data to estimate the impact at the registration stage; however, using petition data ensures wage levels are validated and provides a reliable basis for analysis.

The beneficiary-centric change reduced the issue of duplicate registrations for the same individual and substantially reduced any potential divergence between petition distributions and registration-level wage mixes for multi-registration beneficiaries. This effort has anchored the registration process to real registration entries rather than speculative ones. For the remaining small number of multi-registration beneficiaries, assigning the lowest wage level across multiple registrations as proposed and finalized in this rule prevents gaming and creates a consistent beneficiary-level input for weighting. Because the lowest wage level will govern selection probability at the registration stage under the new rule when multiple registrations are submitted for the same beneficiary or the beneficiary will work in multiple locations, unique beneficiaries have less incentive to choose to have multiple registrations submitted on their behalf at different wage levels. Therefore, DHS's use of petition data to estimate the wage-level distribution of the registration population is expected to reasonably reflect the wage-level distribution that will occur under the new rule.

Comment: A commenter stated that DHS calculations combined both the regular cap (65,000 visas) and the advanced degree exception pool (20,000 visas). However, the distribution of beneficiaries across wage levels is different for these two groups. Specifically, a much higher proportion of advanced degree beneficiaries are at wage level I (36 percent) compared to other beneficiaries (20 percent). Because advanced degree holders get two chances in the lottery (first in the advanced degree pool, then in the regular pool if not selected), they are more likely to be chosen. Without accounting for this, DHS calculations overstated how much the new weighted selection process would reduce the share of low-wage (level I) petitions.

Response: Since the wage level distribution of advanced degree registrants is slightly different from that of regular cap registrants and advanced degree registrants have slightly higher concentration in wage level I compared to regular cap registrants, DHS recognizes combining the pool of beneficiaries for the regular cap and the advanced degree exemption would result in a decrease in wage level I beneficiaries under the rule. However, modeling the proposed weighted selection as a single pooled draw across all registrations is more tractable and clarifies the rule's impact with minor loss of accuracy.

Despite the difference, the wage level distribution of advanced degree registrants and regular cap registrants is similar between groups: concentrations at wage level I and II are heavy, while wage level III and IV are lighter. The difference between the two-step and pooled model is small because only 20,000 out of 85,000 cap slots go towards the advanced degree exemption, and the wage-level mix of advanced degree filings is broadly similar to that of the total pool. See Table 12 of the NPRM and the analysis in this final rule. As a result, DHS expects the two-step selection process model would affect the overall wage-level share by only a small amount, while the weighting itself changes selection rates by much larger margins. The analysis provided aims to help readers better understand how the rule may modify the selection process, while recognizing that it cannot precisely capture all potential impacts.

Comment: A commenter questioned the accuracy of Figures 2 and 3 in the NPRM, noting they show civil engineers, statisticians, and architects (except landscape and naval) with no or virtually no petitions above wage level I, and "Computer Occupations, All

Other" with no petitions at wage level I, despite other data indicating otherwise. The commenter noted that USCIS data on H-1B petitions obtained by Bloomberg merged with the DOL LCA data indicate that in FYs 2021–2024, over 5 percent of petitions with the SOC title "Computer Occupations, All Other" were at wage level I. The commenter stated that this is inconsistent with the claim in the notice that there were no petitions in that occupation at wage level I during fiscal years 2020–2024. The commenter also objected to the NPRM's claim that "Electronics Engineers, Except Computer," "Materials Engineers," and "Engineers, All Other" would have no petitions at wage level I under the proposed weighting, citing evidence that these occupations have had non-trivial wage level I shares under the current process. The commenter added that the USCIS data on H-1B petitions obtained by Bloomberg merged with the DOL LCA data indicate that in fiscal years 2021–2024 almost 20 percent of petitions with the SOC title "Electronics Engineers, Except Computer" were at wage level I, over 12 percent of petitions with the SOC title "Materials Engineers" were at wage level I, and almost 45 percent of petitions with the SOC title "Engineers, All Other" were at wage level I. The commenter stated that it is unclear why DHS asserted in the NPRM that these occupations "are not expected to contain any wage level I registrations" under the proposed rule.

Response: Figures 2 and 3 show only the top five SOC 6-digit occupations within SOC major group 15 (Computer and Mathematical Occupations) and SOC major group 17 (Architecture and Engineering Occupations). DHS presented only the top five because they cover more than 70 percent of the distribution and are intended to illustrate that DHS projected distributional changes in occupations due to the rule. Both figures have titles that indicate these are the top five SOC 6-digit codes. The figures illustrate the distributional impacts across SOC codes and should not be interpreted as indicating that no petitions exist for occupations or wage levels not shown. Figure 2 shows, for each wage level, the top five six-digit SOC codes within the Computer and Mathematical Occupations category. SOC 15–1299 does not appear in the top five at wage level I, but it does at wage levels II, III, or IV. The NPRM misstated that there were no petitions at certain wage levels within specific SOC codes. Such petitions did exist but for those wage levels, the relevant SOC codes did not

have enough petitions to appear among the top five SOC codes presented in the figures. This has been clarified in the final rule. It did not affect the underlying analysis or conclusions.

c. Distributional Effects and Transfers

Comment: A commenter stated that the distributional effects and transfers associated with the proposed process were not appropriately analyzed. The commenter wrote that the proposed weighting favors higher-wage firms and certain regions or occupations with high prevailing wages, while disadvantaging small, resource-constrained employers and lower-wage areas. Additionally, if weighting results in higher offered wages, it constitutes a transfer from employers to workers, which the commenter said should be described and, where possible, quantified across different firm sizes and geographic locations. Another commenter further claimed that DHS failed to monetize the economic impact of employers offshoring jobs due to reduced access to entry-level H-1B workers, as well as the loss of revenue from declining foreign student enrollment at U.S. institutions. The commenter wrote that these transfer costs, money and economic activity moving abroad should have been quantified and balanced against any supposed benefits of the rule. The commenters concluded that because DHS omitted this analysis, its cost-benefit assessment is incomplete and procedurally flawed, undermining the justification for the proposed rule.

Response: DHS disagrees that distributional effects and transfers were not appropriately analyzed. The regulatory impact analysis quantifies transfers and evaluates distributional effects across SOC codes, and the IRFA presents impacts by firm size. With respect to geography, wage weighting uses prevailing wages by occupation and area of intended employment, which normalizes for local labor markets and mitigates any systematic advantage for higher-cost regions.

DHS disagrees that the economic impact of employers potentially offshoring jobs and the loss of revenue from potentially declining foreign student enrollment at U.S. institutions are transfers that an economic analysis for this rule is able to isolate and monetize. Decisions to offshore work or changes in foreign student enrollment are influenced by numerous factors beyond this rule. DHS is unable to isolate the factors contributing to any potential future decline in foreign student enrollment from the impacts of this rule. The commenter did not provide data to support the assertion

that this rule would result in a decline in foreign student enrollment.

DHS is currently unable to effectively model the economic impact of employers potentially offshoring jobs, as there is no reliable publicly available data on how many specific jobs are currently offshored due to unsuccessful H-1B petitions or how that number might change as a result of this rule. Additionally, the commenter did not provide any data or a methodology to quantify the economic impact of one company offshoring a job due to not receiving an H-1B petition in the lottery versus another company retaining a position in the U.S. after successfully obtaining a petition. While DHS acknowledges that this may be a business decision some companies are already making, DHS is unable to determine how the changes in the weighted selection process under this rule might influence these decisions in the future.

d. Assessment of Alternatives

Comment: Some commenters stated that the cost-benefit analysis did not compare the proposed weighted selection process to reasonable alternatives, such as maintaining a purely random selection, adjusting weighting by region or occupation, or reserving selections for small entities. Commenters stated that DHS could have analyzed, for instance, a beneficiary-centric random selection with enhanced anti-fraud measures, partial weighting (e.g., with limited multipliers) versus steep weighting (increasing weighting for higher wage levels), geographic or occupation-adjusted weighting to avoid penalizing low-cost areas, and safeguards for small entities, such as floors or set-asides.

Response: In the NPRM DHS considered reasonable alternatives but determined that they do not sufficiently meet the rule's policy objective of facilitating the admission of higher skilled, higher paid beneficiaries, or would undermine program integrity and administrability. DHS also carefully reviewed and considered a number of alternatives suggested by commenters and addressed them in detail in the Alternatives Considered section of the economic analysis portion of this preamble. Regarding the alternatives proposed by the commenter, DHS provides the following responses. Retaining a purely random selection process (with or without anti-fraud measures) does not advance the policy objective and leaves incentives for mass registration at lower wage levels. Anti-fraud tools are complementary and not substitutes for an allocation mechanism.

Partial vs steep weighting does not meet the objectives of the rule because partial weighting produces only modest adjustments that leave selection outcomes largely unchanged from the current selection process, and steep weighting would function more akin to a carve-out for wage levels III and IV wages while crowding out wage levels I and II even more aggressively.⁹⁸ Geographic or occupation adjusted weighting is moot because the weighted selection process already normalizes by local labor market via prevailing wage levels for the occupation and area of intended employment. Adding explicit regional or occupation carve-outs would be complex, subjective, and more susceptible to gaming. Any alternative process that provides a different, preferential weighting scheme especially for small entities would undermine the overall utility of this rule, which is to generally favor the allocation of H-1B visas to higher-skilled and higher-paid aliens.

e. Costs to Employers

Comment: A commenter stated that the analysis failed to fully account for the significant costs to employers. According to the commenter, while DHS acknowledged that the new weighted selection process would sharply reduce the chances of selecting registrations or petitions for entry-level positions, it did not adequately analyze the broader economic consequences for employers. Specifically, the agency overlooked the increased liability risks associated with artificially raising wage rates for H-1B workers, which could expose employers to claims of wage discrimination under Federal law if domestic workers are not similarly compensated. To avoid such litigation, employers may be forced to raise wages for all entry-level employees, resulting in substantial, unaddressed costs, especially for small businesses operating on fixed contracts and narrow margins. The commenter wrote that DHS's analysis only considered transfer costs to H-1B workers and failed to provide a comprehensive cost analysis of these broader impacts, despite acknowledging its ability to do so. This omission is a fundamental flaw, as many small employers may be unable to absorb these costs, jeopardizing their ability to hire skilled workers and fulfill existing contracts.

⁹⁸ The commenter referenced "partial weighting" whereby minimally acceptable weights might apply to only a portion of locations or occupations to correct for differences within specific subgroups, whereas "steep weighting" refers to assigning relatively larger weights to correct for overall differences.

Response: DHS assesses the primary economic effect as distributional transfers among petitioners due to a reallocation of selections from wage level I to higher wage levels within a fixed cap. This leads to an unquantified cost in terms of lost producer surplus for employers who registered at wage level I and were not selected, and a corresponding benefit in producer surplus for employers at higher wage levels whose registrations have higher selection probabilities. The rule does not require employers to artificially raise wages nor does it encourage wage discrimination. Businesses are unlikely to offer higher wages if the employee's skills do not justify the cost. DHS expects that companies will continue to make business decisions that align with their operational and financial interests.

The weighted selection process does not mandate any specific wage level; employers remain legally obligated to pay H-1B workers at least the prevailing wage or the actual wage, whichever is higher. *See* INA sec. 212(n)(1), 8 U.S.C. 1182(n)(1). Differentiated wages are already required under existing law, if necessary to comply with the prevailing wage obligation, and this rule does not change those existing obligations or create additional wage liabilities.

f. Other Comments

Comment: A commenter stated that the economic analysis underpinning the proposed rule overly relies on outdated studies and does not account with sufficient care for USCIS' own recent statistics. The commenter pointed to Figure 1 in the proposed rule and said that it clearly shows the vast majority of H-1B petitions for positions within the most relevant SOC codes are filed at wage level I and II, with the overwhelming majority of computer and mathematical occupations filed at level II. The commenter added that presenting the wage level selection effect proposed by DHS by looking only at the two-digit SOC code, which breaks occupations down only into broad "major groups," is itself misleading because wage levels are provided for H-1B by the DOL based on six-digit SOC codes, which breaks the classification down much further into detailed, specific jobs. The commenter concluded that the wage level construct does not allow for effective comparison or ordering among specific, detailed occupations.

Response: DHS disagrees with the comment. The RIA uses the most current H-1B registration and petition data available and presents wage-distribution information at both the two-digit SOC "major group" level and the

six-digit detailed SOC level. Figure 1 in the RIA provides a program-wide overview of wage distributions across major occupational groups to orient readers to broad patterns, while Figures 2 and 3 supply the more granular six-digit SOC analysis that the commenter claims is missing.

Comment: A commenter asserted that the weighted selection process does not sufficiently reduce the number of level I workers selected. The commenter showed self-selected examples of wage level distribution of which level I registrations still have a big share and concluded DHS's new system is flawed. The commenter proposed much more aggressive weighing (up to sixteen times for level IV) to shift selections toward level III and IV. The commenter also recommended visa reservations for specific occupations, restrictions on remote H-1B work, removal of the master's cap exemption, and prioritization based on university rankings.

Response: DHS disagrees with the comment that the rule is "flawed" based on the commenter's illustrative tables. The commenter picked an example where level I registrations are extremely dominant so even with weighting, the percentage of selected level I registrations is extremely high such that the commenter concludes that DHS's system is flawed since it could not redistribute the selected outcome using the proposed weighting. The weighted selection process does not guarantee that level I registrations will be eliminated or reduced to some specific target number but rather increases relative selection probabilities by corresponding wage level. If level I registrations massively outnumber registrations at higher wage levels, level I registrations would still get a substantial selected share. DHS declines to use much more aggressive weighting. DHS believes that the extremely steep weighting ratios would create disproportionate selection distribution, including the exclusion of workers at levels I and II. DHS does not intend to exclude level I and II workers from participation in H-1B program. Also, DHS must ensure that the weighted selection process remains administrable, predictable, and transparent. Extreme weighting would greatly exacerbate year-to-year variation in selection outcomes, which create instability and uncertainty for employers. The commenter mentioned occupation specific visa reservations, limitations on remote work, and elimination of the congressionally mandated master's cap exemption, but these fall outside of the scope of the rule. DHS also declines to

adopt the commenter's recommendation to prioritize registrations based on university's ranking because specialty occupation is not based on the prestige or ranking of the academic institution.

Comment: A commenter, citing several studies, wrote that the proposed rule ignores evidence showing that H-1B workers earn more than their U.S. counterparts. Meanwhile, the commenter claimed that the studies cited in the proposed rule fail to adjust for observable characteristics, such as age and experience when comparing U.S. and foreign workers and do not provide support for the wage-level weighting framework. The commenter reasoned that because the proposed rule aims to increase average salaries of H-1B workers and given that the average H-1B worker already makes more than similar U.S. workers, it is significant that the rule fails to show the need to prioritize senior workers. Like other comments, the commenter also stated that wage level may not reflect skill and does not allow for cross-occupational comparisons. Finally, the commenter reasoned that a selection process based only on wage levels may shift wage distribution leftward as upper wage level, low wage occupations dominate the selection process.

Response: DHS acknowledges that it is important to control for observable characteristics when comparing wages of H-1B workers and U.S. workers. However, DHS relies on OEWS wage levels reported in LCA filings for H-1B positions, which show that most petitions are submitted at wage levels I and II. Because OEWS wage levels are structured so that wage level III represents the median wage for an occupation and geographic area, the concentration of filings at level I and II indicate that H-1B positions are generally offered below the local median wage. The rule is intended to increase the likelihood that petitions offering wages at level III and IV will be filed. As shown in Table 12, the wage-level distribution of cap-subject petition receipts is approximately 28% (level I), 55% (level II), 12% (level III), and 5% (level IV). Because receipts are concentrated in lower levels I and II, a purely random selection would mirror that distribution. The rule's shift from random to weighted selection is intended to encourage petitioners to offer wages that reflect higher-skilled specialty occupation positions, and to reduce incentives to rely on the program for relatively lower-paid, lower-skilled positions to displace U.S. workers. As discussed in the RIA, moving to a weighted selection process is expected to increase the number and share of

level IV wage selections, resulting in higher average offered wages among selected H-1B cap-subject workers.

4. Costs

a. Impacts on the Economy, Employers/Registrants/Petitioners, Legal Services Providers/HR Specialists

Comment: A commenter indicated that the NPRM's estimate of \$1.6 billion in "gains" from higher H-1B wages is "illusory," as this number ignores the costs to U.S. workers who have lost jobs or promotion opportunities to H-1B workers, including "family costs and billions in suppressed labor that stifles necessary upskilling."

Response: DHS disagrees that the NPRM's estimated \$1.6 billion in wage gains is illusory. The estimate reflects the material change in wages that arises when H-1B cap-subject visas are more likely to be allocated to higher-paid, higher-skilled H-1B workers under the weighted selection process. DHS quantified the change in the number of affected cap-subject workers relative to the baseline and the average wage differential between higher-wage and lower-wage offers and multiplied these values to produce the economic impact. This is the direct impact of the change in the H-1B cap selection process. The commenter's references to family costs are outside the scope of the wage gain estimate, although DHS agrees that the rule may not have captured all the effects of the H-1B program at large on U.S. workers and their families.

Comment: One commenter noted that the rule would increase administrative burdens, likely in excess of the \$15 million annually that USCIS estimated at the registration stage. Another commenter said that requiring detailed documentation of wage levels and SOC codes across multiple worksites would impose new administrative burdens on employers, particularly smaller employers.

Response: The commenter provides no empirical support for the assertion that annual burden will exceed DHS's estimate. As shown in Table 10, the change will add additional requirements for registrants, and it will increase the time burden by an estimated 20 minutes. DHS estimates the additional annual cost for registrants (employers), whether completed by an HR specialist, in-house lawyer, or outsourced lawyer, to be approximately \$15 million. The change will add questions to the petition form, increasing the estimated time burden by 15 minutes. DHS estimates the additional annual cost to petitioners (employers) at approximately \$15 million (see Table

18). The total estimated annual cost to employers will be about \$30 million.

Comment: Some commenters stated that the DHS analysis did not adequately assess the impact of international students and workers' contribution to the STEM workforce and the resulting impact on the U.S. economy. A commenter cited economic research that demonstrates high-skilled immigration, especially those with STEM training, causes large increases in productivity and economic growth in the United States. Specifically, the commenter wrote, the increase in U.S. city-level productivity caused by inflows of foreign STEM workers from 1990 to 2010 is sufficient in magnitude to explain between 30 and 50 percent of all aggregate productivity growth in the United States during that period. Moreover, the influx of highly skilled immigrant graduates to the United States during the 1990s caused a 12 to 21 percent rise in the annual number of high-technology innovations reflected by annual patent applications, which in turn raised U.S. GDP per capita by between 1.4 and 2.4 percent—the equivalent, in today's dollars, of adding \$267–458 billion to the U.S. economy each year. And "a substantial reduction in the supply of foreign talent to the U.S. workforce will have large, negative, and lasting effects on productivity and economic growth in the United States."

The commenter further estimated that if the number of foreign STEM graduates from U.S. universities drops by 10 percent, due to policies that deter foreign students from enrolling or staying, this would reduce the total supply of high-skilled STEM workers in the United States by 1.9 percent. In turn, this reduction in high-skilled foreign STEM workers would decrease annual Total Factor Productivity growth by 0.024 to 0.048 percentage points. Over a decade, this would make U.S. GDP 0.24 to 0.48 percent smaller than it otherwise would have been. In today's terms, that would equal a loss of \$72–\$145 billion—comparable to the entire economy of a small U.S. state, such as Delaware or New Hampshire. The loss of international STEM talent would not just affect tech hubs like Silicon Valley and Boston, but also innovation clusters across the country—including the South, Midwest, and smaller cities that rely on international graduates to compete globally. These regions could see weakened innovation ecosystems and reduced competitiveness.

Another commenter stated international students are critical to the U.S. STEM workforce, making up about 20 percent of all STEM graduates and 44 percent of advanced STEM degree

recipients. They contribute disproportionately to U.S. innovation, filing more patents and starting more businesses than U.S. natives or other immigrants. Similarly, although H-1B nonimmigrants are a small share of the total U.S. workforce, they make up a significant portion of highly educated workers in technology-intensive industries. The commenter cited academic research showing that H-1B workers earn more than similar U.S. workers, fill critical skill shortages, boost productivity, and drive innovation, helping the United States maintain a competitive edge in science and technology. According to the commenter, the proposed process could make it harder for international students to transition from F-1 to H-1B status, narrowing the early-career talent pipeline. This would reduce the economic benefits of the H-1B program and threaten U.S. competitiveness in key sectors. The potential costs of this reduction could far outweigh any wage gains from the new system. Finally, a commenter estimated that the present value of the lost contributions from even a single talented worker over a 30–40-year career would easily reach millions of dollars in economic value. Multiplied across 10,000 workers annually, the long-term cost to the American economy would reach hundreds of billions of dollars.

Response: DHS appreciates the commenters' detailed discussion of the economic literature on the contributions of international students and highly skilled foreign workers to U.S. innovation, productivity, and long-run economic growth. DHS recognizes that highly skilled foreign STEM graduates and H-1B workers play an important role in the U.S. economy and that high-skilled migration has been associated with increased patenting, productivity growth, and expansions in technology-intensive sectors. DHS also acknowledges that international students constitute a substantial share of advanced STEM degree recipients and contribute to U.S. research and development capacity.

However, DHS disagrees that the H-1B weighted selection process would diminish these contributions or that the rule requires a separate productivity- or innovation-specific economic impact analysis. The commenters' discussion largely describes the macroeconomic benefits of high-skilled immigration in general, not the direct effects of any particular H-1B selection mechanism. The new weighted selection process does not reduce the overall number of H-1B cap-subject workers, but it changes the likely distribution of

selection across wage levels. The rule does not restrict participation by employers in STEM fields, innovation hubs, or critical technology sectors. Accordingly, the assertions that the rule would reduce the overall foreign talent are speculative and lack empirical support.

b. Impacts on U.S. Workers

Comment: A commenter stated that contrary to DHS claims that H-1B workers displace U.S. workers, research by the National Foundation for American Policy demonstrates that H-1B professionals complement U.S. workers. The commenter wrote that the presence of H-1B workers is associated with lower unemployment rates among college graduates, faster earnings growth for U.S. workers in fields with more H-1B nonimmigrants, and better career alignment for U.S.-born graduates. The commenter argued that data show that increasing the share of H-1B workers in an occupation reduces unemployment and boosts wage growth for U.S. workers, with no evidence of displacement, even among recent graduates. Thus, restricting H-1B visas could inadvertently harm U.S. workers by reducing opportunities for collaboration, innovation, and overall job growth. Another commenter cited research indicating that H-1B workers are generally complements, not substitutes, for U.S. workers, and help prevent offshoring of jobs.

Response: DHS appreciates the commenters' reference to research suggesting that high-skilled foreign workers, including H-1B workers, complement U.S. workers and may contribute to innovation, collaboration, and economic growth. However, DHS disagrees with the commenters that the new weighted selection process would restrict H-1B visas. The rule is designed to increase the chance of selection for higher-paid, higher-skilled beneficiaries in years of excess demand for numerically limited H-1B visas. The rule does not restrict access to the program, reduce the number of H-1B workers, or respond to general labor-market effects. Also, the analysis cited by the commenter does not suggest that a reduction in the share of H-1B workers in an occupation would increase unemployment or lower wage growth. The studies the commenter cites generally examine correlations between higher H-1B presence and positive labor-market indicators. These studies do not establish causality.

c. Impacts on USCIS

Comment: One commenter predicted that the new rule would result in a

greater burden on USCIS employees to examine and differentiate between occupational definitions, increasing the time spent reviewing each petition. Another commenter suggested that verification requirements of ensuring that the petition wages match registration wages could increase processing times and increase operational costs for USCIS, potentially leading to increased fees.

Response: DHS agrees that the new weighted selection process will require updates to USCIS IT systems for registration and additional time by USCIS adjudicators to review newly required information during the adjudication of the petition. DHS notes that if the rule increases USCIS' costs, then the fee schedule adjustment would be determined at USCIS' next comprehensive biennial fee review.

5. Benefits

Comment: A commenter supporting the proposed weighted selection process stated that a benefit of the rule could be increased average salaries in specialty occupations and that could raise wages for U.S. workers. The commenter further stated that this rule could benefit U.S. STEM graduates who are currently facing difficulties finding employment, explaining that U.S. tech workers have been harmed by the abuse of the H-1B program to bring in lower-paid workers compared to U.S. workers.

Response: DHS appreciates comments and analysis submitted by U.S. tech workers who believe their careers have been harmed by decades of industries' reliance on the H-1B program to provide foreign entry-level workers at level I and II wages that are, by definition, below the median for their occupation. The Department aims to implement the numerical cap in a way that incentivizes employers to offer higher wages, or to petition for positions requiring higher skills and higher-skilled aliens, that are commensurate with higher wage levels. The rule would favor the allocation of H-1B visas to higher-skilled and higher-paid aliens, while maintaining the opportunity for employers to secure H-1B workers at all wage levels. DHS believes that this is expected to increase average salaries among selected H-1B cap-subject workers, while also better protecting the wages, working conditions, and job opportunities of U.S. workers.

Comment: A commenter disagreed with the Department's assessment that increased wages paid to H-1B nonimmigrants would benefit the U.S. economy. While DHS's analysis concluded that higher wages paid to H-1B workers could increase overall

economic activity and tax revenue, the commenter stated that U.S. employers are more likely to lose access to essential skills, leading to delays in productivity and innovation, disruption of critical services, and even the abandonment or relocation of projects outside the United States. The commenter wrote that these consequences impose real costs on the American economy that outweigh the theoretical benefits that DHS assessed.

Response: DHS disagrees with the commenter. The commenter's predictions that the rule will cause employers to lose access to essential skills, abandon projects, or relocate work outside the United States are speculative. The commenter did not provide any empirical evidence, such as documented cases, case level data, or any quantitative or qualitative analyses to support the claim. Without substantiating data, DHS cannot verify these claimed impacts or conclude that they would outweigh the benefits identified in the regulatory impact analysis. The rule does not change the statutory cap, restrict eligibility for H-1B classification, limit access for any particular industry, or alter employers' ability to hire.

Comment: A commenter said that estimated benefits (total salary increases) in Table 15 are unverifiable because H-1B petition data are not public and urged DHS to release petition and registration data. The commenter said DHS must provide the underlying data and assumptions so the public can assess the validity and impact of the proposed rule, and that the current record does not provide enough information for meaningful evaluation. The commenter specifically questioned how DHS converted hourly, weekly, or monthly pay into annual figures and handled implausibly low or high salaries that may reflect typos. Pointing to what the commenter described as factual and mathematical errors, the commenter urged DHS to release the underlying data and assumptions so the public can assess the validity of its conclusions and their impact on the H-1B program. The commenter argued that the notice does not provide enough information for meaningful public evaluation of the proposed rule.

Response: DHS declines to release individual level raw data because DHS believes that the rulemaking record provides sufficient detail to allow meaningful evaluation of the estimates in Table 15 without disclosing raw data. Average annual salary estimates for H-1B cap-subject workers were derived from LCA wage data by converting all

reported pay frequencies to annual amounts using standard factors (hourly $\times 2,080$; weekly $\times 52$; monthly $\times 12$; annual as reported) and then computing the mean. To mitigate undue influence from extreme high values and apparent entry errors, annualized wages were top coded at \$1,000,000.⁹⁹ A review of the lower tail identified no anomalies, so no bottom-coding or exclusions were applied. DHS conducted quality checks to ensure internal consistency in the average annual salary for H-1B cap-subject workers. For these reasons, DHS disagrees that the estimates are unverifiable and regardless, DHS maintains that the current record provides adequate information for public review of the rule's economic impact.

6. Transfers

Comment: A commenter stated that the DHS analysis that estimated \$502 million in annual benefits from the proposed rule is misleading. Rather than representing new economic value, the figure reflects a transfer of wages from lower-paid (level I) workers to higher-paid workers. According to the commenter, such a transfer is not a true benefit but a redistribution of existing resources and therefore DHS did not demonstrate that the rule creates new value or improved efficiency.

Response: DHS disagrees with the commenter. As explained in the RIA, the estimated \$502 million first-year effect reflects higher average wages among cap-subject H-1B workers selected under the weighted selection process relative to the baseline. The benefit captures the increased amount of total wages paid after implementation. The NPRM discusses separately the transfer of wages from lower-paid workers to higher-paid workers in the RIA. The estimated annual transfer is \$858 million; with the fixed number of caps, shifting selections from level I to higher wage levels reallocates earnings from wage level I to higher wage levels. This reallocated portion of the earnings is captured as transfers, which is the total earnings of wage level I workers in the baseline.

7. Paperwork Reduction Act (PRA)

Comment: A few commenters expressed support for the proposed information collection regarding wage levels, stating that these questions are necessary to ensure that the weighted selection process will function as intended and that the H-1B program is

used to bring in highly skilled workers. These commenters stated that the burden of reporting the required information is minimal, especially compared to the benefits.

Response: DHS agrees that the proposed information collection is necessary and beneficial, and will finalize the H-1B registration, petition form, and form instructions as proposed.

Comment: A commenter said that the PRA burden is negligible compared to the costs that the failures of the H-1B program has imposed on U.S. workers and the United States economy through lost wages, displaced jobs, foregone innovation, and human costs. The commenter further said that the PRA analysis should be expanded to quantify these costs.

Response: DHS believes that the PRA burden is relatively minor compared to the benefits of this rule. The new information collection is necessary and beneficial to enhance the integrity of the H-1B program and further prevent the harms that the commenter described. DHS declines to expand the PRA analysis because the PRA analysis is limited to the burdens associated with the information collection on the Form I-129, Form I-129 instructions, and the registration tool. The Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*, requires federal agencies to minimize paperwork burdens on the public; it does not require an agency to address costs outside of the information collection requirement.

Comment: A commenter said that DHS's treatment of information collection under the PRA is incomplete. Implementing a weighted selection process for H-1B visas would require new or revised information to be collected during registration, such as offered wage, DOL OEWS wage level, SOC code, and worksite location. These requirements would increase the time and cost for each registration, especially for employers without in-house immigration counsel, resulting in hundreds of thousands of additional burden hours and millions of dollars in annual costs. The commenter asserted that the proposal does not provide a clear, itemized accounting of these new burdens or evaluate alternatives to reduce them. The commenter asserts that DHS must publish a revised 60-day PRA notice with specific burden-hour and cost estimates, consider less burdensome alternatives, and obtain Office of Management and Budget (OMB) approval before implementing the proposed process. Another commenter said that because DHS has proposed form revisions to implement

this rule, employers will need time not only to review and comment on the proposed revisions, but also to adopt and "operationalize" the revised forms. This commenter said the introduction of revised forms would be "extremely disruptive" to firms already planning for the FY 2027 cap season.

Response: DHS believes that the data collection requirements proposed with the NPRM will provide the information needed to implement the weighted selection process and no additional data elements are being added through this final rule. With no change to the form or instructions resulting from this comment, no change in burden needs to be addressed and updated from the burden estimate included in the NPRM. DHS also believes that the burden estimate associated with the data collections was accurately captured in the proposed rule, and no additional time for comment is necessary. DHS disagrees that the introduction of the new data collection requirements on the revised form will be extremely disruptive. DHS believes that the public has received sufficient notice of the weighted selection process and that employers will have sufficient time to operationalize the new data collection requirements on the revised form.

Comment: A commenter opposed the information collection related to this rule, noting several concerns with the proposed additions to Form I-129, specifically, the proposed addition of questions 7, 8, 9, 10, and 11 on the H-1B and H-1B1 Data Collection and Filing Fee Exemption Supplement. The commenter claimed that these additional questions are unnecessary, inconsistent with DOL processes, outside of DHS's authority, represent a significant burden which was not adequately assessed in the proposed rule, and are beyond the scope of the rule. The commenter also stated that the information collection changes to the registration tool fail to provide adequate guidance to ensure compliance.

Regarding Form I-129, H-1B and H-1B1 Data Collection and Filing Fee Exemption Supplement, the commenter claimed the additional questions 7 through 11 are unnecessary, as the LCA already provides information about the SOC code, wage level and area of intended employment. The commenter claimed that these questions are outside the scope of the proposed rulemaking, as these questions relate to the prevailing wage level determination and the specialty occupation determination whereas the proposed rule is limited to the issue of administering the registration process for cap-subject petitions. The commenter additionally

⁹⁹ Wages above one million were recoded to one million to mitigate effects of extreme outliers without shaping the original distribution.

claimed that these questions are ultra vires because they solicit information about how a prevailing wage determination was made during the LCA process, so that USCIS can question whether the appropriate SOC code and wage level was selected. The commenter concluded that this information would be used to “second-guess” DOL’s determinations on the LCA which “exceeds USCIS’ authority over LCAs because Congress clearly vested the DOL with exclusive authority over LCAs” at INA section 212(n).

Further, the commenter said that DHS failed to adequately assess the burden of adding these questions to the form, as these questions are applicable to all H-1B petitioners, not just those that are cap-subject. The commenter claimed that “[t]he proposed rule lacks any assessment of the impact in terms of the total universe of petitions filed with USCIS that would be subject to and impacted by this change.”

Additionally, the commenter noted that the questions did not contain corresponding instructions. The commenter claimed that these questions are overly broad and confusing, and that the lack of instructions is a “fatal error.”

Finally, regarding the registration tool, the commenter stated that the proposed form does not provide meaningful guidance for situations in which the OEWS wage information is unavailable for the relevant SOC code. The commenter requested a link to DOL guidance and ideally more detailed instructional language.

Response: DHS disagrees with this commenter. Questions 7 through 11 on the supplement form are directly related to this rule. As stated in the NPRM and in this final rule, the submission of additional information on the petition form (including wage level information and the SOC code) allows USCIS to further improve the integrity of the H-1B cap selection and adjudication processes. Specifically, these new questions allow USCIS to confirm that: the registrant selected the correct wage level for the proffered position; the position information provided in the selected registration is the same as the information provided in the petition; the position information on the registration was true and correct and represents a bona fide job offer; and the filing of a new or amended petition was not part of an attempt to unfairly increase the odds of selection during the registration (or petition, if applicable) selection process. While DHS acknowledges that these questions have greater applicability beyond these purposes, these questions are nevertheless necessary for USCIS to

ensure the integrity of the weighted selection process and the adjudication process.

These questions do not merely duplicate the LCA process. While the LCA does provide information about the SOC code, wage level, and area of intended employment, DHS cannot rely solely on the information provided on the LCA for registration purposes because the LCA process differs from the process by which a registrant selects a wage level on the registration. Specifically, the weighted selection process takes into account the highest wage level that the proffered salary equals or exceeds, whereas the LCA wage level is based solely on the requirements of the position. In instances where the wage level marked on the registration differs from the LCA wage level, USCIS will rely on these questions to assess whether the wage level marked on the registration was appropriate. These questions are necessary for USCIS to determine whether there was any gaming during the registration process, which is fully consistent with USCIS’s authority to administer the cap selection process and ensure program integrity.

DHS disagrees with the commenter’s assertion that these questions are outside the scope of DHS’ authority or that DOL has “exclusive authority over LCAs.” Contrary to the commenter’s assertion, DHS has broad authority to administer and enforce the INA. *See* INA sec. 103(a)(1), 8 U.S.C. 1103(a)(1). USCIS may consider LCA-related issues in exercising its own authority to administer and enforce the INA, including provisions pertaining to the H-1B program. *See ITServe All., Inc. v. DHS*, 71 F.4th 1028, 1037 (D.C. Cir. 2023) (“[P]olicing compliance with the terms of an LCA plainly constitutes ‘administration and enforcement’ of the INA, which section 1103(a)(1) independently authorizes.”).

DHS also disagrees with the claim that the burden estimate was inadequate because all petitioners, not just those that are cap-subject, need to respond to these questions. In the NPRM, DHS estimated the burden of these additional questions “for all H-1B petitions, not just H-1B cap-subject petitions, because these requirements would apply to any H-1B petitions.” 90 FR at 46011. DHS believes the proposed placement of these questions in section 1 of the supplement was reasonable, as section 1 requires petitioners to provide general information about the position including the major/primary field of study, rate of pay, SOC code, and NAICS code. DHS will maintain these

questions in section 1 of the supplement.

Further, DHS declines to add corresponding instructions for these questions. DHS disagrees that these questions are overly broad and confusing, and instead, believes these questions are self-explanatory. These questions generally derive from DOL prevailing wage guidance, with which most if not all H-1B petitioners should be familiar.¹⁰⁰ For example, question 7, which asks, “What level of education is required for the position?,” tracks with step 3 of the DOL guidance, which requires petitioners to compare the education requirement generally required for an occupation to the education requirement in the employer’s job offer.

Finally, DHS disagrees that the registration tool fails to provide adequate guidance. As stated in the NPRM, in the limited instance where there is no current OEWS prevailing wage information for the proffered position, the registrant would follow DOL guidance on PWDs to determine which OEWS wage level to select on the registration. 90 FR 45986, 45993 (Sept. 24, 2025). This sentence included a footnote to the proper guidance in effect as of the time of publication of the NPRM.¹⁰¹ It is possible that DOL will update their guidance in the future. In such case, registrants would use any updated version of the Prevailing Wage Determination guidance published by DOL.

8. Other Regulatory Requirements

Comment: A commenter said that the rule contradicts the deregulation goals of Executive Order 14192, *Unleashing Prosperity Through Deregulation*.

Response: DHS disagrees with the commenter’s assertion that this rule contradicts E.O. 14192, as this E.O. expressly states that it does not include regulations issued with respect to an immigration-related function of the United States. This final rule pertains to the administration of the annual numerical allocations for H-1B nonimmigrants under section 214(g) of the INA, 8 U.S.C. 1184(g), and is therefore an immigration-related function of the United States.

Comment: A commenter said that DHS should be required to clarify its Unfunded Mandates Reform Act of 1995

¹⁰⁰ While these questions derive from DOL prevailing wage guidance, DHS emphasizes that these questions serve different purposes than the LCA.

¹⁰¹ DOL, Employment and Training Administration (ETA), Prevailing Wage Determination Policy Guidance: Nonagricultural Immigration Programs (last modified Nov. 2009).

(UMRA) determination and explain the basis for concluding that private-sector expenditures do not meet UMRA thresholds because the proposed weighted selection process would likely increase private-sector compliance expenditures (as discussed under the PRA) and create significant distributional effects.

Response: DHS disagrees with the commenter that it should clarify its UMRA statement in the rule. As discussed in that section of this rule, neither the proposed nor the final rule constitute a Federal mandate for purposes of UMRA.¹⁰² Particularly with respect to the Federal private sector mandates, this rule imposes no enforceable duty on the private sector. Rather the H-1B program is voluntary, and this rule establishes a process for selection where employers may, but are not required to, offer higher wages to beneficiaries they wish to sponsor in order to increase their chances of selection. For these reasons, no further analysis is required.

H. Out of Scope

Numerous commenters provided comments outside the scope of this rulemaking (e.g., comments seeking changes in regulations and agency policies unrelated to the changes proposed in the NPRM). DHS provides a brief overview of the out of scope comments below. However, DHS is not providing substantive responses to those comments as they address policy questions beyond the limited changes proposed and cannot be resolved through this rulemaking. Comments that DHS considered out of scope include:

- General comments about terminating the H-1B program or halting immigration in general;
- General comments about the qualities of H-1B workers;
- General comments calling for comprehensive H-1B reform and urging

DHS to make structural changes, including changes to the statutory cap;

- Comments solely about the \$100,000 fee pursuant to the H-1B Proclamation;
- Comments about H-1B renewals, including suggestions for new fees for renewals;
- General concerns about staffing or outsourcing companies, and requests to ban such companies from the H-1B program permanently or for a limited period of time;
- Comments that would require DOL action, such as increasing the H-1B prevailing wage and improving DOL audits;
- Comments that would require joint DHS and DOL action, such as enhanced employee screening and deploying a digital platform to aid recruitment of U.S. workers;
- Comments about the L-1 visa program and perceived abuse of that program;
- Comments about the F-1 visa program and OPT/Curricular Practical Training;
- Comments about H-4 nonimmigrant status and employment authorization for H-4 spouses;
- Comments about other immigration programs, including the J-1, O-1, and H-2 nonimmigrant classifications and the EB-1 immigrant classification.

IV. Statutory and Regulatory Requirements

A. Executive Orders 12866 (Regulatory Planning and Review), 13563 (Improving Regulation and Regulatory Review), and 14192 (Unleashing Prosperity Through Deregulation)

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review) direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Executive Order 14192 (Unleashing Prosperity Through Deregulation) directs agencies to

significantly reduce the private expenditures required to comply with Federal regulations and provides that “any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.”

This rule has been designated a “significant regulatory action” that is economically significant, under section 3(f)(1) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

This rule is not an Executive Order 14192 regulatory action because it is being issued with respect to an immigration-related function of the United States. The rule’s primary direct purpose is to implement or interpret the immigration laws of the United States (as described in INA sec. 101(a)(17), 8 U.S.C. 1101(a)(17)) or any other function performed by the U.S. Federal Government with respect to aliens. See OMB Memorandum M-25-20, Guidance Implementing Section 3 of Executive Order 14192, titled ‘Unleashing Prosperity Through Deregulation’ (Mar. 26, 2025).

1. Summary of Changes From the Notice of Proposed Rulemaking

In this final rule, the estimated 10-year total benefits and transfers are 17 percent higher than in the NPRM. This change reflects updated data on the average tenure of cap-subject H-1B workers, including extensions. The NPRM assumed a 4-year average period of stay as an H-1B nonimmigrant. The final rule uses a 5-year average based on observed extensions, including those available beyond the standard six-year limit. The longer average duration means benefits and transfers accrue for more time, increasing the 10-year totals by accounting for an additional year of annual benefits (\$502 million) and transfers (\$858 million). Figures in Tables 4 and 16–21 have been updated to reflect the most recent data source and may differ immaterially from those in the NPRM. Table 1.2 summarizes the changes in estimated annualized and discounted impacts from the proposed rule to the final rule.

¹⁰² Under 2 U.S.C. 658(6) and 1502, the term “Federal mandate” means a Federal intergovernmental mandate or a Federal private sector mandate, as defined in 2 U.S.C. 658(5) and (7). Specifically, UMRA defines the term “Federal private sector mandate” as any provision in legislation, statute, or regulation that would impose an enforceable duty upon the private sector except, among other things, a duty arising from participation in a voluntary Federal program.

Table 1.2 Changes in Estimated Impacts From Proposed to Final Rule,
(10-year period of analysis, \$ millions)

	NPRM		Final Rule	
	Annualized 3 % Discounted	Annualized 7% Discounted	Annualized 3% discounted	Annualized 7% Discounted
Costs	\$30	\$30	\$30	\$30
Benefits	\$1,672	\$1,625	\$1,955	\$1,885
Total Net Benefits	\$1,642	\$1,594	\$1,925	\$1,854
Transfers	\$2,859	\$2,778	\$3,343	\$3,222

Source: USCIS Analysis

2. Summary of Changes

As discussed in the preamble, the purpose of this rule is to amend DHS regulations governing the process by which USCIS selects H-1B registrations for filing of H-1B cap-subject petitions (or H-1B petitions for any year in which the registration requirement will be suspended), by implementing a process in which all unique beneficiaries, while still randomly selected, will be weighted generally according to the highest OEWS wage level that the proffered wage equals or exceeds for the relevant SOC code in the area(s) of intended employment. Specifically, USCIS will weight and select each unique beneficiary (or petition, if registration is suspended) as follows: a

beneficiary (or petition) assigned to wage level IV will be entered into the selection pool four times, a beneficiary (or petition) assigned to wage level III will be entered into the selection pool three times, a beneficiary (or petition) assigned to wage level II will be entered into the selection pool two times, and a beneficiary (or petition) assigned to wage level I will be entered into the selection pool one time.

For the 10-year implementation period of the rule (FY2026 through FY2035), DHS estimates the annual costs will be about \$30 million. DHS estimates the annual net benefits (undiscounted) will be approximately \$472 million in FY2026, \$974 million in FY2027, \$1,476 million in FY2028, \$1,978 million in FY2029, and \$2,480

million in each year from FY2030 through FY2035. DHS estimates the annualized net benefits of the rule will be about \$1,925 million at 3 percent and \$1,854 million at 7 percent. DHS estimates the annual transfers (undiscounted) will be approximately \$858 million in FY2026, \$1,717 million in FY2027, \$2,575 million in FY2028, \$3,434 million in FY2029 and \$4,292 million in each year from FY2030 through FY2035. DHS estimates the annualized transfers of the rule will be about \$3,343 million at 3 percent and \$3,222 million at 7 percent.

Table 1.3 provides a detailed summary of estimated quantifiable and unquantifiable impacts of the final rule.

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Table 1.3. Summary of Provisions and Impacts of the Rule

Final Rule Provisions	Description of the Change to Provisions	Estimated Costs/Transfers of Provisions	Estimated Benefits of Provisions
1. Required Information on the Registration	A registrant will be required to select the box for the highest OEWS wage level that the beneficiary's wage generally equals or exceeds and also will be required to provide the SOC code for the proffered position and the area of intended employment that served as the basis for the OEWS wage level indicated on the registration.	Quantitative: Petitioners - ☐ DHS estimates costs will be \$15 million due to the additional time burden associated with the registration tool. DIIS/USCIS - ☐ None Qualitative: Petitioners - ☐ None DHS/USCIS - ☐ None	Quantitative: Petitioners - ☐ None DHS/USCIS - ☐ None Qualitative: Petitioners - ☐ None ☐ DHS/USCIS — Submission of additional wage level information, the SOC code, and area of intended employment on the electronic registration form will allow USCIS to further improve the integrity of the H-1B cap selection processes.
2. Weighting and Selecting Registrations (or petitions if registration is suspended)	DHS implements a wage-based selection process that will operate in conjunction with the existing beneficiary-centric selection process for registrations. When there is random selection USCIS will enter each unique beneficiary (or petition, as applicable) into the selection pool in a weighted manner: a beneficiary (or petition) assigned wage level IV will be entered into the selection pool four times; level III, three times; level II, two times; and level I, one time.	Quantitative: Petitioners - ☐ None DHS/USCIS - ☐ None Qualitative: Petitioners - ☐ None Transfer: H-1B workers ☐ Due to the weighted registration selection process, DHS estimates that \$858 million of wages will be transferred from wage level I H-1B workers to higher wage level H-1B workers in FY2026, \$1,717 million in FY2027, \$2,575 million in FY2028, \$3,434 million in FY2029, and \$4,292 million in each year from FY2030 through FY2035. This	Quantitative: Petitioners and H-1B Workers- ☐ Total benefits of \$502 million in FY2026, \$1,004 million in FY2027, \$1,506 million in FY2028, \$2,008 million in FY2029, and \$2,510 million in each year from FY2030 through FY2035 estimated in difference of wage paid to the higher wage level H-1B workers. DHS/USCIS - ☐ By engaging in a wage-level-based weighting of registrations for unique beneficiaries, DHS will better ensure

		transfer will be a cost to the wage level I H-1B worker who will lose the wage associated with selected H-1B registrations. This transfer also will be a benefit to the higher wage level H-1B workers who will receive a wage associated with selected H-1B registrations. Petitioners – - There will be an unquantifiable transfer from the petitioners who would have hired wage level I H-1B workers to the petitioners who will hire workers at higher wage levels. This transfer will be a cost in terms of lost producer surplus to the petitioners who registered at wage level I and were not selected due to the changes. This transfer will be an unquantifiable benefit in terms of gained producer surplus to the petitioners who registered at higher wage levels and got their H-1B registrations selected due to the higher probability of getting selected. - There will also be an unquantified transfer and benefit from an increase in state and Federal payroll taxes paid to the government by the petitioner. DHS/USCIS – ☐ None	that initial H-1B visas and status grants will more likely go to the higher-skilled or higher-paid beneficiaries. Facilitating the admission of higher-skilled workers “would benefit the economy and increase the United States’ competitive edge in attracting the ‘best and the brightest’ in the global labor market,” consistent with the goals of the H-1B program. Qualitative: Petitioners - ☐ None DHS/USCIS - None
3. Required Information on the Petition	The information required for the registration process will also be collected on the petition. Petitioners will be	Quantitative: Petitioners - DHS estimates this cost will be \$15	Quantitative: Petitioners - None

	required to submit evidence of the basis of the wage level selected on the registration as of the date that the registration underlying the petition was submitted.	million due to the additional time burden associated with filing the H-1B petition. DHS/USCIS - ☐ None Qualitative: Petitioners – ☐ None DHS/USCIS – ☐ None	DHS/USCIS - ☐ None Qualitative: Petitioners – ☐ None DHS/USCIS - ☐ Submission of additional information on the petition form (including wage level information and the SOC code), and evidence of the basis of the wage level selected, will allow USCIS to further improve the integrity of the H-1B cap selection and adjudication processes.
4. Process Integrity	The final rule will require an H-1B petition filed after registration selection to contain and be supported by the same identifying information and position information, including OEWS wage level, SOC code, and area of intended employment provided in the selected registration and indicated on the LCA used to support the petition. The final rule will also allow USCIS to deny a subsequent new or amended petition or revoke an approved petition if USCIS were to determine that the filing of the new or amended petition was part of the petitioner's attempt to unfairly increase odds of selection during the registration selection process.	Quantitative: Petitioners - ☐ None DHS/USCIS - ☐ None Qualitative: Petitioners – ☐ DHS estimates that the final rule could lead to an increase in the number of denials or revocations of H-1B petitions DHS/USCIS – ☐ None	Quantitative: Petitioners - ☐ None DHS/USCIS - ☐ None Qualitative: Petitioners – ☐ None DHS/USCIS – ☐ These changes will lead to improved program integrity for USCIS.

In addition to the impacts summarized in Table 1.3, and as required by OMB Circular A–4, Table 2 presents the prepared accounting statement showing the costs and benefits that will result in this final rule.¹⁰³

¹⁰³ OMB, Circular A–4 (Sept. 17, 2003), trumpwhitehouse.archives.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf.

Table 2. OMB A-4 Accounting Statement (\$ millions, FY 2023*)
Time Period: FY 2026 through FY 2035

Category	Primary Estimate	Minimum Estimate	Maximum Estimate	Source Citation
BENEFITS				
Annualized Monetized Benefits at 3%		\$1,955		Regulatory impact analysis (RIA)
Annualized Monetized Benefits at 7%		\$1,885		RIA
Annualized quantified, but unmonetized, benefits		N/A		RIA
Qualitative (unquantified) Benefits	- Submission of additional wage level information, the SOC code, and area of intended employment on the electronic registration form will allow USCIS to further improve the integrity of the H-1B cap selection processes. - By engaging in a wage-level-based weighting of registrations for unique beneficiaries, DHS will better ensure that initial H-1B visas and status grants will more likely go to the higher-skilled or higher-paid beneficiaries. Facilitating the admission of higher-skilled workers “would benefit the economy and increase the United States’ competitive edge in attracting the ‘best and the brightest’ in the global labor market,” consistent with the goals of the H-1B program. -The increased wages will also provide an increase in payroll taxes paid to the state and Federal government.			RIA
COSTS				
Annualized monetized costs at 3%		\$30		RIA
Annualized monetized costs at 7%		\$30		
Annualized quantified, but unmonetized, costs		N/A		RIA

Qualitative (unquantified) costs	- DHS estimates that the final rule could lead to an increase in the number of denials or revocations of H-1B petitions	RIA
TRANSFERS		
Annualized monetized transfers at 3%	\$3,332	RIA
Annualized monetized transfers at 7%	\$3,222	RIA
From/ To	From wage level I H-1B workers and petitioners to wage level II, III, and IV H-1B workers and petitioners.	RIA
Annualized unquantified monetized transfers	N/A	RIA
Qualitative (unquantified) transfers	There will be an unquantifiable transfer from the petitioners who would hire wage level I H-1B workers to the petitioners who would hire workers at higher wage levels in terms of producer surplus. This transfer will be a cost in terms of lost producer surplus to the petitioners who registered at wage level I and were not selected due to the changes. This transfer will be an unquantifiable benefit in terms of gained producer surplus to the petitioners who registered at higher wage levels and got their H-1B registrations selected due to the higher probability of getting selected.	RIA
From/To	From wage level I H-1B petitioners to wage level II, III, and IV H-1B petitioners.	RIA
Effects on State, local, or Tribal governments	N/A	RIA
Effects on small businesses	DHS estimates that the final rule will result in a significant economic impact on 5,193 small entities (30 percent of small entities that filed a cap-subject petition in FY 2024) due to loss of labor.	Regulatory Flexibility Act (RFA) analysis
Effects on wages	N/A	RIA
Effects on growth	N/A	RIA

*Note that costs are measured in FY 2023 dollars using U.S. Bureau of Labor Statistics (BLS) wages, but benefits and transfers are measured in average of FY 2023 and FY 2024 dollars using filed LCA wages.

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3. Background and Population

The H-1B nonimmigrant visa program allows U.S. employers to temporarily hire foreign workers to perform services in a specialty occupation, services related to a DOD cooperative research and development project or coproduction project, or services of distinguished merit and ability in the field of fashion modeling.¹⁰⁴ A specialty occupation is defined as an occupation

that requires the (1) theoretical and practical application of a body of highly specialized knowledge and (2) attainment of a bachelor's or higher degree in the specific specialty (or its equivalent) as a minimum qualification for entry into the occupation in the United States. *See* INA sec. 214(i)(1), 8 U.S.C. 1184(i)(1).

The number of aliens who may be issued initial H-1B visas or otherwise provided initial H-1B nonimmigrant status during any fiscal year has been capped at various levels by Congress over time, with the current numerical limit being 65,000 per fiscal year. *See* INA sec. 214(g)(1)(A), 8 U.S.C.

1184(g)(1)(A). Congress has also provided for various exemptions from this annual numerical limit, including an exemption for 20,000 aliens who have earned a master's or higher degree from a U.S. institution of higher education. *See* INA secs. 214(g)(5) and (7), 8 U.S.C. 1184(g)(5) and (7).

Under the current regulation, all petitioners seeking to file an H-1B cap-subject petition must first electronically submit a registration for each beneficiary on whose behalf they seek to file an H-1B cap-subject petition, unless USCIS suspends the registration requirement. *See* 8 CFR 214.2(h)(8)(iii)(A). USCIS monitors the

¹⁰⁴ *See* INA sec. 101(a)(15)(H)(i)(b), 8 U.S.C. 1101(a)(15)(H)(i)(b); Immigration Act of 1990, Public Law 101-649, sec. 222(a)(2), 104 Stat. 4978 (Nov. 29, 1990); 8 CFR 214.2(h).

number of H-1B registrations for unique beneficiaries properly submitted during the announced registration period of at least 14 days. At the conclusion of that period, if more registrations for unique beneficiaries are submitted than projected as needed to reach the numerical allocations, USCIS randomly selects from among unique beneficiaries for whom registrations were properly submitted, the number of unique beneficiaries projected as needed to reach the H-1B numerical allocations. See 8 CFR 214.2(h)(8)(iii)(A)(5) and (6). Under this purely random H-1B registration selection process, USCIS first selects from a pool of all unique beneficiaries, including those eligible for the advanced degree exemption. USCIS then selects from the remaining unique beneficiaries a sufficient number projected as needed to reach the advanced degree exemption. A prospective petitioner that properly registered for a beneficiary who is selected is notified of the selection and instructed that the petitioner is eligible to file an H-1B cap-subject petition for the beneficiary named in the selected registration within a filing period that is at least 90 days in duration. See 8 CFR 214.2(h)(8)(iii)(D)(3). When registration is required, a petitioner seeking to file an H-1B cap-subject petition is not eligible to file the petition unless the petition is based on a valid, selected

registration for the beneficiary named in the petition. See 8 CFR 214.2(h)(8)(iii)(A)(1). In general, prior to filing an H-1B petition, the employer is required to obtain a certified LCA from the DOL. See 8 CFR 214.2(h)(4)(i)(B). The LCA collects information about the employer and the occupation for the H-1B worker(s). The LCA requires certain attestations from the employer, including, among others, that the employer will pay the H-1B worker(s) at least the required wage. See 20 CFR 655.731 through 735. This final rule will amend DHS regulations concerning the selection of electronic registrations submitted by or on behalf of prospective petitioners seeking to file H-1B cap-subject petitions (or the selection of petitions, if the registration process is suspended), which includes petitions subject to the regular cap and those asserting eligibility for the advanced degree exemption, to allow for weighting and selection generally based on OEWS wage levels for simultaneously submitted registrations (including registrations submitted within the same window of time). When applicable, USCIS will weight and select the registrations for unique beneficiaries (or petitions) received generally based on the highest OEWS wage level that the beneficiary's proffered wage would

equal or exceed for the relevant SOC code and in the area(s) of intended employment. Although the allocation of regular cap (65,000) slots and advanced degree exemption (20,000) slots are approximately 75 percent and 25 percent respectively, the multiple-stage random selection process results in an increased probability that H-1B beneficiaries with a qualifying master's degree or higher will be selected. Table 3 shows the number of H-1B registrations received for beneficiaries without a qualifying master's degree (Non-master's), and with a qualifying master's degree or above (Master's or higher) for FY 2020 through FY 2024.¹⁰⁵ Table 3 includes the number of unique beneficiaries because DHS implemented a beneficiary-centric selection process for H-1B registrations in FY 2024 (for the FY 2025 cap selection process), which is when USCIS started selecting registrations by unique beneficiary instead of selecting by registration. 89 FR 7456 (Feb. 2, 2024). Based on a 5-year annual average, DHS estimates the annual average receipts of registrations to be 465,523. The 5-year annual average of registrations received for non-master's is 299,935, the 5-year annual average of registrations received for master's or higher is 165,587, and the 5-year annual average of number of unique beneficiaries with eligible registrations is 320,711.

Table 3. H-1B Registrations for FY 2020 through FY 2024

Fiscal Year	Number of Registrations (Non-master's + Master's or higher)	Non-master's	Master's or higher	Number of Unique Beneficiaries with Eligible Registrations
2020	274,237	148,142	126,095	118,026
2021	308,613	161,820	146,793	235,435
2022	483,927	334,360	149,567	356,633
2023	780,884	529,530	251,354	450,354
2024	479,953	325,825	154,128	443,108
5-Year Total	2,327,614	1,499,677	827,937	1,603,556
5-Year Average	465,523	299,935	165,587	320,711

Source: USCIS, OPQ, Benefits Hub, queried 3/2025, TRK #17347. Registrations submitted in each fiscal year are for the beneficiaries to begin work as an H-1B nonimmigrant the following fiscal year. Cap-subject petitions filed in each fiscal year are generally for the beneficiaries to begin work as H-1B nonimmigrants the following fiscal year.

Table 4 shows the number of H-1B cap-subject petitions (Form I-129, Petition for Nonimmigrant Worker) received for non-master's and master's or higher as well as historical Form G-

28 filings by attorneys or accredited representatives accompanying H-1B cap-subject petitions for FY 2020 through FY 2024. DHS notes that these forms are not mutually exclusive. Based

on the 5-year average, DHS estimates 80 percent of H-1B cap-subject petitions will be filed with Form G-28.¹⁰⁶ Although the advanced degree exemption cap is 20,000, there are more

¹⁰⁵ The terms "Non-master's" and "Master's or higher" used in this analysis refer to the

beneficiary's degree type, not which cap type they were selected under.

¹⁰⁶ Calculation: 76,372 5-Year Average Forms G-28 ÷ 94,900 5-Year Average Form I-129 petitions = 80 percent.

petitions for beneficiaries with master's or higher degrees than 20,000 because

some beneficiaries with master's or higher degrees are selected during the

regular cap selection process. *See* 8 CFR 214.2(h)(8)(iii)(A)(5).

Table 4. H-1B Cap-Subject Petitions Received for FY 2020 through FY 2024

Fiscal Year	H-1B Cap-Subject Petitions Received (Non-master's + Master's or higher)	Non-master's	Master's or higher	Number of Petitions Filed with Form G-28*
2020	100,498	40,740	59,758	82,740
2021	90,104	40,641	49,463	73,157
2022	94,702	51,046	43,656	74,970
2023	92,830	50,533	42,297	74,372
2024	96,367	48,933	47,434	76,619
5-Year Total	474,501	231,893	242,608	381,858
5-Year Average	94,900	46,379	48,522	76,372

Source: USCIS, OPQ, CLAIMS3 and ELIS, queried 3/2025, TRK #17265, TRK #19261 (Form G-28 data queried 10/2025)

Number of Petitions Filed with Form G-28*: This column's values differ from the NPRM because the NPRM presented data by fiscal year of G-28 submission. DHS revised this column to align with the rest of the columns, which generally are H-1B cap-subject petitions filed in each fiscal year for the beneficiaries to begin work as H-1B nonimmigrants the following fiscal year.

In this analysis, DHS uses historical data of both registrations and received petitions to estimate the future registration and petition population. Specifically, DHS uses 5-year averages to estimate the number of registrations and H-1B cap-subject petitions received annually. DHS does not adjust these estimates to account for the H-1B Proclamation because, as discussed earlier in this preamble, (1) that Proclamation applies to only a subset of H-1B petitions, (2) exceptions to the \$100,000 payment may be granted by the Secretary of Homeland Security to any individual alien, all aliens working for a company, or all aliens working in an industry; and (3) the H-1B Proclamation will expire, absent extension, 12 months from its effective date. This rule, in contrast, will continue indefinitely. DHS acknowledges that the rule's effects could differ in years when the H-1B Proclamation or a similar policy is in effect, but for the reasons stated above DHS is unable to adjust for the potential impacts of the Proclamation.

4. Costs, Transfers, and Benefits of the Final Rule

a. Required Information on the Registration

For purposes of the weighting and selection process in this rulemaking, a registrant will be required to select the box for the highest OEWS wage level ("wage level IV," "wage level III," "wage level II," or "wage level I") that the beneficiary's proffered wage

generally equals or exceeds for the relevant SOC code in the area(s) of intended employment. *See* new 8 CFR 214.2(h)(8)(iii)(A)(4)(i). The registrant will also be required to provide the appropriate SOC code of the proffered position and the area of intended employment that served as the basis for the OEWS wage level indicated on the registration, in addition to any other information required on the electronic registration form (and on the H-1B petition) as specified in the registration form instructions.

For registrants relying on a prevailing wage that is not based on the OEWS survey, if the proffered wage is less than the corresponding level I OEWS wage, the registrant will select the "wage level I" box on the registration form. *See* new 8 CFR 214.2(h)(8)(iii)(A)(4)(i). If the proffered wage is expressed as a range, the registrant will select the OEWS wage level that the lowest wage in the range will equal or exceed. If the H-1B beneficiary will work in multiple locations, or in multiple positions if the registrant is an agent, the registrant will select the box for the lowest equivalent wage level among the corresponding wage levels for each of those locations or each of those positions and will list the location corresponding to that lowest equivalent wage level as the area of intended employment.¹⁰⁷ *Id.* The

¹⁰⁷ Providing the area of intended employment that corresponds to the lowest equivalent wage level at registration will not preclude the registrant, if selected and eligible to file a petition, from listing

provision to require a registrant to select the lowest among the corresponding wage levels if a beneficiary will work in multiple locations, or in multiple positions if the registrant is an agent, is meant to prevent gaming of the weighted selection process.¹⁰⁸

DHS recognizes that some occupations do not have current OEWS prevailing wage information available on DOL's OFLC Wage Search website.¹⁰⁹ In the limited instance where there is no current OEWS prevailing wage information for the proffered position, such that there are not four wage levels for the occupational classification or there are not wage data for the area of intended employment, the registrant will follow DOL guidance on PWDs to determine which OEWS wage level to select on the

any additional concurrent work location(s) on the petition.

¹⁰⁸ For instance, in the case of multiple positions, if DHS were to instead require registrants to select the box for the highest corresponding OEWS wage level that the proffered wage were to equal or exceed, then a petitioner could place the beneficiary in a lower paying position for most of the time and a higher paying position for only a small percent of the time, but use that higher paying position to increase their chances of being selected in the registration process. Similarly, in the case of multiple locations, a petitioner could place the beneficiary in a higher paying locality for only a small percent of time but use that higher paying locality to increase their chances of being selected in the registration process.

¹⁰⁹ OFLC, a component of DOL, administers the OFLC Wage Search for OEWS prevailing wage information at <https://flag.dol.gov/wage-data/wage-search> (last visited Dec. 8, 2025).

registration.¹¹⁰ DHS expects each registrant will be able to identify the appropriate SOC code for the proffered position because all petitioners are required to identify the appropriate SOC code for the proffered position on the LCA, even when there are no applicable wage level data available or the OEWS survey is not used as the prevailing wage source on the LCA. Using the SOC code and the previously mentioned DOL guidance, all registrants will be able to determine the appropriate OEWS wage level for purposes of completing the

registration, regardless of whether they were to specify an OEWS wage level or utilize the OEWS program as the prevailing wage source on an LCA. This change will add additional requirements for registrants. DHS estimates that this change will increase the time burden by 20 minutes for each registration (0.3333 hours) from 36 minutes (0.6 hours) to 56 minutes (0.9333 hours). The change will offer qualitative benefits. Specifically, submission of additional wage level information and the SOC code on both

an electronic registration and on Form I-129 will result in the benefit of allowing USCIS to further improve the integrity of the H-1B cap selection and adjudication processes. Table 5 shows the number of total H-1B registrations and estimated total registrations with Form G-28 attached. Based on a 5-year annual average, DHS estimates the annual average registrations are 465,523. The estimated 5-year annual average of registrations with Form G-28 attached is 180,970.

Table 5. H-1B Registrations and Attached Form G-28 for FY 2020 through FY 2024

Fiscal Year	Total Registrations (A)	Total Eligible Registrations (B)	Eligible Registrations with Form G-28 (C)	Percentage of Eligible Registrations with Form G-28 (C/B)	Estimated Total Registrations with Form G-28* (A x C/B)
2020	274,237	269,424	74,356	28%	75,684
2021	308,613	301,447	147,350	49%	150,853
2022	483,927	474,421	205,335	43%	209,449
2023	780,884	758,994	249,579	33%	256,777
2024	479,953	470,342	207,634	44%	211,877
5-Year Total	2,327,614	2,274,628	884,254	39%	904,852
5-Year Average	465,523	454,926	176,851	39%	180,970

Source: USCIS OPQ, Benefits Hub, queried 3/2025, TRK #17518.
*Estimated Total Registrations with Form G-28 is estimated using the Percentage of Eligible Registrations with Form G-28 and Total Registrations.

DHS estimates the opportunity cost of time of gathering and preparing information by multiplying the estimated increased time burden for those submitting an H-1B registration by the compensation rate of a human resources (HR) specialist, in-house lawyer, or outsourced lawyer, respectively.

In order to estimate the opportunity cost of time for completing and submitting an H-1B registration, DHS assumes that a prospective petitioner will use an HR specialist, an in-house lawyer, or an outsourced lawyer to

prepare an H-1B registration.¹¹¹ DHS uses the mean hourly wage of \$36.57 for HR specialists to estimate the opportunity cost of the time for preparing and submitting an H-1B registration.¹¹² Additionally, DHS uses the mean hourly wage of \$84.84 for in-house lawyers to estimate the opportunity cost of the time for preparing and submitting an H-1B registration.¹¹³

DHS accounts for worker benefits when estimating the total costs of compensation by calculating a benefits-to-wage multiplier using the Bureau of

Labor Statistics (BLS) report detailing the average employer costs for employee compensation for all civilian workers in major occupational groups and industries. DHS estimates that the benefits-to-wage multiplier is 1.45 and, therefore, is able to estimate the full opportunity cost per registration, including employee wages and salaries and the full cost of benefits, such as paid leave, insurance, retirement, etc.¹¹⁴ DHS multiplied the average hourly U.S. wage rate for HR specialists and in-house lawyers by 1.45 to account for the full cost of employee benefits, for a total

¹¹⁰ DOL, ETA, Prevailing Wage Determination Policy Guidance: Nonagricultural Immigration Programs (last modified Nov. 2009), https://www.dol.gov/sites/dolgov/files/ETA/oflc/pdfs/NPWHC_Guidance_Revised_11_2009.pdf.
¹¹¹ DHS limited its analysis to HR specialists, in-house lawyers, and outsourced lawyers to present estimated costs. However, DHS understands that not all entities employ individuals with these occupations and, therefore, recognizes equivalent occupations may also prepare and submit these registrations.

¹¹² See BLS, DOL, Occupational Employment and Wage Statistics, Occupational Employment and Wages, May 2023, 13-1071 Human Resources Specialists, <https://www.bls.gov/oes/2023/may/oes131071.htm> (last modified Apr. 3, 2024).
¹¹³ See BLS, DOL, Occupational Employment and Wage Statistics, Occupational Employment and Wages, May 2023, 23-1011 Lawyers, <https://www.bls.gov/oes/2023/may/oes231011.htm> (last modified Apr. 3, 2024).
¹¹⁴ The benefits-to-wage multiplier is calculated as follows: (Total Employee Compensation per

hour) ÷ (Wages and Salaries per hour) = (\$45.42 Total Employee Compensation per hour) ÷ (\$31.29 Wages and Salaries per hour) = 1.45158 = 1.45 (rounded). See BLS, DOL, Economic News Release, Employer Costs for Employee Compensation—December 2023, Table 1. Employer Costs for Employee Compensation by ownership [Dec. 2023] (Mar. 13, 2024), https://www.bls.gov/news.release/archives/ecec_03132024.htm. The Employer Costs for Employee Compensation measures the average cost to employers for wages and salaries and benefits per employee hour worked.

of \$53.03 per hour for an HR specialist¹¹⁵ and \$123.02 per hour for an in-house lawyer.¹¹⁶ DHS recognizes that a firm may choose, but is not required, to outsource the preparation of these registrations and, therefore, presents two wage rates for lawyers. To determine the full opportunity costs of time if a firm hired an outsourced lawyer, DHS multiplied the average hourly U.S. wage rate for lawyers by 2.5

for a total of \$212.10 to approximate an hourly cost for an outsourced lawyer to prepare and submit an H-1B registration.¹¹⁷

DHS does not know the exact number of registrants who will choose an in-house or an outsourced lawyer but assumes it may be a 50/50 split and, therefore, provides an average. The estimated number of registrations with Form G-28 attached is 180,970 from

Table 5. Table 6 shows the current total annual average cost for a lawyer to complete the registration on behalf of a prospective petitioner. The current opportunity cost of time for submitting an H-1B registration using an attorney or other representative is estimated to range from \$13,357,758 to \$23,030,242, with an average of \$18,194,000.

Table 6. Current Average Opportunity Costs of Time for Submitting an H-1B Registration with an Attorney or Other Representative

	Population Submitting with a Lawyer	Time Burden to Complete H-1B Registration (Hours)	Cost of Time	Total Current Opportunity Cost
	A	B	C	D=(A×B×C)
In-house lawyer	180,970	0.6	\$123.02	\$13,357,758
Outsourced lawyer	180,970	0.6	\$212.10	\$23,030,242
Average				\$18,194,000

Source: USCIS analysis.

To estimate the current remaining opportunity cost of time for an HR specialist submitting an H-1B registration without a lawyer, DHS

applies the estimated public reporting time burden (0.6 hours) to the compensation rate of an HR specialist. Table 7 estimates the current total

annual opportunity cost of time to HR specialists completing and submitting an H-1B registration will be approximately \$9,053,907.

Table 7. Current Average Opportunity Costs of Time for Submitting an H-1B Registration, without an Attorney or Accredited Representative

	Population	Time Burden to Complete H-1B Registration (Hours)	HR Specialist's Opportunity Cost of Time	Total Opportunity Cost of Time
	A	B	C	D=(A×B×C)
Estimate of H-1B Registrations	284,553	0.6	\$53.03	\$9,053,907

Source: USCIS analysis. Note that 284,553 = 465,523 (number of total registrations) – 180,970 (number of registrations filed by lawyers) from Table 5.

Table 8 shows the final estimated time burden will increase by 20 minutes (0.3333 hours) to 56 minutes (0.9333 hours) to the eligible population and compensation rates of those who may submit registrations with or without a

lawyer due to changes in the instructions, adding clarifying language regarding denying or revoking approved H-1B petitions, adding passport or travel document instructional language, and providing the corresponding wage

level, the appropriate SOC code of the proffered position, and the area of intended employment that served as the basis for the OEWS wage level indicated on the registration. DHS does not know the exact number of registrants who will

¹¹⁵ Calculation: $\$36.57 \times 1.45 = \$53.03$ total wage rate for HR specialist.

¹¹⁶ Calculation: $\$84.84 \times 1.45 = \$123.02$ total wage rate for in-house lawyer.

¹¹⁷ Calculation: $\$84.84 \times 2.5 = \$212.10$ total wage rate for an outsourced lawyer.

The DHS analysis in Exercise of Time-Limited Authority to Increase the Fiscal Year 2018

Numerical Limitation for the H-2B Temporary Nonagricultural Worker Program, 83 FR 24905 (May 31, 2018), used a multiplier of 2.5 to convert in-house attorney wages to the cost of outsourced attorney wages.

The U.S. Immigration and Customs Enforcement rule, Final Small Entity Impact Analysis: 'Safe-Harbor Procedures for Employers Who Receive a

No-Match Letter' at G-4 (Aug. 25, 2008), <https://www.regulations.gov/document/ICEB-2006-0004-0922>, also used a multiplier of 2.5 to convert in-house attorney wages to the cost of outsourced attorney based on information received in public comment to that rule. The methodology used in that analysis remains sound for using 2.5 as a multiplier for outsourced labor wages in this rule.

choose an in-house or an outsourced lawyer but assumes it may be a 50/50 split and therefore provides an average.

DHS estimates that these current opportunity costs of time for submitting an H-1B registration using an attorney

or other representative will range from \$20,777,992 to \$35,823,542, with an average of \$28,300,767.

Table 8. New Opportunity Costs of Time for an H-1B Registration, Registrants Submitting with an Attorney or Other Representative

	Population of Registrants Submitting with a Lawyer	Time Burden to Complete H-1B Registration (Hours)	Cost of Time	Total Opportunity Cost
	A	B	C	D=(A×B×C)
In House Lawyer	180,970	0.9333	\$123.02	\$20,777,992
Outsourced Lawyer	180,970	0.9333	\$212.10	\$35,823,542
Average				\$28,300,767

Source: USCIS analysis.

To estimate the current remaining opportunity cost of time for an HR specialist submitting an H-1B registration without a lawyer, DHS

applies the final estimated public reporting time burden (0.9333 hours) to the compensation rate of an HR specialist. Table 9 estimates the current

total annual opportunity cost of time to HR specialists completing and submitting the H-1B registration will be approximately \$14,083,353.

Table 9. Final Average Opportunity Costs of Time for an H-1B Registration, Submitting without an Attorney or Accredited Representative

	Population	Time Burden to Complete H-1B Registration (Hours)	HR Specialist's Opportunity Cost of Time (\$48.40/hr.)	Total Opportunity Cost of Time
	A	B	C	D=(A×B×C)
Estimate H-1B Registration	284,553	0.9333	\$53.03	\$14,083,353

Source: USCIS analysis.

DHS estimates the total additional annual cost for attorneys and HR specialists to complete and submit H-1B registrations will be approximately

\$15,136,213 as shown in Table 10. This table shows the current total opportunity cost of time to submit an

H-1B registration and the final total opportunity cost of time.

Table 10. Total Costs to Complete the H-1B Registration

Average Current Opportunity Cost Time for Lawyers to Complete the H-1B Registration	\$18,194,000
Average Current Opportunity Cost Time for HR Specialist to Complete the H-1B Registration	\$9,053,907
Total (A)	\$27,247,907
Average Final Opportunity Cost Time for Lawyers to Complete the H-1B Registration	\$28,300,767
Average Final Opportunity Cost Time for HR Specialist to Complete the H-1B Registration	\$14,083,353
Total (B)	\$42,384,120
Final Additional Opportunity Costs of Time to Complete the H-1B Registration (Total (B) minus Total (A))	\$15,136,213

Source: USCIS analysis.

b. Weighting and Selecting Registrations

In the current selection process for H-1B registrations, USCIS randomly selects from among properly submitted registrations the number of unique beneficiaries projected as needed to reach the H-1B numerical allocations. This final rule will change the way USCIS selects unique beneficiaries, and the registrations submitted on their behalf for H-1B cap-subject petitions (or petitions, if the registration process is suspended), including those eligible for the advanced degree exemption. USCIS will weight and select the registrations for unique beneficiaries (or petitions) received generally on the basis of the highest OEWS wage level that the beneficiary's proffered wage will equal or exceed for the relevant SOC code in the area(s) of intended employment. The changes to weight and select

registrations will result in the benefit of increasing the chance that registrations or petitions, as applicable, will be selected for higher paid, and presumably higher-skilled or higher-valued, beneficiaries.

Congress has established the limits on certain initial H-1B nonimmigrant visas or status grants each fiscal year not to exceed 65,000 (regular cap) with an annual exemption for those who have earned a qualifying U.S. master's degree or higher from a U.S. institution of higher education not to exceed 20,000 (advanced degree exemption). USCIS monitors the number of H-1B registrations for unique beneficiaries it receives during the announced registration period. At the conclusion of the registration period, USCIS randomly selects from among properly submitted registrations a number of registrations for unique beneficiaries projected as

needed to reach the H-1B numerical allocations. Although the allocation of regular cap (65,000) and advanced degree exemption (20,000) are approximately 75 percent and 25 percent respectively, the multiple-stage random selection process results in an increased probability that H-1B beneficiaries with a master's degree or higher will be selected. Table 11 shows the historical numbers of H-1B cap-subject petitions received by wage level and by the beneficiary's degree type for FY 2020 through FY 2024. Based on the 5-year annual average, DHS estimates the annual average receipts of H-1B cap-subject petitions are 94,900 per year. The 5-year annual average of non-master's degree receipts is 46,379, and the 5-year annual average of master's or higher degree receipts is 48,522.

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Table 11. Form I-129, H-1B Cap-Subject Petition Received by Wage Level for FY 2020 through FY 2024

Fiscal Year		Level I	Level II	Level III	Level IV	N/A*	All Levels
2020		26,152	53,665	10,854	4,531	5,296	100,498
	Non-master's	6,962	23,380	5,530	2,881	1,987	40,740
	Master's or higher	19,190	30,285	5,324	1,650	3,309	59,758
2021		21,990	49,130	10,515	4,353	4,116	90,104
	Non-master's	6,475	24,023	5,663	2,810	1,670	40,641
	Master's or higher	15,515	25,107	4,852	1,543	2,446	49,463
2022		22,361	54,020	11,143	4,502	2,676	94,702
	Non-master's	8,570	32,628	6,140	2,683	1,025	51,046
	Master's or higher	13,791	21,392	5,003	1,819	1,651	43,656
2023		26,107	48,656	10,416	4,205	3,446	92,830
	Non-master's	11,082	30,060	5,675	2,430	1,286	50,533
	Master's or higher	15,025	18,596	4,741	1,775	2,160	42,297
2024		29,435	43,558	10,370	4,431	8,573	96,367
	Non-master's	11,111	24,782	5,897	2,734	4,409	48,933
	Master's or higher	18,324	18,776	4,473	1,697	4,164	47,434
5-Year Total	Non-master's	126,045	249,029	53,298	22,022	24,107	474,501
	Master's or higher	44,200	134,873	28,905	13,538	10,377	231,893
5-Year Average		25,209	49,806	10,660	4,404	4,821	94,900
	Non-master's	8,840	26,975	5,781	2,708	2,075	46,379
	Master's or higher	16,369	22,831	4,879	1,697	2,746	48,522

Source: USCIS, OPQ, CLAIMS3 and ELIS, queried 3/2025, TRK #17265. LCA data from DOL. Disclosure Files for LCA Programs (H-1B, H-1B1, E-3), FY 2018 – FY 2024. DOL data downloaded from <https://www.dol.gov/agencies/eta/foreign-labor/performance>.

*N/A: Approximately 5 percent of H-1B cap-subject receipts have wage levels not available. Most N/As use an independent survey or other survey sources to determine the prevailing wage rather than using the OFLC online data center provided by DOL.

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Table 12 presents the percentage of H-1B cap-subject receipts by wage levels for the estimated 94,900 average annual receipts, based on corresponding 5-year averages for FY 2020 through FY 2024. For both non-master's degree and master's or higher degree, wage level II has the most H-1B receipts followed, in order, by level I, level III, and level IV. Master's or higher degree petitions have slightly more receipts in level I and level II as shown by the cumulative percentage of 86 percent compared to the non-master's degree petitions' cumulative percentage of 81 percent. Currently, wage level data are only collected for those beneficiaries who were selected in the registration selection process and on whose behalf a Form I-129 for H-1B petition was

filed because H-1B petitioners must obtain a certified LCA from DOL that includes the applicable wage level. An LCA is not a requirement for registration. Therefore, DHS does not have information on the number of registrations for each wage level. DHS assumes that the H-1B cap-subject petition receipts percentages by wage levels from LCA data are predictive of the H-1B registrations percentages by wage levels. However, to the extent that proffered wages may exceed the wage levels indicated on the LCA, the projections in this discussion will represent the upper bound of the impact of the final rule. DHS does not have a way to estimate how many registrants will select a higher wage level than required on the LCA, so DHS uses LCA

wage level data as a reasonable proxy for registration wage level data.

DHS uses the percentages of H-1B cap-subject petition receipts by wage level to estimate the distribution of registrations for beneficiaries by wage level. Table 12 shows that the distribution of current H-1B cap-subject petition receipts, 94,900, by wage level is 28 percent, 55 percent, 12 percent, and 5 percent for wage levels I, II, III, and IV, respectively. DHS uses the 5-year average of the number of unique beneficiaries with eligible registrations, 320,711 from Table 3 and applies the distribution of current H-1B cap-subject petition receipts to estimate the number of unique beneficiaries with eligible registrations by wage level shown in Table 12.

Table 12. Percentage of H-1B Cap-Subject Receipts and Estimated Number of Beneficiaries with Eligible Registrations by Wage Level for 5-Year Average for FY 2020 through FY 2024

5-Year Average	Level I	Level II	Level III	Level IV	Total
Non-master's	9,254	28,238	6,052	2,834	46,379
Total %	20%	61%	13%	6%	
Cumulative %	20%	81%	94%	100%	
Master's or higher	17,351	24,201	5,171	1,799	48,522
Total %	36%	50%	11%	4%	
Cumulative %	36%	86%	96%	100%	
Cap-Subject Total	26,605	52,439	11,223	4,633	94,900
	28%	55%	12%	5%	100%
Estimated Number of Beneficiaries with Eligible Registration by Wage Level	89,911	177,216	37,928	15,657	320,711

Source: USCIS analysis. N/A counts in H-1B cap-subject receipts by wage level were redistributed among wage levels using the percent of total. For example, for wage level II, 28,238 is 26,975, the 5-year average of non-master's for level II from Table 11, plus 1,264, which is 61 percent of the total N/A count, 2,075.

The estimated number of beneficiaries with eligible registrations by wage level is estimated using percentages by wage level (level I, 28%; level II, 55%; level III, 12%; and level IV, 5%) of the 5-year average of the number of beneficiaries with eligible registrations, 320,711. The 5-year annual average of number of beneficiaries with eligible registrations, 320,711, is from Table 3.

This final rule will change the way USCIS selects registrations for H-1B cap-subject petitions (or petitions, if the registration process is suspended), including those eligible for the advanced degree exemption. When random selection is required, USCIS will weight and select unique beneficiaries with properly submitted registrations generally based on the highest OEWS wage level that the beneficiary's proffered wage will equal or exceed for the relevant SOC code in the area(s) of intended employment. A registrant will be required to select the box for the highest OEWS wage level ("wage level IV," "wage level III," "wage level II," or "wage level I") that the proffered wage generally equals or exceeds for the relevant SOC code in the area of intended employment or otherwise select the appropriate box according to the form instructions. Registrations for unique beneficiaries or petitions will be assigned to the relevant OEWS wage level and entered into the selection pool as follows: registrations for unique beneficiaries or petitions assigned wage level IV will be entered into the selection pool four times, those assigned wage level III will be entered into the selection pool three times, those assigned wage level II will be entered into the selection pool two times, and those assigned wage level I will be entered into the selection pool one time. Each unique beneficiary will only be counted once toward the numerical

allocation projections, regardless of how many registrations were submitted for that beneficiary or how many times the beneficiary is entered in the selection pool. If a beneficiary has multiple registrations, the unique beneficiary will be allotted to the lowest wage level of all registrations submitted on his or her behalf. This rule will increase the odds of being selected to file H-1B cap-subject petitions for beneficiaries with proffered wages that correspond to higher wage levels. DHS examines the impacts of the change in three different dimensions: probability of being selected, estimated number of unique beneficiaries selected by wage levels, and economic impact of the change.

Under the current H-1B selection process, if more registrations for unique beneficiaries are submitted than projected as needed to reach the numerical allocations, USCIS randomly selects from among unique beneficiaries for whom registrations were properly submitted, the number of unique beneficiaries projected as needed to reach the H-1B numerical allocations. Under this random H-1B registration selection process, USCIS first selects from a pool of all unique beneficiaries, including those eligible for the advanced degree exemption. USCIS then selects from the remaining unique beneficiaries a sufficient number projected as needed to reach the advanced degree exemption. 8 CFR 214.2(h)(8)(iii)(A)(5) through (6). This

process allows beneficiaries who have earned a qualifying U.S. master's degree or higher a greater chance to be selected. The final rule will maintain this two-stage selection process to keep a higher chance of beneficiaries with a qualifying U.S. master's degree or higher of being selected. However, for the simplicity of comparing the probabilities of being selected in the current random selection process and in the weighted selection process, DHS combines the pool of beneficiaries for the regular cap and the advanced degree exemption and presents the probabilities of being selected at different wage levels in this analysis.¹¹⁸

Table 13 compares the probabilities of being selected and corresponding estimated petition receipts by wage level for the current random selection process and new weighted selection process. Under the current random selection process in which every unique beneficiary has an equal chance of being selected, the probability of being selected to file an H-1B cap-subject petition for a unique beneficiary is 29.59 percent across all the wage levels. Under the new weighted selection, DHS

¹¹⁸ DHS recognizes combining the pool of beneficiaries for the regular cap and the advanced degree exemption would result in a decrease in wage level I beneficiaries under the final rule. However, modeling the weighted selection as a single pooled draw across all registrations is more tractable and clarifies the rule's impact with minor loss of accuracy.

estimates that the probability of being selected to file a H-1B cap-subject petition for a unique beneficiary will be 15.29 percent for level I, 30.58 percent for level II, 45.87 percent for level III, and 61.16 percent for level IV.¹¹⁹ The estimated petition receipts for the current selection process and new

selection process are shown in Table 13. DHS estimates that the percentage change in probability of being selected to file an H-1B cap-subject petition from the current to the new process will decrease by 48 percent for level I and will increase by 3 percent, 55 percent, and 107 percent for level II, level III,

and level IV, respectively. DHS projects, based on the weighted selection process, that the probability of being selected to file an H-1B cap-subject petition will be allocated more to levels II, III, and IV, and less to level I.

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Table 13. Probability of Being Selected and Estimated H-1B Cap-Subject Petition Receipts by Wage Level

	Level I	Level II	Level III	Level IV	Total
(A) Estimated Number of Beneficiaries with Eligible Registration by Wage Level	89,911	177,216	37,928	15,657	320,711
(B) Probability of Being Selected to File H-1B Cap-Subject Petitions under Current Random Selection by Wage Level	29.59%	29.59%	29.59%	29.59%	
(C) Estimated Petition Receipts (Random Selection)	26,605	52,439	11,223	4,633	94,900
(D) Probability of Being Selected to File H-1B Cap-Subject Petitions under New Weighted Selection by Wage Level	15.29%	30.58%	45.87%	61.16%	
(E) Percentage Change in Probability of Being Selected to File H-1B Cap-Subject Petitions from Current to Weighted Selection System	-48.33%	3.35%	55.02%	106.69%	
(F) Estimated Petition Receipts (Weighted Selection)	15,330	55,089	16,243	8,239	94,900

Source: (A) USCIS analysis.

(B) The probability of being selected under random selection is 29.59% = (94,900 ÷ 320,711) × 100% regardless of different wage levels.

(C) = (A) x (B).

(D) The probability of being selected under weighted selection for level I is 15.29% = (94,900 ÷ (89,911 × 1 + 177,216 × 2 + 37,928 × 3 + 15,657 × 4)) × 100%. Level II, 30.58% = (probability of being selected for level I, 15.29%) × 2. Level III, 45.87% = 15.29% × 3. Level IV, 61.16% = 15.29% × 4.

(E) Percentage Change in Probability for Level I = (15.29 - 29.59)/29.59x100%= -48.33%; for Level II, III, and IV follow the same calculation.

(F) Because beneficiaries can be selected only once, DHS simulated the process of selecting registrations; multiplying petitions by selection probabilities ((A) x (D)) does not accurately reflect the selection process because once a person is selected, that person does not re-enter the pool of registrants and would overstate impacts. Since weighted probabilities without replacement are not tractable to compute explicitly, DHS used Monte Carlo simulation to estimate line F.

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Table 14 shows the estimated difference in H-1B cap-subject petitions by wage level from the current to the new selection process. DHS applies 85,000, which is the statutory limit on the number of initial H-1B visas, rather

than the historical 5-year annual average of H-1B cap-subject petition receipts, which is 94,900,¹²⁰ because approximately 85,000 beneficiaries will be granted initial H-1B status and paid the applicable required H-1B wage. The estimated number of annual H-1B cap-

subject visas will decrease by 10,099 for level I petitions, and will increase by 2,373 for level II petitions, 4,496 for level III petitions, and 3,230 for level IV petitions.

¹¹⁹ Calculating weighted probability is complex due to the involvement of conditional probabilities and distributional assumptions. For this analysis, DHS uses simple weighted probabilities to approximate the expected distribution of each wage level in the sample (see Table 13), comparing probabilities of being selected. The new weighted probability distribution assumes that companies

will keep their current wage rates when submitting registrations or petitions. As a result, the analysis may underestimate the number of registrations or petitions for higher-wage positions selected in the future if companies offer higher wages to improve their chance of selection.

¹²⁰ Note that the estimated number of H-1B cap-subject petitions (94,900) exceeds the number of H-1B visas authorized under the statutory cap (approximately 85,000, after certain deductions are made for certain numerical set-asides) to allow for the possibility that some approved workers would either not seek a visa or admission, would not be issued a visa, or would not be admitted to the United States.

Table 14. Estimated Distributional Difference in H-1B Cap-Subject Petitions by Wage Level for Current (Random) and New (Weighted) Selection Process

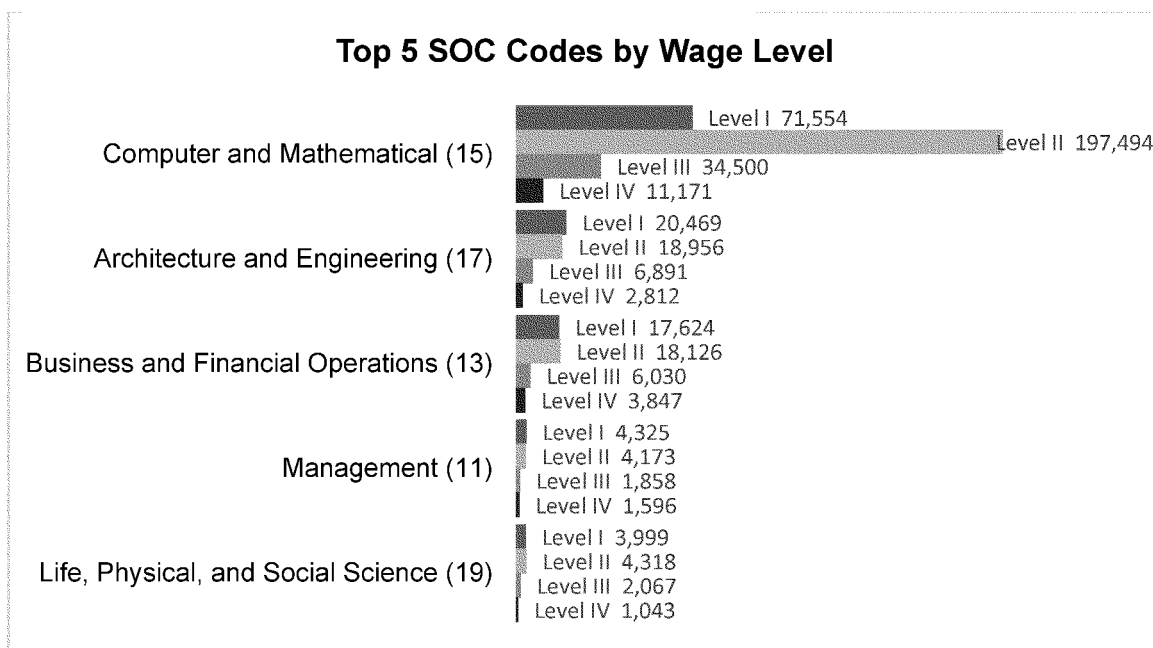
	Level I	Level II	Level III	Level IV	Total
Estimated H-1B Cap-Subject Petition Receipts (Random)	26,605	52,439	11,223	4,633	94,900
Estimated H-1B Cap-Subject Petition Receipts (Weighted)	15,330	55,089	16,243	8,239	94,900
Statutory Limit on the Number of Initial H-1B Visa					85,000
Estimated H-1B Cap-Subject Visa Granted (Random)*	23,830	46,968	10,052	4,150	85,000
Estimated H-1B Cap-Subject Visa Granted (Weighted)*	13,731	49,342	14,548	7,379	85,000
Difference in Estimated H-1B cap-subject Visa Granted from Random to Weighted Selection	-10,099	2,373	4,496	3,230	0

*Note that Estimated H-1B Cap-Subject Visa Granted (Random/Weighted) is equal to Estimated H-1B Cap-Subject Petition Receipts (Random/Weighted) multiplied by 85,000/94,900. This scaling is applied to each wage level.

All LCAs that are required for H-1B petitions specify SOC codes for the prospective jobs. The top two SOC major group codes, Computer and Mathematical Occupations (2-digit SOC major group code 15) and Architecture and Engineering Occupations (2-digit SOC major group code 17), make up 81 percent of H-1B cap-subject petitions received in FY 2020–FY 2024. The top five SOC major group codes make up 96

percent of total petitions. Figure 1 breaks out the wage levels for these SOC codes. The H-1B cap-subject petitions by wage level presented in previous tables show that most of the petitions are at wage level II. As seen in Figure 1, this is driven by Computer and Mathematical Occupations. Petitions for Computer and Mathematical Occupations are overwhelmingly at wage level II, whereas petitions for

Architecture and Engineering Occupations are greater at wage level I than wage level II. For the rest of the top five SOC major group codes, the number of H-1B cap-subject petitions filed at wage level II is greater than level I, but not as drastically different as Computer and Mathematical Occupations.

Figure 1. Top Five SOC Codes for FY 2020–FY 2024, by Wage Level

Source: USCIS, OPQ, CLAIMS3 and ELIS, queried 3/2025, TRK #17265. Merged with LCA data from DOL. Disclosure Files for LCA Programs (H-1B, H-1B1, E-3), FY 2018 – FY 2024.

Given that the analysis estimates a 48 percent drop in selections for wage level I beneficiaries, the distribution of wage levels at the SOC code will determine the effects of the final rule for occupations under that SOC code. DHS examines these effects for the top two SOC major group codes (15 and 17) by breaking out the distribution into 6-digit SOC codes. The results are summarized in Figure 2 and Figure 3.

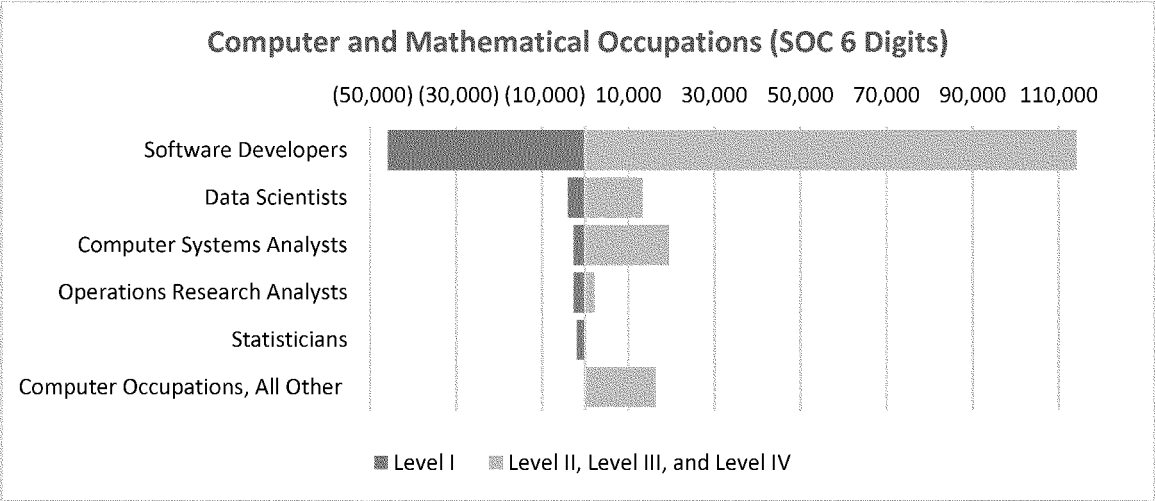
Of the 470,023 H-1B cap-subject petitions received in FY 2020–FY 2024, 69 percent (326,000) were associated with SOC major group 15 (Computer and Mathematical Occupations). This major occupation group contains 460 distinct 6-digit SOC codes, each corresponding to a different detailed

occupation. Examples of detailed occupations include 15–1252 (Software Developers) and 15–2051 (Data Scientists). The top five detailed occupations make up 71 percent of the 326,000 petitions received under SOC major group 15. Figure 2 details the counts for these five detailed occupations, separated by whether they were grouped at wage level I or at one of the higher wage levels (II, III, IV). As Figure 2 shows, all detailed occupations under SOC major group 15 have counts of petitions in wage level I and in higher wage levels except 15–2041 (Statistician).

The final rule does not project a significant increase in the selection of higher wage level workers in the 15–

2041 (Statistician) occupation.¹²¹ SOC code 15–1299 (Computer Occupations, All Other) is also one of the notable exceptions—it is not one of the top five SOC codes for level I petitions.¹²² SOC code 15–1299 is used to encompass detailed occupations that do not have a specific code within the broad group. The final rule will have material effects on these detailed occupations since registrations under this code will receive a large boost in probability that they are selected.

Figure 2. Top Five SOC Code 6-Digit in Computer and Mathematical Occupations for FY 2020–FY 2024, by Wage Level



Source: USCIS, OPQ, CLAIMS3 and ELIS, queried 3/2025, TRK #17265. Merged with LCA data from DOL. Disclosure Files for LCA Programs (H-1B, H-1B1, E-3), FY 2018 – FY 2024. Note that SOC 6 digits are 2018 SOC classification.

¹²¹ However, it is possible that such prospective employers already pay a wage that corresponds to a higher wage level such that the chance of selection would not be reduced under the final rule, or that they would choose to pay a wage that

corresponds to a higher wage level in order to increase the chance of selection for workers in level I positions.

¹²² This does not mean there are no petitions filed at Wage Level I for SOC 15–1299 (Computer

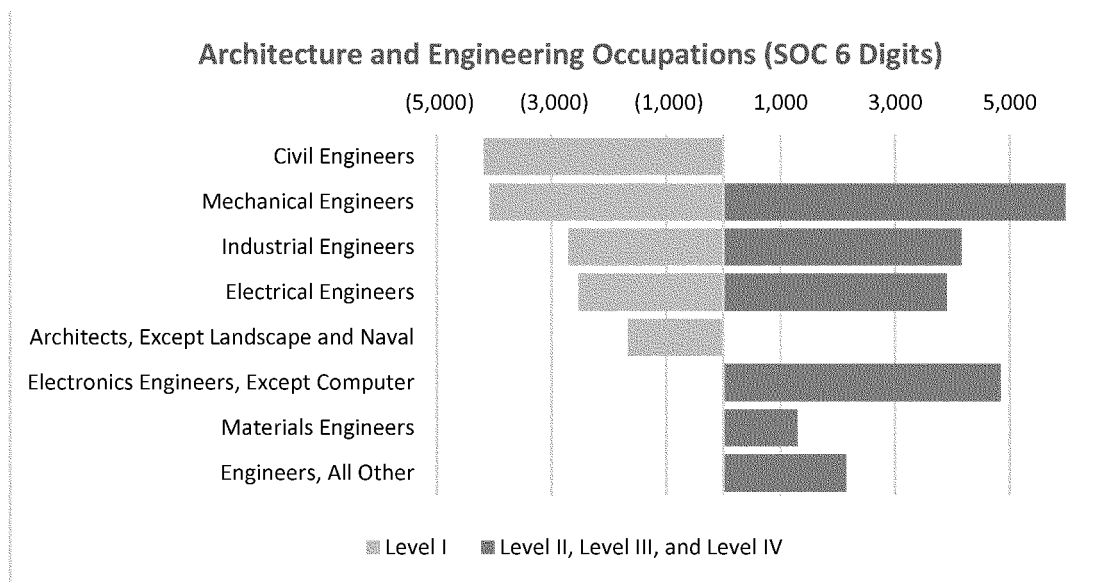
Occupations, All Other). The figure shows, by wage level, the top five six-digit SOC codes within the Computer and Mathematical Occupations category. SOC 15–1299 does not rank in the top five at Wage Level I, but it does at Wage Levels II, III, or IV.

After SOC major group code 15, the major group with the next greatest number of petitioners is SOC major group code 17 (Architecture and Engineering Occupations). This major group had 52,402 petitions filed in FY 2020 through FY 2024. Figure 3 details the counts for the top five detailed occupations within SOC major group code 17 that had the greatest number of petitions in FY 2020 through FY 2024. As for SOC major group code 17, many of these occupations have petition counts in wage level I and in higher wage levels. SOC code 17–2051 (Civil

Engineers) and 17–1011 (Architects, Except Landscape and Naval) are also a notable exception since all the petitions under this code in the figure were wage level I. The final rule will reduce the number of selected H–1B registrations for Civil Engineers and Architects by up to 48 percent, assuming such registrations will be submitted at wage level I consistent with historical LCA wage level data for Civil Engineers.¹²³ On the other hand, the final rule will likely increase the number of selected H–1B registrations for SOC code 17–2072 (Electronics Engineers except

Computer), SOC code 17–2131 (Materials Engineers), and 17–2100 (Engineers, All Other) since these detailed occupations are not top five SOC codes for wage level I registrations, assuming such registrations will be submitted at higher wage levels consistent with historical LCA wage level data for these occupations.¹²⁴

Figure 3. Top Five SOC Code 6-Digit in Architecture and Engineering Occupations for FY 2020–FY 2024, by Wage Level



Source: USCIS, OPQ, CLAIMS3 and ELIS, queried 3/2025, TRK #17265. Merged with LCA data from DOL. Disclosure Files for LCA Programs (H-1B, H-1B1, E-3), FY 2018 – FY 2024. Note that SOC 6 digits are 2018 SOC classification.

Most of the petitions are filed with the same top 6-digit SOC codes across wage levels, with several exceptions. The final rule projects that almost half of the registrations for beneficiaries with a proffered wage that corresponds to a wage level I typically associated with entry-level workers will not be selected but registrations for beneficiaries with a proffered wage that corresponds to a higher wage level typically associated with more experienced workers will be selected in the same occupational categories.¹²⁵ However, for certain

occupations that have historically included only petitions for level I positions, such as Civil Engineers or Architects, except Landscape and Naval, the final rule does not project a significant increase in the selection of higher wage level workers in the same occupations.¹²⁶ Instead, the final rule projects increased distribution in occupations that have historically included petitions for higher wage level positions, such as Computer Occupations (all other), Electronics Engineers (except computer), Materials

Engineers, or Engineers, All Other shown in Figure 2 and Figure 3. Therefore, DHS expects that the final rule will have an impact on the occupational distribution of H–1B workers.

A prospective petitioner (employer) may respond to the final rule in several ways. An employer could choose to increase the proffered wage to increase the probability of getting its H–1B registration selected. If employers choose to increase the proffered wage, or if employers were already offering a

¹²³ To the extent that some of these employers may already be paying a wage, or offering to pay a wage, that corresponds to a higher wage level, or may choose to do so, DHS recognizes this projected reduction represents the upper bound of estimated impact. However, because DHS does not have a way to estimate how many registrants would pay a proffered wage that corresponds to a higher wage level than the wage level required on the LCA, DHS uses the wage level selected on the LCA as a proxy

for the wage level that is likely to be selected on the registration.

¹²⁴ See the previous footnote.

¹²⁵ Wage level I, II, III, and IV are defined as entry, qualified, experienced, and fully competent, respectively. DOL, ETA, Prevailing Wage Determination Policy Guidance: Nonagricultural Immigration Programs (last modified Nov. 2009), https://www.dol.gov/sites/dolgov/files/ETA/oflc/pdfs/NPWHC_Guidance_Revised_11_2009.pdf.

¹²⁶ However, it is possible that such prospective employers already pay a wage that corresponds to a higher wage level such that the chance of selection would not be reduced under the final rule, or that they would choose to pay a wage that corresponds to a higher wage level in order to increase the chance of selection for workers in level I positions.

salary corresponding to a higher wage level, then this final rule might result in more registrations (or petitions, if registration is suspended) with a proffered wage that will correspond to wage level II, III, or IV, and fewer registrations corresponding to wage level I. It is also possible that an employer may choose not to make any changes in response to this rule, especially those employers that were already offering a salary corresponding to a higher wage level.

Other prospective employers may leave the position vacant if the alien beneficiary they registered is not selected, because they will not be able to justify raising the proffered wage to an amount that corresponds to a higher wage level and that will have improved their chance of selection. These employers might be unable to fill their position(s). And other employers might incur additional costs to find available replacement workers, such as by seeking out and/or training other workers.¹²⁷

¹²⁷ DHS has not quantified this cost but notes that in the analysis accompanying the 2021 final rule,

The effects of this rulemaking on any given employer will depend in part on the interaction of a number of complex variables that constantly are in flux, including national, state, and local labor market conditions, economic and business factors, the type of occupations and skills involved, and the substitutability between H–1B workers and U.S. workers.

DHS acknowledges costs incurred associated with loss of output from not being able to employ H–1B beneficiaries. Costs incurred associated with loss of potential output will be discussed as a transfer later in this section.

DHS “assume[d] that an entity whose H–1B petition is denied will incur an average cost of \$4,398 per worker (in 2019 dollars) . . . to search for and hire a U.S. worker in place of an H–1B worker during the period of this economic analysis. If petitioners cannot find suitable replacements for the labor H–1B cap-subject beneficiaries would have provided if selected and, ultimately, granted H–1B status, this final rule primarily will be a cost to these petitioners through lost productivity and profits.” 86 FR 1676, 1724 (Jan. 8, 2021).

Table 15 shows the annual quantified economic impacts of the final rule. To estimate the economic impact of the final rule, DHS uses the average annual salary of H–1B cap-subject workers by wage level in FY 2024. In Table 15, the average annual salary for wage level I is \$85,006, for wage level II is \$103,071, for wage level III is \$131,454, and for wage level IV is \$162,528. The estimated total annual salary paid to H–1B cap-subject workers under the current selection process in FY 2024 dollars will be \$8,862,595,799. However, under the weighted selection process, the estimated total annual salary paid to initial H–1B cap-subject workers will increase because there will be fewer wage level I workers and more wage level II, III, and IV workers. DHS estimates that the total annual salaries paid to H–1B workers will increase by \$502,080,486 to \$9,364,676,285. The \$502 million increase is the estimated quantifiable economic benefit resulting from the final rule in the first year.

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Table 15. Annual Distributional Impacts by Wage Levels

	Level I	Level II	Level III	Level IV	Total
Estimated Annual H-1B Cap-Subject Visa Granted (Random)					
	23,830	46,968	10,052	4,150	85,000
Estimated Annual H-1B Cap-Subject Visa Granted (Weighted)					
	13,731	49,342	14,548	7,379	85,000
Difference in Estimated Annual H-1B Cap-Subject Visa Granted between Random and Weighted Selection					
	-10,099	2,373	4,496	3,230	0
Average Annual Salary of H-1B Cap-Subject Workers					
	\$85,006	\$103,071	\$131,454	\$162,528	
Estimated Total Annual Salary Paid to H-1B Cap-Subject Workers (Random)*					
	\$2,025,655,768	\$4,841,088,469	\$1,321,409,280	\$674,442,282	\$8,862,595,799
Estimated Total Annual Salary Paid to H-1B Cap-Subject Workers (Weighted)*					
	\$1,167,185,470	\$5,085,685,684	\$1,912,441,622	\$1,199,363,508	\$9,364,676,285
Benefits**	-\$858,470,298	\$244,597,215	\$591,032,342	\$524,921,226	\$502,080,486
Transfers***					\$858,470,298

Source: USCIS analysis. USCIS OPQ, CLAIMS3 and ELIS, queried 3/2025, TRK #17265. Merged with LCA data from DOL. Disclosure Files for LCA Programs (H-1B, H-1B1, E-3), FY 2018 – FY 2024. DOL data downloaded from <https://www.dol.gov/agencies/eta/foreign-labor/performance>.

Estimated Total Annual Salary Paid to H-1B Cap-Subject Workers*: Multiplying Estimated Annual H-1B Cap-Subject Petition Approved by Average Annual Salary of H-1B Cap-Subject Workers for Random or Weighted. The numbers may vary slightly due to rounding.

Benefit**: Difference between estimated total annual salary paid to H-1B cap-subject workers for weighted and random selection process. \$502,080,486 = \$9,364,676,285 – \$8,862,595,799. The aggregate benefits include the distributional impacts at each wage level.

Transfer***: Total annual salary paid to level I workers under random selection process who no longer work. This annual salary is transferred to level II, level III, and level IV workers for part of their annual salary under weighted selection process. \$858,470,298 = \$2,025,655,768 – \$1,167,185,470.

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The maximum initial granted period of stay for H-1B status is three years, with extensions for up to three years thereafter. An H-1B worker is generally limited to a six-year period of authorized stay, unless eligible for an exemption from the general 6-year period of stay limitation under 8 CFR 214.2(h)(13)(iii)(D) and (E). Based on a DHS analysis of FY2017 through FY2019 cohort of initial H-1B cap-subject approvals, the average total validity period, including extensions, is 5.2 years among beneficiaries whose extension basis for classification is

“Continuation of previously approved employment without change with the same employer.”¹²⁸ DHS recognizes that H-1B extensions vary across petitions and workers. For the purpose of this analysis, DHS believes it is appropriate to assume the average H-1B cap-subject worker’s duration of H-1B status is 5 years to estimate the benefits and transfers of the final rule.

The estimated economic benefits in the first year when the new registration selection process is in effect are

¹²⁸ USCIS, OPQ, CLAIMS3 and ELIS queried 10/2025, TRK #18875.

approximately \$502 million. Assuming H-1B cap-subject workers work an average of five years in the United States, these benefits will accrue for four additional years. The benefits in the second year will be about \$1,004 million, which includes the initial \$502 million in benefits accrued from new H-1B cap-subject workers with higher wages in the first year plus an estimated \$502 million in benefits accrued from new H-1B cap-subject workers in the second year. Similarly, the benefits in years 3 and 4 are \$1,506 million and \$2,008 million, respectively, reflecting granted H-1B cap-subject workers

granted in the current year and the prior two years (year 3) and in the current year and the prior three years (year 4). From year 5 onward, accrued five-year benefits are \$2,510 million each year.

In addition to the \$502 million in first-year benefits discussed previously, the \$9.4 billion in first-year H-1B wages resulting from the final rule also contains a transfer from wage level I workers to wage level II, III, and IV workers. When a regulation generates a gain for one group and an equal-dollar-value loss for another group, the regulation is said to cause a transfer from the latter group to the former.¹²⁹ When H-1B allocations change from wage level I workers to higher wage level workers, the benefits of the H-1B classification are transferred from wage level I workers to higher wage level workers. For example, if a wage level IV worker whose annual salary is \$160,000 is selected instead of a wage level I worker whose annual salary is \$85,000, then \$85,000 of benefits are transferred from the wage level I worker to the wage level IV worker (the difference of \$75,000 is a benefit to the level IV worker). DHS estimates that transfers from wage level I workers to other wage level workers will be \$858 million in the first year under the final rule.

Assuming H-1B cap-subject workers work an average of five years in H-1B nonimmigrant status, transfers will also accrue for four additional years. The transfers in the second year will be approximately \$1,717 million and in years 3 and 4 the transfers will be about \$2,575 million and \$3,434 million, respectively. In years 5 and beyond, the transfers will be approximately \$4,292 million. These transfers are the costs incurred associated with loss of output from not being able to employ the labor of wage level I H-1B workers for the employers who registered H-1B workers at wage level I. Whereas the transfers are a benefit to the employers who registered H-1B workers at higher wage levels because they will expect gains in

output by being able to employ H-1B workers. To the extent that benefits and transfers are estimated using LCA data, and proffered wages may exceed the wage levels indicated on the LCA, the projections in this discussion will represent the upper bound of the impact of the final rule.

There is an unquantifiable transfer from the employers who will lose an opportunity to employ wage level I H-1B workers to the employers who will gain an opportunity to employ higher wage level workers in terms of output produced. When an employer gets into an economic activity of hiring workers and producing output, they will expect the output to at least recover the labor cost of hiring workers. DHS is not able to quantify this producer surplus. According to this analysis, half of the employers who hire H-1B workers at wage level I will lose the opportunity to gain the surplus under the final rule. This gained surplus will be transferred to the employers who will have an opportunity to hire workers at higher wage levels.

By engaging in a wage-level-based weighting of registrations for unique beneficiaries, DHS will increase the chances that initial H-1B visas and status grants will go to higher-skilled or higher-paid beneficiaries. Facilitating the admission of higher-skilled workers “will benefit the economy and increase the United States’ competitive edge in attracting the ‘best and the brightest’ in the global labor market,”¹³⁰ consistent with the goals of the H-1B program.

c. Required Information on Petition

Unless registration is suspended, a petitioner may file an H-1B petition for a beneficiary who may be counted

under section 214(g)(1)(A) of the Act, or eligible for exemption under section 214(g)(5)(C) of the Act, only if the petition is based on a valid selected registration. *See* 8 CFR

214.2(h)(8)(iii)(A)(1). An H-1B cap-subject petition filed on behalf of a beneficiary will be required to contain and be supported by the same identifying information and position information, including SOC code, provided in the selected registration. *See* new 8 CFR 214.2(h)(8)(iii)(D)(1). Such petition will be required to include a proffered wage that equals or exceeds the prevailing wage for the corresponding OEWS wage level in the registration for the SOC code in the area(s) of intended employment as indicated on the LCA used to support the petition. *Id.* Petitioners will be required to submit evidence of the basis of the wage level selected on the registration as of the date that the registration underlying the petition was submitted. *Id.*

This change will add additional questions for petitioners for both the Form I-129 and the H-1B and H-1B1 Data Collection and Filing Fee Exemption Supplement (paper and online e-file). DHS estimates that these additional questions will increase the time burden by 15 minutes for each petition (0.25 hours) for all H-1B petitions, not just H-1B cap-subject petitions, because these questions will be on the forms completed and submitted by all H-1B petitioners. The change will offer qualitative benefits. Specifically, submission of additional information on the petition form (including wage level information and the SOC code), and evidence of the basis of the wage level selected will allow USCIS to further improve the integrity of the H-1B cap selection and adjudication processes.

Based on a 5-year annual average, between FY 2020 and FY 2024 from Table 16, DHS estimates the annual average H-1B petition receipts are 422,759. The 5-year annual average of Form I-129 H-1B receipts with Form G-28 is 336,023.

¹²⁹ OMB, Circular A-4 (Sept. 17, 2003), trumpwhitehouse.archives.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf.

¹³⁰ *See* Muzaffar Chishti & Stephen Yale-Loehr, Migration Policy Institute, The Immigration Act of 1990: Unfinished Business a Quarter-Century Later (July 2016), https://www.migrationpolicy.org/sites/default/files/publications/1990-Act_2016_FINAL.pdf (“Sponsors of [the Immigration Act of 1990, which created the H-1B program as it exists today,] believed that facilitating the admission of higher-skilled immigrants would benefit the economy and increase the United States’ competitive edge in attracting the ‘best and the brightest’ in the global labor market.”).

Table 16. H-1B Petitions Received, FY 2020 through FY 2024

	H-1B Petitions Received	H-1B Petition Received with Form G-28	Percent with Form G-28
2020	427,289	337,096	79%
2021	398,281	319,147	80%
2022	474,315	385,473	81%
2023	386,597	304,568	79%
2024	427,315	333,829	78%
5-year Total	2,113,797	1,680,113	79%
5-year Annual Average	422,759	336,023	79%

Source: USCIS OPQ, CLAIMS3, ELIS, PAER #18821, 9/2025.

Note that the figures have been updated to reflect the most recent data source and may differ immaterially from those in the NPRM.

DHS does not know the exact number of petitioners who will choose an in-house or an outsourced lawyer but assumes it may be a 50/50 split and therefore provides an average. Table 17

shows the additional annual average cost for a lawyer to complete the petition on behalf of a petitioner. The additional opportunity cost of time for completing and submitting an H-1B

petition using an attorney or other representative is estimated to range from \$10,334,387 to \$17,817,620 with an average of \$14,076,004.

Table 17. Additional Average Opportunity Costs of Time for Submitting an H-1B Petition with an Attorney or Other Representative

	Population Submitting with a Lawyer	Time Burden to Complete H-1B Petition (Hours)	Cost of Time	Total Current Opportunity Cost
	A	B	C	D=(A×B×C)
In-house lawyer	336,023	0.25	\$123.02	\$10,334,387
Outsourced lawyer	336,023	0.25	\$212.10	\$17,817,620
Average				\$14,076,004

Source: USCIS analysis.

To estimate the current remaining opportunity cost of time for an HR specialist submitting an H-1B petition without a lawyer, DHS applies the estimated increased public reporting

time burden 15 minutes (0.25 hours) to the compensation rate of an HR specialist. Table 18 estimates the current total annual opportunity cost of time to HR specialists completing and

submitting an H-1B petition will be approximately \$1,149,903.

Table 18. Additional Average Opportunity Costs of Time for Submitting an H-1B Petition, without an Attorney or Accredited Representative				
	Population	Time Burden to Complete H-1B Petition (Hours)	HR Specialist's Opportunity Cost of Time	Total Opportunity Cost of Time
	A	B	C	D=(A×B×C)
Estimate of H-1B Petitions	86,736	0.25	\$53.03	\$1,149,903
Source: USCIS analysis. Note that 86,736, the number of petitions filed by an HR specialist, is 422,759, the total number of petitions, minus 336,023, the number of petitions filed with a Form G-28.				

DHS estimates the additional total annual cost for attorneys and HR specialists to complete and submit an H-1B petition will be \$15,225,907 as shown in Table 19.

Table 19. Total Additional Costs to Complete H-1B Petition

Additional Average Opportunity Cost of Time for Lawyers to Complete an H-1B Petition	\$14,076,004
Additional Average Opportunity Cost of Time for HR Specialist to Complete an H-1B Petition	\$1,149,903
Total	\$15,225,907

Source: USCIS analysis.

d. Process Integrity

DHS is revising 8 CFR 214.2(h)(10)(ii) to clarify that a valid registration must represent a bona fide job offer. The final rule will also require an H-1B petition filed after registration selection to contain and be supported by the same identifying information and position information, including SOC code, provided in the selected registration and indicated on the LCA used to support the petition. See new 8 CFR 214.2(h)(8)(iii)(D)(1). Such petition must also include a proffered wage that equals or exceeds the prevailing wage for the corresponding OEWS wage level in the registration for the SOC code in the area(s) of intended employment as described in 8 CFR 214.2(h)(8)(iii)(A)(4)(i). *Id.*

The final rule will allow USCIS to deny a subsequent new or amended petition filed by the petitioner, or a related entity, on behalf of the same beneficiary if USCIS were to determine that the filing of the new or amended petition was part of the petitioner's attempt to unfairly increase the odds of selection during the registration (or petition, if applicable) selection process, such as by reducing the proffered wage to an amount that will be equivalent to a lower wage level than that indicated on the original registration or petition.

See new 8 CFR 214.2(h)(10)(iii). In this context, attempting to “unfairly increase the odds of selection” generally refers to attempting to derive the benefit from the increased chance of selection associated with a higher corresponding wage level without having a bona fide job offer at the corresponding wage level attested to during registration. Additionally, a new or amended petition containing a proffered wage equivalent to a lower wage level than that indicated on the original registration or petition may reveal an attempt to “unfairly increase the odds of selection” or indicate that the registration or petition did not in fact represent a bona fide job offer, which will violate the requirement that a valid registration represents a bona fide job offer.

As is currently required, the entity submitting a registration or petition will be required to certify the veracity of the contents of such submissions. DHS estimates that the final rule could lead to an increase in the number of denials or revocations of H-1B petitions. DHS cannot quantify this impact. The changes in process integrity will lead to improved program integrity for USCIS.

5. Alternatives Considered

DHS considered proposing the methodology from the 2020 H-1B Selection NPRM (85 FR 69236 (Nov. 2,

2020)) and the 2021 H-1B Selection Final Rule (86 FR 1676 (Jan. 8, 2021)). Under the 2021 H-1B Selection Final Rule, USCIS would have ranked and selected registrations generally based on the highest prevailing wage level that the proffered wage equals or exceeds for the relevant SOC code and area(s) of intended employment. The rule was expected to result in the likelihood that registrations for level I wages would not be selected, as well as a reduced likelihood that registrations for level II would be selected. As discussed earlier in this preamble, DHS believes the selection process finalized under the 2021 H-1B Selection Final Rule was a reasonable approach to facilitate the admission of higher-skilled or higher-paid workers. However, DHS believes that rule did not capture the optimal approach because it effectively left little or no opportunity for the selection of lower wage level or entry level workers, some of whom may still be highly skilled. DHS also considered various alternatives suggested by commenters, such as weighted selection by various factors (occupational preferences, industry preferences, preferences for certain educational degrees, etc.), but declined to adopt those suggested alternatives for the reasons previously explained in the comment responses.

Accordingly, DHS is instead finalizing the weighted selection process as proposed in the NPRM to better ensure that initial H-1B visas and status grants would more likely go to the highest skilled or highest paid beneficiaries, while not effectively precluding those at lower wage levels.

6. Total Quantified Costs, Benefits, and Transfers of Regulatory Changes

In this section, DHS presents the total annual costs, benefits, and transfers

annualized over a 10-year period of analysis. DHS summarizes the annual costs, benefits, and transfers (undiscounted) of this final rule in Table 20. DHS estimates the total annual cost will be \$30,362,120 for FY 2026 through FY 2035. In Table 20, DHS estimates the total annual benefit will be \$502,080,486 in FY2026, \$1,004,160,972 in FY2027, \$1,506,241,458 in FY2028, \$2,008,321,944 in FY2029, and \$2,510,402,430 in each year from FY2030 through FY2035. DHS estimates

annual transfers (undiscounted) will be \$858,470,298 in FY2026, \$1,716,940,595 in FY2027, \$2,575,410,893 in FY2028, \$3,433,881,191 in FY2029, and \$4,292,351,489 in each year from FY2030 through FY2035. The net benefit will be calculated by subtracting the cost from the benefit each year. 10-Year undiscounted total net benefits to the public of \$19,779,598,238 are the total benefits minus total costs.¹³¹

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Table 20. Summary of Costs, Benefits, and Transfers for FY 2026 through FY 2035

Description	Costs	Benefits	Net Benefits	Transfers
Required Information on Registration and Petition	\$15,136,213			
Weighting and Selecting Registrations		\$502,080,486		\$858,470,298
H-1B Cap-Subject Petition Filing Following Registration	\$15,225,907			
First Year Total (FY 2026)	\$30,362,120	\$502,080,486	\$471,718,366	\$858,470,298
FY2027	\$30,362,120	\$1,004,160,972	\$973,798,852	\$1,716,940,595
FY2028	\$30,362,120	\$1,506,241,458	\$1,475,879,338	\$2,575,410,893
FY2029	\$30,362,120	\$2,008,321,944	\$1,977,959,824	\$3,433,881,191
FY2030-FY2035	\$30,362,120	\$2,510,402,430	\$2,480,040,310	\$4,292,351,489
10 Year Total	\$303,621,200	\$20,083,219,438	\$19,779,598,238	\$34,338,811,909

Source: USCIS analysis. Note that costs are measured in FY 2023 dollars using BLS wages, but benefits and transfers are measured in average of FY 2023 and FY 2024 dollars using filed LCA wages.

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Table 21 illustrates that over a 10-year period of analysis of the final rule, DHS estimates that annualized net benefits will be \$1,924,995,394 discounted at 3

percent and \$1,854,251,990 discounted at 7 percent. Table 21 also shows that over a 10-year period of analysis of the final rule, that annualized transfers will

be \$3,343,321,229 discounted at 3 percent and \$3,222,362,314 discounted at 7 percent.

¹³¹ Calculations: \$19,779,598,238 Total Net Benefits for 10-year total (FY2026-FY2035) =

\$20,083,219,438 Total Benefits – \$303,621,200 Total Costs.

Table 21. Discounted Net Benefits Over a 10-Year Period of Analysis

	Total Estimated Benefits		Total Estimated Net Benefits		Total Estimated Transfers	
10-Year Undiscounted	\$20,083,219,438		\$19,779,598,238		\$34,338,811,909	
Fiscal Year	Discounted at 3 percent	Discounted at 7 percent	Discounted at 3 percent	Discounted at 7 percent	Discounted at 3 percent	Discounted at 7 percent
2026	\$487,456,782	\$469,234,099	\$457,978,996	\$440,858,286	\$833,466,308	\$802,308,689
2027	\$946,518,024	\$877,073,082	\$917,898,814	\$850,553,631	\$1,618,381,181	\$1,499,642,410
2028	\$1,378,424,307	\$1,229,541,704	\$1,350,638,666	\$1,204,757,170	\$2,356,865,798	\$2,102,302,444
2029	\$1,784,368,035	\$1,532,139,195	\$1,757,391,685	\$1,508,976,079	\$3,050,958,962	\$2,619,691,519
2030	\$2,165,495,188	\$1,789,882,237	\$2,139,304,557	\$1,768,234,465	\$3,702,620,100	\$3,060,387,289
2031	\$2,102,422,513	\$1,672,787,138	\$2,076,994,715	\$1,652,555,575	\$3,594,776,796	\$2,860,175,036
2032	\$2,041,186,906	\$1,563,352,465	\$2,016,499,724	\$1,544,444,463	\$3,490,074,559	\$2,673,060,782
2033	\$1,981,734,860	\$1,461,077,070	\$1,957,766,722	\$1,443,406,040	\$3,388,421,902	\$2,498,187,646
2034	\$1,924,014,427	\$1,365,492,589	\$1,900,744,390	\$1,348,977,607	\$3,289,730,002	\$2,334,754,810
2035	\$1,867,975,172	\$1,276,161,298	\$1,845,382,903	\$1,260,726,736	\$3,193,912,623	\$2,182,013,841
10-year Total	\$16,679,596,215	\$13,236,740,878	\$16,420,601,172	\$13,023,490,053	\$28,519,208,233	\$22,632,524,467
Annualized	\$1,955,357,514	\$1,884,614,110	\$1,924,995,394	\$1,854,251,990	\$3,343,321,229	\$3,222,362,314

Source: USCIS analysis. 10-Year Undiscounted Total Costs will be \$303,621,200 and estimated annualized costs will be \$30,362,120 discounted both at 3 percent and 7 percent.

7. Costs to the Federal Government

DHS is revising the regulations governing the selection of registrations for unique beneficiaries submitted by prospective petitioners (also referred to as registrants) seeking to file H–1B cap-subject petitions (or the selection of petitions, if the registration process were suspended). This final rule will require updates to USCIS IT systems and additional time spent by USCIS to review newly required information during the adjudication of the petition and maintain program integrity.

The INA provides for the collection of fees at a level that will ensure recovery of the full costs of providing adjudication and naturalization services by DHS, including administrative costs and services provided without charge to certain applicants and petitioners.¹³² DHS establishes USCIS fees according to the estimated cost of adjudication based on its relative adjudication burden and use of USCIS resources. Fees are established at an amount that is necessary to recover these assigned costs, such as clerical, officer, and managerial salaries and benefits, plus an amount to recover unassigned overhead (e.g., facility rent, IT equipment and systems) and immigration benefits provided without a fee charge. These costs will be captured in the fees

collected for the benefit request from petitioners. DHS established the current fee for H–1B registrations and petitions in its FY2024 fee rule based on empirical cost estimates. DHS notes that if the final rule increases USCIS' costs, then the fee schedule adjustment will be determined at USCIS' next comprehensive biennial fee review.

B. Regulatory Flexibility Act of 1980

The Regulatory Flexibility Act of 1980 (RFA), Public Law 96–354, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121, 5 U.S.C. 601 through 612, requires Federal agencies to consider the potential impact of regulations on small businesses, small governmental jurisdictions, and small organizations during the development of their rules. 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 50,000.¹³³ An “individual” is not considered a small entity and costs to an individual are not considered a small entity impact for RFA purposes. In addition, the courts

have held that the RFA requires an agency to perform a regulatory flexibility analysis of small entity impacts only when a rule directly regulates small entities.¹³⁴ Consequently, indirect impacts from a rule on a small entity are not considered as costs for RFA purposes. The Final Regulatory Flexibility Analysis for this final rule focuses on the population of employers who submit H–1B petitions (Form I–129, Petition for a Nonimmigrant Worker) and H–1B registrations.

DHS believes that the changes in this final rule will have a significant economic impact on a substantial number of small entities that file H–1B cap-subject petitions.

¹³⁴ See U.S. Small Business Administration (SBA), A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act, at 22 (Aug. 2017), <https://advocacy.sba.gov/wp-content/uploads/2019/06/How-to-Comply-with-the-RFA.pdf>. In *Aeronautical Repair Station Association, Inc. v. FAA*, the D.C. Circuit made clear that an entity is not “subject to” a regulation unless the regulation “imposes responsibilities directly on” the entity. 494 F.3d 161, 177 (D.C. Cir. 2007); see also *Mid-Tex Elec. Coop., Inc. v. FERC*, 773 F.2d 327, 342 (D.C. Cir. 1985) (holding that the RFA’s requirements apply only to “small entities that would be directly regulated” by a challenged rule).

¹³² See INA sec. 286(m), 8 U.S.C. 1356(m).

¹³³ A small business is defined as any independently owned and operated business not dominant in its field that qualifies as a small business per the Small Business Act, 15 U.S.C. 632.

1. Final Regulatory Flexibility Analysis

a. A Statement of Need for, and Objectives of, This Final Rule

DHS's objectives and legal authority for this final rule are discussed earlier in the preamble. DHS is amending its regulations governing H-1B specialty occupation workers. The purpose of the changes is to better ensure that initial H-1B visas or grants of status are more likely to be awarded to petitioners seeking to employ higher-paid and higher-skilled beneficiaries, while not effectively precluding those at lower wage levels. DHS believes these changes will disincentivize use of the H-1B program to fill relatively lower paid, lower skilled positions, better aligning the H-1B program with congressional intent.

b. A Statement of Significant Issues Raised by the Public Comments in Response to the Initial Regulatory Flexibility Analysis, a Statement of Assessment of Any Changes Made in the Proposed Rule as a Result of Such Comments

Comment: Some commenters stated that the Regulatory Flexibility Analysis (RFA) conducted by DHS is both flawed and incomplete and makes it difficult to assess the rule's effects. Some commenters stated that while DHS acknowledged that a substantial majority of H-1B petitioning entities are small businesses and that a significant portion would be economically affected, the analysis does not examine the distributional effects across industry sectors, geographic regions, and business models reliant on entry- or mid-level professional workers. Furthermore, the commenters stated that the analysis did not adequately quantify the magnitude and scope of these impacts, nor did it present alternative frameworks as required by statute. Another commenter stated that the IRFA failed to adequately quantify the impact on small entities in terms of lost growth opportunities, higher recruitment and training costs, and increased turnover for small businesses.

Further, another commenter stated that despite acknowledging the negative impacts for small businesses, DHS did not propose exemptions, transitional relief, or offsetting mechanisms that 5 U.S.C. 603 requires for small entities. Some commenters recommended what analyses would be needed to ensure a rigorous cost-benefit analysis. A commenter stated that the analysis should incorporate empirical data by industry and firm size, model cumulative costs and opportunity losses, and explicitly consider flexible

approaches that preserve program integrity while mitigating disproportionate harm to small U.S. employers. Another commenter stated that DHS should "prepare a supplemental regulatory analysis under E.O. 12866 and OMB Circular A-4 that: (a) quantifies the distributional effects and transfers produced by weighting across firm sizes, regions, and occupations; (b) rigorously evaluates reasonable alternatives (including keeping a beneficiary-centric random selection, partial weighting, geographic/occupation-adjusted weighting, and small-entity safeguards); and (c) explains why the chosen approach best meets the stated objectives at least cost." Furthermore, the commenter suggested the need for an IRFA, including a robust analysis of significant alternatives to minimize small entity impacts. Finally, a commenter stated that the DHS analysis should have accounted for other major costs, such as reduced competitiveness for U.S. businesses in terms of lost market share and innovation, weakened research institutions, the strategic advantage gained by competitor nations that attract the excluded talent, inefficiencies from wage inflation, barriers to entrepreneurship for small businesses, and reduced innovation and business formation.

Response: DHS relied on the best available empirical data and analyzed potential effects on small entities and industries through the RIA and the IRFA. In these analyses, DHS quantified a projected decrease of 10,099 level I workers under the new selection system and found that 61 percent of petitions filed by small entities were at wage level I. DHS estimated the value of lost output using the average wage of affected workers (\$85,006) and discussed additional costs to identify or train replacement workers (estimated at \$4,398).

The RIA quantifies transfers and evaluates distributional effects across SOC codes, and the IRFA presents impacts by firm size. With respect to geography, the weighted selection process generally relies on prevailing wage levels by occupation and 5. area of intended employment, which normalizes for local labor markets and mitigates any systematic advantage for higher-cost regions.

DHS considered reasonable alternatives against the rule's objectives—increasing the chance of selection for higher-paid, higher skilled aliens while maintaining program integrity and administrative efficiency—and explained why other options were not adopted (see 5. Alternatives

Considered). Retaining a purely random selection process (with or without additional anti-fraud measures) does not advance the policy allocation objective and preserves incentives for mass registration at lower wage levels. Anti-fraud tools are complementary to, not substitutes for, an allocation mechanism. Partial weighting does not materially improve the status quo, while very steep weighting would overly favor high-wage cases and likely crowd out lower wage levels entirely.¹³⁵

Geographic- or occupation-adjusted weighting is unnecessary because the weighted selection process implemented by this final rule will normalize by local labor markets via prevailing wage levels for the occupation and area of intended employment. Adding explicit regional or occupational carveouts would introduce unnecessary complexity, subjectivity, and greater susceptibility to gaming. Any alternative that provides preferential weighting—including for small entities—would undermine the rule's objective to efficiently and effectively administer a cap selection process that generally favors allocation to higher-skilled and higher-paid workers across industries, occupations, and geographic areas.

DHS acknowledges that the rule is likely to have a significant economic impact on a substantial number of small entities. Under the new rule, employers or industries with higher share of wage level III or IV may see improved selection outcomes. In contrast, those with a higher share of wage level I may experience lower relative selection outcomes. However, DHS does not believe it would be fair, effective, and administratively efficient or practical within the H-1B cap selection process to create carveouts for specific employers, industries, or occupations. Accordingly, DHS is finalizing the weighted cap selection process as proposed to ensure that all employers—including small entities and those in essential occupations—retain meaningful opportunities for selection.

DHS appreciates the commenter's concerns regarding the potential negative impact U.S. competitiveness, innovation, research, entrepreneurship, and business growth on small businesses and their role in creating barriers to small business entrepreneurship. However, the RFA

¹³⁵ The commenter referenced "partial weighting" whereby minimally acceptable weights might apply to only a portion of locations or occupations to correct for differences within specific subgroups, whereas "steep weighting" refers to assigning relatively larger weights to correct for overall differences.

does not require agencies to assess indirect or secondary effects, such as broader economic impacts or downstream consequences on the economy as a whole. The IRFA and Final Regulatory Flexibility Analysis (FRFA) prepared for this rule focus on the direct economic impacts on small entities that are subject to the proposed selection process. While DHS recognizes the importance of small businesses to the U.S. economy and innovation, the broader economic considerations raised by the commenter are not part of the RFA’s requirements.

Comment: Some commenters expressed concerns associated with the Regulatory Flexibility Act portion of the proposed rule since the proposed weighted selection process would significantly disadvantage small entities. A commenter referenced DHS data that stated that 44 percent of cap-subject petitions filed by small entities fall within the level I wage category, while only 3 percent are at level IV; in contrast, larger entities have a lower proportion at level I (25 percent) and a higher proportion at level IV (6 percent). This disparity means the proposed process has an outsized, negative impact on small entities and rural regions, reducing their ability to secure skilled workers through the H–1B program. Another commenter referenced DHS data that showed that 76 percent of H–1B petitioners are small business owners, and text in the preamble that stated that “2,665 small businesses would experience a cost increase that is greater than 5 percent of its revenue[,]” and that “5,193 small entities would experience a cost increase that is greater than 1 percent of its revenue.” Another commenter referenced additional data related to the fact that small entities are much more likely to submit H–1B petitions at lower wage levels (levels I and II) compared to larger firms; citing

that 61 percent of wage level I petitions in FY2024 came from small businesses, compared to 47 percent for all cap-subject petitions. Under the proposed rule, the share of H–1B visas awarded to small businesses would fall from almost 68 percent in recent years to 65 percent, which would have a negative impact on small businesses and the competitiveness of the U.S. economy overall.

Response: DHS acknowledges the commenters’ concern regarding impacts on small entities. However, any alternative process that provides a different, preferential weighting scheme especially for small entities would undermine the overall utility of this rule, which is to generally favor the allocation of H–1B visas to higher-skilled and higher-paid aliens. This rule will benefit those small entities that are applying for relatively higher-wage employees, as they will have a greater chance of their employees being selected compared to the current random selection process. If a small-sized entity is unable to pay a beneficiary a wage that corresponds to a higher wage level for a greater chance of selection, they could try to find a substitute U.S. worker. DHS selected a nationally consistent approach that advances program integrity and administrability while ensuring all employers, including small entities and those in rural regions, retain meaningful opportunities for selection under the same criteria.

c. The Response of the Agency to Any Comments Filed by the Chief Counsel for Advocacy of the Small Business Administration in Response to the Rule, and a Detailed Statement of Any Change Made to the Final Rule as a Result of the Comments

The Chief Counsel for Advocacy of the Small Business Administration did

not file any comments in response to this rule.

d. A Description of and an Estimate of the Number of Small Entities to Which This Final Rule Will Apply or an Explanation of Why No Such Estimate Is Available

For this analysis, DHS used internal data for employers filing H–1B cap-subject petitions for FY 2024 merged with LCA data.¹³⁶ DHS merged the internal employer data with the U.S. Small Business Administration (SBA)’s table of size standards¹³⁷ to identify small entities and with LCA data¹³⁸ to identify wage levels for the petitions.

To determine whether an entity is small for purposes of the RFA, DHS first identified the entity’s NAICS code and then used SBA guidelines to classify the revenue or employee count threshold for each entity. Some entities were classified as small based on their annual revenue, and some by their number of employees. Approximately 20 percent of petitions were not matched using SBA’s table of size standards. These unmatched employers were considered small entities if their number of employees was less than 500.

Using FY 2024 internal data on actual filings of H–1B cap-subject petitions, there were 94,873 petitions filed. DHS recognized 23,452 unique entities and was able to classify 22,453 as either small entities or not small entities. DHS determined that 76 percent of the total 22,453 unique entities that filed Form I–129 under the H–1B classification and cap-subject were small entities. See Table 22. The estimated annual number of small entities impacted by this final rule is 17,069.

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Table 22. Number of Small Entities Filing H-1B Cap-Subject Petitions, FY 2024

Unique Entities	Number of Small Entities	Proportion of Population (%)
22,453	17,069	76%

Source: USCIS OPQ, CLAIMS3 and ELIS, queried 3/2025, TRK #17293.

Table 23 shows the Top 10 NAICS Code for small entities filing H–1B cap-subject petitions for FY2024. The table shows the size standards for each

NAICS code in millions of dollars or by number of employees. Of the top 10 NAICS codes three are related to the computer industry, and two are related

to manufacturing. The remaining five top industries are engineering services, offices of lawyers, research and development in biotechnology,

¹³⁶ USCIS, OPQ, CLAIMS3 and ELIS, queried 3/2025, TRK #17293. LCA data from DOL, Disclosure Files for LCA Programs (H–1B, H–1B1, E–3), FY 2024. DOL data downloaded from <https://www.dol.gov/agencies/eta/foreign-labor/performance> (last visited Nov. 24, 2025).

¹³⁷ SBA, Table of Size Standards (Mar. 17, 2023), <https://www.sba.gov/document/support-table-size-standards>.

¹³⁸ DOL, Disclosure Files for LCA Programs (H–1B, H–1B1, E–3), FY 2018–FY 2024. Downloaded from <https://www.dol.gov/agencies/eta/foreign-labor/performance> (last visited Nov. 24, 2025).

administrative management and general processing, web hosting, and related
management consulting services, services.
computing infrastructure providers, data

Table 23. Top 10 NAICS Code for Small Entities Filing H-1B Cap-Subject Petitions, FY2024

NAICS Code	NAICS Code Description	Size Standards in Millions of Dollars	Size Standards in Number of Employees
541511	Custom Computer Programming Services	\$34.0	
541512	Computer Systems Design Services	\$34.0	
541330	Engineering Services	\$25.5	
541519	Other Computer Related Services	\$34.0	
334413	Semiconductor and Related Device Manufacturing		1,250
334111	Electronic Computer Manufacturing		1,250
541110	Offices of Lawyers	\$15.5	
541714	Research and Development in Biotechnology (except Nanobiotechnology)		1,000
541611	Administrative Management and General Management Consulting Services	\$24.5	
518210	Computing Infrastructure Providers, Data Processing, Web Hosting, and Related Services	\$40.0	

Table 24 shows the number of H-1B cap-subject petitions filed by small entities for FY 2024 by wage level. Out of 94,873 H-1B petitions filed, DHS was able to classify the petitioners of 82,204 H-1B petitions as either small entities

or not small entities and identify the number of petitions filed by such petitioners by wage level, as well as the percentage of petitions filed at each wage level by small entities. As shown in Table 24, more small entities filed

petitions at wage levels I and II (61 percent and 47 percent) than at wage levels III and IV (25 percent and 29 percent).

Table 24. Number of H-1B Cap-Subject Petitions filed by Small Entities for FY 2024 by Wage Level

	Level I	Level II	Level III	Level IV	Unknown	Total
Small Entity	16,904	18,056	2,279	1,136	410	38,785
Not Small Entity	10,734	20,075	6,814	2,762	3,034	43,419
Total	27,638	38,131	9,093	3,898	3,444	82,204
% of Small	61%	47%	25%	29%	12%	47%

Source: USCIS OPQ, CLAIMS3 and ELIS, queried 3/2025, TRK #17293. Merged with OPQ TRK #17265 and LCA data from DOL. Disclosure Files for LCA Programs (H-1B, H-1B1, E-3), FY 2024.

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The quantifiable economic impact, represented as a percentage, for each small entity is the total quantified costs of the changes divided by the entity's sales revenue. There are two sources of quantifiable costs. One is the opportunity cost of time to submit H-1B registrations or to file H-1B petitions, or both. This cost is relatively small, so it is not considered in this analysis. The other cost is the loss of output for employers who registered with wage level I but are not selected due to the change in the selection process by the

final rule and thus are unable to file an H-1B petition. DHS estimates the loss of output as a transfer, \$858,470,298, from the lost wages of wage level I workers to those higher wage level workers. The loss of output from the loss of labor is considered as a cost to employers because less output means less profit. The loss of output from the loss of labor is estimated using the wage of the lost labor, which is the wage level I average annual salary, \$85,006 (Table 15). Therefore, DHS projects in the final rule that some small entities who filed H-1B

petitions at wage level I will incur costs of approximately \$85,006.¹³⁹ This assumes, solely for purposes of the RFA, that the employer will be unable to otherwise fill the position or perform the work. Internal data show that there

¹³⁹ Small entities that register with wage levels II, III, and IV would likely benefit because the final rule increases the probability that their registrations will be selected and that they may be authorized to employ the alien beneficiary named in their registration.

are 9,428 unique small entities that filed petitions at wage level I in FY2024.¹⁴⁰

DHS divides \$85,006 by the revenue for each entity then finds that 5,193 small entities will experience a cost increase that is greater than 1 percent of its revenue and 2,665 will experience a cost increase that is greater than 5 percent of its revenue.¹⁴¹ DHS considers an impact greater than 1 percent of a small entity's revenue as significant for purposes of the RFA. As such, DHS estimates that the final rule will result in a significant impact on 5,193 small entities, or 30 percent of the 17,069 small entities affected by the final rule. DHS considers 30 percent as a substantial number. This final rule will also benefit small entities that are applying for higher-earning employees as they will have a greater chance of their employees being selected compared to the current purely random selection process.

Based on this analysis, DHS believes that the changes in this final rule will have a significant economic impact on a substantial number of small entities that file H-1B cap-subject petitions.

e. A Description of the Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Final Rule, Including an Estimate of the Classes of Small Entities That Will Be Subject to the Requirement and the Types of Professional Skills Necessary for Preparation of the Report or Record

The selection process in the final rule will result in an additional burden to employers reporting additional information, including a beneficiary's appropriate wage level, SOC code, and area of intended employment in the registration system, on the Form I-129 petition, and on the H-1B and H-1B1 Data Collection and Filing Fee Exemption Supplement to Form I-129. DHS estimates the increased burden to submit an H-1B registration is 20 minutes and the increased burden to file the Form I-129, Petition for Nonimmigrant Worker, to request H-1B classification is 15 minutes. DHS believes this will be completed by an HR specialist, in-house lawyer, or outsourced lawyer.

f. Description of the Steps the Agency Has Taken To Minimize the Significant Economic Impact on Small Entities Consistent With the Stated Objectives of the Applicable Statutes, Including a Statement of Factual, Policy, and Legal Reasons for Selecting the Alternative Adopted in the Final Rule and Why Each One of the Other Significant Alternatives to the Rule Considered by the Agency Which Affect the Impact on Small Entities Was Rejected

DHS considered alternative solutions that are described in further detail in the section on Executive Orders 12866 and 13563 earlier in the preamble of this rule, as well as in the comment summaries and responses. While the collection of additional information and the change to a weighted selection process will impose a burden on some prospective small employers, USCIS found no other alternatives that achieved the stated objectives with less burden to small entities.

Under the 2021 H-1B Selection Final Rule, USCIS would have ranked and selected registrations generally based on the highest prevailing wage level. The rule was expected to result in the likelihood that registrations for level I wages would not be selected, as well as a reduced likelihood that registrations for level II would be selected. Compared to this final rule, DHS believes that the 2021 H-1B Selection Final Rule approach would have an even greater negative effect on small businesses hiring lower wage level or entry level workers.

As stated earlier in this analysis, this final rule will also benefit small entities that are applying for higher-earning employees who will be weighted at level III or level IV as they will have a greater chance of their employees being selected compared to the current random selection process. Thus, it is possible that any alternative that imposes a lower burden on small entities generally could also reduce those employers' chance of selection for higher wage level workers. For example, if USCIS were to artificially elevate the corresponding wage level for small businesses compared to other businesses, such an alternative could actually decrease the likelihood that those small entities' registrations with a level IV wage will be selected, relative to the selection process under the final rule, if other small businesses are artificially elevated to level IV equivalency based on factors other than the corresponding wage amount. Furthermore, given that 76 percent of unique cap-subject H-1B filers are small entities, and 47 percent of H-1B cap

petitions in FY 2024 were filed by small entities, any alternative process that provides a different, preferential weighting scheme especially for small entities would undermine the overall utility of this final rule, which is to generally favor the allocation of H-1B visas to higher-skilled and higher-paid aliens.

C. Congressional Review Act

The Office of Information and Regulatory Affairs has determined that this final rule is a major rule, as defined in 5 U.S.C. 804, also known as the "Congressional Review Act" (CRA), as enacted in section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104-121, sec. 251, 110 Stat. 868, 873, and codified at 5 U.S.C. 801 *et seq.* Therefore, the rule requires at least a 60-day delayed effective date. DHS has complied with the CRA's reporting requirements and has sent this final rule to Congress and to the Comptroller General as required by 5 U.S.C. 801(a)(1).

D. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (UMRA) is intended, among other things, to curb the practice of imposing unfunded Federal mandates on State, local, and Tribal governments. Title II of UMRA requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a final rule that includes any Federal mandate that may result in a \$100 million or more expenditure (adjusted annually for inflation) in any one year by State, local, and Tribal governments, in the aggregate, or by the private sector. *See* 2 U.S.C. 1532(a).

The inflation adjusted value of \$100 million in 1995 is approximately \$206 million in 2024 based on the Consumer Price Index for All Urban Consumers (CPI-U).¹⁴² This final rule does not

¹⁴⁰ USCIS, OPQ, CLAIMS3 and ELIS, queried 3/2025, TRK #17293. LCA data from DOL. Disclosure Files for LCA Programs (H-1B, H-1B1, E-3), FY 2024. DOL data downloaded from <https://www.dol.gov/agencies/eta/foreign-labor/performance> (last visited Nov. 24, 2025).

¹⁴¹ *Id.*

¹⁴² *See* DOL, BLS, Historical Consumer Price Index for All Urban Consumers (CPI-U): U.S. city average, all items, by month, <https://www.bls.gov/cpi/tables/supplemental-files/home.htm>, Historical CPI-U, September 2025 (XLSX)(database) (last visited Dec. 11, 2025). Calculation of inflation percentage: (1) Calculate the average monthly CPI-U for the reference year (1995) and the current year (2024); (2) Subtract reference year CPI-U from current year CPI-U; (3) Divide the difference of the reference year CPI-U and current year CPI-U by the reference year CPI-U; (4) Multiply by 100 = [(Average monthly CPI-U for 2024 - Average monthly CPI-U for 1995) ÷ (Average monthly CPI-U for 1995)] × 100 = [(313.689 - 152.383) ÷ 152.383] = (161.306 ÷ 152.383) = 1.059 × 100 = 105.86 percent = 106 percent (rounded).

Calculation of inflation-adjusted value: Convert 106% inflation percentage to an inflation factor = 1 + 106/100 = 2.06. \$100 million in 1995 dollars × 2.06 = \$206 million in 2024 dollars.

contain a Federal mandate as the term is defined under UMRA.¹⁴³ The requirements of title II of UMRA, therefore, do not apply, and DHS has not prepared a statement under UMRA.

E. Executive Order 13132 (Federalism)

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

F. Executive Order 12988 (Civil Justice Reform)

This final rule was drafted and reviewed in accordance with E.O. 12988, Civil Justice Reform. This final rule was written to provide a clear legal standard for affected conduct and was carefully reviewed to eliminate drafting errors and ambiguities, so as to minimize litigation and undue burden on the Federal court system. DHS has determined that this final rule meets the applicable standards provided in section 3 of E.O. 12988.

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

This final rule does not have “tribal implications” because it will not have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, E.O. 13175, Consultation and Coordination with Indian Tribal Governments, requires no further agency action or analysis.

H. National Environmental Policy Act

DHS and its components analyze regulatory actions to determine whether the National Environmental Policy Act (NEPA), 42 U.S.C. 4321 *et seq.*, applies to them and, if so, what degree of analysis is required. DHS Directive 023–01 Rev. 01 “Implementing the National Environmental Policy Act” (Dir. 023–01 Rev. 01) and Instruction Manual 023–01–001–01 Rev. 01 (Instruction Manual)¹⁴⁴ establish the policies and

procedures that DHS and its components use to comply with NEPA.

NEPA allows Federal agencies to establish, in their NEPA implementing procedures, categories of actions (“categorical exclusions”) that experience has shown do not, individually or cumulatively, have a significant effect on the human environment and, therefore, do not require an environmental assessment or environmental impact statement. *See* 42 U.S.C. 4336(a)(2), 4336e(1). The Instruction Manual, Appendix A lists the DHS Categorical Exclusions.¹⁴⁵

Under DHS NEPA implementing procedures, for an action to be categorically excluded, it must satisfy each of the following three conditions: (1) the entire action clearly fits within one or more of the categorical exclusions; (2) the action is not a piece of a larger action; and (3) no extraordinary circumstances exist that create the potential for a significant environmental effect.¹⁴⁶

This final rule is limited to amending DHS’s existing regulations at 8 CFR 214.2(h)(8), (10), and (11) to provide for the selection of unique beneficiaries toward the H–1B annual numerical limitations and the advanced degree exemption in a weighted manner based on the wage level listed in each H–1B registration that corresponds to the prospective petitioner’s proffered wage. DHS has reviewed this final rule and finds that no significant impact on the environment, or any change in environmental effect, will result from the amendments being promulgated in this final rule.

Accordingly, DHS finds that the promulgation of this final rule’s amendments to current regulations clearly fits within categorical exclusion A3 established in DHS’s NEPA implementing procedures as an administrative change with no change in environmental effect, is not part of a larger Federal action, and does not present extraordinary circumstances that create the potential for a significant environmental effect.

I. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501–12, DHS must submit to OMB, for review and approval, any reporting requirements inherent in a rule unless they are exempt. In accordance with the PRA, the information collection notice was

published in the **Federal Register** to obtain comments regarding the proposed edits to the information collection instruments.

H–1B Registration Tool (OMB Control No. 1615–0144)

(1) *Type of Information Collection:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* H–1B Registration Tool.

(3) *Agency form number, if any, and the applicable component of DHS sponsoring the collection:* OMB–64; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for-profit. USCIS uses the data collected on this form to determine which employers will be informed that they may submit a USCIS Form I–129, Petition for Nonimmigrant Worker, for H–1B classification.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection H–1B Registration Tool (Businesses) is 20,950 and the estimated hour burden per response is 0.9333 hours.¹⁴⁷ The estimated total number of respondents for the information collection H–1B Registration Tool (Attorneys) is 19,339 and the estimated hour burden per response is 0.9333 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection of information is 331,872 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is \$0.

Form I–129 (OMB Control No. 1615–0009)

(1) *Type of Information Collection:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Petition for Nonimmigrant Worker.

(3) *Agency form number, if any, and the applicable component of DHS sponsoring the collection:* I–129, E–1/E–2 Classification Supplement, Trade

¹⁴³ The term “Federal mandate” means a Federal intergovernmental mandate or a Federal private sector mandate. *See* 2 U.S.C. 1502(1) and 658(6).

¹⁴⁴ The Instruction Manual, which contains DHS’s procedures for implementing NEPA, was

issued on November 6, 2014, and is available at <https://www.dhs.gov/ocrso/eed/epb/nepa> (last modified July 29, 2025).

¹⁴⁵ *See* Appendix A, Table 1.

¹⁴⁶ Instruction Manual 023–01 at V.B(2)(a)–(c).

¹⁴⁷ This rule is not expected to impact the number of respondents. For PRA purposes, DHS uses the currently approved volume for OMB Control number 1615–0144 of 20,950. *See* <https://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=1615-0144> (last visited Dec. 8, 2025).

Agreement Supplement, H Classification Supplement, H-1B and H-1B1 Data Collection and Filing Fee Exemption Supplement, L Classification Supplement, O and P Classification Supplement, Q-1 Classification Supplement, and R-1 Classification Supplement; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for-profit. USCIS uses Form I-129 and accompanying supplements to determine whether the petitioner and beneficiary(ies) is (are) eligible for the nonimmigrant classification. A U.S. employer, or agent in some instances, may file a petition for nonimmigrant worker to employ foreign nationals under the following nonimmigrant classifications: H-1B, H-2A, H-2B, H-3, L-1, O-1, O-2, P-1, P-2, P-3, P-1S, P-2S, P-3S, Q-1, or R-1 nonimmigrant worker. The collection of this information is also required from a U.S. employer on a petition for an extension of stay or change of status for E-1, E-2, E-3, Free Trade H-1B1 Chile/Singapore nonimmigrants and TN (United States-Mexico-Canada Agreement workers) who are in the United States.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection I-129 (paper filing) is 527,606 and the estimated hour burden per response is 2.55 hours. The estimated total number of respondents for the information collection I-129 (online electronic filing) is 45,000 and the estimated hour burden per response is 2.333 hours. The estimated total number of respondents for the information collection E-1/E-1 Classification Supplement is 12,050 and the estimated hour burden per response is 0.67 hours. The estimated total number of respondents for the information collection Trade Agreement Supplement (paper filing) is 10,945 and the estimated hour burden per response is 0.67 hours. The estimated total number of respondents for the information collection Trade Agreement Supplement (online electronic filing) is 2,000 and the estimated hour burden per response is 0.5833 hours. The estimated total number of respondents for the information collection H Classification (paper filing) is 426,983 and the estimated hour burden per response is 2.3 hours. The estimated total number of respondents for the information collection H Classification (online electronic filing) is 45,000 and the estimated hour burden per response is

2 hours. The estimated total number of respondents for the information collection H-1B and H-1B1 Data Collection and Filing Fee Exemption Supplement (paper filing) is 353,936 and the estimated hour burden per response is 1.25 hours. The estimated total number of respondents for the information collection H-1B and H-1B1 Data Collection and Filing Fee Exemption Supplement (online electronic filing) is 45,000 and the estimated hour burden per response is 1 hour. The estimated total number of respondents for the information collection L Classification Supplement is 40,358 and the estimated hour burden per response is 1.34 hours. The estimated total number of respondents for the information collection O and P Classification Supplement is 28,434 and the estimated hour burden per response is 1 hour. The estimated total number of respondents for the information collection Q-1 Classification Supplement is 54 and the estimated hour burden per response is 0.34 hours. The estimated total number of respondents for the information collection R-1 Classification Supplement is 6,782 and the estimated hour burden per response is 2.34 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection of information is 3,124,836 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is \$149,694,919.

List of Subjects in 8 CFR Part 214

Administrative practice and procedure, Aliens, Cultural exchange program, Employment, Foreign officials, Health professionals, Reporting and recordkeeping requirements, Students.

Accordingly, DHS amends chapter I of title 8 of the Code of Federal Regulations as follows:

PART 214—NONIMMIGRANT CLASSES

■ 1. The authority citation for part 214 continues to read as follows:

Authority: 6 U.S.C. 202, 236; 8 U.S.C. 1101, 1102, 1103, 1182, 1184, 1186a, 1187, 1188, 1221, 1281, 1282, 1301–1305, 1357, and 1372; sec. 643, Pub. L. 104–208, 110 Stat. 3009–708; Pub. L. 106–386, 114 Stat. 1477–1480; section 141 of the Compacts of Free Association with the Federated States of Micronesia and the Republic of the Marshall Islands, and with the Government of Palau, 48 U.S.C. 1901 note and 1931 note, respectively; 48 U.S.C. 1806; 8 CFR part 2;

Pub. L. 115–218, 132 Stat. 1547 (48 U.S.C. 1806).

■ 2. Amend § 214.2 by:

■ a. Revising paragraphs (h)(8)(iii)(A)(3), (h)(8)(iii)(A)(4), (h)(8)(iii)(A)(5)(i), (h)(8)(iii)(A)(5)(ii), (h)(8)(iii)(A)(6)(i), (h)(8)(iii)(A)(6)(ii), (h)(8)(iii)(A)(7), (h)(8)(iii)(D)(1), (h)(8)(iv)(B) and (h)(10)(ii);

■ b. Redesignating paragraphs (h)(10)(iii) and (h)(10)(iv) as paragraphs (h)(10)(iv) and (h)(10)(v);

■ c. Adding new paragraph (h)(10)(iii);

■ d. Revising paragraphs (h)(11)(iii)(A)(6) and (h)(11)(iii)(A)(7); and

■ e. Adding paragraph (h)(11)(iii)(A)(8).

The revisions and additions read as follows:

§ 214.2 Special requirements for admission, extension, and maintenance of status.

* * * * *

(h) * * *

(8) * * *

(iii) * * *

(A) * * *

(3) *Initial registration period.* The annual initial registration period will last a minimum of 14 calendar days and will start at least 14 calendar days before the earliest date on which H-1B cap-subject petitions may be filed for a particular fiscal year, consistent with paragraph (h)(2)(i)(I) of this section. USCIS will announce the start and end dates of the initial registration period on the USCIS website at www.uscis.gov for each fiscal year. USCIS will announce the start of the initial registration period at least 30 calendar days in advance of such date.

(4) *Selecting registrations based on unique beneficiaries.* Registrations will be counted based on the number of unique beneficiaries who are registered. The selection will be made via computer-generated selection based on unique beneficiary. Each unique beneficiary will only be counted once toward the numerical allocation projections, regardless of how many registrations were submitted for that beneficiary or how many times the beneficiary is entered in the selection pool as provided in paragraph (h)(8)(iii)(A)(4)(ii) of this section. USCIS will separately notify each registrant that its registration on behalf of a beneficiary has been selected, and that the petitioner(s) may file a petition(s) for that beneficiary. A petitioner may file an H-1B cap-subject petition on behalf of a registered beneficiary only after the petitioner's properly submitted registration for that beneficiary has been selected for that fiscal year.

(i) *Required information.* On the registration, the registrant must select

the highest Occupational Employment and Wage Statistics (OEWS) wage level that the beneficiary's proffered wage equals or exceeds for the relevant Standard Occupational Classification (SOC) code in the area(s) of intended employment. If the beneficiary's proffered wage is lower than OEWS wage level I, because it is based on a prevailing wage from another legitimate source (other than OEWS) or an independent authoritative source, the registrant must select "wage level I." If the beneficiary will work in multiple locations, or in multiple positions if the registrant is an agent, the registrant must select the lowest corresponding OEWS wage level that the beneficiary's proffered wage will equal or exceed. If the beneficiary's proffered wage is expressed as a range, the registrant must select the OEWS wage level that the lowest wage in the range will equal or exceed. Where there is no current OEWS prevailing wage information for the beneficiary's proffered position, the registrant must select the OEWS wage level that corresponds to the requirements of the beneficiary's proffered position using the Department of Labor's prevailing wage guidance. The registrant must also provide the SOC code of the proffered position, the area of intended employment that served as the basis of the wage level selected on the registration, the beneficiary's valid passport or travel document information, and all other requested information, as well as make the necessary certifications, as specified on the registration form and instructions. Each beneficiary must only be registered under one valid passport or travel document, and if or when the beneficiary is abroad, the passport information or travel document information must correspond to the passport or travel document the beneficiary intends to use to enter the United States.

(ii) *Weighted selection.* If a random selection is necessary, USCIS will assign each unique beneficiary to the lowest OEWS wage level among all registrations submitted on the beneficiary's behalf and will enter each unique beneficiary into the selection pool in a weighted manner as follows: a beneficiary assigned wage level IV will be entered into the selection pool four times, a beneficiary assigned wage level III will be entered into the selection pool three times, a beneficiary assigned wage level II will be entered into the selection pool two times, and a beneficiary assigned wage level I will be entered into the selection pool one time.

(5) * * *

(i) *Fewer registrations than needed to meet the H-1B regular cap.* At the end of the annual initial registration period, if USCIS determines that there are fewer unique beneficiaries on whose behalf registrations were properly submitted than needed to meet the H-1B regular cap, USCIS will notify all petitioners that have properly registered that their registrations have been selected. USCIS will keep the registration period open beyond the initial registration period, until it determines that it has received a sufficient number of registrations for unique beneficiaries to meet the H-1B regular cap. Once USCIS determines there is a sufficient number of properly registered unique beneficiaries to meet the H-1B regular cap, USCIS will no longer accept registrations for petitions subject to the H-1B regular cap under section 214(g)(1)(A) of the Act. USCIS will monitor the number of unique beneficiaries with properly submitted registrations and will notify the public of the date that USCIS has received the necessary number of registrations for unique beneficiaries (the "final registration date"). The day the public is notified will not control the applicable final registration date. If USCIS has received more registrations for unique beneficiaries on the final registration date than necessary to meet the H-1B regular cap under section 214(g)(1)(A) of the Act, USCIS will weight each unique beneficiary as described in paragraph (h)(8)(iii)(A)(4)(ii) of this section and randomly select the number of unique beneficiaries deemed necessary to meet the H-1B regular cap.

(ii) *Sufficient registrations to meet the H-1B regular cap during initial registration period.* At the end of the initial registration period, if USCIS determines that there is more than a sufficient number of unique beneficiaries on whose behalf registrations were properly submitted to meet the H-1B regular cap, USCIS will no longer accept registrations under section 214(g)(1)(A) of the Act and will notify the public of the final registration date. USCIS will weight each unique beneficiary as described in paragraph (h)(8)(iii)(A)(4)(ii) of this section and randomly select the number of unique beneficiaries deemed necessary to meet the H-1B regular cap.

(6) * * *

(i) *Fewer registrations than needed to meet the H-1B advanced degree exemption numerical limitation.* If USCIS determines that there are fewer unique beneficiaries on whose behalf registrations were properly submitted than needed to meet the H-1B advanced degree exemption numerical limitation, USCIS will notify all petitioners that

have properly registered that their registrations have been selected. USCIS will continue to accept registrations to file petitions for beneficiaries who may be eligible for the H-1B advanced degree exemption under section 214(g)(5)(C) of the Act until USCIS determines that there is a sufficient number of properly registered unique beneficiaries to meet the H-1B advanced degree exemption numerical limitation. USCIS will monitor the number of unique beneficiaries with properly submitted registrations and will notify the public of the date that USCIS has received the necessary number of registrations for unique beneficiaries (the "final registration date"). The day the public is notified will not control the applicable final registration date. If USCIS has received more registrations for unique beneficiaries on the final registration date than necessary to meet the H-1B advanced degree exemption numerical limitation under section 214(g)(1)(A) and 214(g)(5)(C) of the Act, USCIS will weight each unique beneficiary as described in paragraph (h)(8)(iii)(A)(4)(ii) of this section and randomly select the number of unique beneficiaries deemed necessary to meet the H-1B advanced degree exemption numerical limitation.

(ii) *Sufficient registrations to meet the H-1B advanced degree exemption numerical limitation.* If USCIS determines that there is more than a sufficient number of unique beneficiaries on whose behalf registrations were properly submitted to meet the H-1B advanced degree exemption numerical limitation, USCIS will no longer accept registrations that may be eligible for exemption under section 214(g)(5)(C) of the Act and will notify the public of the final registration date. USCIS will weight each unique beneficiary as described in paragraph (h)(8)(iii)(A)(4)(ii) of this section and randomly select the number of unique beneficiaries deemed necessary to meet the H-1B advanced degree exemption numerical limitation.

(7) *Increase to the number of beneficiaries projected to meet the H-1B regular cap or advanced degree exemption allocations in a fiscal year.* Unselected properly submitted registrations for unique beneficiaries will remain on reserve for the applicable fiscal year. If USCIS determines that it needs to increase the number of registrations for unique beneficiaries projected to meet the H-1B regular cap or advanced degree exemption allocation, and select additional unique beneficiaries, USCIS will select from among the unique beneficiaries with

properly submitted registrations that are on reserve a sufficient number to meet the H-1B regular cap or advanced degree exemption numerical limitation, as applicable. If all of the unique beneficiaries on reserve are selected and there are still fewer unique beneficiaries than needed to meet the H-1B regular cap or advanced degree exemption numerical limitation, as applicable, USCIS may reopen the applicable registration period until USCIS determines that it has received a sufficient number of registrations for unique beneficiaries projected as needed to meet the H-1B regular cap or advanced degree exemption numerical limitation. USCIS will monitor the number of properly registered unique beneficiaries and will notify the public of the date that USCIS has received the necessary number of registrations (the new “final registration date”). The day the public is notified will not control the applicable final registration date. When selecting additional unique beneficiaries under this paragraph (h)(8)(iii)(A)(7), USCIS will select unique beneficiaries with properly submitted registrations in accordance with paragraphs (h)(8)(iii)(A)(4) through (6) of this section. If the registration period will be reopened, USCIS will announce the start of the re-opened registration period on the USCIS website at www.uscis.gov.

* * * * *

(D) * * *

(1) *Filing procedures.* In addition to any other applicable requirements, a petitioner may file an H-1B petition for a beneficiary who may be counted under section 214(g)(1)(A) of the Act or eligible for exemption under section 214(g)(5)(C) of the Act only if the petition is based on a valid registration, which means that the registration was properly submitted in accordance with § 103.2(a)(1) of this chapter, paragraph (h)(8)(iii) of this section, and the registration tool instructions; and was submitted by the petitioner, or its designated representative, on behalf of the beneficiary who was selected for that cap season by USCIS. A petitioner may not substitute the beneficiary named in the original registration or transfer the registration to another petitioner. An H-1B petition filed on behalf of a beneficiary must contain and be supported by the same identifying information and position information, including SOC code, provided in the selected registration and indicated on the labor condition application used to support the petition, and must include a proffered wage that equals or exceeds the prevailing wage for the

corresponding OEWS wage level in the registration for the SOC code in the area(s) of intended employment as described in paragraph (h)(8)(iii)(A)(4)(i) of this section. Petitioners must submit evidence of the basis of the wage level selected on the registration as of the date that the registration underlying the petition was submitted. Petitioners must also submit evidence of the passport or travel document used at the time of registration to identify the beneficiary. In its discretion, USCIS may find that a change in the beneficiary’s identifying information in some circumstances would be permissible. Such circumstances could include, but are not limited to, a legal name change due to marriage or a change in passport number or expiration date due to renewal or replacement of a stolen passport, in between the time of registration submission and petition filing. In its discretion, USCIS may find that a change in the area(s) of intended employment would be permissible, provided such change is consistent with the requirement of a bona fide job offer at the time of registration as stated in paragraph (h)(10)(ii) of this section. USCIS may deny or revoke the approval of an H-1B petition that does not meet these requirements.

* * * * *

(iv) * * *

(B) *Petition-based cap-subject selections in event of suspended registration process.* In any year in which USCIS suspends the H-1B registration process for cap-subject petitions, USCIS will allow for the submission of H-1B petitions notwithstanding paragraph (h)(8)(iii) of this section and conduct a cap-subject selection process based on the petitions that are received. Each petitioner must select the highest OEWS wage level that the beneficiary’s proffered wage equals or exceeds for the relevant SOC code in the area(s) of intended employment. If the beneficiary’s proffered wage is lower than OEWS wage level I, because it is based on a prevailing wage from another legitimate source (other than OEWS) or an independent authoritative source, the petitioner must select “wage level I.” If the beneficiary will work in multiple locations, or in multiple positions if the petitioner is an agent, the petitioner must select the lowest corresponding OEWS wage level that the beneficiary’s proffered wage will equal or exceed. Where there is no current OEWS prevailing wage information for the beneficiary’s proffered position, the petitioner must select the appropriate wage level that corresponds to the requirements of the beneficiary’s

proffered position using the Department of Labor’s prevailing wage guidance. If a random selection is necessary, each petition will be assigned the OEWS wage level selected in accordance with form instructions and will be entered into the selection pool in a weighted manner as follows: a petition assigned wage level IV will be entered into the selection pool four times, a petition assigned wage level III will be entered into the selection pool three times, a petition assigned wage level II will be entered into the selection pool two times, and a petition assigned wage level I will be entered into the selection pool one time. The selection will be made via computer-generated selection. Petitioners must submit evidence of the basis of the selected wage level as of the date the petition is submitted. USCIS will deny petitions indicating that they are exempt from the H-1B regular cap and the H-1B advanced degree exemption if USCIS determines, after the final receipt date, that they are not eligible for the exemption sought. If USCIS determines, on or before the final receipt date, that the petition is not eligible for the exemption sought, USCIS may consider the petition under the applicable numerical allocation and proceed with processing of the petition. If a petition is denied under this paragraph (h)(8)(iv)(B), USCIS will not return or refund filing fees.

(1) *H-1B regular cap selection in event of suspended registration process.* In determining whether there are enough H-1B cap-subject petitions to meet the H-1B regular cap, USCIS will consider all petitions properly submitted in accordance with § 103.2 of this chapter relating to beneficiaries who may be counted under section 214(g)(1)(A) of the Act, including those who may be eligible for exemption under section 214(g)(5)(C) of the Act. When calculating the number of petitions needed to meet the H-1B regular cap, USCIS will take into account historical data related to approvals, denials, revocations, and other relevant factors. USCIS will monitor the number of petitions received and will announce on its website the date that it receives the number of petitions projected as needed to meet the H-1B regular cap (the “final receipt date”). The date the announcement is posted will not control the final receipt date. If the final receipt date is any of the first five business days on which petitions subject to the H-1B regular cap may be received (in other words, if the numerical limitation is reached on any one of the first five business days that filings can be made),

USCIS will weight each petition as described in paragraph (h)(8)(iv)(B) of this section and randomly select the number of petitions properly submitted during the first five business days deemed necessary to meet the H-1B regular cap.

(2) *Advanced degree exemption selection in event of suspended registration process.* After USCIS has received a sufficient number of petitions to meet the H-1B regular cap and, as applicable, completed the random selection process of petitions for the H-1B regular cap, USCIS will determine whether there is a sufficient number of remaining petitions to meet the H-1B advanced degree exemption numerical limitation. When calculating the number of petitions needed to meet the H-1B advanced degree exemption numerical limitation, USCIS will take into account historical data related to approvals, denials, revocations, and other relevant factors. USCIS will monitor the number of petitions received and will announce on its website the date that it receives the number of petitions projected as needed to meet the H-1B advanced degree exemption numerical limitation (the “final receipt date”). The date the announcement is posted will not control the final receipt date. If the final receipt date is any of the first five business days on which petitions subject to the H-1B advanced degree exemption may be received (in other words, if the numerical limitation is reached on any one of the first five business days that filings can be made), USCIS will weight each petition as described in paragraph (h)(8)(iv)(B) of this section and

randomly select the number of petitions properly submitted during the first five business days deemed necessary to meet the H-1B advanced degree exemption numerical limitation.

* * * * *

(10) * * *

(ii) *Denial for statement of facts on the petition, H-1B registration, temporary labor certification, or labor condition application, or invalid H-1B registration.* The petition will be denied if it is determined that the statements on the petition, the H-1B registration (if applicable), the application for a temporary labor certification, or the labor condition application were inaccurate, fraudulent, or misrepresented a material fact, including if the certifications on the registration are determined to be false. An H-1B cap-subject petition also will be denied if it is not based on a valid registration submitted by the petitioner (or its designated representative), or a successor in interest, for the beneficiary named or identified in the petition. A valid registration must represent a bona fide job offer.

(iii) *Denial for attempt to unfairly increase the chance of selection.* USCIS may deny a subsequent new or amended petition filed by the petitioner, or a related entity, on behalf of the same beneficiary, if USCIS determines that the filing of the new or amended petition is part of the petitioner's attempt to unfairly increase the chance of selection during the registration or petition selection process, as applicable, such as by changing the proffered wage in a subsequent new or amended petition to an amount that would be

equivalent to a lower wage level than that indicated on the registration, or the original cap-subject petition if the registration process was suspended.

* * * * *

(11) * * *

(iii) * * *

(A) * * *

(6) The H-1B cap-subject petition was not based on a valid registration submitted by the petitioner (or its designated representative), or a successor in interest, for the beneficiary named or identified in the petition;

(7) The petitioner failed to timely file an amended petition notifying USCIS of a material change or otherwise failed to comply with the material change reporting requirements in paragraph (h)(2)(i)(E) of this section; or

(8) The petitioner, or a related entity, filed a new or amended petition on behalf of the same beneficiary, if USCIS determines that the filing of the new or amended petition is part of the petitioner's (or related entity's) attempt to unfairly increase the chance of selection during the registration or petition selection process, as applicable, such as by changing the proffered wage in a subsequent new or amended petition to an amount that would be equivalent to a lower wage level than that indicated on the registration, or the original cap-subject petition if the registration process was suspended.

* * * * *

Kristi Noem,

Secretary, U.S. Department of Homeland Security.

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Part III

Department of Health and Human Services

Office of the Secretary

45 CFR Parts 170 and 171

Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory
Actions To Unleash Prosperity; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Parts 170 and 171

RIN 0955-AA09

Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions To Unleash Prosperity

AGENCY: Assistant Secretary for Technology Policy (ASTP)/Office of the National Coordinator for Health Information Technology (ONC) (collectively, ASTP/ONC), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule focuses on deregulatory actions identified in HHS regulations regarding Health information technology standards, implementation specifications, and certification criteria and certification programs for health information technology, and information blocking. This proposed rule seeks to reduce burden, offer flexibility to both developers and providers, and support innovation through the removal and revisions of certain certification criteria and regulatory provisions. This proposed rule also seeks to address reported misuse and abuse of information blocking definitions and exceptions.

DATES: To be assured consideration, written or electronic comments must be received at one of the addresses provided below, no later than 5 p.m. Eastern Time on February 27, 2026.

ADDRESSES: You may submit comments, identified by RIN 0955-AA09, by any of the following methods (please do not submit duplicate comments). Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

- *Federal eRulemaking Portal:* Follow the instructions for submitting comments. Attachments should be in Microsoft Word, Microsoft Excel, or Adobe PDF; however, we prefer Microsoft Word. <http://www.regulations.gov>.

- *Regular, Express, or Overnight Mail:* Department of Health and Human Services, Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology, Attention: Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions to Unleash Prosperity Proposed Rule, Mary E.

Switzer Building, Mail Stop: 7033A, 330 C Street SW, Washington, DC 20201. Please submit one original and two copies.

- *Hand Delivery or Courier:* Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology, Attention: Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions to Unleash Prosperity Proposed Rule, Mary E. Switzer Building, Mail Stop: 7033A, 330 C Street SW, Washington, DC 20201. Please submit one original and two copies. (Because access to the interior of the Mary E. Switzer Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the mail drop slots located in the main lobby of the building.)

Inspection of Public Comments: All comments received before the close of the comment period will be available for public inspection, including any personally identifiable or confidential business information that is included in a comment. Please do not include anything in your comment submission that you do not wish to share with the general public. Such information includes, but is not limited to, the following: a person's social security number; date of birth; driver's license number; state identification number or foreign country equivalent; passport number; financial account number; credit or debit card number; any personal health information; or any business information that could be considered proprietary. We will post all comments that are received before the close of the comment period at <http://www.regulations.gov>.

Docket: For access to the docket to read background documents, comments received, or the plain-language summary of the proposed rule of not more than 100 words in length required by the Providing Accountability Through Transparency Act of 2023, go to <http://www.regulations.gov> or the Department of Health and Human Services, Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology, Mary E. Switzer Building, Mail Stop: 7033A, 330 C Street SW, Washington, DC 20201 (call ahead to the contact listed below to arrange for inspection).

FOR FURTHER INFORMATION CONTACT: Michael Lipinski, Office of Policy, Assistant Secretary for Technology Policy/Office of the National

Coordinator for Health Information Technology, 202-690-7151.

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I. Executive Summary

A. Purpose of Deregulatory Action

1. Administration Deregulatory Priorities

On January 31, 2025, President Trump issued Executive Order (E.O.) 14192 “Unleashing Prosperity Through Deregulation,”¹ which states that it is the policy of the Administration to significantly reduce the private expenditures required to comply with Federal regulations to secure America’s economic prosperity and national security and the highest possible quality of life for each citizen. ASTP/ONC is issuing this proposed rule in an effort to streamline and reduce administrative burdens on health care providers, health information technology (IT) developers, and the health IT community overall. This proposed rule would also improve patient and health care provider access to electronic health information (EHI) and promote health IT and health care market competition with proposals to revise the information blocking regulations.

In order to implement the President’s deregulatory initiatives, and to better promote the health and well-being of the American people, HHS intends to dramatically expand its deregulatory efforts. An important component of Making America Healthy Again is making sure that health care providers and caretakers can focus on preventing and treating chronic diseases. By proposing to remove duplicative and unnecessary requirements of the ONC Health IT Certification Program (Certification Program), we will support providers in caring for their patients. Developers of certified health IT will have more time to support providers’ specific technological needs. Providers may also have more health IT choices to meet their needs through increased competition in the certified health IT market that may come from reduced barriers to entry for the certification of health IT. Further, proposed revisions to the information blocking regulations would support health care providers in using innovative third-party software with their EHRs as well as their access, exchange, and use of patients’ EHI.

2. ASTP/ONC Implementation

a. Certification Program and Information Blocking

Since the inception of the Certification Program, ASTP/ONC has aimed to implement and administer the

Certification Program in the least burdensome manner that supports an administration’s policy goals. Throughout the years, we have worked to improve the Certification Program with a focus on ways to reduce burden, offer flexibility to both developers and providers, and support innovation. Over the past 15 years, we have established a set of regulatory requirements that have provided a foundation for our voluntary Certification Program. As we look to the future, there is an opportunity to review the existing requirements and make updates as needed. Through both formal notice and comment rulemaking and informal engagements, we have received suggestions on how to update the Certification Program to meet current market needs. This proposed rule proposes deregulatory actions that: take into consideration these suggestions; account for the current and future state of technology; reduce burden by eliminating redundant requirements; and promote innovation for health IT developers, providers, and other interested parties. We have also evaluated the information blocking regulations and propose the removal of one exception, removal and revisions of conditions of other exceptions, and revisions of definitions to better promote EHI access, exchange, and use. Together, these efforts directly align with Administration goals as outlined in E.O. 14192 (Unleashing Prosperity through Deregulation)² and E.O. 14267 (Reducing Anti-Competitive Regulatory Barriers).³

b. America’s FHIR-Forward Future Background

In 2012, Health Level Seven (HL7®) first published for industry feedback what is now called the Fast Healthcare Interoperability Resources (FHIR®)⁴ standard. FHIR aimed to build on prior HL7 work, including well-established messaging and document standards (e.g., HL7 Version 2, Clinical Document Architecture (CDA)). It also sought to improve developer usability and ease of implementation by leveraging internet-scale tooling common to modern web services. Rooted in a RESTful architectural style,⁵ FHIR organizes data into granular “resources” (e.g., Patient, Observation,

² <https://www.federalregister.gov/documents/2025/02/06/2025-02345/unleashing-prosperity-through-deregulation>.

³ <https://www.federalregister.gov/documents/2025/04/15/2025-06463/reducing-anti-competitive-regulatory-barriers>.

⁴ <https://hl7.org/fhir/summary.html>.

⁵ https://ics.uci.edu/~fielding/pubs/dissertation/fielding_dissertation.pdf.

¹ <https://www.federalregister.gov/documents/2025/02/06/2025-02345/unleashing-prosperity-through-deregulation>.

MedicationRequest) that can be created, read, updated, or deleted through standard HTTP operations and expressed in formats such as JSON. FHIR was designed to help reduce implementer variation, allow for widespread web security conventions to be layered in (e.g., OAuth 2.0, OpenID Connect, and TLS), and facilitate more incremental adoption through modularity.

Since FHIR Draft Standard for Trial Use (DSTU) 1 was officially published in September 2014, HL7 has iteratively advanced FHIR through a comprehensive ballot process that combines industry pilots, Connectathons, and formal community review. In 2015, ONC released the “2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications” Final Rule (2015 Edition Final Rule) (80 FR 62602), which among other requirements, adopted non-standards-based, functional application programming interface (API) certification criteria (45 CFR 170.315(g)(7), (8), and (9)). The adoption of these certification criteria combined with the data elements specified in the “common clinical data set” (CCDS) helped catalyze the industry to focus on developing a consistent implementation guide for FHIR-based API deployment in the United States (US). This industry-led effort resulted in the “Argonaut Data Query Implementation Guide” based on FHIR DSTU 2, which became commonly deployed in production and used as the basis to build early versions of patient access applications with the potential for nationwide scale.⁶

In parallel to this wave of standards development and industry implementation, API-focused interoperability policy also advanced. The 21st Century Cures Act (Cures Act) (Pub. L. 114–255) was signed into law at the end of 2016 and ASTP/ONC subsequently engaged in rulemaking to implement its provisions. This included, among other new policies, the adoption of a FHIR-based API certification criterion (45 CFR 170.315(g)(10)) and the establishment of an API Condition of Certification, which focused on the publication of APIs that would allow EHI “to be accessed, exchanged, and used without special effort . . . including providing access to all data elements of a patient’s

electronic health record . . .”. On May 1, 2020, ONC published the “21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program” Final Rule (Cures Act Final Rule) (85 FR 25642), which adopted a suite of FHIR-based requirements in the Certification Program. This final rule required support for HL7’s FHIR US Core Implementation Guide (IG) (based on FHIR Release 4 and consistent with United States Core Data for Interoperability (USCDI) v1 data elements), FHIR Bulk Data Access Implementation Guide, and HL7® SMART Application Launch Framework Implementation Guide. We stated that developers of certified health IT certified to the applicable criteria were required to upgrade certified health IT to these FHIR API standards and provide them to their customers by no later than May 2, 2022, in the Cures Act Final Rule (85 FR 25948). We then extended the compliance date to December 31, 2022, in the “Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID–19 Public Health Emergency Interim” Final Rule (85 FR 70072).

In the years since the Cures Act Final Rule, ASTP/ONC and industry established an iterative, annual cycle whereby a new USCDI version is released that then helps inform further data element constraints for a new version of the FHIR-based US Core IG. This predictable, consistent, and collaborative approach has been transformative for standards development and FHIR-based policy making. It has also positioned the US as a world leader in FHIR adoption and use. Other federal agencies, such as the Centers for Medicare & Medicaid Services (CMS), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), and National Institutes of Health (NIH) have also pursued FHIR-oriented regulatory policy and program implementations based on this foundation.

Resetting the Certification Program for a FHIR-Enabled Future

America’s interoperability arc in health care has bent decisively toward FHIR-based APIs. An open, interoperable health data ecosystem invites entrepreneurship, drives innovation, and cements American leadership and competitiveness in the expanding digital health marketplace. As discussed in this deregulatory

proposed rule, we propose to aggressively reduce and remove long-standing functionality-oriented and non-FHIR-based certification criteria from the Certification Program. While this approach would directly and rapidly reduce compliance burdens for health IT developers that participate in the Certification Program, more broadly, it enables ASTP/ONC to reset the Certification Program’s regulatory scope and establish a new foundation on which to build FHIR-based API requirements in the future. This would allow more creative artificial intelligence (AI)-enabled interoperability solutions that combine FHIR with newer standards to emerge, such as Model Context Protocol (MCP) which “standardizes how applications provide context to Large Language Models (LLMs)”,⁷ and further embrace the Cures Act’s reference to “. . . successor technology or standards . . .” in the API Condition of Certification.⁸

While FHIR provides the potential for better, faster, and more consistent ways to address emerging market needs and policy imperatives, more work is needed for certain use cases. We intend to continue to fully engage industry and our federal partners, such as CMS, to rapidly advance FHIR specifications for regulatory readiness. We also intend to sharpen the Certification Program’s future focus to prioritize FHIR-based APIs that: (1) enhance automation and API performance; (2) move beyond read-only interactions; and (3) expand the scope of data available to support clinical efficiency, patient-centered care, and timely reporting (e.g., public health, quality, government programs) use cases.

The transition to a FHIR-based API ecosystem is a strategic imperative and an investment in the US’s interoperability future. To execute this vision, it will require a collective commitment from policymakers, software developers, clinicians, payers, and patients alike. Together, we can build interoperable solutions that meet today’s challenges and anticipate tomorrow’s opportunities.

In this proposed rule, our proposals remove or revise certain certification criteria that are consistent with our drive toward and our support for the FHIR standard, as discussed above. The push toward universal adoption of FHIR is not just important for secure, streamlined data access, it is a critical step toward modernizing our health care system with the ultimate goal of Making America Healthy Again.

⁶ See <https://www.healthit.gov/buzz-blog/health-it/the-heat-is-on-us-caught-fhir-in-2019>; and also <https://www.apple.com/newsroom/2018/01/apple-announces-effortless-solution-bringing-health-records-to-iPhone/>.

⁷ <https://modelcontextprotocol.io/introduction>.

⁸ 42 U.S.C. 300jj–11(c)(5)(D)(iv).

B. Summary of Major Provisions

1. Health Information Technology Standards, Implementation Specifications, and Certification Criteria and Certification Programs for Health Information Technology (Part 170)

a. Certification Criteria for Health Information Technology

We have identified certification criteria for proposed removal or revision. The removal or revision of the identified certification criteria would reduce burden and costs for health IT developers and clinicians, for reasons including but not limited to, eliminating the need to design and meet specific certification functionalities; prepare, test, and certify health IT in certain instances; and maintain conformance to certification requirements. We do not anticipate that the proposed removals or revisions would alter behavior across product implementations by health IT developers for the capabilities that have thus far been included as part of certification criteria in the Certification Program. We have observed over time that certification is likely no longer a primary factor driving improvements or compliance in particular areas, such as with respect to privacy and security. Generally, at the time of certification, developers have (in some cases for over a decade) consistently demonstrated for many certification criteria that their certified health IT can perform required functionalities in a conformant manner.⁹ Throughout this proposed rule, we have included proposed revisions and removals of certification criteria that, among other factors, we believe are no longer necessary to advance interoperability and no longer provide a strong market driver for initial adoption and implementation of the certified functionalities.

In total, out of the 60 certification criteria that are currently in effect, we propose to remove 34 and revise seven. Of the revised criteria, one of the proposed revisions would reduce the scope of the “decision support interventions” certification criterion to fully remove the artificial intelligence (AI) “model card” requirements. We intend to retain and make no changes to 19 certification criteria, which include new and revised certification criteria that were adopted in the Health Data, Technology, and Interoperability: Electronic Prior Authorization and Real-Time Prescription Benefit (HTI-4) Final Rule (90 FR 37130). This final rule was published as a part of the “Medicare Program; Hospital Inpatient Prospective

Payment Systems for Acute Care Hospitals (IPPS) and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year (FY) 2026 Rates; Changes to the FY 2025 IPPS Rates Due to Court Decision; Requirements for Quality Programs; and Other Policy Changes; Health Data, Technology, and Interoperability: Electronic Prescribing, Real-Time Prescription Benefit and Electronic Prior Authorization” (FY2026 IPPS/LTCH PPS) Final Rule, which was published by CMS on August 4, 2025 (90 FR 36536).

b. Standards and Implementation Specifications for Health Information Technology

In some instances where we propose to remove or revise a certain certification criterion, we also propose to remove the standard(s) that is referenced by the certification criterion. In some cases, we propose to remove standards consistent with a certification criterion transition period until January 1, 2027. In very limited circumstances, we retain a standard referenced in a certification criterion proposed for removal for purposes of health IT interoperability alignment.¹⁰ We also propose to remove standards that are outdated and no longer referenced in the Certification Program. Lastly, we propose to adopt USCDI v3.1 in § 170.213.

c. Terms and Definitions

Because of the proposed removal of certain certification criteria as discussed above, we propose to make conforming edits to the terms and definitions in § 170.102. We propose to revise the definition of “Base EHR” to remove references to criteria that we have proposed to remove from the Code of Federal Regulations (CFR). We also propose to remove the definitions of “Common Clinical Data Set,” “Global Unique Device Identification Database (GUDID),” and “Production Identifier” because these terms are no longer referenced in 45 CFR part 170.

d. Conditions and Maintenance of Certification Requirements for Health IT Developers

We propose to make conforming edits for several Conditions and Maintenance of Certification requirements, including

the “Assurances” (§ 170.402), “Application Programming Interfaces” (§ 170.404), and “Attestations” (§ 170.406) Conditions and Maintenance of Certification requirements. In addition to conforming edits, we also propose to descope the “Real World Testing” Condition and Maintenance of Certification requirements (§ 170.405) with deregulatory actions related to real world testing plans, results, and the use of the standards version advancement process (SVAP). These proposals are consistent with the enforcement discretion notice we issued on June 30, 2025.¹¹ Lastly, we propose to remove and descope measures associated with the “Insights” Condition and Maintenance of Certification requirements (§ 170.407), consistent with the enforcement discretion we issued on April 29, 2025,¹² to limit reporting requirements only to the “use of FHIR in apps through certified health IT” measure.

e. ONC Health IT Certification Program Administrative Requirements

We propose to make conforming edits, to remove references to certification criteria that we propose to remove in this proposed rule, in subpart E of 45 CFR part 170. Specifically, in §§ 170.523, 170.550, 170.555, and 170.570.

2. Information Blocking (Part 171)

We propose to revise the § 171.102 “access” and “use” definitions to emphasize that the definitions include automated means of access, exchange, or use of EHI—including, without limitation, autonomous AI systems. As an alternative proposal, we propose, in addition to updating the “access” and “use” definitions, to revise the “exchange” definition in a similar manner.

We propose to remove the *third party seeking modification use* condition from the Infeasibility Exception (§ 171.204(a)(3)). This condition is susceptible to misuse by actors withholding EHI to unnecessarily inhibit access, exchange, and use of EHI by third parties that patients and health care providers want. Where any requested access, exchange, or use of EHI poses concerns such as specific threats to the confidentiality, integrity, or availability of the EHI involved, this condition is unnecessary. Activities reasonable and necessary to address

¹⁰ Section 13111 and 13112 of the HITECH Act requires health IT systems and products to utilize standards adopted under section 3004 of the PHSA in specified circumstances. The HHS Health IT Alignment Program, led by ASTP/ONC builds upon the HITECH to advance interoperability across HHS investments. See <https://www.healthit.gov/topic/hhs-health-it-alignment-program>.

¹¹ <https://www.healthit.gov/topic/real-world-testing-condition-and-maintenance-certification-requirements-enforcement>.

¹² <https://www.healthit.gov/topic/insights-condition-and-maintenance-certification-enforcement-discretion-notice>.

⁹ <https://chpl.healthit.gov/>.

those concerns are covered by other exceptions.

We propose to revise or, in the alternative, remove the *manner exception exhausted* condition (§ 171.204(a)(4)) from the Infeasibility Exception. Similar to the *third party seeking modification use* condition (§ 171.204(a)(3)), we believe this condition as currently codified is susceptible to misuse by actors holding EHI to unnecessarily inhibit access, exchange, and use of EHI. The revisions we propose to the *manner exception exhausted* condition (§ 171.204(a)(4)) would narrow its application to better align with our intent for this condition and reduce the risk of an actor misusing it. In the alternative, we propose to remove the entire condition to address our concerns.

We propose to revise the Manner Exception's *manner requested* condition (§ 171.301(a)) to ensure that it is clear that the Manner Exception cannot be met with contracts that are not market rate, are contracts of adhesion, or are contracts containing unconscionable terms.

We propose to remove subpart D from 45 CFR part 171, which includes the Trusted Exchange Framework and Common Agreement™ (TEFCA™) Manner Exception (§ 171.403) and associated definitions. Based on TEFCA's continued implementation, maturation, and public comments received—including those received in response to the CMS–ASTP/ONC Request for Information; Health Technology Ecosystem (90 FR 21034) (CMS–ASTP/ONC RFI)—we believe the removal of the TEFCA Manner Exception (§ 171.403) is appropriate.

C. Severability

It is our intent that if any provision of this rule were, if or when finalized, held to be invalid or unenforceable facially, or as applied to any person, plaintiff, or stayed pending further judicial or agency action, such provision shall be severable from other provisions of this rule, and from rules and regulations currently in effect, and not affect the remainder of this rule. It is also our intent that, unless such provision shall be held to be utterly invalid or unenforceable, it be construed to give the provision maximum effect permitted by law including in the application of the provision to other persons not similarly situated or to other, dissimilar circumstances from those where the provision may be held to be invalid or unenforceable.

In this rule, we propose provisions that are intended to and will operate independently of each other, even if

multiple of them serve the same or similar general purpose(s) or policy goal(s). Where a provision is necessarily dependent on another, the context generally makes that clear (such as by cross-reference to a particular standard, requirement, condition, or prerequisite). Where a provision that is dependent on one that is stayed or held invalid or unenforceable (as described in the preceding paragraph) is included in a subparagraph, paragraph, or section within part 170 or 171 of 45 CFR, we intend that other provisions of such subparagraph(s), paragraph(s), or section(s) that operate independently of said provision would remain in effect.

For example, if any proposed revision of any section or paragraph of part 170, if finalized, were stayed or held utterly invalid or unenforceable, we would intend for all other finalized revisions in part 170 that do not depend upon the stayed or invalidated revision to remain in full effect. To illustrate, if a removal of a certification criterion were to be finalized and then held to be entirely invalid or unenforceable, any corresponding removal of a cross-reference to that provision would depend on that revision and would be affected by the holding of invalidity or unenforceability. But in direct contrast, any revision to any other certification criterion or other Certification Program requirement or provision codified in part 170 that is not made based specifically on the removal of the certification criterion for which removal was held invalid or unenforceable, is intended to remain in full effect even if both revisions were proposed in this same proposed rule and were to be finalized in a single final rule.

To provide another example, if we were to finalize the proposed removal of paragraph (a)(3) from § 171.204 (the Infeasibility Exception), and the removal of this paragraph was stayed or held facially invalid or unenforceable in whole or in part, we would intend for other finalized revisions in part 171, including without limitation the proposed revision or, in the alternative, removal of paragraph (a)(4) from § 171.204 (the Infeasibility Exception) to continue in effect. Each of the conditions (subparagraphs) within § 171.204(a) is designed to stand independent of any and every other subparagraph in § 171.204(a). Moreover, each information blocking exception is intended and designed to stand independent of any and every other exception unless any specific provision of an exception might explicitly reference another exception. Likewise, any dependency on cross-referenced provision(s) is intended to be limited to

the exact provision, or function of such provision, that relies upon the cross-reference. For example, paragraph (a)(4) in § 171.204 cross-references subparagraphs (1)(i) and (1)(ii) in § 171.301(b) (the Manner Exception's *alternative manner* condition). If either § 171.301(b)(1)(i) or (ii) were to be held facially invalid or unenforceable, paragraph (a)(4) in § 171.204 as currently codified is intended to remain in effect, including with respect to its cross-references to § 171.301(b) as a whole and to whichever of the cross-referenced paragraphs ((i) or (ii)) in § 171.301(b)(1) was not held facially invalid or unenforceable.

If any revision to any provision of part 170 or 171 (such as the removal or revision of a specific condition within one information blocking exception in part 171 or a revision to a certification criterion in part 170) were stayed or held to be invalid or unenforceable as applied to any person, plaintiff, or circumstance, it is our intent that such provision—and any section or paragraph of part 171 or 170 that may reference such provision—be construed to give the provision maximum effect permitted by law including in the application of the provision to other persons not similarly situated or to other, dissimilar circumstances from those where the provision may be held to be invalid or unenforceable.

D. Costs and Benefits

The Regulatory Impact Analysis (RIA) includes an updated analysis of the costs and benefits associated with the proposals in this proposed rule. The proposed deregulatory actions provide substantial relief for developers of certified health IT and significant cost savings realized from the revision and removal of certain Certification Program requirements. The cost savings have been estimated using the best available data and modeled on the costs estimated and finalized in prior ASTP/ONC rulemakings. The proposed deregulatory actions reduce the effort of developers of certified health IT to meet ongoing Certification Program requirements and reduce entry barriers for new Certification Program participants. The proposed actions, importantly, return effort back to developers of certified health IT to innovate with their technology, improve interoperability and third-party integration, and focus on the needs of their customers. We do not expect costs to be associated with these deregulatory proposals. We expect the proposed deregulatory actions to result in significant benefits for health IT developers, providers, ONC–Authorized Certification Bodies (ONC–

ACBs), ONC-Authorized Testing Laboratories (ONC-ATLs), and ASTP/ONC. Generally, these benefits are in the form of cost and time savings and reductions in administrative burden to comply with Certification Program requirements. The proposed actions reduce the scope and breadth of Certification Program requirements.

The analysis included in this proposed rule indicates that the proposed updates to the Certification Program would result in \$0 in implementation costs on developers of certified health IT. However, we do estimate some costs for reviewers who review this proposed rule. We estimate those costs to be \$284,132 in total for an estimated 644 reviewers, which include developers and medical associations. We do not quantify benefits for this proposed rule and instead rely on our calculation of cost savings to developers of certified health IT to quantify in dollars the time and effort developers would have expended had these requirements remained in effect in perpetuity. In total, this proposed rulemaking would result in a present value of cost savings of \$1.53 billion in 2024 dollars and discounted at a rate of 7%, beginning in 2027 and in perpetuity.

II. Background

A. Statutory Basis

The Health Information Technology for Economic and Clinical Health Act (HITECH Act), Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5), was enacted on February 17, 2009. The HITECH Act amended the Public Health Service Act (PHSA) and created “Title XXX—Health Information Technology and Quality” (Title XXX) to improve health care quality, safety, and efficiency through the promotion of health IT and electronic health information (EHI) exchange.

The 21st Century Cures Act (Pub. L. 114–255) (Cures Act) was enacted on December 13, 2016, to accelerate the discovery, development, and delivery of 21st century cures, and for other purposes. The Cures Act, through Title IV—Delivery, amended the HITECH Act by modifying or adding certain provisions to the PHSA relating to health IT.

1. Standards, Implementation Specifications, and Certification Criteria

The HITECH Act established two Federal advisory committees, the Health IT Policy Committee (HITPC) and the Health IT Standards Committee

(HITSC). Each was responsible for advising the National Coordinator for Health Information Technology (National Coordinator) on different aspects of standards, implementation specifications, and certification criteria.

Section 4003(e) of the Cures Act amended sections 3002 and 3003 of the PHSA by replacing, in an amended section 3002, the HITPC and HITSC with one committee named the Health Information Technology Advisory Committee (Health IT Advisory Committee or HITAC). Section 3002(a) of the PHSA, as added by the Cures Act, establishes that the HITAC recommends to the National Coordinator policies and standards, implementation specifications, and certification criteria, relating to the implementation of a health information technology infrastructure, nationally and locally, that advances the electronic access, exchange, and use of health information. Further described in section 3002(b)(1) of the PHSA, this includes recommending to the National Coordinator a policy framework to advance interoperable health information technology infrastructure, updating recommendations to the policy framework, and making new recommendations, as appropriate. Section 3002(b)(2)(A) of the PHSA specifies that in general, the HITAC shall recommend to the National Coordinator for purposes of adoption under section 3004, standards, implementation specifications, and certification criteria and an order of priority for the development, harmonization, and recognition of such standards, specifications, and certification criteria. Like the process previously required of the former HITPC and HITSC, section 3002(b)(5) of the PHSA requires the HITAC to develop a schedule, updated annually, for the assessment of policy recommendations, which the Secretary publishes in the **Federal Register**.

Section 3004 of the PHSA establishes a process for the adoption of health IT standards, implementation specifications, and certification criteria and authorizes the Secretary to adopt such standards, implementation specifications, and certification criteria. As specified in section 3004(a)(1), the Secretary is required, in consultation with representatives of other relevant federal agencies, to jointly review standards, implementation specifications, and certification criteria endorsed by the National Coordinator in section 3001(c) and subsequently determine whether to propose the adoption of such standards, implementation specifications, or

certification criteria. Section 3004(a)(3) requires the Secretary to publish all such determinations in the **Federal Register**.

Section 3004(b)(3) of the PHSA, titled, Subsequent Standards Activity, provides that the Secretary shall adopt additional standards, implementation specifications, and certification criteria as necessary and consistent with the schedule published by the HITAC. We consider this provision in the broader context of the HITECH Act and Cures Act to grant the Secretary the authority and discretion to adopt standards, implementation specifications, and certification criteria that have been recommended by the HITAC and endorsed by the National Coordinator, as well as other appropriate and necessary health IT standards, implementation specifications, and certification criteria.

2. Health IT Certification Program

Section 3001(c)(5) of the PHSA provides the National Coordinator with the authority to establish a certification program or programs for the voluntary certification of health IT. Section 3001(c)(5)(A) specifies that the National Coordinator, in consultation with the Director of the National Institute of Standards and Technology (NIST), shall keep or recognize a program or programs for the voluntary certification of health IT that is in compliance with applicable certification criteria adopted in section 3004 of the PHSA.

The certification program(s) must also include, as appropriate, testing of the technology in accordance with section 13201(b) of the HITECH Act. Overall, section 13201(b) of the HITECH Act requires that, with respect to the development of standards and implementation specifications, the Director of NIST shall support the establishment of a conformance testing infrastructure, including the development of technical test beds. The HITECH Act also indicates that the development of this conformance testing infrastructure may include a program to accredit independent, non-federal laboratories to perform testing.

Section 4002(a) of the Cures Act amended section 3001(c)(5) of the PHSA by adding section 3001(c)(5)(D), which requires the Secretary, through notice and comment rulemaking, to require conditions of certification and maintenance of certification for the Certification Program. Specifically, the health IT developers or entities with technology certified under the Certification Program must, in order to maintain such certification status, adhere to certain conditions and

maintenance of certification requirements concerning information blocking; assurances regarding appropriate exchange, access, and use of electronic health information; communications regarding health IT; APIs; real world testing; attestations regarding certain conditions and maintenance of certification requirements; and submission of reporting criteria under the EHR Reporting Program in accordance with section 3009A(b) of the PHSA.

B. Regulatory History

The Secretary issued an interim final rule with request for comments on January 13, 2010, “Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology” (the “S&CC January 2010 Interim Final Rule”) (75 FR 2014), which adopted an initial set of standards, implementation specifications, and certification criteria. On March 10, 2010, the Secretary issued a proposed rule, “Proposed Establishment of Certification Programs for Health Information Technology” (75 FR 11328), that proposed both temporary and permanent certification programs for the purposes of testing and certifying health IT. A final rule establishing the temporary certification program was published on June 24, 2010, “Establishment of the Temporary Certification Program for Health Information Technology” (75 FR 36158), and a final rule establishing the permanent certification program was published on January 7, 2011, “Establishment of the Permanent Certification Program for Health Information Technology” (76 FR 1262).

After consideration of the comments received on the S&CC January 2010 Interim Final Rule, a final rule was issued to complete the adoption of the initial set of standards, implementation specifications, and certification criteria and realign them with the final objectives and measures established for the EHR Incentive Programs Stage 1, titled “Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology” (75 FR 44590, July 28, 2010) (2011 Edition Final Rule). The 2011 Edition Final Rule also established the first version of the certified electronic health record technology (CEHRT) definition. Subsequent to the 2011 Edition Final Rule, on October 13, 2010, we issued an interim final rule “Health Information Technology: Revisions to Initial Set of Standards, Implementation Specifications, and

Certification Criteria for Electronic Health Record Technology” with a request for comment to remove certain implementation specifications related to public health surveillance that had been previously adopted in the 2011 Edition Final Rule (75 FR 62686).

The standards, implementation specifications, and certification criteria adopted by the Secretary in the 2011 Edition Final Rule established the capabilities that CEHRT must include in order to, at a minimum, support the achievement of EHR Incentive Programs Stage 1 by eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) under the “Medicare and Medicaid Programs; Electronic Health Record Incentive Program” final rule (75 FR 44314, July 28, 2010) (EHR Incentive Programs Stage 1 Final Rule).

On March 7, 2012, the Secretary issued a proposed rule with request for comments titled “Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology” (77 FR 13832) (2014 Edition Proposed Rule), which proposed new and revised standards, implementation specifications, and certification criteria.

After consideration of the comments received on the 2014 Edition Proposed Rule, a final rule titled “Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology” (77 FR 54163) (2014 Edition Final Rule) was issued on September 4, 2012, to adopt the 2014 Edition set of standards, implementation specifications, and certification criteria and realign them with the final objectives and measures established for the EHR Incentive Programs Stage 2, as well as Stage 1 revisions. The 2014 Edition Final Rule adopted a proposal to change the Permanent Certification Program’s name to the “ONC HIT Certification Program,” revised the process for permitting the use of newer versions of “minimum standard” code sets, modified the certification processes ONC–ACBs need to follow for certifying EHR Modules in a manner that provides clear implementation direction and compliance with the new certification criteria, and eliminated the certification requirement that every EHR Module be certified to the “privacy and security” certification criteria.

The standards, implementation specifications, and certification criteria adopted by the Secretary in the 2014 Edition Final Rule established the capabilities that CEHRT must include in order to, at a minimum, support the achievement of the EHR Incentive Programs Stage 2 by EPs, eligible hospitals, and CAHs under the “Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2” final rule (77 FR 53968, September 4, 2012) (EHR Incentive Programs Stage 2 Final Rule).

On December 7, 2012, an interim final rule with a request for comment, titled “Health Information Technology: Revisions to the 2014 Edition Electronic Health Record Certification Criteria; and Medicare and Medicaid Programs; Revisions to the Electronic Health Record Incentive Program” (77 FR 72985), was jointly issued and published by ONC and CMS to update certain standards that had been previously adopted in the 2014 Edition Final Rule. The interim final rule also revised the EHR Incentive Programs by adding an alternative measure for the Stage 2 objective for hospitals to provide structured electronic laboratory results to ambulatory providers, corrected the regulation text for the measures associated with the objective for hospitals to provide patients the ability to view online, download, and transmit information about a hospital admission, and made the case number threshold exemption policy for clinical quality measure (CQM) reporting applicable for eligible hospitals and CAHs beginning with FY 2013. In addition, the interim final rule provided notice of CMS’s intent to issue technical corrections to the electronic specifications for CQMs released on October 25, 2012. On September 4, 2014, a final rule “Medicare and Medicaid Programs; Modifications to the Medicare and Medicaid Electronic Health Record (EHR) Incentive Program for 2014 and Other Changes to the EHR Incentive Program; and Health Information Technology: Revisions to the Certified EHR Technology Definition and EHR Certification Changes Related to Standards” (79 FR 52910) was published adopting these proposals.

On November 4, 2013, the Secretary published an interim final rule with a request for comment titled “2014 Edition Electronic Health Record Certification Criteria: Revision to the Definition of ‘Common Meaningful Use (MU) Data Set’ ” (78 FR 65884) to make a minor revision to the Common MU Data Set definition. This revision was intended to allow more flexibility with respect to the representation of dental

procedures data for EHR technology testing and certification.

On February 26, 2014, the Secretary published a proposed rule titled “Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements” (79 FR 10880) (“Voluntary Edition Proposed Rule”). The proposed rule proposed a voluntary edition of certification criteria that was designed to enhance interoperability, promote innovation, and incorporate “bug fixes” to improve upon the 2014 Edition. The Voluntary Edition Proposed Rule also included proposals that focused on improving regulatory clarity, simplifying the certification of EHR Modules that are designed for purposes other than meeting requirements of the EHR Incentive Programs, and discontinuing the use of the Complete EHR definition. A correction notice was published for the Voluntary Edition Proposed Rule on March 19, 2014, entitled “Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements; Correction” (79 FR 15282). This correction notice corrected the preamble text and gap certification table for four certification criteria that were omitted from the list of certification criteria eligible for gap certification for the 2015 Edition EHR certification criteria. On September 11, 2014, a final rule was published titled “2014 Edition Release 2 Electronic Health Record (EHR) Certification Criteria and the ONC HIT Certification Program; Regulatory Flexibilities, Improvements, and Enhanced Health Information Exchange” (79 FR 54430) (2014 Edition Release 2 Final Rule). The final rule adopted a small subset of the original proposals in the Voluntary Edition Proposed Rule as optional and revised 2014 Edition EHR certification criteria that provide flexibility, clarity, and enhance health information exchange. It also finalized administrative proposals (*i.e.*, removal of regulatory text from the CFR) and proposals for the ONC HIT Certification Program that provide improvements. We issued the 2014 Edition Release 2 Final Rule to complete the rulemaking for the Voluntary Edition Proposed Rule. The 2014 Edition Release 2 Final Rule discontinued the “Complete EHR” certification concept beginning with the proposed 2015 Edition, adopted an updated standard (ISO/IEC 17065) for the accreditation of ONC-ACBs, and adopted the “ONC Certified HIT” certification and design mark for

required use by ONC-ACBs under the Certification Program.

On May 23, 2014, CMS and ONC jointly published a proposed rule titled “Medicare and Medicaid Programs; Modifications to the Medicare and Medicaid Electronic Health Record Incentive Programs for 2014; and Health Information Technology: Revisions to the Certified EHR Technology Definition” (79 FR 29732). The proposed rule proposed to update the EHR Incentive Programs Stage 2 and Stage 3 participation timeline. It proposed to revise the CEHRT definition to permit the use of EHR technology certified to the 2011 Edition to meet the CEHRT definition for FY/CY 2014. It also proposed to allow EPs, eligible hospitals, and CAHs that could not fully implement EHR technology certified to the 2014 Edition for an EHR reporting period in 2014 due to delays in the availability of such technology to continue to use EHR technology certified to the 2011 Edition or a combination of EHR technology certified to the 2011 Edition and 2014 Edition for the EHR reporting periods in CY 2014 and FY 2014. On September 4, 2014, a final rule titled “Medicare and Medicaid Programs; Modifications to the Medicare and Medicaid Electronic Health Record (EHR) Incentive Program for 2014 and Other Changes to the EHR Incentive Program; and Health Information Technology: Revisions to the Certified EHR Technology Definition and EHR Certification Changes Related to Standards” (CEHRT Flexibility Final Rule) was published (79 FR 52910) adopting these proposals.

On March 30, 2015, the Secretary published a proposed rule titled “2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications” (80 FR 16804) (2015 Edition Proposed Rule). The 2015 Edition Proposed Rule proposed revisions to the Certification Program with a revised edition of certification criteria that was designed to enhance interoperability.

On October 16, 2015, the Secretary published a final rule titled “2015 Edition Health Information (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications” (80 FR 62602) (2015 Edition Final Rule). The 2015 Edition Final Rule established a new edition of certification criteria (2015 Edition) and a new 2015 Edition Base EHR definition. CMS subsequently established the 2015 Edition Base EHR definition as encompassing the

minimum capabilities and the related minimum standards and implementation specifications that CEHRT would need to include to support the achievement of “meaningful use” by eligible clinicians, eligible hospitals, and CAHs under the Medicare and Medicaid EHR Incentive Programs (the predecessors to the Medicare Promoting Interoperability Program and the Promoting Interoperability performance category under the Merit-based Incentive Payment System (MIPS)). The final rule also adopted a proposal to change the Certification Program’s name to the “ONC Health IT Certification Program” from the ONC HIT Certification Program, modified the Certification Program to make it more accessible to other types of health IT beyond EHR technology and for health IT that supports care and practice settings beyond the ambulatory and inpatient settings, and adopted new and revised Principles of Proper Conduct (PoPC) for ONC-ACBs. A final rule making corrections and clarifications was published for the 2015 Edition Final Rule (80 FR 76868) on December 11, 2015, to correct preamble and regulatory text errors and clarify requirements of the CCDS, the 2015 Edition privacy and security certification framework, and the mandatory disclosures for health IT developers.

After issuing a proposed rule on March 2, 2016, “ONC Health IT Certification Program: Enhanced Oversight and Accountability” (81 FR 11056), we published a final rule by the same title (81 FR 72404) (EOA Final Rule) on October 19, 2016. The EOA Final Rule finalized modifications and new requirements under the Certification Program, including provisions related to our role in the Certification Program. The EOA Final Rule created a regulatory framework for our direct review of health IT certified under the Certification Program, including, when necessary, requiring the correction of non-conformities found in health IT certified under the Certification Program and suspending and terminating certifications issued to Complete EHRs and Health IT Modules. The final rule also set forth processes for us to authorize and oversee accredited testing laboratories under the Certification Program. In addition, it included provisions for expanded public availability of certified health IT surveillance results.

On March 4, 2019, the Secretary published a proposed rule titled “21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program” (84 FR

7424) (Cures Act Proposed Rule). The proposed rule proposed to implement certain provisions of the 21st Century Cures Act (Cures Act) that would advance interoperability and support the access, exchange, and use of electronic health information.

On May 1, 2020, the Cures Act Final Rule was published in the **Federal Register** (85 FR 25642). The final rule implemented certain provisions of the Cures Act, including Conditions and Maintenance of Certification requirements for health IT developers, the voluntary certification of health IT for use by pediatric health providers, and reasonable and necessary activities that do not constitute information blocking. The final rule also implemented certain parts of the Cures Act to support patients' access to their electronic health information (EHI), and the implementation of information blocking policies that support patient electronic access. Additionally, the final rule modified the 2015 Edition health IT certification criteria and Certification Program in other ways to advance interoperability, enhance health IT certification, and reduce burden and costs, as well as to improve patient and health care provider access to EHI and promote competition. On November 4, 2020, the Secretary published an interim final rule with comment period titled "Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID-19 Public Health Emergency" (85 FR 70064) (Cures Act Interim Final Rule). The interim final rule extended certain compliance dates and timeframes adopted in the Cures Act Final Rule to offer the health care system additional flexibilities in furnishing services to combat the COVID-19 pandemic, including extending the applicability date for information blocking provisions to April 5, 2021.

On April 18, 2023, the Secretary published a proposed rule titled "Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing" (88 FR 23746) (HTI-1 Proposed Rule). The HTI-1 Proposed Rule proposed to implement the EHR Reporting Program provision of the Cures Act by establishing new Conditions and Maintenance of Certification requirements for health IT developers under the Certification Program. The HTI-1 Proposed Rule also proposed several updates to certification criteria and implementation specifications recognized by the Certification Program, including revised certification criteria for: "clinical

decision support," "patient demographics and observations," and "electronic case reporting." The HTI-1 Proposed Rule also proposed to establish a new baseline version of the USCDI. Additionally, the HTI-1 Proposed Rule also proposed enhancements to support information sharing under the information blocking regulations.

On January 9, 2024, the Secretary issued the "Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing" final rule (HTI-1 Final Rule), which implemented the EHR Reporting Program provision of the 21st Century Cures Act and established new Conditions and Maintenance of Certification requirements for health IT developers under the Certification Program (89 FR 1192). The HTI-1 Final Rule also made several updates to certification criteria and standards recognized by the Certification Program. The Certification Program updates included revised certification criteria for "decision support interventions" (DSIs), "patient demographics and observations," and "electronic case reporting," as well as adopted a new baseline version of the USCDI standard, USCDI Version 3 (v3). Additionally, the HTI-1 Final Rule provided enhancements to support information sharing under the information blocking regulations. Through these provisions, we sought to advance interoperability, improve algorithm transparency, and support the access, exchange, and use of EHI. The HTI-1 Final Rule also updated numerous technical standards in the Certification Program to advance interoperability, enhance health IT certification, and reduce burden and costs for health IT developers and users of health IT.

On August 5, 2024, the Secretary published a proposed rule titled "Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability" (89 FR 63498) (HTI-2 Proposed Rule). The HTI-2 Proposed Rule sought to advance interoperability, improve transparency, and support the access, exchange, and use of EHI through proposals for: standards adoption; adoption of certification criteria to advance public health data exchange; expanded uses of certified APIs, such as for electronic prior authorization, patient access, care management, and care coordination; and information sharing under the information blocking regulations. Additionally, the HTI-2 Proposed Rule proposed to establish a new baseline

version of the USCDI standard and proposed to update the Certification Program to enhance interoperability and optimize certification processes to reduce burden and costs. The HTI-2 Proposed Rule also proposed to implement certain provisions related to TEFCA, which would support the reliability, privacy, security, and trust within TEFCA.

On December 16, 2024, the Secretary issued the "Health Data, Technology, and Interoperability: Trusted Exchange Framework and Common Agreement (TEFCA)" final rule (89 FR 101772) (HTI-2 Final Rule) which implemented advancements to interoperability, improved transparency, and supported the access, exchange, and use of electronic health information. The HTI-2 Final Rule codified definitions of certain TEFCA terms in § 171.401 of the information blocking regulations and finalized the 45 CFR part 172 TEFCA provisions.

On December 17, 2024, the Secretary issued the "Health Data, Technology, and Interoperability: Protecting Care Access" final rule (89 FR 102512) (HTI-3 Final Rule). The HTI-3 Final Rule finalized certain proposals from the HTI-2 Proposed Rule to support the access, exchange, and use of EHI. The final rule amended the information blocking regulations to revise two existing information blocking exceptions and established an additional reasonable and necessary activity that does not constitute information blocking referred to as the Protecting Care Access Exception.

On July 31, 2025, ASTP/ONC finalized the "Health Data, Technology, and Interoperability: Electronic Prescribing, Real-Time Prescription Benefit and Electronic Prior Authorization" final rule (90 FR 37130) (HTI-4 Final Rule), as a part of the FY2026 IPPS/LTCH PPS Final Rule, published by CMS on August 4, 2025 (90 FR 36536). The HTI-4 Final Rule finalized a limited subset of the proposals in the HTI-2 Proposed Rule (89 FR 63498) and focused on improving care delivery and reducing administrative burden through the exchange of clinical and administrative information. The HTI-4 Final Rule updated the ONC Health IT Certification Program to add several new certification criteria that advance health care providers' ability to engage in electronic prescribing, real-time prescription benefit checks, and electronic prior authorization.

III. Health Information Technology Standards, Implementation Specifications, and Certification Criteria and Certification Programs for Health Information Technology (Part 170)

Reading This Proposed Rule

In this preamble, we present our proposals in an order that begins with the certification criteria we propose to remove and subsequently the standards, definitions, and other related Certification Program provisions proposed for removal or revision. This approach should make it easier for readers to follow our proposed Certification Program removals, in part, due to the natural cascading effects of proposing to remove or revise a certification criterion. For example, we propose to remove the “application access—all data request” certification criterion in 45 CFR 170.315(g)(9), the referenced HL7 CDA R2 Implementation Guide: C—CDA Templates for Clinical Notes R2.1 Companion guide, Release 2—US Realm, October 2019 (45 CFR 170.205(a)(5)), and the “application access—all data request” certification criterion from the Base EHR definition. In some cases, we propose to remove a standard consistent with a certification criterion transition period until January 1, 2027. In very limited circumstances, we retain a standard that is cross-referenced in a certification criterion that we propose to remove. We do this because the standard is cross-referenced in another criterion and/or supports health IT interoperability alignment. For example, although we propose to remove the “transport methods and other protocols” certification criteria in § 170.315(h), we propose to retain the Direct Project transport standard adopted in § 170.202(a)(2) because we believe keeping the primary Direct Project standard would acknowledge the current utilization of the Direct standard, while removing the certification criteria in § 170.315(h) recognizes the ongoing technological advancements related to transport, including movement toward FHIR-based standards, and would encourage and provide space for further innovation and market competition in this area. We also propose to remove the certification criteria in § 170.315(h) from the “Base EHR” definition. Additionally, we solely propose to remove standards when they are no longer referenced by existing certification criteria. Further, as noted above, we propose to remove certain Conditions and Maintenance of Certification requirements and other Certification Program requirements.

RFI Feedback

Recently, the Office of Management and Budget (OMB), the Department, and CMS—ASTP/ONC issued requests for information (RFIs) related to deregulation. We reviewed comments related to ASTP/ONC. In response to the CMS—ASTP/ONC Request for Information; Health Technology Ecosystem (90 FR 21034) (CMS—ASTP/ONC RFI), commenters expressed a strong desire to modernize the Certification Program to be more modular, API-focused, and less centered on specific EHR functionalities. Commenters recommended simplifying the process, reducing costs, and expanding certification requirements to ensure payers and other health IT systems adhere to the same interoperability standards. There was an overwhelming demand to strengthen, expand, and mandate the use of FHIR-based APIs. Commenters strongly advocated for retiring outdated, less efficient standards to reduce complexity. A central theme from commenters was the need for regulatory modernization to reduce administrative and financial burdens on providers and technology developers. Commenters also expressed concern that existing certification requirements are often too rigid, costly, and not aligned with emerging care models like value-based care or specialized technologies such as AI and remote monitoring. A commenter that responded to the HHS RFI expressed concerns with the Real World Testing and Insights Conditions of Certification, stating that the requirements are overly burdensome and offer limited value to providers or patients. The commenter also recommended retiring low-value certification criteria requirements that add complexity without improving care. A commenter that responded to the OMB RFI suggested that revisions could be made to the Conditions and Maintenance of Certification requirements that focus on streamlined and meaningful oversight without placing undue demands on developers, especially where those demands offer limited direct benefit to health care provider customers or their patients. The commenter also suggested the removal of “non-interoperability-focused, redundant, or valueless” criteria and focus on promoting standardized and scalable interoperability. ASTP/ONC addresses a number of these comments in the proposals below, specifically the suggestions to remove non-interoperability-focused and redundant certification criteria. Commenters were

strongly supportive of our focus on FHIR-based standards. Some commenters, however, included suggestions related to new regulatory actions. These suggestions are out of scope for this proposed deregulatory rule, but we may consider the suggestions for a future rulemaking.

A. Certification Criteria for Health Information Technology

In this proposed rule we have identified certification criteria for removal or revision. For some of the criteria below, we justify removing the certification criteria because they have been “widely adopted” or “widely implemented.” To determine if the certification criterion is “widely adopted” or “widely implemented,” we considered whether and for how long the certification criterion has been included in the Base EHR definition in § 170.102, or the Certified Electronic Health Record Technology (CEHRT) definitions established by CMS in 42 CFR 495.4 and 414.1305. The CEHRT definitions incorporate the Base EHR definition and may also incorporate certification criteria necessary to report applicable objectives and measures under the Medicare Promoting Interoperability (PI) Program or the Promoting Interoperability performance category in the Merit-based Incentive Payment System (MIPS), certification criteria determined applicable for an Alternative Payment Model (APM), and other certification criteria as specified. To participate in the Promoting Interoperability Program and the MIPS Promoting Interoperability performance category, eligible hospitals, CAHs, and eligible clinicians must use CEHRT as specified by the applicable definition. In addition, CEHRT is required for the purposes of determinations under 42 CFR 414.1415 and 414.1420 regarding Advanced APM status. ASTP/ONC tracks and publishes data on the adoption and use of health IT, including CEHRT, by US hospitals and office-based physicians. Our most recent survey data from 2021 shows that 96 percent of hospitals and 78 percent of physicians reported having a certified EHR.¹³ As discussed in more detail below, we provide this analysis and consider certain certification criteria as “widely adopted” or “widely implemented” because they are included in the Base EHR or CEHRT definitions and adopted by 96 and 78 percent of hospitals and physicians, respectively. Our proposals to remove or

¹³ <https://www.healthit.gov/data/quickstats/national-trends-hospital-and-physician-adoption-electronic-health-records>.

revise certain certification criteria are also consistent with our drive toward and our support for the FHIR standard as mentioned above in section I.A and

are responsive to comments we received on the recently issued RFIs. We explain our proposals in detail in their respective sections of the preamble and

have provided a table (see Table 1) for a list of all proposed certification criteria removals and revisions.

TABLE 1—PROPOSED REMOVALS OR REVISIONS OF CERTIFICATION CRITERIA

Certification criteria	Reference	Remove/revise	Timing
Patient demographics and observations	§ 170.315(a)(5)	Revise	Effective date of final rule.
Clinical decision support	§ 170.315(a)(9)	Remove	Effective date of final rule.
Family health history	§ 170.315(a)(12)	Remove	Effective January 1, 2027.
Implantable device list	§ 170.315(a)(14)	Remove	Effective date of final rule.
Transitions of care	§ 170.315(b)(1)	Revise	Effective January 1, 2027.
Clinical information reconciliation and incorporation	§ 170.315(b)(2)	Remove	Effective January 1, 2027.
Security tags—summary of care—send	§ 170.315(b)(7)	Remove	Effective date of final rule.
Security tags—summary of care—receive	§ 170.315(b)(8)	Remove	Effective date of final rule.
Care plan	§ 170.315(b)(9)	Remove	Effective date of final rule.
Decision support interventions	§ 170.315(b)(11)	Revise	Effective date of final rule.
Clinical quality measures—report	§ 170.315(c)	Revise	Effective date of final rule.
Clinical quality measures—filter	§ 170.315(c)(4)	Remove	Effective January 1, 2027.
Authentication, access control, authorization	§ 170.315(d)(1)	Remove	Effective date of final rule.
Auditable events and tamper-resistance	§ 170.315(d)(2)	Remove	Effective date of final rule.
Audit report(s)	§ 170.315(d)(3)	Remove	Effective date of final rule.
Amendments	§ 170.315(d)(4)	Remove	Effective date of final rule.
Automatic access time-out	§ 170.315(d)(5)	Remove	Effective date of final rule.
Emergency access	§ 170.315(d)(6)	Remove	Effective date of final rule.
End-user device encryption	§ 170.315(d)(7)	Remove	Effective date of final rule.
Integrity	§ 170.315(d)(8)	Remove	Effective date of final rule.
Trusted connection	§ 170.315(d)(9)	Remove	Effective date of final rule.
Auditing actions on health information	§ 170.315(d)(10)	Remove	Effective date of final rule.
Accounting of disclosures	§ 170.315(d)(11)	Remove	Effective date of final rule.
Encrypt authentication credentials	§ 170.315(d)(12)	Remove	Effective date of final rule.
Multi-factor authentication	§ 170.315(d)(13)	Remove	Effective date of final rule.
View, download, and transmit to 3rd party	§ 170.315(e)(1)	Revise	Effective date of final rule.
Patient health information capture	§ 170.315(e)(3)	Remove	Effective January 1, 2027.
Transmission to cancer registries	§ 170.315(f)(4)	Remove	Effective January 1, 2027.
Transmission to public health agencies—electronic case report- ing.	§ 170.315(f)(5)	Revise	Effective date of final rule.
Transmission to public health agencies—antimicrobial use and resistance reporting.	§ 170.315(f)(6)	Revise	Effective date of final rule.
Transmission to public health agencies—health care surveys ...	§ 170.315(f)(7)	Remove	Effective January 1, 2027.
Automated numerator recording	§ 170.315(g)(1)	Remove	Effective January 1, 2027.
Automated measure calculation	§ 170.315(g)(2)	Remove	Effective January 1, 2027.
Safety-enhanced design	§ 170.315(g)(3)	Remove	Effective date of final rule.
Quality management system	§ 170.315(g)(4)	Remove	Effective date of final rule.
Accessibility-centered design	§ 170.315(g)(5)	Remove	Effective date of final rule.
Consolidated CDA creation performance	§ 170.315(g)(6)	Remove	Effective date of final rule.
Application access—patient selection	§ 170.315(g)(7)	Remove	Effective January 1, 2027.
Application access—all data request	§ 170.315(g)(9)	Remove	Effective January 1, 2027.
Direct Project	§ 170.315(h)(1)	Remove	Effective date of final rule.
Direct Project, Edge Protocol, and XDR/XDM	§ 170.315(h)(2)	Remove	Effective date of final rule.

1. Clinical Certification Criteria

a. Patient Demographics

In the 2014 Edition Final Rule, we included “demographics” in the Base EHR definition in § 170.102 (77 FR 54265). We noted that including demographics in the Base EHR definition aligns with the statutory “Qualified EHR” definition and is intended to facilitate the recording, capture, and access to a patient’s demographic data. In the 2015 Edition Final Rule (80 FR 62602), we added the requirement to record, capture, and access a patient’s sex, sexual orientation, and gender identity for Health IT Modules certified to the demographics’ certification criterion

(§ 170.315(a)(5)) (80 FR 62747). The 2015 Edition Final Rule also defined a required set of standardized terminology to represent each of these data elements (80 FR 62618 through 62620).

In the HTI–1 Final Rule (89 FR 1428), we adopted USCDI v3, which includes data elements for Sex, Sexual Orientation, and Gender Identity. To ensure consistent capture of these data elements across health IT, we made updates to the data elements in § 170.315(a)(5) to incorporate the newly adopted data elements in USCDI v3. Specifically, these same data elements were adopted as “sex” (§ 170.315(a)(5)(i)(C)), “sexual orientation” (§ 170.315(a)(5)(i)(D)), and

“gender identity” (§ 170.315(a)(5)(i)(E)). To ensure consistency with our adoption of USCDI v3, we finalized the name change of the certification criterion in § 170.315(a)(5) from “demographics” to “patient demographics and observations” due to the inclusion of data elements based on clinical observations.

Additionally, in the HTI–1 Final Rule, we finalized the replacement of the specific concepts referenced in § 170.315(a)(5)(i)(D) and (E), sexual orientation and gender identity, respectively, with the SNOMED Clinical Terms U.S. Edition (SNOMED CT®) U.S. Edition code set, as referenced in the standard in § 170.207(o)(3). In

§ 170.315(a)(5)(C), sex, we finalized adoption that a Health IT Module enable sex to be recorded in accordance with the standard specified in § 170.207(n)(1) for the period up to and including December 31, 2025; or § 170.207(n)(2). The standards specified in § 170.207(n)(1) (sex) require that birth sex must be coded in accordance with HL7® Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor, up until the adoption of this standard expires January 1, 2026, attributed as follows: (i) Male. M; (ii) Female. F; (iii) Unknown. NullFlavor UNK. The code sets referenced in § 170.207(n)(1), as cross-referenced in § 170.315(a)(5)(i)(C), would expire on January 1, 2026, but we also stated that health IT developers could continue to use the specific codes referenced in § 170.207(n)(1) through December 31, 2025, to provide adequate time for Health IT Modules certified to the relevant certification criteria to transition to the updated terminology standards. Lastly, we finalized the addition of “sex parameter for clinical use” as a new data element in § 170.315(a)(5)(i)(F), “name to use” in § 170.315(a)(5)(i)(G), and “pronouns” in § 170.315(a)(5)(i)(H).

After publication of the HTI–1 Final Rule and our adoption of the revisions in § 170.315(a)(5), we began exercising enforcement discretion and issued certification guidance for the Certification Program regarding Health IT Module conformance with certain data elements in the patient demographics and observations certification criterion.¹⁴ In our enforcement discretion notice, we explained that § 170.550 requires an ONC–ACB, when certifying Health IT Modules, to certify in accordance with the applicable certification criteria adopted in regulation. Under this enforcement discretion and certification guidance, we noted that ASTP/ONC will not take any enforcement action under § 170.565 against an ONC–ACB based on non-compliance with § 170.550 for certifying a Health IT Module that is presented for certification to the patient demographics and observations certification criterion (§ 170.315(a)(5)) where the Health IT Module does not demonstrate conformance with any or all of the following data and observations in paragraph (a)(5)(i): sex parameter for clinical use, sexual orientation, gender identity, name to use, and pronouns; or does not demonstrate conformance with any or all of data and observations in

§ 170.315(a)(5)(i)(D) through (H). We also stated that ASTP/ONC will not take action against Health IT Modules certifying or currently certified to the patient demographics and observations certification criterion in § 170.315(a)(5) that only demonstrate, for conformance with paragraph (a)(5)(i)(C) (sex), that it can record sex in accordance with either the standard specified in § 170.207(n)(1) for the period up to and including December 31, 2025, or the SNOMED CT® U.S. Edition codes found in the standard specified in § 170.207(n)(2): 248152002 Female (finding) and 248153007 Male (finding).¹⁵ We noted that we would not exercise our direct review authority under § 170.580 for any non-conformity, potential or actual, that arises solely from a Health IT Module not demonstrating the capabilities specified in our enforcement discretion notice. We stated that the enforcement discretion and certification guidance will remain in effect for 12 months from the date of the notice or until the Department completes a regulatory action to revise the applicable regulations, whichever comes first.

We have reviewed the requirements in § 170.315(a)(5)(i) and have determined that removal of certain requirements in § 170.315(a)(5)(i) would result in burden reduction for health IT developers and cost savings associated with the (1) enforcement discretion and (2) ongoing maintenance costs affected by the proposed updates to the certification criterion. Accordingly, for these reasons and reasons discussed below, we propose the following revisions to § 170.315(a)(5)(i).

We propose to revise § 170.315(a)(5)(i)(C) to remove the reference to the standard in § 170.207(n)(1) (HL7 Administrative Gender and NullFlavor). As discussed above, in the HTI–1 Final Rule, we finalized that the adoption of the code sets referenced in § 170.207(n)(1) will expire on January 1, 2026. Beginning January 1, 2026, a Health IT Module certified to § 170.315(a)(5) is required to demonstrate, for conformance with paragraph (a)(5)(i)(C), that it can record sex in accordance with the SNOMED CT® U.S. Edition codes found in the standard specified in § 170.207(n)(2). Given the timing of publication of this proposed rule, the reference to § 170.207(n)(1) in § 170.315(a)(5)(i)(C) is outdated and no longer relevant. Therefore, we propose to remove the cross-reference to § 170.207(n)(1) in § 170.315(a)(5)(i)(C) because retaining

the reference may cause confusion for interested parties. Our proposed revision would keep the cross-reference to § 170.207(n)(2) in § 170.315(a)(5)(i)(C). We propose that to demonstrate conformance with § 170.315(a)(5), a Health IT Module would only need to demonstrate that it can record sex in accordance with either the 248152002 Female (finding) or 248153007 Male (finding) SNOMED CT® U.S. Edition codes found in the standard specified in § 170.207(n)(2). A Health IT Module would not need to demonstrate that it can record sex with any other code found in SNOMED CT® U.S. Edition.

We have reviewed and evaluated the data elements in § 170.315(a)(5)(i)(D) through (H) for consistency with our overall deregulatory approach, and we have determined that it is no longer necessary to include the paragraphs specified in § 170.315(a)(5)(i)(D) through (H) (*i.e.*, patient observations data) as part of the Certification Program. As part of this evaluation, we considered the general statutory requirement of the Qualified EHR definition (further implemented with the “Base EHR” definition in § 170.102) to capture patient demographics, which neither identifies demographic data elements nor requires certain demographic elements to be included in the definition. The removal of these elements would reduce burden by narrowing how many data elements are required for purposes of certification to the criterion and for meeting the Base EHR definition. This would produce cost savings for developers regulated under the Certification Program. Health IT developers would no longer need to support these data elements as part of the voluntary certification process including not only for initial certification but also for ongoing maintenance requirements over time. In this regard, we invite readers to review section VIII (Regulatory Impact Analysis) for a detailed discussion of our estimated impacts and cost savings associated with our proposed revisions in § 170.315(a)(5)(i). In addition, the observational data elements proposed for removal do not support the meeting of specific measures under the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category, and therefore, are not essential for inclusion in certified health IT that is used to meet the CEHRT definitions and support meeting measures under those programs. Lastly, we note that the proposed removal of the data elements in § 170.315(a)(5)(i)(D) through (H) aligns with our proposal

¹⁴ USCDI v3 Data Elements Enforcement Discretion | <https://www.healthit.gov/topic/uscdi-v3-data-elements-enforcement-discretion-notice>.

¹⁵ <https://www.healthit.gov/test-method/patient-demographics-and-observations>.

related to the removal of data elements from USCDI v3 and reflected in proposed USCDI v3.1 (see section III.B.1).

We propose a conforming name change of the certification criterion from “patient demographics and observations” to “patient demographics.” This revision is not a substantive change to certification requirements, but would return the certification criterion’s naming convention to as it was prior to the HTI–1 Final Rule, as well as acknowledge that the data described in § 170.315(a)(5) is understood to be demographic information. We note that our proposed revisions are limited to § 170.315(a)(5)(i), and we do not propose to revise the “inpatient setting only” requirements in § 170.315(a)(5)(ii). We welcome comments on these proposals.

b. Clinical Decision Support

We propose to remove the “clinical decision support” (CDS) certification criterion and reserve § 170.315(a)(9).

In 2012, we established a new set of requirements for Health IT Modules to support CDS. These requirements included capabilities to support evidence-based CDS based on a defined set of data elements; CDS configuration for both inpatient and ambulatory settings; and the display of source attribute or bibliographic citation of CDS (77 FR 54212). In the 2015 Edition Final Rule, we finalized an updated CDS certification criterion in § 170.315(a)(9) (80 FR 62622). In the HTI–1 Proposed Rule, we noted our belief that the continued evolution of decision support software, especially as it relates to AI or machine learning-driven Predictive DSIs, necessitates new requirements for the Certification Program’s CDS certification criterion (88 FR 23781).

In the HTI–1 Final Rule, we finalized an expiration date of January 1, 2025, for the CDS certification criterion in § 170.315(a)(9) and incorporate certain policies with modifications in the “decision support intervention” certification criterion in § 170.315(b)(11) (89 FR 1237). We finalized a conforming expiration date for the CDS certification criterion in the Base EHR definition in § 170.102. We noted that no action is required for developers relating to the expiration of § 170.315(a)(9) in the Base EHR. However, we also noted that developers with Health IT Modules certified to § 170.315(a)(9) wishing to maintain certification to the Base EHR definition, needed to update to the DSI certification criterion in § 170.315(b)(11) by December 31, 2024.

As of January 1, 2025, the CDS certification criterion in § 170.315(a)(9) is no longer available in the Certification Program. Therefore, we propose to remove and reserve § 170.315(a)(9). This proposal would be effective upon the effective date of a subsequent final rule. We welcome feedback on this proposal.

c. Family Health History

We propose to remove the “family health history” certification criterion and reserve § 170.315(a)(12). Health IT Modules certified to § 170.315(a)(12) must enable a user to record, change, and access a patient’s family health history in accordance with the familial concepts or expressions included in, at a minimum, the version of the standard in § 170.207(a)(1) (SNOMED CT®, U.S. Edition, March 2022 Release). This certification criterion is not included in the Base EHR definition but is included in the CEHRT definitions established by CMS for the Medicare Promoting Interoperability Program (42 CFR 495.4) and the MIPS Promoting Interoperability performance category (42 CFR 414.1305).

We adopted the family health history certification criterion in the 2015 Edition Final Rule as a revised iteration of the 2014 Edition family health history certification criterion adopted in § 170.314(a)(13) (80 FR 62624). In the 2014 Edition Proposed Rule, we proposed the first iteration of the family health history certification criterion to align with a Meaningful Use Stage 2 proposal (77 FR 13838). We solicited comment on whether we should adopt the HL7 Pedigree standard and/or the Systematized Nomenclature of Medicine—Clinical Terms (SNOMED CT® U.S. Edition) terms for familial conditions. We also sought comment on a tool produced by the HHS Office of the Surgeon General for capturing family health histories. In the 2014 Edition Final Rule, we finalized a certification criterion that required, at a minimum, that health IT must enable a user to record, change, and access information about a patient’s first degree relative within the said patient’s record (see also 77 FR 54174). We also finalized that health IT certified to § 170.314(a)(13) could meet this certification criterion by either being able to capture a patient’s family health history in SNOMED CT® U.S. Edition or in the HL7 Pedigree standard. We noted that because the use of SNOMED CT® U.S. Edition was required for meeting several other certification criteria, it would not be a challenge to meet the certification criterion. In the 2015 Edition Proposed Rule, we proposed

two separate certification criteria for family health history—one based on functionality according to the SNOMED CT® U.S. Edition standard and one based on functionality according to the HL7 Pedigree standard (80 FR 16822 through 16823). However, we only adopted the family health history certification criterion (§ 170.315(a)(12)) based on SNOMED CT® U.S. Edition, stating that the functionality should be available to providers for more comprehensive patient care (80 FR 62624).

In light of our overall deregulatory approach, we have determined that we should remove the family health history certification criterion in § 170.315(a)(12). The functionality of this certification criterion has been part of the Certification Program and associated with the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category (including prior iterations such as the EHR Incentives Programs and the CEHRT definitions) for over 12 years. As such, the functionality is embedded in certified health IT and has been widely adopted by hospitals and physicians due to participation in those programs.¹⁶ Further, similar to what we stated when we adopted the certification criterion, the ability to code to SNOMED® CT U.S. Edition (including the entire adopted version) is required to meet many of the remaining certification criteria, including those referencing the USCDI v3 and those criteria that would include the proposed USCDI v3.1 standard.¹⁷ These certification criteria included criteria that are in the Base EHR definition and not proposed for removal in this proposed rule. Therefore, we expect that many developers of certified health IT will still conform to the SNOMED CT® U.S. Edition and the functionality to code family health history with SNOMED CT® U.S. Edition will remain in certified health IT adopted by hospitals and physicians. Moreover, USCDI v6 includes a new Family Health History data element.¹⁸ We note that health IT developers can use the SVAP to voluntarily implement and become certified using the most recent National Coordinator-approved version of USCDI without waiting for ASTP/ONC to require that newer version via rulemaking (85 FR 25669). While USCDI v6 has not been adopted in regulation at

¹⁶ <https://www.healthit.gov/data/quickstats/national-trends-hospital-and-physician-adoption-electronic-health-records>.

¹⁷ We discuss USCDI v3.1 in section III.B.1.

¹⁸ <https://www.healthit.gov/isp/united-states-core-data-interoperability-uscdi#draft-uscdi-v6>.

this time, our expectations, as with every prior version of USCDI, are that USCDI v6 would go through the SVAP approval process and be approved for SVAP certification in 2026.

As noted above, the family health history certification criterion in § 170.315(a)(12) is included in the CEHRT definitions. Therefore, to provide sufficient time for CMS to update the CEHRT definitions to remove reference to the certification criterion, we propose a January 1, 2027, effective date for the removal of this certification criterion. We welcome comments on these proposals.

d. Implantable Device List

We propose to remove and reserve the “implantable device list” certification criterion in § 170.315(a)(14). The implantable device list certification criterion requires Health IT Modules certified to § 170.315(a)(14) to exchange, record, and allow a user to access a list of Unique Device Identifiers (UDIs) associated with a patient’s implantable devices. There is no adopted standard or implementation guide associated with this functionality. However, the implantable device list certification criterion is included in the Base EHR definition, and we propose a conforming revision in § 170.102 to remove § 170.315(a)(14) from the Base EHR definition (please see section III.C.1 of this proposed rule).

In the 2015 Edition Final Rule, we adopted § 170.315(a)(14) with the purpose of establishing a baseline functionality to support the exchange and use of UDIs in certified health IT (80 FR 62748). We explained that the need to exchange and have access to this information wherever patients seek care is broadly relevant to all clinical users of health IT, regardless of setting or specialty, so that they may know what devices their patients are using (or have used) and thereby prevent device-related adverse events and deliver safe and effective care (80 FR 62625 through 62627). We also stated that this need is most acute for implantable devices, which by their nature are difficult to detect and identify in the absence of reliable clinical documentation.

We acknowledged the challenges of fully implementing UDIs in health IT in the 2015 Edition Final Rule, yet believed our adoption of the certification criterion, as well as including the certification criterion in the 2015 Base EHR definition and a UDI data element in the 2015 CCDS definition, were important steps to support electronic exchange and use of UDIs (80 FR 62625 through 62626). In responding to comments on the 2015

Edition Proposed Rule, we recognized that fully implementing UDIs in health IT will take time and require addressing a number of challenges, so we adopted a certification criterion that focused narrowly on baseline health IT capabilities that developers could feasibly implement. We stated that these capabilities would provide the foundation for broader adoption and more advanced capabilities and use cases. This approach minimized the potential burden while maximizing the impact of this certification criterion for all stakeholders.

We have reviewed the implantable device list certification criterion in § 170.315(a)(14) and, as explained below, have determined that we have achieved our policy goals associated with the exchange and use of UDIs. In consideration of this outcome and our overall regulatory goals to reduce burden and offer flexibility to both health IT developers and health care providers, we propose to remove the implantable device list certification criterion and reserve § 170.315(a)(14).

First, we have achieved our stated policy goal of broad adoption of § 170.315(a)(14). As we explained in prior rulemakings, we believe in a foundational approach as the first step to broader adoption of health IT capabilities (80 FR 16824, 80 FR 62626). We added the implantable device list certification criterion to the 2015 Edition Base EHR definition in the 2015 Edition Final Rule. The Base EHR definition (2015 Edition and subsequent versions) is part of the CEHRT definitions under the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category.¹⁹ As such, health care providers participating in these programs are required to adopt health IT certified to the implantable device list certification criterion. As discussed earlier in this preamble, survey data indicates widespread adoption by hospitals and physicians of certified health IT products meeting the Base EHR definition, which includes Health IT Modules certified to the implantable device list certification criterion.²⁰ The widespread adoption of the implantable device list functionality is now well-established in health IT products, and we do not believe that removing the certification criterion from the Certification Program will result in health IT developers removing the functionality from their products, which

would likely be both a costly endeavor and counter to the interests of their customers (*i.e.*, hospitals and physicians).

Second, our proposed removal of the implantable device list certification criterion would reduce burden and costs. We have historically, where feasible and appropriate, taken measures to reduce burden within the Certification Program and make the Certification Program more effective, flexible, and streamlined. We believe our proposal to remove the implantable device list certification criterion would result in reduced burden, increased flexibility, and cost savings. Developers of certified health IT would have the flexibility to implement those functionalities supporting the exchange and use of UDIs that best meet the needs of their clients without additional regulatory burden, which could also lead to innovations in these and related functionalities.

Third, support for UDIs within certified health IT is incorporated into other Certification Program elements besides the implantable device list certification criterion. For example, UDIs are a required data element in USCDI v3, and the proposed USCDI v3.1 standard, as the “Unique Device Identifier(s) for a patient’s implantable device(s)” data element. We believe retaining a functional data capture certification criterion that requires the same information as the USCDI v3 standard supports (as part of key criteria enabling health information exchange) would be duplicative and unnecessary (we refer readers to section III.B.1 of this proposed rule for a discussion on the proposed USCDI v3.1).

We also note that in USCDI v6, published in July 2025, we adopted a significantly modified definition of the UDI data element to include non-implantable devices.²¹ Health IT developers can use SVAP to voluntarily implement and become certified using the most recent National Coordinator-approved version of USCDI without waiting for ONC to require that newer version via rulemaking (85 FR 25669). While USCDI v6 has not been adopted in regulation at this time, our expectations, as with every prior version of USCDI, are that USCDI v6 would go through the SVAP approval process and be approved for SVAP certification in 2026.

Therefore, we believe that some health IT developers may choose to voluntarily update relevant certified Health IT Modules to utilize USCDI v6

¹⁹ 42 CFR 495.4 and 42 CFR 414.130.

²⁰ <https://www.healthit.gov/data/quickstats/national-trends-hospital-and-physician-adoption-electronic-health-records>.

²¹ <https://www.healthit.gov/isp/united-states-core-data-interoperability-uscdi#draft-uscdi-v6>.

with the modified definition of the UDI data element. Such actions would provide for new data exchange capabilities to expand beyond the baseline functionality in § 170.315(b)(14). This proposal, if finalized, would be effective as of the effective date of a subsequent final rule. We welcome comments on this proposal.

2. Care Coordination Certification Criteria

a. Transitions of Care

We propose to revise the “transitions of care” certification criterion in § 170.315(b)(1) to simplify its requirements, with an effective date of January 1, 2027. We propose to reduce the scope of the criterion to focus on enabling the receipt of a Consolidated CDA (C-CDA) document as a way to position this criterion for a future evolution to receipt of FHIR-formatted data. The transitions of care criterion supports the structured transition of care summaries and referral summaries that help ensure continuity and care coordination as patients move between providers. In the 2014 Edition Final Rule, we finalized adoption of the C-CDA standard for this criterion because it accommodated formatting of a summary care record that included all of the data elements that CMS proposed be available for inclusion in a summary care record (77 FR 54217). We also stressed that an EHR technology’s ability to incorporate data for medications, medication allergies, and problems in structured form from a C-CDA document was the minimum necessary to meet this certification criterion and encouraged EHR technology developers to go beyond this minimum (77 FR 54219). Additionally, in the 2014 Edition Final Rule we included § 170.315(b)(1) in the Base EHR definition (77 FR 54265).

In the Cures Act Final Rule, we updated the transitions of care criterion’s data requirements to include USCDI v1 (85 FR 25667), and in the HTI-1 Final Rule we updated the data requirements to include USCDI v3 (89 FR 1298). We note that the certification criterion in § 170.315(b)(1) is currently associated with several measures under the Health Information Exchange Objective of the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category. Specifically, the certification criterion in § 170.315(b)(1) is specified as required for the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and

Reconciling Health Information measures and specified as an example of a criterion that may be used to support the actions of the Health Information Exchange (HIE) Bi-directional Exchange and Enabling Exchange under TEFCA measures.²²

We have reviewed and evaluated the transitions of care certification criterion in § 170.315(b)(1) in order to identify ways to reduce burden while still supporting our policy goals. As we noted in the S&CC January 2010 Interim Final Rule, we take an iterative approach to addressing the interoperability of health IT and consider factors such as maturity, market prevalence, and complexity of implementation to inform our adoption of standards and certification criteria (75 FR 2020). Our approach then and now is intended to be “pragmatic, but forward looking” and involves sustainable and incremental steps to harmonize current and future standards, as well as phase out standards and certification criteria when needed (75 FR 2021).

Several industry trends have led us to propose revising this certification criterion. First, FHIR supports the functionalities of a contemporary web-based architecture, using technologies such as RESTful APIs, JSON, and XML, making the standard more approachable to software developers and enabling easier integration with web-based and mobile applications than the C-CDA standard. Second, FHIR is a more granular data standard, enabling exchange of more discrete data concepts rather than entire documents. C-CDA is a document-centric standard that does not support retrieval of information at the data element level, which can lead to information overload during transitions of care. Finally, we believe that FHIR supports easier scalability to support real-time data exchange, which will support a broader ecosystem of health IT tools than C-CDA. Various capabilities, such as CDS Hooks, Subscriptions, and SMART Health Links, support new interoperability paradigms that are much more difficult to do using C-CDA. These trends notwithstanding, we remain cognizant that the C-CDA standard is widely adopted, and we anticipate its

continued use over the near-term, especially for transitions of care among health care delivery settings, such as inpatient and long-term and post-acute care.

In detail, we propose to revise the transitions of care certification criterion in § 170.315(b)(1) as of January 1, 2027. We propose to remove the requirements in § 170.315(b)(1)(i) “send and receive via edge protocol” and in § 170.315(b)(1)(iii) “create” and to simplify the requirements in § 170.315(b)(1)(ii) “validate and display” to focus on the ability to receive and validate C-CDA documents. We propose to remove the requirements in § 170.315(b)(1)(ii)(B) and (C). We also propose to move the requirements in § 170.315(b)(1)(ii)(A) “validate C-CDA conformance—system performance” to § 170.315(b)(1)(i) and to rename § 170.315(b)(1) to read “transitions of care—receive and validate.” Additionally, in § 170.315(b)(1)(ii)(A) we propose to remove the references to § 170.205(a)(3) and to replace the references to § 170.205(a)(5), which expires on January 1, 2026, with references to § 170.205(a)(6). We welcome feedback on these proposals.

b. Clinical Information Reconciliation and Incorporation

We propose to remove the “clinical information reconciliation and incorporation” certification criterion in § 170.315(b)(2) with an effective date of January 1, 2027, and to reserve that section. The clinical information reconciliation and incorporation (CIRI) certification criterion allows health care providers to reconcile and incorporate patient health information sent from external sources to maintain a more accurate and up-to-date patient record. The CIRI certification criterion is not currently included in the Base EHR definition; however, the criterion is required for the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure and specified as an example of a criterion that may be used to support the actions of the HIE Bi-Directional Exchange and Enabling Exchange under TEFCA measures in the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category.²³

Our requirements for CIRI in the Certification Program were first established in the S&CC January 2010 Interim Final Rule to enable a user to

²² See the “Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program” (CY 2026 PFS) Proposed Rule (90 FR 32352) Table 62, available at <https://www.federalregister.gov/d/2025-13271/p-3055andtheFY2026IPPS/LTCHPPS> Final Rule (90 FR 36536) Table X.F.–05 available at <https://www.federalregister.gov/d/2025-14681/p-4161>.

²³ See the CY 2026 PFS Proposed Rule Table 62, available at <https://www.federalregister.gov/d/2025-13271/p-3055andtheFY2026IPPS/LTCHPPS> Final Rule Table X.F.–05 available at <https://www.federalregister.gov/d/2025-14681/p-4161>.

electronically complete medication reconciliation of two or more medication lists (75 FR 2046). In the 2011 Edition Final Rule, we revised the certification criterion to require that Certified EHR Technology be capable of providing a user with the ability to electronically compare two or more medication lists (75 FR 44613). We expanded these requirements in the 2014 Edition Final Rule to require clinical information reconciliation for problems, medications, and medication allergies (77 FR 54289). In the 2014 Edition Release 2 Final Rule, we added incorporation requirements and adopted the updated CIRI certification criterion as an optional 2014 Edition certification criterion in § 170.314(b)(9) (79 FR 54438). In the 2015 Edition Final Rule, we finalized a revised 2015 Edition CIRI certification criterion in § 170.315(b)(2) (80 FR 62749), and we updated the related C-CDA standards for the certification criterion in § 170.315(b)(2) in both the Cures Act Final Rule (85 FR 25677) and the HTI-1 Final Rule (89 FR 1224).

We have reviewed and evaluated the CIRI certification criterion in § 170.315(b)(2), seeking to identify ways to reduce burden while still supporting our policy goals. As we have stressed in prior rulemaking, we take an incremental approach to improving health IT interoperability and performance, relying on factors such as market prevalence and industry readiness to harmonize current and future standards and phase out standards and certification criteria as needed (75 FR 2020). Our review of industry adoption of the CIRI certification criterion indicates widespread adoption. Review also indicates that its capabilities are widely implemented and used in health IT at this time and thus not likely to go away as supported capabilities by developers of certified health IT solely on the basis of removal of the criterion from the Certification Program²⁴ (see section

III.A for a discussion on “widely adopted” and “widely implemented”). We also have seen indications that removing the certification criterion from the Certification Program could spur greater development and innovation in this area. In conversations with developers and implementers, we have seen technology that innovates on CIRI, providing functionality beyond Certification Program requirements that supports direct incorporation of information received from trusted sources.

We have concluded that removing the CIRI certification criterion in § 170.315(b)(2) would reduce burden for health IT developers, such as testing and other burden associated with certification to this criterion, while still allowing ASTP/ONC to achieve our policy goals of supporting interoperability and access to quality EHI at the point of care. Additionally, we believe that removing this C-CDA-based certification criterion from the Certification Program would encourage movement toward FHIR-based standards which can further spur innovation and development in this area, improving interoperability and patient care. Because the certification criterion in § 170.315(b)(2) is a requirement for Promoting Interoperability measures, we believe a transition date for removal is needed. We propose a January 1, 2027, effective date for the removal of the CIRI certification criterion in § 170.315(b)(2). We welcome feedback on these proposals.

c. Security Tags—Summary of Care

We propose to remove the “security tags—summary of care—send” certification criterion in § 170.315(b)(7) and the “security tags—summary of care—receive” certification criterion in § 170.315(b)(8) and reserve those sections. Together, these certification criteria support the application and persistence of security labels for document-based exchange. The security tags—summary of care—send certification criterion in § 170.315(b)(7) enables a user to create a summary record that is tagged as restricted and subject to restrictions on re-disclosure, while the security tags—summary of care—receive certification criterion in § 170.315(b)(8) enables a user to receive a summary record that is tagged as restricted and subject to restrictions on re-disclosure. These criteria are not currently included in the Base EHR definition.

The certification criteria in § 170.315(b)(7) and (b)(8) were originally adopted in the 2015 Edition Final Rule as “data segmentation for

privacy” (DS4P) certification criteria and only required security tagging of C-CDA documents at the document level (80 FR 62646 and 62647). In the Cures Act Final Rule, we updated the requirements to support security tagging of C-CDA documents at the document, section, and entry levels (85 FR 25646).

We have reviewed the security tags—summary of care—send certification criterion in § 170.315(b)(7) and the security tags—summary of care—receive certification criterion in § 170.315(b)(8), evaluating how to reduce burden while still addressing policy priorities to support privacy protections in information exchange. As we have stated previously in this proposed rule, we consider factors such as market prevalence and the uptake in implementation of criteria by developers of health IT when making revisions to Certification Program certification criteria. Currently, 35 unique Health IT Modules are certified to the criterion in § 170.315(b)(7), and 36 unique Health IT Modules are certified to the criterion in § 170.315(b)(8), out of a total of 707 active and non-suspended certifications listed on the Certified Health IT Product List (CHPL), a comprehensive listing of all certified health IT successfully tested and certified under the Certification Program.²⁵ We believe that in this case the low number of Health IT Modules certified to these criteria indicate that the criteria may not be of sufficient value to health IT developers to warrant continued inclusion in the Certification Program. Additionally, as the industry moves toward greater use of FHIR-based standards, the removal of these C-CDA-based criteria in the Certification Program would help spur further innovation and advancement in this area.

We have concluded that removing the certification criteria in § 170.315(b)(7) and (8) would reduce burden for health IT developers and health care providers while still supporting our policy goals to support privacy protections in information exchange. We propose to remove the security tags—summary of care—send certification criterion in § 170.315(b)(7) and the security tags—summary of care—receive certification criterion in § 170.315(b)(8) as of the effective date of a final rule. We welcome feedback on these proposals.

d. Care Plan

We propose to remove the “care plan” certification criterion in § 170.315(b)(9) and reserve that section. This criterion

²⁴ Real World Testing results (accessible via <https://chpl.healthit.gov/>) for 2024 from three large EHR developers with significant market share in the United States attest to routine clinician use of Clinical Information Reconciliation and Incorporation (§ 170.315(b)(2)): Epic customers reconciled 66 million medications, 7 million allergies, and 40 million problems out of 135 million transition of care CCDs received; Oracle Health clinicians added ~491 k and rejected 2.69 million external medications per month, evidencing active review; and MEDITECH's Expanse product processed 17 million CCD Retrieve Document Set exchanges with a 99.67% success rate. Given that Epic, Oracle (Cerner), and MEDITECH together provide the majority of EHR systems used in the U.S., these findings indicate that CIRI capabilities are broadly adopted and meaningfully used in clinical care.

²⁵ <https://chpl.healthit.gov/> search conducted June 2025.

helps improve coordination of care by providing a structured format for documenting patient information such as goals, health concerns, health status evaluations, and interventions. The criterion is not currently included in the Base EHR definition. The certification criterion in § 170.315(b)(9) was first adopted in the 2015 Edition Final Rule and required a Health IT Module to enable a user to record, change, access, create, and receive care plan information in accordance with the C-CDA Release 2.1 standard in § 170.205(a)(4) (80 FR 62648). We updated the criterion in the Cures Act Final Rule to also require the HL7 CDA® R2 Implementation Guide: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2 standard in § 170.205(a)(5) (85 FR 25943). In the HTI-1 Final Rule, we updated the criterion to require the HL7 CDA® R2 Implementation Guide: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2 standard in § 170.205(a)(5) for the time period up to and including December 31, 2025, or the C-CDA Companion Guide Release 4.1 standard in § 170.205(a)(6) (89 FR 1224).

We have evaluated the care plan certification criterion in § 170.315(b)(9) with a goal of reducing burden on health IT developers and health care providers while still achieving our policy priorities. Currently, 54 unique Health IT Modules are certified to the criterion in § 170.315(b)(9) out of a total of 707 active and non-suspended certifications listed on the CHPL. We believe this may indicate low interest by health IT developers in certifying to this criterion.²⁶ As discussed previously in this proposed rule, the industry is moving away from C-CDA-based standards to the use of FHIR-based standards that offer greater flexibility and potential for innovation. ASTP/ONC recently highlighted the development of FHIR-based care plan IGs, including the Multiple Chronic Condition eCare Plan and the Electronic Long Term Services & Support Care Plan IGs, in a January 2025 standards bulletin.²⁷ Additionally, input from industry has indicated that the care plan document type is less frequently adopted than other C-CDA document types, and where it is utilized, health IT developers are not likely to cease supporting the functionality if the

criterion is removed from the Certification Program.

We have concluded that removing the certification criterion in § 170.315(b)(9) would reduce burden for health IT developers and health care providers while still supporting our goals. Additionally, as discussed previously, moving away from C-CDA-based requirements in the Certification Program would help promote greater innovation and advancement in this area. We propose to remove the care plan certification criterion in § 170.315(b)(9) as of the effective date of a final rule. We welcome feedback on these proposals.

e. Decision Support Interventions

We propose to revise the “decision support interventions” (DSI) certification criterion in § 170.315(b)(11). The DSI certification criterion ensures that users can leverage health IT for clinical decision-making by supporting their selection of both evidence-based and predictive DSIs and enabling users’ access to transparent information on DSI performance and quality. In the HTI-1 Final Rule, we adopted the DSI certification criterion in § 170.315(b)(11) as both an update and replacement criterion for the CDS certification criterion in § 170.315(a)(9) (89 FR 1236). We also added § 170.315(b)(11) to the Base EHR definition in the HTI-1 Final Rule (89 FR 1197). When we finalized the DSI certification criterion in the HTI-1 Final Rule, we cited E.O. 14091 on Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (February 16, 2023), which addressed bias in AI, and E.O. 14110 on Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence (October 30, 2023), which addressed the risks of AI (89 FR 1232). These EOs were revoked in E.O. 14148 on Initial Rescissions of Harmful Executive Orders and Actions (January 20, 2025).

We have reviewed and evaluated the DSI certification criterion in § 170.315(b)(11), focusing on ways to reduce burden while still supporting our policy priorities. As we have noted previously in this proposed rule and in prior rulemakings, we consider factors such as standards maturity, market adoption, and complexity of implementation when adopting, revising, or phasing out standards and certification criteria (75 FR 2020). Currently, the requirements in § 170.315(b)(11) reference data expressed in the USCDI standards in § 170.213. We have received feedback from developers of certified health IT

that requiring support of predictive DSIs that use *any* data element in one of the USCDI standards in § 170.213 has proven burdensome and costly to implement, with questionable value. While many USCDI data elements are routinely used in decision support and would be important inputs to predictive DSI, other USCDI data elements, such as phone number and phone number type data elements, are not likely to be used as inputs.

We propose to revise the DSI certification criterion in § 170.315(b)(11) as detailed below as of the effective date of a subsequent final rule. We propose to remove the requirement in § 170.315(b)(11)(ii)(B) to enable interventions when a patient’s medications, allergies and intolerance, and problems are incorporated from a transition of care or referral summary received and pursuant to paragraph § 170.315(b)(2)(iii)(D). As described above in section III.A.2.b, we propose to remove § 170.315(b)(2), which is a C-CDA-based criterion, from the Certification Program completely as of January 1, 2027. Thus, we propose to remove the requirement in § 170.315(b)(11)(ii)(B), which references § 170.315(b)(2), as well. We also propose to redesignate the certification criterion currently in § 170.315(b)(11)(ii)(C) as § 170.315(b)(11)(ii)(B).

We propose to remove the parenthetical reference in § 170.315(b)(11)(iii) to “drug-drug and drug-allergy contraindication checking” upon the effective date of a final rule. We have retained the “drug-drug, drug-allergy interaction checks for CPOE” certification criterion in § 170.315(a)(4), and in order to simplify overall Certification Program requirements, we do not believe it is necessary to reference this capability as part of decision support functionality in § 170.315(b)(11)(iii). We note that this reference was initially included as part of the revisions made to the Certification Program’s decision support certification criterion (then referenced in § 170.314(a)(8)) in 2012 (see 77 FR 54215). Since this time, the Certification Program has taken deliberate actions to support a more modular marketplace for health IT (see 84 FR 7428, 89 FR 63567 through 63568, and 90 FR 37158). Removal of this specified capability within § 170.315(b)(11) to support drug-drug and drug-allergy contraindication checking furthers this goal of modularity without precluding support for such interaction checks, due to the retention of requirements in § 170.315(b)(11)(iii)(A)(2) and (3) regarding enabling evidence-based DSIs that include “Medications” and

²⁶ <https://chpl.healthit.gov/> search conducted June 2025.

²⁷ https://www.healthit.gov/topic/standards_bulletin_25-1.

“Allergies and Intolerances,” respectively, as data types.

Additionally, we propose to revise the requirements in § 170.315(b)(11)(iii)(B), which currently relate to enabling predictive DSIs that use any data expressed in the standards in § 170.213, to limit the application of the certification criterion to just data expressed in § 170.315(b)(11)(iii)(A) as well as data expressed in the Clinical Notes and the Assessment and Plan of Treatment data classes in the standards in § 170.213. While we originally wanted to apply the requirements of this certification criterion to any data expressed in the standards in § 170.213 in order to reflect our focus on the USCDI and the variety of data for which DSIs may be enabled, we believe a number of USCDI data elements are not likely to be used as inputs, as mentioned above. We believe that revising the requirements to focus on fewer data elements would significantly reduce burden for health IT developers without diminishing users’ ability to select (*i.e.*, activate) a wide variety of predictive DSIs that use remaining USCDI data elements as inputs.

Finally, we propose to remove the requirements in § 170.315(b)(11)(iv) and (v) regarding source attribute support, access, and modification and in § 170.315(b)(11)(vi) regarding intervention risk management for predictive DSIs. In addition to reducing burden, removal of these requirements would comply with E.O. 14179 on Removing Barriers to American Leadership in Artificial Intelligence (January 23, 2025). E.O. 14179 calls for the review of regulations and other actions taken pursuant to revoked E.O. 14110, and any actions taken that are inconsistent with the policy set forth in E.O. 14179 to “sustain and enhance America’s global AI dominance in order to promote human flourishing, economic competitiveness, and national security”²⁸ shall be suspended, revised, or rescinded as appropriate and consistent with applicable law.²⁹ Despite proposing source attribute information transparency and intervention risk management more than six months prior to issuance of E.O. 14110,³⁰ we note that many of our fundamental assumptions and objectives were aligned with the stated

goals of E.O. 14110 to advance “safe, secure, and trustworthy development and use of artificial intelligence.”

Additionally, we note several factors supporting the proposal to modify the DSI certification criterion. First, developers of certified health IT have reported that during care delivery, most clinical users lack the time or technical background to engage with source attribute information for either evidence-based DSIs or predictive DSIs supplied by the developer of certified health IT.³¹ Despite having access to source attribute information since the beginning of 2025, when Health IT Modules certified to § 170.315(b)(11) began to be first deployed, we have no publicly available evidence indicating that a single doctor, nurse, or administrator has accessed, recorded, or modified a single source attribute. Further, we have no publicly available evidence that transparency requirements in § 170.315(b)(11) have led to positive impacts on patient care, such as removing deficient or untested algorithms, or testing a deployed algorithm on local data. We believe that the underlying assumption that source attribute information would be valuable to health care delivery organizations and health care professionals when deciding whether to implement or use a DSI (as stated in the HTI–1 Final Rule)³² was incorrect.

Second, transparency regarding how a predictive or generative AI application was designed, developed, tested, evaluated, and should be used may not have the savings and benefits we anticipated. As described in the regulatory impact analysis (RIA) to the HTI–1 Final Rule, we estimated considerable benefits from this policy (89 FR 1411), noting that transparency into AI applications would result in health care delivery organizations selecting and using more accurate AI applications. We quantified associated benefits for two illustrative cases, sepsis detection and ambulatory care sensitive admissions (89 FR 1412 through 1414), estimating that our policies would result in a 10-year savings of up to \$3 billion for the sepsis use case through increased application of more sensitive predictive models for this condition. We have not encountered supporting evidence or published research indicating that

source attribute transparency requirements in § 170.315(b)(11)(iv) have improved health care delivery organizations’ evaluation and effective use of AI. We understand that the benefits articulated in the HTI–1 Final Rule impact analysis are not being realized.

Third, developers of certified health IT have reported an inconsistent approach to oversight of other parties producing similar, health-based AI systems.³³ They note that “[t]he current model of imposing rigorous requirements [*i.e.*, algorithmic transparency and risk management]] on certified health IT but not the many other tech companies working in this space is simply unacceptable and needs to be remedied.”³⁴ While we attempted to encourage more consistent and ubiquitous transparency requirements across similar applications in our April 2023 proposals for predictive DSI in the HTI–1 Proposed Rule (88 FR 23782), and have worked with federal partners on alignment with similar policy objectives since finalization of the HTI–1 Final Rule in January 2024,^{35 36} we acknowledge that our authorities have limitations that inhibit our collective efforts to treat similar technologies similarly under a single Department-wide policy.

Finally, in order to promote innovation of AI in health care, we propose to remove transparency and risk management requirements established in the HTI–1 Final Rule. Additionally, we have heard from health IT developers that the requirements are burdensome and detrimental to such innovation and growth, which is the opposite of our stated policy intent to optimize the ubiquitous use of high-quality AI in health care.

For these and the aforementioned reasons, we propose to remove all requirements related to source attributes in § 170.315(b)(11)(iv), their access in § 170.315(b)(11)(v)(A), and their modification in § 170.315(b)(11)(v)(B), as well as requirements to manage risks related to the development and deployment of predictive DSIs supplied by health IT developers as part of their product in § 170.315(b)(11)(vi). We welcome comments on these proposals.

²⁸ <https://www.federalregister.gov/d/2025-02172/p-3>.

²⁹ **Federal Register**: Removing Barriers to American Leadership in Artificial Intelligence (90 FR 8741).

³⁰ <https://www.federalregister.gov/documents/2023/04/18/2023-07229/health-data-technology-and-interoperability-certification-program-updates-algorithm-transparency-and>.

³¹ See letter to Acting Assistant Secretary for Technology Policy, Acting National Coordinator for Health Information Technology Posnack, April 16, 20215: <https://www.ehra.org/sites/ehra.org/files/EHR%20Association%20Letter%20to%20ASTP-ONC%20-%20Certification%20Program%20Deregulatory%20Suggestions.pdf#page=7>.

³² See 88 FR 23780 at <https://www.federalregister.gov/d/2023-07229/p-547>.

³³ <https://www.ehra.org/sites/ehra.org/files/EHR%20Association%20Letter%20to%20ASTP-ONC%20-%20Certification%20Program%20Deregulatory%20Suggestions.pdf#page=7>.

³⁴ *Ibid.*

³⁵ See 89 FR 1264 for discussion of alignment with FDA policies.

³⁶ See 89 FR 37643 for discussion of alignment with OCR policies.

3. Clinical Quality Measures Certification Criteria

a. Clinical Quality Measures—Report

We propose to revise the “clinical quality measures—report” certification criterion in § 170.315(c)(3) as of the effective date of a final rule. We propose to remove the requirement in § 170.315(c)(3)(ii), as this provision may no longer be used to support certification to the criterion. In the Cures Act Interim Final Rule, we revised § 170.315(c)(3) to include a corrected compliance transition timeline for the criterion in § 170.315(c)(3)(ii), which specified the use of standards in § 170.205(h)(2) and in § 170.205(k)(1) and (2), for the period before December 31, 2022 (85 FR 70075, 70083). We propose to remove paragraph § 170.315(c)(3)(ii) because that transition time period has elapsed. We also propose to move the requirements in § 170.315(c)(3)(i) to § 170.315(c)(3), thus removing all subparagraphs and including all criterion requirements in the main paragraph for § 170.315(c)(3). We welcome comments on our proposal.

b. Clinical Quality Measures—Filter

We propose to remove the “clinical quality measures—filter” certification criterion in § 170.315(c)(4) with an effective date of January 1, 2027. This certification criterion assesses whether a Health IT Module can filter quality data based on a set of standardized data elements for electronic clinical quality measures (eCQM) calculated using certified health IT.

In the Voluntary Edition Proposed Rule, we proposed a new certification criterion in § 170.315(c)(4) that would require health IT to record structured data allowing CQM results to be grouped by patient characteristics (79 FR 10903 and 10904).³⁷ We proposed this capability to support eCQM reporting by group practice or accountable care organization (ACO). We also proposed capturing patient characteristics that support identification of health disparities, that help providers identify gaps in quality, and that support delivery of specialized care to needful patient subgroups. We did not adopt this certification criterion in the 2014 Edition Release 2 Final Rule as we received comments

recommending refinement of the use cases and performance of more analysis on which data elements are being captured in standardized ways (79 FR 54462).

In the 2015 Edition Proposed Rule (80 FR 16844) we proposed to add § 170.315(c)(4) as a new certification criterion for CQM filtering based on the rationale that health IT should support an organization’s ability to filter individual and aggregate eCQM results in ways that support administrative reporting, identification of health disparities, and identification of gaps in care.

In the 2015 Edition Final Rule, we adopted the “CQMs—filter” certification criterion in § 170.315(c)(4), along with three other CQM certification criteria: “CQMs—record and export” (§ 170.315(c)(1)), “CQMs—import and calculate” (§ 170.315(c)(2)), and “CQMs—report” (§ 170.315(c)(3)) (80 FR 62649 through 62655). Together, these four criteria were adopted to support providers’ quality improvement activities and to support reporting to programs such as the EHR Incentive Programs, Quality Payment Program, and Comprehensive Primary Care plus initiative.

The 2015 Edition Final Rule adopted § 170.315(c)(4) as a new 2015 Edition certification criterion that supports the capability of a clinician to filter eCQM results using data captured for quality improvement and quality reporting purposes. We finalized that Health IT Modules certified to § 170.315(c)(4) must be able to: record data and filter CQM results at both patient and aggregate levels; filter by any combination of the data elements established as part of the criterion with associated vocabulary standards; create a data file of the filtered data in accordance with the QRDA Category I and Category III standards; and display the filtered data in a human readable format.

This certification criterion is not included in the Base EHR definition in § 170.102 but is included in the CEHRT definition for MIPS in 42 CFR 414.1305 as an optional criterion. While we recognize the value of this functionality, we propose to remove this criterion for multiple reasons. We reviewed and evaluated existing regulations to identify deregulatory actions that would reduce administrative burden, and the private expenditures required for compliance with federal regulations. We have identified that the administrative costs of certification for the CQMs—filter certification criterion are no longer offset by the benefits of advancing the specific functionality supported by the

criterion. Further, we do not believe that quality measure filtering functionality would be removed from health IT systems because of our proposal to remove this criterion.

Quality reporting programs, such as those required by states and CMS programs, require broader supplemental data and capabilities beyond what we currently require for certification. In addition, health IT developers have widely implemented technology solutions that expand beyond the baseline requirements of the certification criterion (see section III.A for a discussion on “widely implemented”). Through listening sessions with a wide range of health care provider types and sites of service, public correspondence, and CHPL data, we understand that the use of the CQMs—filter certified functionality is fairly low relative to the other certification criteria that support clinical quality measure capabilities. According to CHPL data, as of August 2025, there are 340 active Health IT Modules certified to § 170.315(c)(1), (2), or (3), but only 71 active Health IT Modules certified to § 170.315(c)(4). Among the feedback we have received, health care providers participating in CMS alternative payment models, as well as health IT developers supporting quality initiatives, have reported that they have different options to filter eCQM results, including using customized systems and/or the support of third parties to support innovative, specialty-specific quality measurement and reporting tailored to their particular needs. We therefore believe the value of maintaining this certification criterion is minimal as health IT developer time and resources would be better spent on quality data system modernization efforts leveraging FHIR-based APIs for quality data exchange.

We therefore propose to remove the certification criterion in § 170.315(c)(4) as of January 1, 2027.

4. Privacy and Security Certification Criteria

We propose to remove all the privacy and security certification criteria in § 170.315(d) and the associated Privacy and Security Certification Framework under § 170.550(h) as of the effective date of a subsequent final rule.

We first adopted a version of the privacy and security certification criteria currently found in § 170.315(d) (and associated standards) in the 2011 Edition through an interim final rule (75 FR 2033 through 2035). These certification criteria originated from HIT Policy Committee and HIT Standards Committee recommendations. The

³⁷ Practice site and address; Tax Identification Number (TIN), National Provider Identifier (NPI), and TIN/NPI combination; diagnosis; primary and secondary health insurance, including identification of Medicare and Medicaid dual eligible; demographics including age, sex, preferred language, education level, and socioeconomic status.

criteria generally focused on basic technical capabilities that could be included in the development of Health IT Modules that would be certified. We used the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Security Rule (45 CFR 164 parts 160 and 164, subparts A and C) as the starting point for the Certification Program's privacy and security certification criteria, with the intent of ensuring that Certified EHR Technology (now referred to as "certified health IT") included at least one capability to assist a HIPAA covered entity with complying with HIPAA Security Rule requirements. The initial criteria also included a certification criterion ("accounting of disclosures") to support entities regulated under HIPAA that must provide an accounting of disclosures of protected health information³⁸ made in certain circumstances.³⁹ We noted, however, that the interim final rule strictly focused on the capabilities of Certified EHR Technology and did not change existing HIPAA Privacy Rule or Security Rule requirements, guarantee compliance with those requirements, or absolve an eligible professional, eligible hospital or other health care provider from having to comply with any applicable provision of the HIPAA Privacy or Security Rules. In addition, we stated that, while the capabilities provided by Certified EHR Technology may assist an eligible professional, eligible hospital in improving their technical safeguards, the use of Certified EHR Technology alone does not equate to compliance with the HIPAA Privacy or Security Rules. We stated that the capabilities provided by Certified EHR Technology do not in any way affect the analysis that an entity regulated by HIPAA is required to perform by 45 CFR 164.306(b) and (d) (75 FR 2035).

With the 2014 Edition, we included the privacy and security certification criteria in the Base EHR definition in an attempt to provide both developers and health care providers more flexibility in meeting Certification Program requirements, while still providing health care providers with basic technical options that could support compliance with parts of the HIPAA Privacy and Security Rules (77 FR 54265). Based on recommendations from the HIT Standards Committee, we established a third privacy and security certification approach under § 170.550(h) for the new 2015 Edition so

that each certification criterion also had a set of separate privacy and security certification criteria attributed to them that were applicable to the criterion's functionality (80 FR 62705 through 62707). In doing so, we established the current Privacy and Security Certification Framework, which has been in place for the past 10 years. Under this framework, health IT developers have two options for meeting requirements: build the capabilities themselves natively into their certified health IT; or provide system documentation to demonstrate that the certified health IT could integrate (via service interfaces) with required privacy and security capabilities (80 FR 62707).

We have come to the conclusion that, despite the Certification Program providing various certification flexibilities and approaches to accommodate the privacy and security certification criteria (*i.e.*, different approaches for the 2011, 2014 and 2015 Editions), the costs and burden of these Certification Program requirements far exceed their intended purpose and benefits.

First, we have found that health IT developers have changed their development processes to build in privacy and security capabilities to meet these certification requirements rather than attempting to demonstrate that their technology could interface with other health IT that provides these capabilities. This has led to negative experiences for health care providers who have sought to use a best-of-breed, non-certified security technology to work across their deployed enterprise (*e.g.*, a third-party audit log).

Second, as certified health IT (which is generally EHR-focused technology) is often implemented in enterprise-wide settings (*e.g.*, group practices, large health care systems, multi-provider cloud-supported services), such certified health IT cannot in isolation, or independently, provide the necessary privacy and security capabilities for HIPAA Security Rule compliance across all relevant technologies of the enterprise-wide setting.

Third, while certified health IT has always been "linked" to the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category, those programs have not required participating health care providers to use or implement the privacy and security capabilities included in certified health IT for purposes of meeting the security risk analysis measure. Rather, the health care providers must "have" such certified health IT. As such and as discussed in more detail below, health

care providers participating in the Medicare Promoting Interoperability Program or the MIPS Promoting Interoperability performance category are required to adopt certified capabilities that they may not use because, for example, they may prefer a non-certified security health IT product to meet their overall security needs under relevant HIPAA Security Rule requirements.

Fourth, many stakeholders have overinterpreted the Certification Program's limited scope and policy purpose with respect to health IT security and instead assumed that the Certification Program assessed discrete specific security capabilities at significant depths, such as when and how the capabilities are implemented in health care provider or system settings. For example, stakeholders have expressed incorrect expectations of certified health IT and developers, such as expectations that the Certification Program required health IT developers of certified health IT to implement and conduct penetration testing of certified health IT or ensure that certified authentication and authorization capabilities protect against known or unknown vulnerabilities. In contrast, and to allow for significant scalable deployment flexibility, certified health IT must only, for example, demonstrate support for basic authentication and role-based access control.

Finally, there remains a disconnect between health IT certified to the privacy and security certification criteria under the Certification Program and the implementation and compliance responsibilities of most purchasers and users of certified health IT with the HIPAA Privacy and Security Rule requirements. This disconnect has led to the introduction of unnecessary regulatory burden and duplication, as well as unwarranted opportunity costs for innovation. As we noted above and in our rulemakings related to the privacy and security certification criteria, the adoption of health IT certified to the privacy and security certification criteria does not guarantee compliance with the HIPAA Privacy and Security Rule requirements. Further, the adoption of health IT certified to the privacy and security certification criteria does not serve as an affirmative defense, has not been identified as a mitigating factor in assessing HIPAA civil money penalties, and does not exempt a HIPAA-regulated entity from having to comply with any applicable provision of the HIPAA Privacy or Security Rules. These facts alone have created unnecessary burden for health care providers that adopt

³⁸ 45 CFR 160.103 (definition of "protected health information").

³⁹ 42 U.S.C. 17935(c), sec. 13405(c) of the American Recovery and Reinvestment Act of 2009, Public Law 111-5, 123 Stat. 265 (Feb. 17, 2009); 45 CFR 164.528.

certified health IT and health IT developers of certified health IT that also meet the definition of a covered entity or business associate, respectively, and are subject to the HIPAA Privacy and Security Rules.⁴⁰ In fact, we have heard from stakeholders both arguing that our certification requirements go beyond the HIPAA Security Rule requirements (75 FR 44619, 80 FR 62707) or do not go far enough in meeting HIPAA Privacy Rule and Security Rule requirements (80 FR 62691, 62706). As such, our Certification Program requirements are diverting financial resources and efforts from innovative, agile, and comprehensive solutions that can address the threats faced by health care providers and meet their regulatory obligations under the HIPAA Privacy and Security Rules. By removing the privacy and security certification requirements under the Certification Program, we will provide health IT developers with the flexibility to innovate in this area and to develop new solutions to address the needs of their customers. Such an approach should also spur competition and give health care providers, including small practices, the opportunity to choose the best privacy and security technologies that fit their needs at the best price versus being forced to accept those capabilities included in certified health IT that may not fit their health information privacy and security needs for various reasons.

We will continue to collaborate with our colleagues in HHS to promote privacy and security and to strengthen the nation's critical health care infrastructure. Equally, we are not completely foregoing the adoption of privacy and security capabilities within the Certification Program. Instead, going forward, we intend to prioritize the adoption of privacy and security capabilities that are fit for purpose, use case specific, and deliver much needed technical consistency in the market when paired with specific conformance requirements. For example, as we pursue more API-focused certification criteria, if the standards and implementation guides adopted for them do not specify or leave optional specific security requirements, we may look to add further constraints (*e.g.*, multi-factor authentication support). But in all cases, we intend to make security capability conformance a built-in part of a certification criterion's conformance and not the separate and stand-alone conformance assessment

that it is today. With this planned approach in mind, we also request comment on an alternative proposal as discussed below.

In lieu of removing, on the effective date of a subsequent final rule, all of the privacy and security certification criteria in § 170.315(d) and the associated Privacy and Security Certification Framework under § 170.550(h), we would retain the “auditable events and tamper resistance” (§ 170.315(d)(2)), “audit report(s)” (§ 170.315(d)(2)), and “auditing actions on health information” (§ 170.315(d)(10)) certification criteria and associated Privacy and Security Certification Framework certification requirements. These certification criteria and included functionality may serve to help identify fraud and abuse. The functionality may also support health care provider compliance obligations and investigations by relevant entities, including both civil and criminal matters at the federal and state levels. Identifying and addressing fraud and abuse increases confidence in the nation's health care system, reduces inappropriate and wasteful spending, and protects taxpayer dollars when it comes to government spending on health care.

We welcome feedback on these proposals.

5. Patient Engagement Certification Criteria

a. View, Download, and Transmit to a 3rd Party

We propose to revise the “view, download, and transmit to 3rd party” (VDT) certification criterion in three ways as described below. These proposed revisions, if finalized, would be effective as of the effective date of a subsequent final rule.

We first included the Web Content Accessibility Guidelines (WCAG 2.0) standard as a requirement of the view, download, and transmit to 3rd party (VDT) certification criterion (§ 170.315(e)(1)) in the 2014 Edition. Specifically, the VDT certification criterion viewing capability required conformance to WCAG Level A (77 FR 54179). This provided an accessibility baseline for health IT certified to the criterion. With the 2015 Edition, we proposed compliance with WCAG Level AA (as we did for the 2014 Edition) but finalized a policy that gave developers the option of demonstrating conformance with either Level A or Level AA to meet the certification requirements (80 FR 62660).

We now propose to remove the WCAG conformance requirement from the certification criterion (found in § 170.315(e)(1)(i)). As noted above, the WCAG baseline certification standard of Level A was adopted with the 2014 Edition in 2012 and has been part of the VDT certification criterion since that time. The functionality is now sufficiently widespread among certified health IT and health care providers who adopt such technology. This is true because the VDT certification criterion has been part of the CEHRT definitions and specifically supports the patient access measure under the Medicare Promoting Interoperability Program and MIPS Promoting Interoperability performance category since the 2014 Edition. By removing the WCAG certification requirement, health IT developers of health IT currently certified to § 170.315(e)(1) will have the opportunity to consider other innovative ways to provide patients with the viewing functionality. To this point, commenters noted in response to the 2014 Edition WCAG proposals that most patients want functions and content provided in a more visually appealing manner than the WCAG standard allows. Further, as we noted in the 2011 Edition Interim Final Rule and again in response to comments on the 2011 Edition Interim Final Rule, in providing patients with access to their online health information, the accessibility requirements of the Americans with Disabilities Act of 1990 and Section 504 of the Rehabilitation Act of 1973 still apply to entities covered by these federal civil rights laws (75 FR 2036, 75 FR 44643). In addition, Section 1557 of the Patient Protection and Affordable Care Act (Affordable Care Act) prohibits covered entities from subjecting individuals to certain forms of discrimination, including on the grounds prohibited by Section 504 of the Rehabilitation Act, in any health program or activity.⁴¹ Health IT developers and other health programs or activities who receive Federal financial assistance under the Certification Program or other federal programs likely qualify as covered entities⁴² under Section 1557 and would be required to comply with applicable accessibility requirements. Under Section 504 of the Rehabilitation Act, recipients of financial assistance from HHS must conform to certain accessibility requirements, including but not limited to using the WCAG 2.1

⁴¹ [https://www.ecfr.gov/current/title-45/part-92#p-92.4\(Health%20program%20or%20activity\)](https://www.ecfr.gov/current/title-45/part-92#p-92.4(Health%20program%20or%20activity)).

⁴² [https://www.ecfr.gov/current/title-45/part-92#p-92.4\(Covered%20entity\)](https://www.ecfr.gov/current/title-45/part-92#p-92.4(Covered%20entity)).

⁴⁰ 45 CFR 160.103 (definitions of “covered entity” and “business associate”).

AA success criteria for web content and mobile applications, as detailed in 45 CFR 84.82 through 84.89. Additionally, under Section 508 of the Rehabilitation Act (Pub. L. 93–112; Sep. 26, 1973), HHS must ensure the information and communication technology it develops, procures, maintains, or uses, allows comparable access and use for people with disabilities, including by conforming to the success criteria of WCAG 2.0 AA. See 29 U.S.C. 794d; 36 CFR part 1194. As such, we expect health IT developers will continue to meet these requirements and provide the necessary accessibility within their products certified to the VDT certification criterion.

We also propose to remove the VDT requirement in § 170.315(e)(1)(ii)(A)(2) to conform with any Network Time Protocol (NTP) standard for purposes of “date and time each action occurred” under the activity log. In the HTI–1 Final Rule, we revised the requirement from conformance with the Network Time Protocol v4 of the RFC 5905 standard to compliance with *any* Network Time Protocol standard (89 FR 1283; § 170.210(g)). As a result, health IT could be certified by demonstrating that it could use any NTP to synchronize clocks for time accuracy. However, we have received feedback over the years from developers stating that the requirement should not be part of certification because the functionality was not native to the EHR technology (rather part of the operating system within which the EHR technology runs) and was unnecessary for certification because EHRs use of underlying operating system clocks is commonplace (88 FR 23811). Consistent with our overall goal to reduce regulatory burden, we agree that there is currently little value, and unnecessary burden, in maintaining the conformance requirement as part of certification. We do not expect that developers will stop using NTP with their certified health IT. Rather, we expect that developers will continue to use NTPs, such as Microsoft’s MS–SNTP, due to ongoing evolution in the industry.

We propose to remove and reserve § 170.315(e)(1)(i)(A)(1) because the requirement has an expiration date of December 31, 2025, which expires by the time a subsequent final rule will be issued. Additionally, we similarly propose to revise § 170.315(e)(1)(i)(B)(1) and (2) to remove references to § 170.205(a)(5) because the standard codified in this paragraph also has an expiration date of December 31, 2025. Finally, we propose to provide a heading for the paragraph at § 170.315(e)(1)(i), which would be

“general.” This would align the paragraph with similar level paragraphs that have headings (§ 170.315(e)(1)(ii) and (iii)) and would be compliant with the Office of the Federal Register Drafting Handbook.

We welcome comments on these proposals.

b. Patient Health Information Capture

We propose to remove the “patient health information capture” certification criterion in § 170.315(e)(3) with an effective date of January 1, 2027, and to reserve that section. The patient health information capture certification criterion allows health care providers to incorporate unstructured patient generated health data or data from a non-clinical setting into a patient record. The criterion is not currently included in the Base EHR definition; however, the criterion is included in CEHRT definitions established by CMS for the Medicare Promoting Interoperability Program (42 CFR 495.4) and the MIPS Promoting Interoperability performance category (42 CFR 414.1305).

The patient health information capture certification criterion was first adopted in the 2015 Edition Health IT Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications Final Rule (80 FR 62602). The criterion replaced the § 170.314(a)(17) advance directives and applied to various patient health information documents (80 FR 62661). In the 2015 Edition Final Rule, we stated that a Health IT Module would need to enable a user to: (1) identify (*e.g.*, label health information documents as advance directives and birth plans), record (capture and store) and access (ability to examine or review) patient health information documents; (2) reference and link to patient health information documents; and (3) record and access information directly and electronically shared by a patient. This criterion was specifically included in the CEHRT definition to ensure, at a minimum, providers participating in the EHR Incentive Programs (now the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category) had this capability.

The intent of the criterion is to establish at least one means for accepting patient health information directly and electronically from patients in the most flexible manner possible (80 FR 62662). The criterion did not define the types of health information that could be accepted as we believed it should be as broad as possible and

could be documents or health information from devices or applications. The devices and applications could include home health or personal health monitoring devices, fitness and nutrition applications, or a variety of other devices and applications. In addition, patient health information could be accepted directly and electronically through a patient portal, an API, or even email (80 FR 62662). As adopted, we anticipated health IT developers would develop innovative and efficient ways to meet this criterion and simultaneously support providers accepting health information from patients.

We have reviewed and evaluated the patient health information capture certification criterion in § 170.315(e)(3), seeking to identify ways to reduce burden while still supporting our policy goals. As we have stressed in prior rulemaking, we take an incremental approach to improving health IT interoperability and performance, relying on factors such as market prevalence and industry readiness to harmonize current and future standards and phase out standards and certification criteria as needed (75 FR 2021). Our review of industry adoption of the patient health information capture certification criterion has found that the capabilities described in the criterion are widely implemented (as discussed above in section III.A) and used in health IT at this time, suggesting that these capabilities will remain in health IT products even if the corresponding criterion is removed from the Certification Program. We also have seen indications that removing the criterion from the Certification Program could spur greater development and innovation in this area.

We have concluded that removing the patient health information capture certification criterion in § 170.315(e)(3) on January 1, 2027, would reduce administrative burden as well as burden for health IT developers of certified health IT and health care providers while still allowing us to achieve our policy goals. There are other certification criteria that support patient engagement, such as the 2015 Edition view, download, and transmit to 3rd party and “API” certification criteria. We have seen developers integrate the functionality in the patient health information capture certification criterion as part of other patient engagement features, such as patient portals. With these considerations in mind, we believe removing this criterion from the Certification Program will help reduce burden and costs, while also spurring further innovations

in patient engagement. Because the certification criterion in § 170.315(e)(3) is a requirement for CEHRT definitions established by CMS, we believe a transition date is needed. Therefore, we propose to remove the patient health information capture certification criterion in § 170.315(e)(3) effective January 1, 2027. We welcome feedback on this proposal.

6. Public Health Certification Criteria

a. Transmission to Cancer Registries

We propose to remove the “transmission to cancer registries” certification criterion in § 170.315(f)(4) with an effective date of January 1, 2027, and reserve that section. This criterion assesses whether a Health IT Module can properly create and format cancer case information for electronic transmission according to a CDA-based implementation specification for reporting to public health agencies. In the 2014 Edition Final Rule, we expanded the public health-related standards and certification criteria to include a criterion for transmission to cancer registries in § 170.314(f)(6) that we designated as optional for Complete EHR certification (77 FR 54195). We stated that we proposed this criterion to support a new meaningful use objective and measure for reporting cancer cases to cancer registries (77 FR 54194). In the 2015 Edition Final Rule, we finalized a revised transmission to cancer registries criterion in § 170.315(f)(4) which was no longer labeled as optional and required updated standards (80 FR 62666), and in the HTI–1 Final Rule we further updated the associated vocabulary standards (89 FR 1208). The standards currently referenced in the criterion include the Health Level 7 (HL7®) Implementation Guide for CDA® Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1, DSTU Release 1.1, April 2015 in § 170.205(i)(2), the SNOMED CT®, U.S. Edition, March 2022 Release in § 170.207(a)(1), and the Logical Observation Identifiers Names and Codes (LOINC®) Database Version 2.72, February 16, 2022 in § 170.207(c)(1). In the Meaningful Use Stage 3 Final Rule, the transmission to cancer registries certification criterion was identified as one of the criteria that eligible professionals could utilize to report the Public Health Registry measure in the EHR Incentive Programs (80 FR 62882). Subsequently, CMS stated that this criterion could be used to report on the Public Health Registry measure that was included in the MIPS Advancing Care Information performance category (later

renamed the MIPS Promoting Interoperability performance category) (81 FR 77236). Currently, MIPS eligible clinicians that report on the Public Health Registry measure may earn optional bonus points for submitting this data.⁴³

We have reviewed and evaluated the transmission to cancer registries certification criterion in § 170.315(f)(4), seeking to identify ways to reduce burden while still supporting our policy goals. We recognize trends within the industry that support removal of this criterion. Of note, there is specific work being done to move cancer registry reporting from CDA to FHIR through the Helios FHIR Accelerator and updates to the Central Cancer Registry Reporting IG in support of more efficient tumor abstract completion and supportive harmonization and standardization of data elements through USCDI+ Cancer.⁴⁴ Given the movement toward these promising modernization efforts that rely on FHIR rather than CDA, we anticipate health IT developers will find maintaining CDA development support to be both duplicative and a significant burden.

We believe that removing the certification criterion in § 170.315(f)(4) would reduce burden and encourage the ongoing evolution in cancer registry reporting by offering health IT developers space to move toward FHIR standards and modern reporting solutions, further encouraging innovation. We propose a January 1, 2027, effective date for the removal of the transmission to cancer registries certification criterion in § 170.315(f)(4). We welcome feedback on these proposals.

b. Transmission to Public Health Agencies—Electronic Case Reporting

We propose to revise the “transmission to public health agencies—electronic case reporting” (eCR) certification criterion in § 170.315(f)(5). This criterion enables a user to create case reports that can be transmitted electronically to public health agencies. In the 2015 Edition Final Rule, we included a new certification criterion in § 170.315(f)(5) with functional requirements to support the electronic transmission of case reporting information to public health agencies (80 FR 62667). When we originally proposed this criterion, we highlighted several goals, including linking EHR data with other data in a

structured way in order to improve quality, safety, population health, and research, as well as making case reporting from providers to public health agencies more efficient (80 FR 16855). In the 2015 Edition Final Rule, we noted commenter concerns with the proposed standards and recommendations that case reporting continue as a public health reporting option for the EHR Incentive Programs, but without a requirement to use a particular standard (80 FR 62667). We further noted ongoing advancements in FHIR standards and stated that in order to permit flexibility and accommodate evolution, we would not finalize a required standard (80 FR 62667).

In the HTI–1 Final Rule, we finalized a policy to require support for either a FHIR or CDA standard in order to provide technical design flexibility while still supporting the existing CDA-based landscape, and we established a transition period from functional requirements to standards-based requirements (89 FR 1227). Specifically, we finalized requirements in § 170.315(f)(5)(ii) to create case reports consistent with either the HL7 FHIR eCR IG in § 170.205(t)(1) or the HL7 CDA eCR IG in § 170.205(t)(2), and to receive, consume, and process a case report response formatted to either the HL7 FHIR eCR IG in § 170.205(t)(1) or the HL7 CDA RR IG in § 170.205(t)(3) (89 FR 1227). We stated that we would continue monitoring the development of standards for case reporting, and that as FHIR-based standards advanced we intended to transition solely to a FHIR-based approach for case reporting in future rulemaking (89 FR 1227). We also stated in the HTI–1 Final Rule, in response to comments that technology used by public health agencies may not be able to accept incoming FHIR-based reports, that we understood commenters’ “concerns related to performance, scalability, and maintenance, and will monitor standards development and implementation to inform future rulemaking” (89 FR 1229).

Consistent with E.O. 14192, ASTP/ONC published the “Electronic Case Reporting Certification Criterion Enforcement Discretion Notice” on July 31, 2025.⁴⁵ The enforcement discretion notice stated that for calendar year 2025, ASTP/ONC will not exercise its direct review authority for any non-conformity arising solely from certified health IT not complying with the standards in § 170.315(f)(5) as long as the health IT

⁴³ See the CY 2026 PFS Proposed Rule Table 60, available at <https://www.federalregister.gov/d/2025-13271/page-32744>.

⁴⁴ <https://build.fhir.org/ig/HL7/fhir-central-cancer-registry-reporting-ig/index.html>.

⁴⁵ <https://www.healthit.gov/topic/electronic-case-reporting-certification-criterion-enforcement-discretion-notice>.

remains conformant with either § 170.315(f)(5)(i) or with requirements in § 170.315(f)(5)(ii) as specified in the notice. The requirements in § 170.315(f)(5)(ii) specified in the enforcement discretion notice include requirements to: consume and process case reporting trigger codes and identify a reportable patient visit or encounter based on a match with a trigger code value set (*e.g.*, table); create a case report; receive, consume, and process a case report response; and, transmit a case report electronically to a system capable of receiving a case report. Additionally, the enforcement discretion notice stated that for calendar year 2025, ASTP/ONC will not take any enforcement action against an ONC-ACB for certifying a Health IT Module that is presented for certification to § 170.315(f)(5) where the Health IT Module demonstrates and maintains conformance with § 170.315(f)(5)(i) or the requirements in § 170.315(f)(5)(ii) as specified above. For calendar year 2026, the enforcement discretion notice stated that ASTP/ONC will not exercise its direct review authority for any non-conformity arising solely from certified health IT not complying with the standards in § 170.315(f)(5)(ii) as long as the health IT remains conformant with the requirements in § 170.315(f)(5)(ii) as specified above. The enforcement discretion notice also stated that for calendar year 2026, ASTP/ONC will not take any enforcement action against an ONC-ACB for certifying a Health IT Module that is presented for certification to § 170.315(f)(5) where the Health IT Module demonstrates and maintains conformance to the requirements in § 170.315(f)(5)(ii) as specified above. The enforcement discretion notice stated that it remains in effect until December 31, 2026, or until the Department completes a deregulatory action to revise § 170.315(f)(5).

We have reviewed and evaluated the transmission to public health agencies—electronic case reporting certification criterion in § 170.315(f)(5) with a focus on reducing burden while still supporting our policy priorities. We understand from developers of certified health IT that there may be issues with readiness to adopt these standards as well as concerns regarding the performance, scalability, or maintenance of these standards. We also note that the § 170.315(f)(5) certification criterion is required to complete the Electronic Case Reporting measure in the MIPS Promoting Interoperability performance category and the Medicare

Promoting Interoperability Program.⁴⁶ We note that in the CY 2026 PFS Final Rule, CMS finalized a policy to suppress the measure for performance for MIPS eligible clinicians meeting the requirements of the MIPS Promoting Interoperability performance category for the CY 2025 performance period, and eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program for the EHR reporting period in CY 2025 (90 FR 49892).

We propose to revise the eCR certification criterion to be a functional requirement in order to reduce burden and allow for industry innovation. In particular, we propose to rescind the expiration date for the functional requirements defined in § 170.315(f)(5) as of the effective date of a subsequent final rule. We propose to revise the introductory text of the criterion to enable a user to create a case report for electronic transmission meeting the functional requirements described in paragraph (f)(5)(i) of this section. Additionally, we propose to remove the standards-based requirements defined in § 170.315(f)(5)(ii) as of the effective date of a subsequent final rule and reserve that section. We welcome feedback on these proposals.

c. Transmission to Public Health Agencies—Antimicrobial Use and Resistance Reporting

We propose to revise the “transmission to public health agencies—antimicrobial use and resistance reporting” certification criterion in § 170.315(f)(6). This criterion assesses whether Health IT Modules can create and properly format an antimicrobial use and resistance report for electronic transmission, following specified sections of a CDA-based implementation guide. In the 2015 Edition Final Rule, we expanded the public health-related standards and certification criteria to include a new criterion for transmission of antimicrobial use and resistance reporting data to public health registries (80 FR 62668). We stated in the 2015 Edition Final Rule that the antimicrobial use and resistance reporting data is only collected by CDC rather than at the jurisdictional level (80 FR 62668). The transmission to public health agencies—antimicrobial use and resistance reporting certification criterion currently references the Health Level 7 (HL7®) Implementation Guide for CDA®

⁴⁶ See the CY 2026 PFS Proposed Rule Table 62, available at <https://www.federalregister.gov/d/2025-13271/p-3055> and the FY2026 IPPS/LTCH PPS Final Rule Table X.F.-05 available at <https://www.federalregister.gov/d/2025-14681/p-4161>.

Release 2—Level 3: Healthcare Associated Infection (HAI) Reports, Release 1, U.S. Realm, August 2013 standard in § 170.205(r)(1) and only requires conformance to certain sections of the implementation guide. The § 170.315(f)(6) certification criterion is required for completing the Antimicrobial Use Surveillance and Antimicrobial Resistance Surveillance measures in the Medicare Promoting Interoperability Program for eligible hospitals and CAHs.⁴⁷

We have reviewed and evaluated the transmission to public health agencies—antimicrobial use and resistance reporting certification criterion in § 170.315(f)(6) with a focus on achieving burden reduction while still supporting our policy goals. We have identified trends within the industry regarding a shift in reporting approach that supports revision of this criterion.⁴⁸ As CDC works to move reporting to FHIR-based standards,⁴⁹ we believe maintaining an outdated CDA-based standard in the criterion would impose regulatory burden on health IT developers that are seeking to support FHIR-based approaches to reporting. We propose to revise the criterion requirements to be functional only and remove the reference to the standard in § 170.205(r)(1) as of the effective date of a subsequent final rule. This would reduce administrative and development burden by allowing progress in line with other use cases, the use of more recent standards, and modern approaches to reporting. We note that, as with other criteria that include solely functional requirements, use of a specific standard would not be required to meet the proposed requirements of the criterion.

We believe that revising the certification criterion in § 170.315(f)(6) to functional requirements only would reduce burden and allow for standards advancement and adoption of FHIR-based reporting to move more quickly. We welcome feedback on these proposals.

d. Transmission to Public Health Agencies—Health Care Surveys

We propose to remove the “transmission to public health agencies—health care surveys”

⁴⁷ See the FY2026 IPPS/LTCH PPS Final Rule Table X.F.-05 available at <https://www.federalregister.gov/d/2025-14681/p-4161>.

⁴⁸ <https://stacks.cdc.gov/view/cdc/118849#:~:text=July%2027%2C%202021,2021%20Export%20RIS%20Citation%20Information>.

⁴⁹ For information on CDC's National Healthcare Safety Network (NHSN) antimicrobial use and resistance reporting options see <https://www.cdc.gov/nhsn/psc/aur/index.html>.

certification criterion in § 170.315(f)(7) with an effective date of January 1, 2027. This criterion supports the transmission of health care surveys directly to the CDC. In the 2015 Edition Final Rule, we expanded the public health-related standards and certification criteria to include a new criterion for transmission of health care surveys to public health agencies (80 FR 62669). We clarified in the 2015 Edition Final Rule that the finalized implementation guide for this criterion is intended for the transmission of survey data for both the National Ambulatory Medical Care Survey (NAMCS) and the National Hospital Ambulatory Medical Care Survey (NHAMCS) (80 FR 62668). We also clarified that templates included in the implementation guide align with the CDA standard (80 FR 62668). We stated in the 2015 Edition Final Rule that data covered by this criterion will only be collected by the CDC rather than at the jurisdictional level (80 FR 62669). The certification criterion in § 170.315(f)(7) currently references the Health Level 7 (HL7®) Implementation Guide for CDA® Release 2: National Health Care Surveys (NHCS), Release 1—US Realm, Draft Standard for Trial Use, December 2014 standard in § 170.205(s)(1). We note that the § 170.315(f)(7) certification criterion is optional to complete the Public Health Registry measures in the MIPS Promoting Interoperability performance category and the Medicare Promoting Interoperability Program.⁵⁰

We have reviewed and evaluated the transmission to public health agencies—health care surveys certification criterion in § 170.315(f)(7) with a goal of reducing burden while still supporting our policy priorities. We are also seeking to align with CDC priorities around data modernization and encouraging the use of FHIR-based approaches. The removal of this criterion would encourage industry to modernize and scale their reporting approach alongside CDC's efforts.

We believe that removing the certification criterion in § 170.315(f)(7) would reduce burden while at the same time honor our policy goals to ensure health IT interoperability and functionality. Hospitals and clinicians have been actively submitting these surveys for over a decade and continue to meet the technical requirements set by CDC, even when these requirements

outpace the certification criteria.⁵¹ We propose a January 1, 2027, effective date for the removal of the transmission to public health agencies—health care surveys criterion in § 170.315(f)(7). We welcome feedback on these proposals.

7. Design and Performance Certification Criteria

a. Automated Numerator Recording

In the 2015 Edition Final Rule (80 FR 62669), we adopted a certification criterion in § 170.315(g)(1) that requires the capability to create a report or file that enables a user to review the patients or actions that would make the patient or action eligible to be included in the numerator of a percentage-based measure in the MIPS Promoting Interoperability performance category and the Medicare Promoting Interoperability Program. We first adopted this capability for the 2014 edition in § 170.314(g)(1) to complement the “automated measure calculation” certification criterion to support the associated meaningful use objectives in the EHR Incentive Programs. In the Cures Act Final Rule (85 FR 25708), we updated the references to the EHR Incentive Programs in the criterion to reflect CMS' updates to the name of the Programs, which are now the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category.

We propose to remove the “automated numerator recording” certification criterion and reserve § 170.315(g)(1). We have reviewed and evaluated the certification criterion in § 170.315(g)(1), seeking to identify ways to reduce burden while still supporting our policy goals. Health IT developers that facilitate customer participation in the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category have been supporting the recording of numerator data associated with the measures and its previous iterations for many years. CMS establishes the measures and provides any additional information about how the numerator should be recorded through rulemaking and subsequent communications. ASTP/ONC uses the measure specifications established by CMS to develop testing procedures for health IT developers to certify their products to the automated numerator recording certification criterion. Certification of health IT to record the actions of the numerator has played an important role in ensuring health IT developers consistently implemented the measures

established by CMS. However, we believe that developers now have significant experience with implementing CMS requirements, and they will continue to ensure that the measures are recorded in a fashion that meets CMS requirements to ensure that their customers can successfully participate in the absence of additional testing requirements under the ONC Health IT Certification Program. If our removal of the automated numerator recording certification criterion is finalized as proposed, we will work with CMS to ensure relevant guidance and materials for existing measures is consolidated as part of the informational materials that CMS maintains regarding measures in the Medicare Promoting Interoperability Program and MIPS Promoting Interoperability performance category.

We believe that removing the certification criterion in § 170.315(g)(1) will reduce administrative burden, as well as burden for health IT developers and health care providers while still allowing us to achieve our policy goals. Because the certification criterion in § 170.315(g)(1) is specified in the definitions of CEHRT established by CMS for the Medicare Promoting Interoperability Program (42 CFR 495.4) and the MIPS Promoting Interoperability performance category (42 CFR 414.1305), we believe that a transition date is needed. Therefore, we propose to remove the automated numerator recording certification criterion as of January 1, 2027, and reserve § 170.315(g)(1). We welcome comments on this proposal.

b. Automated Measure Calculation

In the 2015 Edition Final Rule (80 FR 62669 through 62670), we adopted the “automated measure calculation” certification criterion in § 170.315(g)(2) that requires the capability to record the numerator and denominator and create a report including the numerator, denominator, and resulting percentage associated with each applicable measure in the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category. This capability was first adopted as a 2011 Edition certification criterion to support the associated meaningful use stage 1 objectives and subsequently adopted in the 2014 Edition in § 170.314(g)(2) (77 FR 54184). In the Cures Act Final Rule (85 FR 25708), we updated the references to the EHR Incentive Programs in the certification criterion to reflect CMS' updated names for the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability

⁵⁰ See the CY 2026 PFS Proposed Rule Table 62, available at <https://www.federalregister.gov/d/2025-13271/p-3055> and the FY2026 IPPS/LTCH PPS Final Rule Table X.F.-05 available at <https://www.federalregister.gov/d/2025-14681/p-4161>.

⁵¹ See <https://build.fhir.org/ig/HL7/fhir-health-care-surveys-reporting-ig/>.

performance category. In the HTI–2 Final Rule (89 FR 101809), we inadvertently removed and reserved § 170.315(g)(2) due to an amendatory instruction drafting error. We corrected this error through a technical correction in the HTI–4 Final Rule published on August 4, 2025, which was included in the CY26 CMS IPPS/LTCH PPS Final Rule as a rider (90 FR 37182).

We now propose to remove the “automated measure calculation” certification criterion and reserve § 170.315(g)(2) with an effective date of January 1, 2027. We have reviewed and evaluated the certification criterion in § 170.315(g)(2), seeking to identify ways to reduce burden while still supporting our policy goals. As with the automated numerator recording certification criterion discussed above, health IT developers that facilitate customer participation in the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category have been supporting the calculation of measures in the program and its previous iterations for many years. CMS establishes these measures and provides any additional information about how the measures should be calculated through rulemaking and subsequent program communications. ASTP/ONC uses the measure specifications established by CMS to develop testing procedures for health IT developers to certify their products to the automated measure calculation certification criterion. Certification of health IT for measure calculation has played an important role in ensuring health IT developers consistently implemented the measures established by CMS. However, we believe that developers now have significant experience with implementing CMS requirements, and that they will continue to ensure that the measures are calculated in a fashion that meets CMS requirements to ensure that their customers can successfully participate in the absence of additional testing requirements under the Certification Program. If our removal of the automated measure calculation certification criterion is finalized as proposed, we will work with CMS to ensure relevant guidance and materials for existing measures is consolidated as part of the informational materials that CMS maintains regarding measures in the Medicare Promoting Interoperability Program and MIPS Promoting Interoperability performance category.

We believe that removing the certification criterion in § 170.315(g)(2) will reduce administrative burden for health IT developers that support customer participation in the Medicare

Promoting Interoperability Program and MIPS Promoting Interoperability performance category. Because the certification criterion in § 170.315(g)(2) is specified in the definitions of CEHRT in 42 CFR 414.1305 and 495.4 and currently required for reporting of Promoting Interoperability measures, we believe that a transition date is needed. Therefore, we propose to remove and reserve the automated measure calculation certification criterion in § 170.315(g)(2) as of January 1, 2027. We welcome comments on this proposal.

c. Safety Enhanced Design

We propose to remove the “safety-enhanced design” certification criterion in § 170.315(g)(3) and the reference to this certification criterion in § 170.550(g)(1) as of the effective date of a final rule for this proposed rule. The safety-enhanced design certification criterion specifies the user-centered design (UCD) testing that must be applied to certain health IT capabilities submitted for certification. Certification to this certification criterion is conditional as its scope and applicability depends on the other certification criteria for which a Health IT Module is presented for certification. Section 170.315(g)(3) prescribes specific requirements for how certified capabilities are designed or made available to users. For example, during the design and development of certified health IT, developers are required to apply UCD processes to the capabilities reference in § 170.315(g)(3). This certification criterion is not included in the Base EHR definition in § 170.102 or the definition of CEHRT established by CMS in 42 CFR 414.1305 and 42 CFR 495.4.

In the 2014 Edition Proposed Rule (77 FR 13842), we provided an overview of the International Organization for Standardization’s (ISO) definition of usability and outlined that EHR technology certification could introduce some improvements that we believed would enhance both the safety and efficiency of CEHRT. This position mirrored statements made by interested parties regarding a gap between optimal usability and the usability offered by some EHR technologies at that time. In November 2011, the Institute of Medicine (IOM) called on the Secretary of HHS to specify the quality and risk management process requirements that health IT vendors must adopt, with a particular focus on human factors, safety culture, and usability. In the 2014 Edition Proposed Rule, we proposed to focus on the process of UCD to improve overall usability. We prioritized eight

certification criteria⁵² and associated capabilities to which the proposed certification criterion would require UCD to be applied. We chose these eight because we believed they posed the greatest risk for patient harm, and therefore, the greatest opportunity for error prevention. We also noted that the methods for how an EHR technology developer could employ UCD are well defined in documents and requirements such as ISO 9241–11, ISO 13407, ISO 16982, and NISTIR 7741. Our proposed approach sought to enable EHR technology developers to choose their UCD approach and not to prescribe specific UCD processes that would be required to meet this certification criterion. We also proposed in the 2014 Edition Proposed Rule (77 FR 13843), that testing to this certification criterion would require EHR technology developers to document that their UCD incorporates all the data elements defined in the Customized Common Industry Format Template for EHR Usability Testing (NISTIR 7742).⁵³ We noted that with respect to demonstrating compliance with this certification criterion that this information would need to be available to an ONC–ACB for review. Finally, we indicated that this documentation would become a component of the publicly available testing results on which a certification is based.

In the 2014 Edition Final Rule (77 FR 54187 through 54190), we adopted § 170.314(g)(3) as proposed, specifying that UCD must be applied to each capability of an EHR technology that is associated with the eight certification criteria named in the safety-enhanced design certification criterion. In addition, we finalized that the information from the NISTIR 7742 was required to be submitted for each of the criteria specified in the 2014 Edition safety-enhanced design certification criterion.

In the 2014 Edition Release 2 Final Rule, we revised the safety-enhanced design certification criterion in to include three CPOE certification criteria (79 FR 54436) and the clinical information reconciliation and incorporation (CIRI) certification criterion (79 FR 54439).

In the 2015 Edition Proposed Rule (80 FR 16856), we proposed to adopt a 2015

⁵² § 170.314(a)(1) (CPOE); § 170.314(a)(2) (drug-drug, drug-allergy interaction checks); § 170.314(a)(6) (medication list); § 170.314(a)(7) (medication allergy list); § 170.314(a)(8) (clinical decision support); § 170.314(a)(16) (electronic medication administration record); § 170.314(b)(3) (electronic prescribing); and § 170.314(b)(4) (clinical information reconciliation).

⁵³ http://www.nist.gov/manuscript-publication-search.cfm?pub_id=907312.

Edition safety-enhanced design certification criterion that reflected updates to the 2014 Edition safety-enhanced design criterion. We proposed to include 17 certification criteria (seven of which were new) in the 2015 Edition safety-enhanced design certification criterion. For each of the referenced certification criteria and their corresponding capabilities presented for certification, we proposed to require that UCD processes must be applied to satisfy the certification criterion. For the 2015 Edition safety-enhanced design criterion, we further proposed to add more specificity around requirements for the information that must be provided to demonstrate compliance with this certification criterion. For instance, we proposed in § 170.315(g)(3)(ii) that information must be submitted on the specific UCD processes used. We further proposed in § 170.315(g)(3)(iii) that a health IT developer must submit information about and findings of the UCD testing conducted for each of the criteria specified in the 2015 Edition safety-enhanced design certification criterion. We proposed that this information would become part of the test results publicly available on CHPL.

In the 2015 Edition Final Rule (80 FR 62670), we adopted the proposed safety-enhanced design certification criterion with modifications. Modifications included adopting a reduced list of criteria for inclusion in the safety-enhanced design certification criterion⁵⁴ and adopting the requirement that ONC-ACBs certify Health IT Modules to § 170.315(g)(3) consistent with the requirements included in the certification criterion.

We anticipate the removal of this criterion would reduce costs and burden for health IT developers and health care providers. For example, when pursuing certification, health IT developers must recruit a minimum of ten participants, conduct the necessary testing, and submit metrics for each certification criterion, for which they seek certification, that is referenced within § 170.315(g)(3). We refer readers to section VIII (Regulatory Impact Analysis) of this proposed rule for more

detailed information on cost estimates of safety-enhanced design and potential cost savings. In addition to reducing costs and burden for health IT developers, we anticipate that removing this certification criterion would allow health IT developers to redirect time and resources towards more innovative approaches to support and improve safety-enhanced design in their products. Additionally, we no longer believe that this certification criterion provides the same benefit to the regulatory burden profile that it did when first adopted over ten years ago. In contrast, its presence in the Certification Program has led to instances where administrative processes to fulfill its requirements have delayed health IT developers from achieving product certifications without added improvements in user-centered design. In short, this certification criterion's impact has diminished since it was first adopted. Moreover, compared to its burden, we have seen little use of the transparent reporting associated with this certification criterion (§ 170.523(f)(1)(xix)).

Consistent with E.O. 14192, “Unleashing Prosperity Through Deregulation,” and the reasons we stated above, we believe it is appropriate to remove this certification criterion. Therefore, we propose to remove the safety-enhanced design certification criterion in § 170.315(g)(3) and the reference to this certification criteria in § 170.550(g)(1) as of the effective date of a subsequent final rule. We welcome comments on our proposal.

d. Quality Management System

We propose to remove the “quality management system” (QMS) certification criterion in § 170.315(g)(4) and the reference to this certification criteria in § 170.550(g)(2) as of the effective date of a final rule for this proposed rule. The QMS certification criterion states for each capability that a technology includes and for which that capability's certification is sought, the use of a QMS in the development, testing, implementation, and maintenance of that capability must be identified and satisfied in one of the following ways: either the QMS used is established by the Federal government or a standards developing organization (SDO) or the QMS used is mapped to one or more QMS established by the Federal government or SDOs. Per § 170.550(g), this certification criterion is mandatory for all certified Health IT Modules.

The 2014 Edition Proposed Rule (77 FR 13842) referenced a report by the

Institute of Medicine (IOM) in which IOM recommended that we “[establish] quality management principles and processes in health IT.” Accordingly, we stated that we were considering including in the final rule an additional certification criterion that would require an EHR technology developer to document how their EHR technology development processes either align with, or deviate from, certain quality management principles and processes (77 FR 13843).

In the 2014 Edition Final Rule, we adopted a new quality management system certification criterion in § 170.314(g)(4) that was intended as a first step to focus on QMS and build on it in an incremental fashion (77 FR 54191). We finalized that all EHR technology certified to the 2014 Edition certification criteria would need to be certified to this certification criterion. In addition, we revised § 170.550 to require that, when certifying EHR Modules to the 2014 Edition EHR certification criteria, ONC-ACBs must certify EHR Modules to this certification criterion.

In the 2015 Edition Proposed Rule (80 FR 16858), we proposed a revised version of the QMS certification criterion in § 170.315(g)(4). We proposed to require the identification of the QMS used in the development, testing, implementation, and maintenance of capabilities certified under the Certification Program. We proposed that for a Health IT Module to be certified, the identified QMS must be compliant with a quality management system established by the Federal government or an SDO, or mapped to one or more quality management systems established by the Federal government or SDOs. In the 2015 Edition Final Rule (80 FR 62672), we adopted the proposed version of the QMS certification criterion in § 170.315(g)(4). In addition, we revised § 170.550 to require ONC-ACBs to certify Health IT Modules to the new criterion in § 170.315(g)(4) when certifying to the 2015 Edition.

When we initially proposed this certification criterion in the 2014 Edition Proposed Rule, we understood that some EHR technology developers already had quality management principles and processes in place, but we did not believe, especially considering the IOM recommendation, that the EHR technology industry consistently followed such processes. Since the adoption of the QMS certification criterion, we find that industry and other interested parties now widely employ quality management principles. As an example,

⁵⁴ § 170.315(a)(1) computerized provider order entry—medications; § 170.315(a)(2) computerized provider order entry—laboratory; § 170.315(a)(3) computerized provider order entry—diagnostic imaging; § 170.315(a)(4) drug-drug, drug-allergy interaction checks; § 170.315(a)(5) demographics; § 170.315(a)(6) problem list; § 170.315(a)(7) medication list; § 170.315(a)(8) medication allergy list; § 170.315(a)(9) clinical decision support; § 170.315(a)(14) implantable device list; § 170.315(b)(2) clinical information reconciliation and incorporation; and § 170.315(b)(3) electronic prescribing.

an ISO 9001-certified quality management system provides a structured set of requirements designed to support quality-focused business operations.⁵⁵ The ISO Survey 2023⁵⁶ showed that 26,833 ISO 9001 certificates were issued in the U.S., demonstrating widespread adoption across diverse industries. Given these advances across industry, we have determined that this certification criterion, and program requirements that all Health IT Modules be certified to the criterion, have become duplicative. Therefore, we propose to remove the criterion in § 170.315(g)(4) and the reference to this certification criterion in § 170.550(g)(2) as of the effective date of a subsequent final rule. We welcome comments on our proposal.

e. Accessibility-Centered Design

We propose to remove the “accessibility-centered design” (ACD) certification criterion in § 170.315(g)(5) and the reference to this certification criteria in § 170.550(g)(3) as of the effective date of a final rule for this proposed rule. This certification criterion requires that all developers of Health IT Modules identify and use a health IT accessibility-centered design standard or law in the development, testing, implementation and maintenance of each capability for which certification is sought. The removal of this certification criterion, if finalized, would not exempt health IT developers and providers from their independent obligations under applicable federal civil rights laws, including Section 504 of the Rehabilitation Act, Section 1557 of the Affordable Care Act, and the Americans with Disabilities Act. The requirements of these civil rights laws include, but are not limited to, providing individuals with disabilities equal access to information and appropriate auxiliary aids and services as provided in the applicable statutes and regulations.

In the 2015 Edition Proposed Rule, we proposed a new accessibility-centered design certification criterion in § 170.315(g)(8) (80 FR 16861). We proposed that this criterion would require the identification of user-centered design standard(s) or laws for accessibility that were applied, or complied with, in the development of specific capabilities included in a Health IT Module or, alternatively, the lack of such application or compliance. We proposed to require that for each

capability that a Health IT Module includes, and for which that capability’s certification is sought, the use of a health IT accessibility-centered design standard or compliance with a health IT accessibility law in the development, testing, implementation, and maintenance of that capability must be identified. We also proposed that the method(s) used to meet this proposed certification criterion would be reported through the open data CHPL and we proposed to revise § 170.550 to require ONC–ACBs to certify all Health IT Modules certified to the 2015 Edition to the accessibility-centered design certification criterion.

The 2015 Edition Final Rule adopted the accessibility-centered design (ACD) certification criterion as proposed, moving it to § 170.315(g)(5) (80 FR 62673). Additionally, we finalized in § 170.550 that ONC–ACBs must certify all 2015 Edition Health IT Modules to the criterion in § 170.315(g)(5).

In the 2015 Edition Proposed Rule we explained that the proposed certification criterion would serve to increase transparency around the application of user-centered design standards for accessibility to health IT and the compliance of health IT with accessibility laws (80 FR 16861). We stated that this transparency would benefit health care providers, consumers, government entities, and other stakeholders, and would encourage health IT developers to pursue the application of more accessibility standards and laws in product development that could lead to improved usability for health care providers with disabilities and health care outcomes for patients with disabilities. Since the adoption of this certification criterion, we find that industry and other interested parties have readily adopted this application of user-centered design as an industry standard. For instance, according to CHPL data, as of August 2025, every single active Certified Health IT Module (721 total) was certified to § 170.315(g)(5). The proposed removal of this certification criterion would reduce the effort of health IT developers to meet ongoing program requirements that duplicate widely adopted accessibility-centered design practices, allowing developers to refocus these resources on innovation and meeting the needs of their clients and end users in other areas.

Therefore, we propose to remove the accessibility-center design certification criterion in § 170.315(g)(5) and the reference to this certification criterion in § 170.550(g)(3) as of the effective date of a final rule for this proposed rule. As

stated earlier, the removal of this certification criterion, if finalized as proposed, would not exempt health IT developers and providers from their independent obligations under applicable federal civil rights laws, including but not limited to, providing individuals with disabilities equal access to information and appropriate auxiliary aids and services. We welcome comments on our proposal.

f. Consolidated CDA Creation Performance

We propose to remove the certification criterion in § 170.315(g)(6) and reserve that section. We also propose to remove § 170.550(g)(4) which references the criterion, as described elsewhere in this proposed rule. The “Consolidated CDA creation performance” certification criterion helps to ensure the proper conformance of Consolidated CDAs (C–CDAs) for transition of care and referral summaries that are sent to and received from external organizations. In the 2015 Edition Final Rule, we adopted a new Consolidated CDA creation performance certification criterion in § 170.315(g)(6) that assesses a product’s C–CDA creation performance if the Health IT Module is presented for certification with C–CDA creation capabilities within its scope (80 FR 62674). In the HTI–1 Final Rule, we updated the associated standards (89 FR 1224).

We have stated elsewhere in this proposed rule that while C–CDA-based standards are still in use, the industry is shifting toward adoption of FHIR-based standards, which are designed to enable greater interoperability and innovation. We believe that maintaining the current level of support for this and other C–CDA-based criteria, including putting effort and resources toward testing and certification, can detract from industry efforts to move toward FHIR-based solutions. We believe that removing the Consolidated CDA creation performance certification criterion in § 170.315(g)(6) would contribute to reducing the effort health IT developers and health care providers are focusing on C–CDA support and allow for redirection of efforts toward greater use of FHIR-based standards in health IT. We propose to remove the Consolidated CDA creation performance certification criterion in § 170.315(g)(6) as of the effective date of a subsequent final rule. We welcome feedback on these proposals.

g. Application Access—Patient Selection

In the 2015 Edition Final Rule (80 FR 62602), we adopted the “application

⁵⁵ <https://amtivo.com/us/resources/insights/iso-9001-meaning-requirements-and-beginners-guide/>.

⁵⁶ <https://www.iso.org/the-iso-survey.html>.

access—patient selection” certification criterion in § 170.315(g)(7) that includes the capability to receive a request with sufficient information to uniquely identify a patient and return an ID or other token that can be used by an application to subsequently execute requests for that patient’s data.

We propose to remove the application access—patient selection criterion and reserve § 170.315(g)(7) as of January 1, 2027. We have reviewed and evaluated the certification criterion in § 170.315(g)(7), seeking to identify ways to reduce burden while still supporting our policy goals. We refer readers to section I.A.2.b for detailed discussion on “America’s FHIR-Forward Future.” Given our increased focus on standards-based APIs in the Certification Program, we believe it is appropriate to remove this functional API criterion at this time. Specifically, since adoption of the SMART App Launch Implementation Guide in § 170.215(c) all Health IT Modules certified to the standardized API for patient and population services certification criterion in § 170.315(g)(10) must support the functional requirement described in § 170.315(g)(7)(i) according to the SMART App Launch Implementation Guide. Further, we are also proposing elsewhere in this proposed rule to remove a corresponding certification criterion in § 170.315(g)(9). Should we finalize removal of the certification criterion in § 170.315(g)(9), the certification criterion in § 170.315(g)(7) would lose its intended utility. We believe that reducing compliance burdens for health IT developers that participate in the Certification Program would foster industry innovation and encourage the development of more creative interoperability solutions. We have similarly also removed the certification criterion in § 170.315(g)(8) via a technical correction in the HTI–4 Final Rule (90 FR 37182), which was published in tandem with the FY2026 IPPS/LTCH PPS Final Rule (90 FR 36536). We had intended to remove § 170.315(g)(8) in the HTI–2 Final Rule, but mistakenly removed § 170.315(g)(2) instead due to an amendatory instruction drafting instruction error. We corrected this error in the HTI–4 Final Rule.

The application access—patient selection certification criterion is included in the Base EHR definition in § 170.102. The criterion is also associated with measures under the Provider to Patient Exchange and Health Information Exchange objectives of the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category.

Accordingly, we believe that a transition date is needed for the removal of this measure, if our proposal is finalized, that would allow CMS to make appropriate program adjustments. Therefore, we propose to remove the application access—all data request certification criterion as of January 1, 2027, and reserve § 170.315(g)(7).

We believe that removing the certification criterion in § 170.315(g)(7) will reduce administrative burden as well as burden for health IT developers and health care providers while still allowing us to achieve our policy goals. We welcome comments on this proposal.

h. Application Access—All Data Request

In the 2015 Edition Final Rule (80 FR 62602), we established the “application access—all data request” certification criterion at § 170.315(g)(9) that requires the capability to respond to requests for patient data for all of the data classes expressed in the standards in § 170.213. In the Cures Act Final Rule (85 FR 25642), we revised § 170.315(g)(9) to add requirements for the USCDI and remove support for the CCDS by a specified date. In the HTI–1 Final Rule (89 FR 1192), we made revisions to support USCDI v2 and v3 updates and changes to data classes and constituent data elements for C–CDA and C–CDA 2.1 Companion Guide.

We propose to remove the application access—all data request certification criterion in § 170.315(g)(9) as of January 1, 2027. We have reviewed and evaluated the certification criterion in § 170.315(g)(9), seeking to identify ways to reduce burden for health IT developers and health care providers while still supporting our policy goals. As we have stated in the above section on our proposal to remove § 170.315(g)(7) and in section I.A.2.b of this rule, we are increasing focus on standards-based APIs, and we believe it is appropriate to remove this functional API criterion at this time. We believe the functionality of the criterion has been widely adopted (as discussed in section III.A) among health IT developers and is not likely to go away as a supported functionality solely because of removal from the Certification Program. We also believe that removing this certification criterion could spur further industry innovation and support the development of more creative interoperability solutions.

We believe that removing the certification criterion in § 170.315(g)(9) will reduce administrative burden as well as burden for health IT developers and health care providers by eliminating

the need for developers of certified health IT to certify to the certification criterion in § 170.315(g)(9). Because the certification criterion in § 170.315(g)(9) is associated with measures under the Provider to Patient Exchange and Health Information Exchange objectives of the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category, we believe that a transition date is needed.⁵⁷ Therefore, we propose to remove the application access—all data request certification criterion as of January 1, 2027 and reserve § 170.315(g)(9). We welcome comments on this proposal.

8. Transport Methods and Other Protocols Certification Criteria

a. Direct Project

In the 2015 Edition Final Rule (80 FR 62602), we adopted a revised certification criterion in § 170.315(h)(1) that includes the capability to send and receive according to the Applicability Statement for Secure Health Transport (the primary Direct Project specification). We previously adopted this capability across different certification criteria as the 2014 Edition EHR Certification Criteria were maintained at § 170.314(b)(1), (b)(2), and (h)(1).

We propose to remove the “transport methods and other protocols—direct project” certification criterion in § 170.315(h)(1) as of the effective date of a final rule. We have reviewed and evaluated the certification criterion in § 170.315(h)(1), seeking to identify ways to reduce burden while still supporting our policy goals. We believe that because this certification criterion was included as part of the 2014 Base EHR definition, the 2015 Base EHR definition (subsequently renamed the Base EHR definition), the functionality of this certification criterion has been widely adopted (as discussed in section III.A) among health IT developers and is not likely to go away as a supported functionality solely because of removal from the Certification Program. We no longer believe there is added benefit to include conformance testing for this functionality in the Certification Program as it is widely relied on and supported in the health care industry and would be incorporated in health IT absent the certification criterion. We further believe that removing this certification criterion could spur further

⁵⁷ See the CY 2026 PFS Proposed Rule Table 62, available at <https://www.federalregister.gov/d/2025-13271/p-3055> and the FY2026 IPPS/LTCH PPS Final Rule Table X.F.–05 available at <https://www.federalregister.gov/d/2025-14681/p-4161>.

industry innovation by enabling health IT developers to redirect investment in certification and testing for this criterion to new areas.

We believe the removal of this certification criterion will reduce administrative burden and costs associated with certification for health IT developers and health care providers by eliminating the need for developers of certified health IT to certify to the certification criterion in § 170.315(h)(1) without substantially impacting our broader policy goals around interoperability and exchange and will allow for further innovation and development. Therefore, we propose to remove the transport methods and other protocols—direct project certification criterion in § 170.315(h)(1) as of the effective date of a subsequent final rule. We welcome comments on this proposal.

b. Direct Project, Edge Protocol, and XDR/XDM

In the 2015 Edition final rule we adopted a variation of the § 170.315(h)(1) certification criterion in § 170.315(h)(2) to accommodate implementation differences. This certification criterion combined three standards conformance requirements (the primary Direct standard, the edge protocol, and XDR/XDM handling). We propose to remove the “transport methods and other protocols—Direct Project, Edge Protocol, and XDR/XDM” certification criterion in § 170.315(h)(2) as of the effective date of a subsequent final rule. We have reviewed and evaluated the certification criterion in § 170.315(h)(2), seeking to identify ways to reduce burden while still supporting our policy goals. Similar to § 170.315(h)(1), we believe the functionality of this certification criterion has been widely adopted (as discussed in section III.A) among health IT developers and is not likely to go away as a supported functionality solely because of removal from the Certification Program, since it has been part of the 2014 Edition Base EHR definition, and 2015 Edition Base EHR definition (renamed the Base EHR definition), and the current criterion has not substantively changed since it was adopted in the 2015 Edition Final Rule. We further believe that removing this criterion could spur further industry innovation in this area by allowing for greater flexibility and reduced burden and costs from the need to certify to the certification criterion. Because removing §§ 170.315(h)(1)–(2) would remove all of the certification criteria under § 170.315(h), we propose to remove and

reserve § 170.315(h) in its entirety. We welcome comments on this proposal.

B. Standards and Implementation Specifications for Health Information Technology

1. United States Core Data for Interoperability Version 3.1 Update (USCDI v3.1)

The USCDI standard in § 170.213 is a baseline set of data that can be commonly exchanged across care settings for a wide range of uses. Certain certification criteria in the Certification Program currently require the use of one of the versions of the USCDI standard in § 170.213. We established USCDI as a standard in the Cures Act Final Rule (85 FR 25670), adopting USCDI Version 1 (USCDI v1) in § 170.213 and incorporating it by reference in § 170.299. USCDI is also referenced by HHS programs and used by the health care community to align interoperability requirements and national priorities for health IT across industry initiatives. For the overall structure and organization of USCDI, including data classes and data elements, please see www.healthIT.gov/USCDI.

We published the “USCDI v3 Data Elements Enforcement Discretion Notice,”⁵⁸ on March 21, 2025, which stated that ASTP/ONC is exercising enforcement discretion, and issued certification guidance for the Certification Program. Specifically, under this enforcement discretion notice and certification guidance, we stated that ASTP/ONC will not take any enforcement action under 45 CFR 170.565 against an ONC–ACB based on non-compliance with 45 CFR 170.550 for certifying a Health IT Module that is presented for certification to a certification criterion or criteria in 45 CFR 170.315 that cross-references USCDI v3, where the Health IT Module:

1. Does not demonstrate the capability to categorize data on individuals based on either or both of the following data elements:

- Sexual orientation; and
- Gender identity; or

2. Only demonstrates the capability to categorize data on individuals for the sex data element in accordance with the following SNOMED CT® codes:

- 248152002 | Female (finding) |; and
- 248153007 | Male (finding) |.

Additionally, under this enforcement discretion notice and certification guidance, we stated that ASTP/ONC will not take any enforcement action under 45 CFR 170.565 against an ONC–ACB based on non-compliance with 45

CFR 170.550 for certifying a Health IT Module that is presented for certification to the “patient demographics and observations” certification criterion (45 CFR 170.315(a)(5)), where the Health IT Module:

1. Does not demonstrate conformance with any or all of the following data and observations in paragraph (a)(5)(i): sex parameter for clinical use, sexual orientation, gender identity, name to use, and pronouns; or

2. Does not demonstrate conformance with any or all of the following paragraphs of (a)(5)(i): (D) (“sexual orientation”), (E) (“gender identity”), (F) (“sex parameter for clinical use”), (G) (“name to use”), and (H) (“pronouns”); or

3. Only demonstrates, for conformance with paragraph (a)(5)(i)(C) (“sex”), that it can record sex in accordance with either the standard specified in § 170.207(n)(1) for the period up to and including December 31, 2025, or the following SNOMED CT® codes found in the standard specified in § 170.207(n)(2):

- 248152002 | Female (finding) |; and
- 248153007 | Male (finding) |.

We stated that ASTP/ONC will not exercise its direct review authority under 45 CFR 170.580 for any non-conformity, potential or actual, that arises solely from a Health IT Module not demonstrating the capabilities specified above or for only demonstrating the limited specified capabilities above, as applicable, for the relevant certification criteria requirements.

We also stated that this enforcement discretion notice, and certification guidance will remain in effect for twelve (12) months from the date of this notice or until HHS completes a regulatory action to revise the applicable regulations, whichever comes first.

In June 2025, we published the USCDI v3.1,⁵⁹ which removes or updates from USCDI v3 the data elements for Sex, Sexual Orientation, and Gender Identity in the Patient Demographics/Information Data Class. We propose to adopt USCDI v3.1 in § 170.213(a) and incorporate it by reference in § 170.299. The removal of data elements from USCDI v3 reflected in USCDI v3.1 aligns with our other proposals related to § 170.315(a)(5) (see section III.A.1.a), resulting in burden reduction for health IT developers and cost savings associated with the enforcement discretion and ongoing maintenance requirements over time. In addition,

⁵⁸ <https://www.healthit.gov/topic/uscdi-v3-data-elements-enforcement-discretion>.

⁵⁹ See https://www.healthit.gov/isp/sites/isp/files/USCDI-Version-3-1_2025_508.pdf.

these data elements (*e.g.*, sexual orientation and gender identity) do not support the meeting of specific measures under the Medicare Promoting Interoperability Program or the MIPS Promoting Interoperability performance category, and are therefore not essential for inclusion in certified health IT that is used to meet the CEHRT definitions and support meeting measures under those programs. Therefore, we propose to remove USCDI v3 in § 170.213(b) and USCDI v1 in § 170.213(a) which expires on January 1, 2026. The effect of these proposals, if finalized in a subsequent final rule, would be that USCDI v3.1 would be the only version of USCDI in § 170.213. In other words, all Health IT Modules that cross-reference § 170.213 would need to conform to USCDI v3.1 as of the effective date of a subsequent final rule. Given that USCDI v3.1 is a reduction, rather than expansion, of required support for data elements, we do not anticipate that Health IT Modules that cross-reference § 170.213 would require further development to conform to USCDI v3.1.

We welcome comments on our proposals.

a. National Technology Transfer and Advancement Act

The National Technology Transfer and Advancement Act (NTTAA) of 1995 (15 U.S.C. 3701 *et. seq.*) and the Office of Management and Budget (OMB) Circular A-119⁶⁰ require the use of, wherever practical, technical standards that are developed or adopted by voluntary consensus standards bodies to carry out policy objectives or activities, with certain exceptions. The NTTAA and OMB Circular A-119 provide exceptions to this general rule, namely when doing so would be inconsistent with applicable law or otherwise impractical. Agencies have the discretion to decline the use of existing voluntary consensus standards if it is determined that such standards are inconsistent with applicable law or otherwise impractical, and instead use a government-unique standard or other standard. In addition to the consideration of voluntary consensus standards, the OMB Circular A-119 recognizes the contributions of standardization activities that take place outside of the voluntary consensus standards process. Therefore, in instances where use of voluntary consensus standards would be inconsistent with applicable law or otherwise impracticable, other

standards should be considered that: meet the agency's regulatory, procurement or program needs; deliver favorable technical and economic outcomes; and are widely utilized in the marketplace. In this proposed rule, we propose to use a government-unique standard which is the USCDI v3.1 standard that we propose to adopt in § 170.213. This standard is a hybrid of government policy (*i.e.*, determining which data to include in the USCDI) and voluntary consensus standards (*i.e.*, the vocabulary and code set standards attributed to USCDI data elements).

We are not aware of any voluntary consensus standard that could serve as an alternative for the purposes we describe in further detail throughout this proposed rule, including for establishing a baseline set of data that can be commonly exchanged across care settings for a wide range of uses.

b. "Reasonably Available" to Interested Parties

The Office of the Federal Register has established requirements for materials (*e.g.*, standards and implementation specifications) that agencies propose to incorporate by reference in the CFR (79 FR 66267: 1 CFR 51.5(a)). To comply with these requirements, in section V ("Incorporation by Reference") of this preamble, we provide a summary of, and a uniform resource location (URL) to, the USCDI standard we propose to adopt and subsequently incorporate by reference in the Code of Federal Regulations. To note, we also provide relevant information about the standard throughout the relevant sections of the proposed rule.

2. Standards and Implementation Specifications

As discussed above, we have proposed to remove or revise certain certification criteria in the Certification Program in an effort to reduce burden, offer flexibility to both developers and health care providers, as well as to support innovation. Included in certain certification criteria are references to standards. In those instances where we have proposed to remove the criterion, we also generally propose to remove the standard that is referenced from the CFR. Where the certification criterion is not removed as of the effective date of a final rule but allows time for transition until January 1, 2027, we generally propose to also remove those referenced standards on January 1, 2027. Only in limited circumstances do we retain a standard that is referenced in a certification criterion proposed for removal.

We propose to remove the following standards as of the effective date of a subsequent final rule because they would no longer be referenced in certification criteria in the CFR: transport standards in § 170.202(b) through (e); functional standards in § 170.204; content exchange standards in § 170.205(a)(3) and (5); vocabulary standards for representing electronic health information in § 170.207(r) and (s); and standards for health information technology to protect electronic health information created, maintained, and exchanged in § 170.210. We note that certain standards in § 170.210 may not be removed contingent on whether we finalize the alternative privacy and security proposal (see section III.A.4). We also propose to remove the following standards as of the effective date of a final rule since we propose to revise the associated certification criterion requirements to no longer reference the given standard: the content and exchange standard in § 170.205(r)(1), including the specific document templates in § 170.205(r)(1)(i) through (iii).

We propose to remove content exchange standards and implementation specifications referenced in certification criteria requirements that have expired in § 170.205(k)(1) and (2) from the CFR. We propose to remove API standards that expire on January 1, 2026, in § 170.215(b)(1)(i) and (c)(1), and we also propose to remove and reserve outdated vocabulary standards in § 170.207(f)(2) and (m)(1).

Where we propose to remove certain certification criteria after a transition period until January 1, 2027, we also propose to remove those standards from the CFR effective on January 1, 2027. Standards referenced in a certification criterion proposed for removal with a transition date of January 1, 2027, include content exchange standards in § 170.205(i)(2), (t)(1) through (4), and (s)(1). We also propose to remove certain vocabulary standards in order to eliminate outdated standards that are no longer referenced or have expired. Therefore, we propose to remove vocabulary standards in § 170.207(a)(4), (c)(3), (e)(3) and (4). We also propose to remove vocabulary standards in § 170.207(d)(1)(ii), (d)(1)(iii), (n)(1) and (3), and (o) from the CFR and reserve these subsections.

We welcome comments on our proposals. Specifically, we request comment on whether we should retain any of the standards and implementation specifications proposed for removal because the standard or implementation specification should be required for purposes of health IT

⁶⁰ https://www.whitehouse.gov/wp-content/uploads/2020/07/revised_circular_a-119_as_of_1_22.pdf.

alignment, for instance, when acquiring, implementing or upgrading health IT systems and products consistent with sections 13111 and 13112 of the HITECH Act.

In certain instances, we have not proposed to remove a standard even though we propose to remove the certification criterion where the standard is referenced. As noted, under section 3004 of the PHSA, we may adopt standards independently of associated criteria in the Certification Program. Standards adopted in 45 CFR 170 subpart B may be referenced by other HHS programs and policies besides the Certification Program. For example, standards adopted in 45 CFR 170 subpart B, regardless of whether they are associated with health IT certification criteria, are also required for use under sections 13111 and 13112 of the HITECH Act when acquiring, implementing or upgrading health IT systems and products in certain instances.

We do not propose to remove the standard in § 170.205(o), data segmentation for privacy, because some developers still rely on these standards, which allow health care providers to tag health care documents with privacy metadata. We also do not propose to remove the Direct Project transport standard in § 170.202(a)(2). We realize that the Direct Project standards are widely utilized in various use cases and emphasize that developers may still use these standards even if they are removed from certification criteria. We welcome comments on these proposals.

We believe that keeping the primary Direct Project standard in § 170.202(a)(2) but removing the other related standards and protocols in § 170.202(b) through (e) from the Certification Program would acknowledge the current utilization of the Direct Project standard while recognizing the ongoing technological advancements related to transport, including movement toward FHIR-based standards, and would encourage and provide space for further innovation and market competition in this area. We propose a minor revision to § 170.205(d)(2) to add the full name of the HL7 Messaging Standard Version 2.5.1 standard. Lastly, we request comments on retaining the “Applicability Statement for Secure Health Transport” requirement found in § 170.315(h)(1)(i).

C. Terms and Definitions

Because of the proposed removal of certain certification criteria from § 170.315 discussed above, we propose

to make conforming edits to the terms and definitions in § 170.102.

1. Base EHR

We propose to make conforming revisions to the Base EHR definition in § 170.102 based on our proposals to remove certification criteria from the CFR that are currently referenced in § 170.102. The Base EHR definition provides a baseline assurance that certified health IT has been developed to possess, at a minimum, a key set of capabilities. We note the Base EHR definition is based on the “Qualified EHR” definition in section 3000(13) of the PHSA (77 FR 54262). As we noted recently, we have generally sought to limit the Base EHR definition to elements required for the Qualified EHR definition in PHSA section 3000 (90 FR 37145). In section (3)(i) of the Base EHR definition, we propose to remove references to § 170.315(a)(14), (g)(7) and (9), and (h)(1) and (2). We propose to remove these certification criteria from the Base EHR definition because we have proposed to remove those certification criteria from the CFR. We also propose to move § 170.315(b)(11) to section (3)(i) of the definition and remove and reserve section (3)(ii) and remove section (3)(iii) because the transition date has passed. We welcome feedback on these proposals.

2. Common Clinical Data Set

We finalized in the Cures Act Final Rule that the CCDS would no longer be applicable for certified Health IT Modules 24 months after the publication date of the Cures Act Final Rule (85 FR 25671), and then extended that date to December 31, 2022, in the interim final rule titled “Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID-19 Public Health Emergency” (85 FR 70073). Because § 170.315(b)(6)(ii)(A), which also referenced CCDS, was available for the period before December 31, 2023, we did not propose to remove the definition of CCDS in § 170.102 at that time. However, now that the date of December 31, 2023, has passed and we finalized the removal § 170.315(b)(6) in the HTI-2 Final Rule (89 FR 101776) and there are no longer any references to CCDS in 45 CFR part 170, we propose to remove the term Common Clinical Data Set in § 170.102. We welcome comments on these proposals.

3. Global Unique Device Identification Database and Production Identifier

In section III.A.1.d, we propose to remove the “implantable device list”

certification criterion in § 170.315(a)(14) and reserve § 170.315(a)(14). The implantable device list certification criterion requires Health IT Modules certified to § 170.315(a)(14) to exchange, record, and allow a user to access a list of Unique Device Identifiers (UDIs) associated with a patient’s implantable devices. The only references to the Global Unique Device Identification Database and Production Identifier in 45 CFR part 170 are in § 170.315(a)(14). Because we propose to remove § 170.315(a)(14), we propose to remove the definitions of Global Unique Device Identification Database and Production Identifier in § 170.102 too as the terms would no longer be referenced in any other section of 45 CFR part 170. We welcome comments on these proposals.

D. Conditions and Maintenance of Certification Requirements for Health IT Developers

1. Assurances

Section 3001(c)(5) of the PHSA (42 U.S.C. 300jj–11) (section 4002 of the Cures Act) requires that a health IT developer, as a Condition of Certification requirement under the Certification Program, provide assurances to the Secretary that, unless for legitimate purpose(s) as specified by the Secretary, the developer will not take any action that constitutes information blocking as defined in section 3022(a) of the PHSA or any other action that may inhibit the appropriate exchange, access, and use of EHI. In the Cures Act Final Rule (85 FR 25718), we implemented this provision through several Conditions of Certification and accompanying Maintenance of Certification requirements, which are set forth in § 170.402. Because the transition dates in § 170.402(b)(2)(i) and (ii) have passed, we propose to revise the Maintenance of Certification requirements in § 170.402(b)(2) to remove the transition dates and only include that a health IT developer that must comply with the requirements of § 170.402(a)(4) must provide all of its customers of certified health IT with the health IT certified to the certification criterion in § 170.315(b)(10).

We also propose to make additional conforming edits to § 170.402(b). Because we propose to remove the requirements in § 170.315(b)(11)(iv) and (v) regarding source attribute support, access, and modification and in § 170.315(b)(11)(vi) regarding intervention risk management for predictive DSIs, we also propose to remove § 170.402(b)(4), which requires

health IT developers to review and update as necessary source attribute information and intervention risk management practices. We welcome feedback on these proposals.

2. Application Programming Interfaces

As a Condition of Certification requirement in section 3001(c)(5) of the PHSA (42 U.S.C. 300jj–11) (section 4002 of the Cures Act), health IT developers are required to publish APIs that allow “health information from such technology to be accessed, exchanged, and used without special effort through the use of application programming interfaces or successor technology or standards, as provided for under applicable law.” Section 4002 of the Cures Act also states that a developer must, through an API, “provid[e] access to all data elements of a patient’s electronic health record to the extent permissible under applicable privacy laws.” The Cures Act Final Rule (85 FR 25642) captured both the technical functionality and behaviors necessary to implement the Cures Act API Condition of Certification requirement. Specifically, we adopted new standards, new implementation specifications, a new certification criterion, and modified the Base EHR definition. In addition, we finalized detailed Condition and Maintenance of Certification requirements for health IT developers of certified health IT in § 170.404. Because the transition dates in § 170.404(b)(2), (3), and (4) have passed, we propose to revise the Maintenance of Certification requirements in § 170.404(b). We propose to revise § 170.404(b)(2) to remove the date, and we propose to remove paragraphs (b)(3) and (b)(4) entirely as they are outdated and, in the case of (b)(4) because it refers to certification criteria that we are proposing to remove. We also propose to revise § 170.404(c) to update certification criteria referenced in the “Certified API technology” definition. We propose to remove the reference to “§ 170.315(g)(7) through” and only keep § 170.315(g)(10) in the “Certified API technology” definition because we are proposing to remove § 170.315(g)(7) through (9). We welcome feedback on these proposals.

3. Real World Testing

Section 3001(c)(5) of the PHSA (42 U.S.C. 300jj–11) (section 4002 of the Cures Act) requires, as a Condition and Maintenance of Certification under the Certification Program, that health IT developers have successfully tested the real world use of the technology for interoperability in the type of setting in

which such technology would be marketed. Section 4003(a)(2) of the Cures Act defines interoperability as health information technology that enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user; allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable state or federal law; and does not constitute information blocking as defined in section 3022(a) of the Cures Act. This definition for interoperability was codified in 45 CFR 170.102.

In the Cures Act Final Rule, through the Real World Testing Condition and Maintenance of Certification requirements, we finalized the implementation of the statute’s real world testing requirements in 45 CFR 170.405 for health IT certified to the following certification criteria:

- The “care coordination” certification criteria in § 170.315(b);
- The “clinical quality measures” certification criteria in § 170.315(c)(1) through (c)(3);
- The “view, download, and transmit to 3rd party” certification criterion in § 170.315(e)(1);
- The “public health” certification criteria in § 170.315(f);
- The certification criteria related to APIs in § 170.315(g)(7) through (g)(10); and
- The “transport methods and other protocols” certification criteria in § 170.315(h).

However, in that same final rule we replaced the “application access—data category request” certification criterion (§ 170.315(g)(8)) with the “standardized API for patient and population services” certification criterion (§ 170.315(g)(10)). The “application access—data category request” certification criterion was only available for certification until December 31, 2022, and we eventually removed the certification criterion from the CFR (89 FR 101776). In the HTI–4 Final Rule, we finalized six new certification criteria. We clarified that because § 170.405(a) cross references § 170.315(b), the new § 170.315(b)(4) “real-time prescription benefit” certification criterion finalized in HTI–4 would be automatically included within real world testing requirements. Similarly, we included five API-focused certification criteria: § 170.315(g)(31) “provider prior authorization API—coverage requirements discovery”; § 170.315(g)(32) “provider prior authorization API—documentation templates and rules”; § 170.315(g)(33)

“provider prior authorization API—prior authorization support”; § 170.315(j)(20) “workflow triggers for decision support interventions—clients”; and § 170.315(j)(21) “subscriptions—client” in scope for real world testing. Health IT certified to the identified real world testing certification criteria are eligible for the SVAP under § 170.405(b)(8) and (9).

Consistent with the “Real World Testing Condition and Maintenance of Certification Requirements Enforcement Discretion Notice”⁶¹ we issued on June 30, 2025, we now propose the following deregulatory actions: (1) removing the requirement to submit real world testing plans for all real world testing certification criteria (§ 170.405(b)(1)); (2) limiting full real world testing results reporting (§ 170.405(b)(2)) to only Health IT Modules that are certified to the API certification criteria identified below; and (3) permitting the use of SVAP for the remaining non-API real world testing certification criteria with minimal reporting requirements.

We note that certain certification criteria would be fully removed from real world testing requirements by virtue of their proposed removal from the Certification Program. We have included such an outcome in our proposed revised Real World Testing Condition of Certification (45 CFR 170.405(a)). If, in a subsequent final rule, we determine to keep any of the criteria proposed for removal and they are currently identified in the Real World Testing Condition of Certification (45 CFR 170.405(a)), they would also remain part of the Real World Testing Condition of Certification. Examples of such criteria would be the public health criteria proposed for removal (“transmission to cancer registries” (§ 170.315(f)(4)) and “transmission to public health agencies—health care surveys” (§ 170.315(f)(7)).

First, we propose to remove the real world testing plan submission requirement from the Real World Testing Maintenance of Certification requirements (§ 170.405(b)). Second, we propose to revise the results reporting requirements under § 170.405(b)(2) to make clear what health IT developers must include in their real world testing results reporting. Specifically, developers will be expected to report on all health IT certified to any of the certification criteria in § 170.315(g) certification criteria as of January 1 of the year in which they must complete real world testing. Developers must also

⁶¹ <https://www.healthit.gov/topic/real-world-testing-condition-and-maintenance-certification-requirements-enforcement>.

report on all health IT certified to any of the certification criteria in § 170.315(g) that undergo updates via Inherited Certified Status during the real world testing year. This is consistent with current requirements to conduct a full calendar year of real world testing (§ 170.405(b)(2)(ii)).

We propose to limit real world testing reporting (§ 170.405(b)(2)) to API-focused certification criteria which are, at this time: “standardized API for patient and population services” (§ 170.315(g)(10)); “provider prior authorization API—coverage requirements discovery” (§ 170.315(g)(31)); “provider prior authorization API—documentation templates and rules” (§ 170.315(g)(32)); and “provider prior authorization API—prior authorization support” (§ 170.315(g)(33)). This approach aligns with our overall move to focus the Certification Program on APIs (see discussion in section I.A.2) with a particular focus on FHIR-based APIs.

SVAP will remain available for all certified health IT subject to the Real World Testing Condition of Certification and Maintenance of Certification requirements. For the API-focused certification criteria identified above, the real world testing SVAP reporting requirements will not change. However, for health IT certified to the remaining real world testing certification criteria identified in § 170.405(a), developers will only need to identify in their real world testing results their voluntary updates (health IT products, certification criteria, and standards/implementation specifications) to standards and implementation specifications that the National Coordinator has approved through SVAP, which is consistent with current requirements under 45 CFR 170.405(b)(2)(ii)(C). This approach will allow developers to continue to voluntarily update to newer versions of standards once approved by the National Coordinator, which supports advancing interoperability. For clarity, we have captured this SVAP requirement separately in proposed 45 CFR 170.405(b)(2)(iv). We also propose a revision to § 170.405(b)(8) to cross-reference paragraph (a) of § 170.405 instead of paragraph (b) due to our proposed revisions.

4. Attestations

Section 4002(a) of the Cures Act requires that a health IT developer, as a Condition and Maintenance of Certification requirement under the Certification Program, provide to the Secretary an attestation to the Conditions of Certification required in

section 3001(c)(5)(D) of the PHSA. In the Cures Act Final Rule, we adopted regulation text implementing the Cures Act’s “Attestations” Condition of Certification requirement in § 170.406 (85 FR 25781). Under § 170.406, health IT developers attest twice a year to compliance with the Conditions and Maintenance of Certification requirements. A health IT developer of certified health IT must provide the Secretary an attestation of compliance with § 170.404, the API Conditions and Maintenance of Certification requirements, according to § 170.406(a)(4). Because we discuss the proposal to remove § 170.315(g)(7) through (9) in section III.A.7 of this proposed rule, we also propose to remove the reference to § 170.315(g)(7) through (9) in § 170.406(a)(4). In § 170.406(a)(5), we also propose to remove the reference to § 170.315(g)(7) through (9). Additionally, we propose to remove the reference to § 170.315(h) in § 170.406(a)(5) because, as we discussed in section III.A.8, we propose to remove § 170.315(h)(1) and (2), in effect removing the entirety of § 170.315(h).

5. Insights

The Cures Act specified requirements in section 4002(c) to establish an EHR Reporting Program to provide transparent reporting on certified health IT in the categories of interoperability, usability and user-centered design, security, conformance to certification testing, and other categories, as appropriate to measure the performance of EHR technology. In the HTI–1 Final Rule (89 FR 1311), we established the EHR Reporting Program as the “Insights Condition and Maintenance of Certification” (also referred to as the “Insights Condition”) and finalized in § 170.407 the first set of measures to reflect the interoperability category required by section 3009A(a)(3)(A)(iii) of the PHSA. The Insights Condition includes seven measures on which health IT developers under the Certification Program must annually report consistent with specified timelines. We refer readers to the HTI–1 Proposed Rule (88 FR 23831) for detailed background on how we engaged with the health IT community for the purpose of identifying measures that developers of certified health IT would be required to report on as a Condition and Maintenance of Certification under the Certification Program.

Consistent with E.O. 14192, “Unleashing Prosperity Through

Deregulation,”⁶² we identified certain regulatory requirements for which the exercise of enforcement discretion may prevent or mitigate the accrual of sunk costs by regulated entities. On April 29, 2025, we published the “Insights Condition and Maintenance of Certification Enforcement Discretion Notice,”⁶³ in which we stated we had exercised the following enforcement discretion:

- ASTP/ONC will not exercise its direct review authority under 45 CFR 170.580 for any non-conformity, potential or actual, that arises solely from a health IT developer not complying with 45 CFR 170.407(b) except for reporting requirements related to the “use of FHIR in apps through certified health IT” measure (45 CFR 170.407(a)(3)(iv)). Stated another way, ASTP/ONC only expects that health IT developers will report on the “use of FHIR in apps through certified health IT” measure (§ 170.407(a)(3)(iv)(A) and (B) beginning in July of 2027 and (a)(3)(iv)(C) beginning in July 2028).

- ASTP/ONC will not conclude that an ONC–ACB has failed to adhere to 45 CFR 170.523(u), find a violation of 45 CFR 170.560(a), or take any enforcement action under 45 CFR 170.565 against an ONC–ACB if an ONC–ACB confirms that the only measure under 45 CFR 170.407(b) for which a health IT developer submits responses is the “use of FHIR in apps through certified health IT” measure (45 CFR 170.407(a)(3)(iv)).

We stated that this enforcement discretion will be in effect beginning on July 1, 2027, and will remain in effect until HHS completes a deregulatory action to remove or revise 45 CFR 170.407 and 170.523(u). Therefore, in this proposed rule, we propose to remove the following measures in § 170.407(a)(3):

- § 170.407(a)(3)(i), Individuals’ access to electronic health information through certified health IT;
- § 170.407(a)(3)(ii), Consolidated clinical document architecture (C–CDA) problems, medications, and allergies reconciliation and incorporation through certified health IT;
- § 170.407(a)(3)(iii), Applications supported through certified health IT;
- § 170.407(a)(3)(v), Use of FHIR bulk data access through certified health IT;
- § 170.407(a)(3)(vi), Immunization administrations electronically submitted

⁶² <https://www.federalregister.gov/documents/2025/02/06/2025-02345/unleashing-prosperity-through-deregulation>.

⁶³ <https://www.healthit.gov/topic/insights-condition-and-maintenance-certification-enforcement-discretion>.

to immunization information systems through certified health IT; and

- § 170.407(a)(3)(vii), Immunization history and forecasts through certified health IT.

Note, given this proposal, we propose to make conforming edits to the list structure in § 170.407(a)(3) to revise the “use of FHIR in apps through certified health IT” as paragraph (i) instead of (iv). In addition, we propose to remove corresponding references to the removed measures in § 170.407(b) as we only expect that health IT developers would report on the “use of FHIR in apps through certified health IT” measure in the newly designated § 170.407(a)(3)(i), specifically, paragraphs (a)(3)(i)(A) and (B) beginning July of 2027 and (a)(3)(i)(C) beginning in July 2028. We believe our proposal to remove the measures listed above reduces cost and burden to the public.

Our proposals ensure that the Insights Condition is aligned with other proposed policies and changes to the Certification Program that prioritize exchange using FHIR-based APIs. Among the measures that related to FHIR-based APIs, the “use of FHIR in apps through certified health IT” provides the most valuable insights related to implementation and use of FHIR. We welcome comments on these proposals.

In the HTI–1 Final Rule (89 FR 1346), we finalized the Insights Condition reporting frequency to annually for any Health IT Module that has or has had an active certification to § 170.407(b)(1) during the prior six months. We propose to revise § 170.407(b)(1) to clarify that a developer must provide an annual response to the Insights Condition of Certification if they had at least one actively certified Health IT Module as of January 1 of the reporting period (*i.e.*, start of the data collection year) and remain certified under the Certification Program at the time of submission (*i.e.*, July of the following year). We understand that Health IT Modules can be certified and withdrawn in cycles; however, this proposal would make clear that we expect health IT developers of certified health IT to be accountable for any data collected during the calendar-year (CY) data collection period, which begins January 1, regardless of how many months the certification remained active. For example, a developer of certified health IT that has a Health IT Module certified to § 170.315(g)(10) for only the first three months of CY 2026 would report data reflecting use during this three-month period even though their Health IT Module was withdrawn or otherwise

no longer certified for the remaining nine months of CY 2026.

This also applies to newer versions of certified health IT leveraging inherited certified status (ICS). We expect that developers of certified health IT requesting ICS for newer versions would include data for all applicable certified health IT, including newer versions in scope of the Insights Condition requirements as of January 1, at the start of the data collection reporting period. We note that developers of certified health IT would not be expected to separate their certified health IT, in scope of ICS, by versions when submitting their response. This has always been the expectation from what we finalized in the HTI–1 Final Rule (89 FR 1348).

We propose to revise the name of § 170.407 (Insights Condition and Maintenance of Certification) to simply “Insights.” This proposed change is intended to ensure consistency and uniformity across all the Conditions and Maintenance of Certification in subpart D of 45 CFR part 170. We welcome comments on our proposals.

Technical Updates in Measure Specification Sheets

In the HTI–1 Final Rule (89 FR 1313), we stated that while the substantive requirements for each measure are defined in rulemaking, we determined that measure specification sheets are a logical and accessible method for the public to also view the technical specification that supports those requirements, and that this is consistent with the approach used by other HHS programs related to measure specifications (*e.g.*, CMS Electronic Clinical Quality Measures (CMS eCQMs)). Additionally, the measure specification sheets provide granular definitions and other information needed to operationalize the metrics to ensure they are implemented in a consistent manner across health IT developers.

We also stated that we intend to provide up to date measure specification sheets to assist with the regulated community’s understanding of the finalized measures and metric calculations (89 FR 1313). In January 2025, we provided developers of certified health IT updated measure specification sheets for certain measures finalized in the HTI–1 Final Rule, with the flexibility to implement either version 2 or version 4 of the measure specification sheets for the first year of

reporting.⁶⁴ We note that this flexibility is only for the first year of reporting (until July 2027) and that we expect developers to comply with the most up to date version of the measure specification sheets provided at www.healthit.gov in subsequent years.

E. *ONC Health IT Certification Program Administrative Requirements*

1. Principles of Proper Conduct for ONC–ACBs

Under the “principles of proper conduct (PoPCs) for ONC–ACBs” in § 170.523, we require ONC–ACBs to provide ASTP/ONC a “certified product listing” in § 170.523(f) which is a current list of Health IT Modules that have been certified. We propose to revise § 170.523(f)(1)(viii) to no longer require ONC–ACBs to provide test data versions used and whether any test data was altered for the certification criterion or criteria to which the Health IT Module has been certified. With this proposed revision, we would still require the test procedure and test tool version used. Through our CHPL, we have tracked user access to the test data versions used and have found engagement to be very infrequent. In addition, an analysis of Health IT Modules in the CHPL indicates that the majority of developers do not employ custom data when conducting certification testing but instead utilize the ASTP/ONC-provided test data. Due to low user engagement and little variance from the use of ASTP/ONC-provided test data, we believe documenting the test data provides little value to the public and represents additional administrative burden for both health IT developers and ONC–ACBs. We believe this proposed revision to remove this requirement aligns with our goals to reduce burden for both health IT developers and ONC–ACBs.

We propose to make conforming revisions to the PoPCs for ONC–ACBs in § 170.523 by removing cross-references to certain certification criteria that we propose to remove in this proposed rule. Specifically, we propose to remove and reserve § 170.523(f)(1)(ix) through (xi) which reference the “privacy and security” certification criteria (§ 170.315(d)), the “quality management system” certification criterion (§ 170.315(g)(4)), and the “accessibility-centered design” certification criterion (§ 170.315(g)(5)). We also propose to remove and reserve § 170.523(f)(1)(xix), which references the “safety enhanced

⁶⁴ https://www.healthit.gov/sites/default/files/page/2025-05/insights_measure_spec_sheet_4_fact_sheet_v03.2_508.pdf.

design” certification criterion (§ 170.315(g)(3)). We also propose to remove and reserve § 170.523(f)(1)(xxi) because this section includes a reference to § 170.315(b)(11)(vi) related to intervention risk management practices and we propose to remove § 170.315(b)(11)(vi) earlier in this proposed rule.

Consistent with the proposals related to the Real World Testing Condition and Maintenance of Certification in § 170.405, we propose to remove the ONC–ACB review and confirmation process for real world testing plans in § 170.523(p)(1) and the reference to submit real world testing plans in § 170.523(p)(3). We welcome comments on our proposals.

2. Health IT Module Certification

We propose to revise the “Health IT Module dependent criteria” in § 170.550(g) by removing § 170.550(g)(1) through (4) to conform with our proposals to remove certain certification criteria related to privacy and security, and design and performance. We also propose to renumber the remaining paragraphs in § 170.550(g)(5) and (g)(6) to (g)(1) and (g)(2), respectively. We propose to remove § 170.550(h) “privacy and security certification framework” and § 170.550(j) “direct project transport method” to also conform with our proposals to remove certification criteria in § 170.315(d) and § 170.315(h).

Lastly, we propose to revise § 170.550(e) “standards updates” to correct a cross-reference from “§ 171.405(b)(7) or (8)” to “§ 170.405(b)(7) or (8).” In the Cures Act Final Rule, we adopted § 170.550(e) “standards updates” requiring ONC–ACBs to provide an option for certification of Health IT Modules consistent with SVAP to one or more of the certification criteria referenced in real world testing requirements in § 170.405(a) based on newer versions of standards (85 FR 25952). However, in the regulatory text we erroneously amended § 170.550(e) to require ONC–ACBs provide an option for certification of Health IT Modules consistent with § 171.405(b)(7) or (8). We intended, as indicated by the preamble, to adopt the reference to the real world testing requirements in 45 CFR part 170 instead of 45 CFR part 171 Information Blocking. Therefore, we propose to revise § 170.550(e) to reference the SVAP requirements in § 170.405(b)(7) and (8). We welcome comments on our proposals.

3. Certification to Newer Versions of Certain Standards

We propose to revise the “certification to newer versions of certain standards” in § 170.555 by removing references to the term “Complete EHR” as it is no longer relevant in our Certification Program. Retaining the references may cause confusion for the public because the ability to maintain “Complete EHR” certification was only permitted with health IT certified to the 2014 Edition certification criteria, and the “Complete EHR” concept was discontinued for the 2015 Edition (80 FR 62719). The Cures Act Final Rule removed the 2014 Edition certification criteria in § 170.314 and references to “Complete EHR”, and in the HTI–1 Final Rule, we removed the “Complete EHR” language from all reference points in §§ 170.523 and 170.524 (89 FR 1209 through 1210). We continued to remove the remaining references to “Complete EHR” in the HTI–2 TECA Final Rule (89 FR 101775) within subpart E of 45 CFR part 170, and we finalized our proposal to remove the term “Complete EHR” including in § 170.555(b)(2). However, we inadvertently excluded amendatory instructions to revise § 170.555(b)(2) in the final rule. Therefore, we propose to revise § 170.555(b)(2) to remove the reference to “Complete EHR.” We welcome comments on our proposal.

4. Effect of Revocation on the Certifications Issued to Health IT Module(s)

We propose to revise the title of § 170.570 from “Effect of revocation on the certifications issued to Complete EHRs and EHR Module(s)” to “Effect of revocation on the certifications issued to Health IT Module(s).” As discussed above, the term “Complete EHRs” is no longer a relevant term in our Certification Program and retaining it may cause confusion for the public. Therefore, we propose to revise the title of § 170.570 to further align with our removals of the outdated “Complete EHR” terminology. We welcome comments on our proposal.

IV. Information Blocking (Part 171)

Comments received in response to the CMS–ASTP/ONC Request for Information; Health Technology Ecosystem (90 FR 21034) (CMS–ASTP/ONC RFI) and other RFIs, such as the Federal Trade Commission’s Request for Public Comment Regarding Reducing Anti-Competitive Regulatory Barriers (FTC–2025–0028), expressed concerns about several exceptions to the information blocking rule as well as

general concerns about the exceptions. Innovators and patient advocates indicated that some of the exceptions as currently codified may be too broad or are being misused in an anti-competitive or obstructive way. For example, some commenters suggested narrowing or eliminating the exceptions for infeasibility, security, and fees. This proposed rule aims to address several prominent themes among the concerns raised by commenters through proposals below. Each of these proposed revisions to the information blocking regulations would be effective, if finalized, on the effective date of a subsequent final rule. We are also considering further actions such as future rulemaking, guidance, and educational outreach in response to other RFI comments and feedback from stakeholders.

A. “Access” and “Use” Definitions

In the Cures Act Final Rule, we finalized definitions of “access,” “exchange,” and “use” (85 FR 25805). We explained that the concepts of access, exchange, and use are closely related, and noted that EHI cannot be used unless it can be accessed, and that this often requires that EHI be exchanged among different individuals or entities and through various technological means (85 FR 25805). Our references to various technological means always included access via automated means, such as robotic process automation (commonly referred to as the use of “bots”)⁶⁵ and autonomous artificial intelligence systems (“agentic artificial intelligence” or “agentic AI”),⁶⁶ but it has come to

⁶⁵ Robotic process automation is software technology in which software “bots” mimic human actions to accomplish computer-based activities, automating otherwise manual tasks or processes that are structured, repetitive, and follow a set of established rules. Illustrative types of tasks include, without limitation, data retrieval, data entry, and transaction processing (e.g., customer returns of products, appointment scheduling). See, e.g., Moore, Sara, 2018, “The bots are coming: robotic process automation saves DLA time, money” (<https://www.dla.mil/About-DLA/News/News-Article-View/Article/1704350/the-bots-are-coming-robotic-process-automation-saves-dla-time-money/>).

⁶⁶ Autonomous artificial intelligence systems that are designed to execute complex tasks autonomously or with little human involvement to accomplish pre-determined goals is often referred to a “agentic AI” because these systems’ capabilities involve them acting independently or having ability or means (“agency”) to act independently (analogous to a human “having agency” or power to do something) or function as an agent of its user. See, e.g., Merriam-Webster “agentic” ([https://www.merriam-webster.com/slang/agentic#:~:text=What%20does%20agentic%20mean?,\(%E2%80%9Chaving%20agency%22\)\)](https://www.merriam-webster.com/slang/agentic#:~:text=What%20does%20agentic%20mean?,(%E2%80%9Chaving%20agency%22)))). See also, e.g., Acharya, et al, 2025, “Agentic AI: Autonomous Intelligence for Complex Goals—A Comprehensive Survey,” *IEEE Access*, Digital Object Identifier

our attention through RFI comments, our own market observations, and stakeholder interactions that both actors and those who seek to access, exchange, or use EHI would appreciate explicit clarity regarding automated means of access, exchange, or use of EHI, particularly with such means as robotic process automation (commonly referenced as “RPA” or “bots”) and autonomous artificial intelligence systems (commonly referenced in the field as “agentic AI”).⁶⁷ Therefore, we propose to add language to the “access” and “use” definitions at 45 CFR 171.102. We propose to explicitly codify that access means the ability or means necessary to make EHI available for exchange or use, including by automation technologies such as robotic process automation and autonomous artificial intelligence systems. Similarly, we propose to explicitly codify that “use” means the ability for EHI, once accessed or exchanged through whatever technological means, to be understood and acted upon, including, without limitation, by automation technologies such as autonomous artificial intelligence systems and robotic process automation.

In addition to the discussion in the Cures Act Final Rule regarding individuals or entities accessing, exchanging, and using EHI (85 FR 25805), we also discussed the concept of automated access in the HTI–1 Final Rule. Specifically, we noted that some entities may provide data services and that such actions are considered access, exchange, or use regardless of the route used to request, access, or receive data (89 FR 1363). The heterogeneity in how individuals and entities may access, exchange, or use EHI as well as the potential for significantly increased use of automated means to improve efficiency⁶⁸ further contributes to a

conclusion that actors and those who interact with them would benefit from explicit regulatory text specifying that the access, exchange, and use definitions are not limited to manual processes but apply equally to access, exchange and use of EHI that occurs via automated means including, without limitation, autonomous artificial intelligence systems and that an actor interfering with such access, exchange, or use may implicate the information blocking definition.

We are also considering to similarly revise the “exchange” definition in § 171.102. We propose to revise the “exchange” definition in addition to the proposed revisions to the “access” and “use” definitions, as an alternative proposal to only revising the “access” and “use” definitions. Under this alternative proposal, we propose that the meaning of “exchange” includes, without limitation, the ability for EHI to be transmitted, through use of automation technologies (e.g., robotic process automation, autonomous artificial intelligence systems) or otherwise, between and among different technologies, systems, platforms, or networks. We seek comments on these proposals, including perspectives on whether actors and those who interact with actors would find these explicit regulatory updates helpful.

We remind readers that, as we have explained in prior rules, the information blocking regulations are designed to operate in a manner consistent with the framework of the HIPAA Privacy Rule and other laws providing privacy rights for patients (85 FR 25812). Any actor (as defined in 45 CFR 171.102) that is also subject to any provision(s) in 45 CFR parts 160, 162, or 164 must continue to comply with such provision(s) when and to the extent such provisions of the HIPAA Rules are applicable to the actor’s conduct (89 FR 1380), such as with providing access, exchange, or use of protected EHI.

B. Infeasibility Exception Revisions

We propose and seek comments on revisions to two separate conditions of the Infeasibility Exception (45 CFR 171.204). Specifically, we propose to remove the “*third party seeking modification use*” condition (§ 171.204(a)(3)) and to revise or remove the “*manner exception exhausted*” condition (§ 171.204(a)(4)).

1. Third Party Seeking Modification Use Condition

In the HTI–1 Final Rule, we finalized the “*third party seeking modification use*” condition of the Infeasibility Exception (§ 171.204(a)(3)). We explained that when this condition applies and the overall exception is met, an actor’s practice of not fulfilling a request for use of EHI in order to modify EHI, including but not limited to creation and deletion functionality, will not be considered information blocking (89 FR 1200 and 89 FR 1376 through 1380). As finalized by the HTI–1 Final Rule and currently codified, § 171.204(a)(3) applies to a request to enable use of EHI in order to modify EHI, provided that the request for such use is not from a health care provider that is a HIPAA covered entity (as defined in 45 CFR 160.103) requesting such use from an actor that is its business associate (as defined in 45 CFR 160.103). Thus, the condition is not available when a health care provider that is also a HIPAA covered entity requests (directly, or through another business associate of the health care provider) such use of EHI from an actor who is the health care provider’s business associate (88 FR 23866, 89 FR 1380).

HTI–1 Proposed Rule commenters expressed concern that certain actors, such as health IT developers of certified health IT, may seek to misuse the proposal to restrict access to EHI in an overly broad manner (89 FR 1377). Of these commenters, some expressed concern that the proposal could potentially inhibit care coordination by making it too easy for an actor holding EHI to simply refuse modification use requests from third parties who also furnish services to the same patient(s) (89 FR 1377).

Commenters on the HTI–1 Proposed Rule stated that the limitation to this condition is not broad enough, and that ASTP/ONC should expand the limitation of this condition to also apply when the actor’s customers are not HIPAA covered entities; or are not health care providers, but are maintaining EHI in systems licensed by an actor (89 FR 1379). For reasons stated in response to these comments in the HTI–1 Final Rule (89 FR 1379), we did not expand the finalized exclusion from applicability of the condition but noted that we may consider amending the condition in the future (89 FR 1379).

In the HTI–2 Proposed Rule, we proposed two revisions to narrow the application and use of the *third party seeking modification use* condition. First, we proposed to narrow the

10.1109/ACCESS.2025.3532853 (<https://ieeexplore.ieee.org/stamp/stamp.jsp?arnumber=10849561>).

⁶⁷ We believe “artificial intelligence” is commonly and generally understood to mean a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments as well as the capability of a computer, computer system, or set of algorithms to imitate intelligent human behavior. See, e.g., National Institute of Standards and Technology Computer Security Research Center glossary entries for “artificial intelligence” (https://csrc.nist.gov/glossary/term/artificial_intelligence) and “artificial intelligence system” (https://csrc.nist.gov/glossary/term/artificial_intelligence_system). See also Merriam-Webster dictionary definition of “artificial intelligence” (<https://www.merriam-webster.com/dictionary/artificial%20intelligence>).

⁶⁸ Moore, Sara, 2018, “The bots are coming: robotic process automation saves DLA time, money” ([https://www.dla.mil/About-DLA/News/News-Article-View/Article/1704350/the-bots-are-](https://www.dla.mil/About-DLA/News/News-Article-View/Article/1704350/the-bots-are-coming-robotic-process-automation-saves-dla-time-money/)

[coming-robotic-process-automation-saves-dla-time-money/](https://www.dla.mil/About-DLA/News/News-Article-View/Article/1704350/the-bots-are-coming-robotic-process-automation-saves-dla-time-money/)).

applicability of the condition by changing the words “health care provider” to “covered entity as defined in 45 CFR 160.103” (89 FR 63625), which would expand the circumstances in which the condition could *not* be used. We noted that this proposed expansion of the exclusion would encompass requests from all covered entities to their business associates (89 FR 63625). Second, we also proposed to exclude from applicability of the condition requests from any health care provider (as defined in § 171.102) who is not a HIPAA covered entity (as defined in 45 CFR 160.103) but who is requesting modification use from an actor whose activities would make the actor a business associate of that same health care provider if that health care provider *were* a HIPAA covered entity (89 FR 63625). This was to align with the definition of “actor” under the information blocking regulations.

Although comments on the HTI–2 Proposed Rule’s potential revisions to the Infeasibility Exception, including but not limited to the *third party seeking modification use* condition, were generally supportive, some commenters once again raised concerns about the potential for actors to misuse the Infeasibility Exception and recommended that we implement measures to mitigate misuse. For example, one commenter suggested requiring an independent review and appeals process for actors’ claims of infeasibility as well as the mandated public reporting of all infeasibility claims to hold actors accountable.

We received a relatively small number of comments specific to the proposed narrowing of the *third party seeking modification use* condition (§ 171.204(a)(3)). These comments indicate a much more mixed response to this specific proposal than to the Infeasibility Exception. Several commenters supported the proposed narrowing of the *third party seeking modification use* condition’s application. Several commenters discussed the proposal as an expansion rather than a contraction of the condition’s application, indicating a misunderstanding of the proposal. Several other commenters requested additional clarification to understand the revised condition or even to fully comment on the proposal. For example, one commenter stated that the proposal was vague, and asked ASTP/ONC to clarify the proposal’s intended function and scope. Another commenter asked for examples of specific types of scenarios so that they could fully understand the proposal. Several other commenters, both supportive of the

proposal’s intent and critical of it for various reasons, suggested actors would need extensive guidance to properly implement the *third party seeking modification use* condition.

We have evaluated not only our previously proposed revisions to the condition but also the *third party seeking modification use* condition (§ 171.204(a)(3)) in light of: the comments we received in response to the proposal in the HTI–2 Proposed Rule; our observation of the health information ecosystem and health IT market as they stand today; the intent of the information blocking regulations, including what are reasonable and necessary practices for not sharing EHI; and current HHS policy priorities. We now believe the condition as a whole is unnecessary and that removing it will better support the access, exchange, and use of EHI and the goals we set out in the Cures Act Final Rule to unleash innovation and competition for the improvement of health outcomes and lower health care costs for all Americans.

In the HTI–1 Proposed Rule, we solicited comment on whether the (then-proposed) *third party seeking modification use* condition should be of limited duration (88 FR 23867). We specifically requested comment on whether ASTP/ONC should consider proposing, in the future, that the condition be eliminated if, at some point, health IT is capable of supporting third-party modification use of EHI by *any* party with a legal right to do so (or no legal prohibition against it), with no or minimal infeasibility or other concerns (88 FR 23867). While the majority of comments on this subject stated either that the proposal should not have a sunset date, or that it would be premature to establish a sunset date at that time, two commenters stated that the condition should or could be eliminated in the future if technology is capable of supporting the aforementioned modification use of EHI, with no or minimal infeasibility or other concerns (89 FR 1378).

We agreed in the HTI–1 Final Rule with those commenters who had indicated that it would be premature to establish at that time a sunset date for § 171.204(a)(3) because the appropriateness of eliminating it depended on the continued development of health IT’s capability to support lawful third-party modification use of EHI by any party and with no or minimal infeasibility or other concerns (89 FR 1378). However, we also said that if advances in health IT capabilities or other changes in the interoperability and information sharing environment

indicated to us that the condition should be modified or sunset, we would anticipate proposing such a change in a future rulemaking (89 FR 1378).

We have observed substantial growth in technical approaches that enable efficient, appropriately secure modification use as well as two-way exchange interactions between different developers’ systems to support modification use of EHI since HHS announced the HTI–1 Final Rule in December, 2023.⁶⁹ These approaches appear to be rapidly maturing. As we increasingly observe modern, innovative approaches efficiently achieving two-way interoperability, we no longer believe it is reasonable or necessary for an actor to dismiss as “infeasible” a request for such use from *any* requestor without engaging in information gathering or analysis to work through the available alternative manners. Thus, we now believe the time is ripe to propose to retire the *third party seeking modification use* condition. Removing the condition in its entirety is also the most efficient option to resolve concerns we have developed from public comments, market observations, and stakeholder interactions. As noted previously, we are concerned that some actors may be misapplying the condition or intentionally abusing customers’ and third parties’ misunderstandings of the condition or, in the case of business associates, the flexibility we provided for them to confirm whether a third-party modification use request is actually from their HIPAA-regulated health care provider customer.⁷⁰ In particular, we are concerned that this condition is being abused by EHR developers to limit third parties, including other actual or potential business associates of the EHR developer’s health care provider customer, from accessing or using a health care provider’s EHR and relevant

⁶⁹ “HHS Finalizes Rule to Advance Health IT Interoperability and Algorithm Transparency,” news release posted Dec 13, 2023, at <https://www.hhs.gov/about/news/2023/12/13/hhs-finalizes-rule-to-advance-health-it-interoperability-and-algorithm-transparency.html>. Archived content available at: <https://us.pagefreeser.com/en-US/wa/browse/0a7f82bb-be6e-448a-ae11-373d22c37842?find-by-timestamp=2024-01-02T03:56:59Z&url=https%3A%2F%2Fwww.hhs.gov%2Fabout%2Fnews%2F2023%2F12%2F13%2Fhhs-finalizes-rule-to-advance-health-it-interoperability-and-algorithm-transparency.html&timestamp=2024-01-02T03:43:14Z>.

⁷⁰ See 89 FR 1380 discussion of flexibility for actors to structure communications and operating procedures as well as our statement that, for purposes of § 171.204(a)(3), an actor may choose to verify that the modification use request came from the health care provider themselves or accept the third party’s representation of a request as coming from a health care provider of which the actor is a business associate.

EHI. This concern is extremely acute for us in that the ability for health care providers to use other innovative health IT to access and use the EHR has been a fundamental goal for Congress and HHS since we first proposed the information blocking regulations.

We are aware that actors may have concerns about third-party modifications relating to the confidentiality, integrity, or availability of EHI, or to the potential risks to patient safety arising from corrupt or misidentified patient data. We remind health care providers, other actors, patients, and others who may have such concerns that we have established exceptions designed for those types of concerns. For example, an actor may choose to satisfy the Security Exception (§ 171.203) where an actor has identified a specific threat that a request for access, exchange, or use poses to the confidentiality, integrity, or availability of EHI in an actor's systems. Similarly, an actor may choose to satisfy the Preventing Harm Exception (§ 171.201) if the actor knows or reasonably suspects specific data a third party seeks to write into the EHI the actor maintains to be misidentified or mismatched, corrupt due to technical failure, or erroneous for another reason. Actors may choose to satisfy other exceptions, where applicable, regardless of whether we finalize retirement of the *third party seeking modification use* condition of the Infeasibility Exception. We refer readers to subparts B, C, and D of 45 CFR part 171 for the full conditions of each established information blocking exception as currently codified. However, we remind readers that for reasons discussed in Section IV.A.2 of this proposed rule, we propose to revise or remove the *manner exception exhausted* condition from the Infeasibility Exception (§ 171.204) and for reasons discussed in Section IV.D of this proposed rule, we propose to remove subpart D of 45 CFR 171: Exceptions That Involve Practices Related to Actors' Participation in The Trusted Exchange Framework and Common Agreement (TEFCASM).

We also remind actors that, if we were to finalize this proposal to remove the *third party seeking modification use* condition, other conditions of the Infeasibility Exception, including the *infeasible under the circumstances* condition would continue to be available to actors. For example, the *infeasible under the circumstances* condition may apply to scenarios where enabling a third party to "write" data to an EHR system would be unduly burdensome on a health IT developer of certified health IT and its health care

provider customers. As always, for any practice to be considered information blocking, it must be examined on a case-by-case basis in order to assess the specific facts and circumstances and determine whether the practice meets the information blocking definition (see § 171.103, *see also* IB.FAQ46.1.2022FEB).⁷¹

We note again, as we did in the HTI–1 Final Rule, that the *third party seeking modification use* condition does not imply or indicate any change to the HIPAA Rules (89 FR 1380). Any actor that is subject to any provision(s) in 45 CFR parts 160, 162, or 164 must continue to comply with such provision(s) when and to the extent such provisions of the HIPAA Rules are applicable to the actor's conduct (89 FR 1380).

To preserve accuracy of references in existing information blocking educational materials to specific conditions of the Infeasibility Exception by CFR citation, we propose to remove and reserve subparagraph (3) within § 171.204(a). We are not proposing at this time to redesignate any of the other conditions currently codified within § 171.204(a), nor are we proposing to make any other changes to any of these conditions or the *responding to requests* condition in § 171.204(b). We welcome comments on our proposal to remove the *third party seeking modification use* condition of the Infeasibility Exception.

2. Manner Exception Exhausted Condition

In the HTI–1 Proposed Rule, we proposed to re-number the "*infeasible under the circumstances*" condition of the Infeasibility Exception (45 CFR 171.204) and to codify at (a)(4) a new *manner exception exhausted* condition. We stated the proposed *manner exception exhausted* condition would apply where an actor is unable to fulfill a request for access, exchange, or use of EHI despite having exhausted the Manner Exception in § 171.301 by offering all alternative manners in accordance with § 171.301(b), so long as the actor does not currently provide to a substantial number of individuals or entities similarly situated to the requestor the same requested access, exchange, or use of the requested EHI (88 FR 23867). We noted that actors expressed concern about circumstances where the actor's inability to satisfy the Manner Exception's conditions rests solely on the requestor refusing to accept access, exchange, or use in *any* manner consistent with § 171.301 and

that fulfilling the request in the manner requested would require substantial technical or financial resources, or both, in the view of the actor, including significant opportunity costs (88 FR 23868). We noted that actors may have been experiencing a problematic level of uncertainty about whether they will be engaging in information blocking if they decline demands from requestors for non-standard, non-scalable solutions that they do not currently support. We noted that an actor might have experienced such uncertainty *even after* that actor had offered to provide access, exchange, or use of EHI in the same manner(s) the actor makes the EHI generally available to its customers or affiliates, *and* through other standards-based manners, consistent with § 171.301—including offering terms for such manners that are consistent with the Fees (§ 171.302) and Licensing (§ 171.303) Exceptions (88 FR 23868). We indicated observing such uncertainty among actors with substantial skills and other resources to develop new, unique or unusual manners of supporting access, exchange, or use of EHI (88 FR 23868).

We explained that the proposed *manner exception exhausted* condition would provide actors the option of satisfying the Infeasibility Exception without needing to assess whether they *could* theoretically or technically meet the requestor's particularized demands regarding the manner and/or the terms in which to achieve access, exchange, or use of requested EHI. We proposed that an actor could satisfy the Infeasibility Exception when the actor met the requirements of the § 171.204(b) *responding to requests* condition and the three factors of *manner exception exhausted* condition were true:

(i) The actor could not reach agreement with a requestor in accordance with § 171.301(a) *manner requested* condition (as we have proposed it in this proposed rule) or was technically unable to fulfill a request for electronic health information in the manner requested;

(ii) The actor offered all alternative manners "in accordance with" § 171.301(b) *alternative manner* condition (as we have proposed it in this proposed rule) for the electronic health information requested but could not reach agreement with the requestor; and

(iii) The actor does not provide the same access, exchange, or use of the requested electronic health information to a substantial number of individuals or entities that are similarly situated to the requester (88 FR 23869).

⁷¹ <https://www.healthit.gov/faq/how-would-any-claim-or-report-information-blocking-be-evaluated>.

We requested comments on all aspects of the proposal. In particular, in regards to the second factor, we asked whether an actor should have to offer access, exchange, or use in manners that would satisfy all three of the alternative manners in § 171.301(b)(1)⁷² or if it should be sufficient for an actor to offer to fulfill the request in two manners that use content and transport standards published by the Federal Government or a standards-developing organization accredited by the American National Standards Institute; or by offering fulfillment in at least one such manner *and* an alternative machine-readable format consistent with § 171.301(b)(1)(iii) (88 FR 23869).

Regarding the third factor, we asked whether the language provided adequate assurance that actors would not be able to misuse the § 171.204(a)(4) *manner exception exhausted* condition to avoid supplying some particular requestor(s) with manner(s) of access, exchange, or use of the requested EHI that would be more accurately characterized as generally available than as new, unique, or unusual (88 FR 23870). In particular, we noted that the third factor is intended to ensure the condition cannot be satisfied where a manner (mechanisms, interoperability elements) is currently supported for a substantial number of individuals or entities but the responding actor wants to deny that mechanism to particular requestor(s) for inappropriate reasons, such as to discriminate against competitors, potential competitors, or those the responding actor may be concerned could use the resultant access, exchange, or use of EHI to furnish, develop, or facilitate development of products or services that could compete with those of the actor (88 FR 23870). We asked if the flexibility of the “substantial number” factor would better recognize variations in actors’ operational contexts, including their organization sizes, as compared to the clarity provided by a simple fixed threshold of “more than one,” or even just one other entity. We also sought comment on whether we should include “similarly situated” requestors or if such a phrase risked allowing actors to discriminate based on requestor size or type (88 FR 23870).

In the HTI–1 Final Rule, we finalized the *manner exception exhausted* condition of the Infeasibility Exception (§ 171.204(a)(4)). In finalizing the

manner exception exhausted condition, we explained that when an actor either technically cannot provide the access, exchange, or use of EHI in the manner requested, or the actor and requestor cannot reach agreeable terms on the manner requested, the actor must attempt to fulfill the request using the alternative manners in § 171.301(b) in order to exhaust the Manner Exception (89 FR 1381). Under the Manner Exception, for any alternative manner, the requestor must either specify the manner they would accept (§ 171.301(b)(1)(i) and (ii)) or specifically agree with the machine-readable format that they would accept (§ 171.301(b)(1)(iii)). We stated that in situations where an actor offers at least two alternative manners and the requestor does not specify or agree to receive the EHI via the offered alternative manners (as may be the case if the requestor does not want to receive the EHI in such a manner or cannot receive the EHI in such a manner), an actor may seek to satisfy the *manner exception exhausted* condition of the Infeasibility Exception (89 FR 1381). In other words, under the *manner exception exhausted* condition, it would not matter whether the requestor specified the alternative manner, which is a requirement to meet the Manner Exception under § 171.301(b)(1)(i) and (ii). And the *manner exception exhausted* condition of the Infeasibility Exception could be met if the requestor did not agree with the actor upon an offered alternative machine-readable format, which is a requirement to meet the Manner Exception under § 171.301(b)(1)(iii).

The *manner exception exhausted* condition of the Infeasibility Exception, as finalized in the HTI–1 Final Rule, considers three factors. First, it requires that the actor could not reach agreement with a requestor in accordance with § 171.301(a) or was technically unable to fulfill a request for EHI in the manner requested (§ 171.204(a)(4)(i), 89 FR 1384 through 85). Second, the condition requires that the actor offered at least two alternative manners in accordance with § 171.301(b) (whether or not the requestor identified the alternative manner and/or agreed to it), one of which must use either technology certified to standard(s) adopted in part 170 (§ 171.301(b)(1)(i)) or published content and transport standards consistent with § 171.301(b)(1)(ii) (*see* § 171.204(a)(4)(ii)). The third factor requires that the actor does not provide the same access, exchange, or use of the requested EHI to a substantial number of individuals or entities that are similarly

situated to the requester (§ 171.204(a)(4)(iii), 89 FR 1385 through 86). We explained what “provide” means in this context (89 FR 1385 through 86), as well as “substantial number” (89 FR 1384 through 85) and “similarly situated” (89 FR 1386).

Specifically, we noted that “similarly situated” would serve to indicate that different specific individuals or entities within a class of such individuals or entities who are similarly situated to one another should be treated in a consistent and non-discriminatory manner, and that it is not our intent for the “individuals or entities that are similarly situated to the requester” criterion of the condition to be used in a way that differentiates the same access to EHI simply based on the requestor’s status, such as an individual (*e.g.*, a patient) or entity (*e.g.*, a healthcare system) (89 FR 1386). We explained that, in determining whether a requestor is similarly situated, an actor shall not discriminate based on certain factors, including whether the requestor is an individual as defined in § 171.202(a)(2), the health care provider type and size, and whether the requestor is a competitor of the actor or whether providing such access, exchange, or use, would facilitate competition with the actor (89 FR 1386). We finalized these factors in § 171.204(a)(4)(iv).

The *manner exception exhausted* condition of the Infeasibility Exception was intended to provide clarity and flexibility for actors. We did not intend for it to cover any unreasonable or unnecessary practice that would allow an actor to avoid providing the access, exchange, or use of EHI in a manner already supported by that actor.

Based on comments received in response to the CMS–ASTP/ONC RFI, questions received through the ASTP/ONC Health IT Feedback and Inquiry Portal,⁷³ and other stakeholder feedback, we are concerned that actors may be abusing the exception in various ways, including claiming to requestors that the *manner exception exhausted* condition applies when the actor has not, in fact, explored whether they *could* reach agreeable terms to fulfill a request in the manner requested, or has not attempted to fulfill the request in at least two other manners consistent with the § 171.301(b) *alternative manner*, or both. Additionally, we are concerned that certain terms and criteria of the condition (*i.e.*, “same,” “substantial number” and “similarly situated”) are being misused to deny requestors access to *existing* APIs and other manners of access, exchange, and use that have

⁷² Here we are referring to § 171.301(b)(2) as it was codified at the time the HTI–1 Proposed Rule published; re-designation of paragraphs within § 171.301 was proposed in that NPRM and finalized in the HTI–1 Final Rule (89 FR 1437, *see also* 89 FR 1372).

⁷³ <https://healthit.gov/feedback>.

been granted to other parties. To address these concerns, we now propose to modify the condition to eliminate the potential for misuse and abuse.

Specifically, we propose (in § 171.204(a)(4)(ii)) to increase the minimum number of alternative manners required to be considered to have “exhausted” the Manner Exception from two to “all,” in line with the original (HTI–1 Proposed Rule) proposal for the condition. In referring to “all alternative manners,” we do not mean all possible manners of exchange other than the manner requested. Rather, we specifically mean those manners that are set forth in subparagraph (i), (ii), or (iii) of § 171.301(b)(1). We seek comment on whether, and to what extent, actors and those who request EHI access, exchange, or use from actors would find useful a further reiteration in the text of the condition that each alternative manner must be attempted consistent with § 171.301(b) (the *alternative manner* condition of the Manner Exception) in order to satisfy the *manner exception exhausted* condition of the Infeasibility Exception (§ 171.204(a)(4)). This addition would further reiterate what the regulation text says at present and what has been stated in the preamble of the HTI–1 Final Rule (see, e.g., 89 FR 1383). Further, we remind actors that a manner that meets any sub-paragraph within § 171.301(b)(1) must be consistent with the entirety of § 171.302(b), which includes § 171.301(b)(2), under which any fees that would be charged by the actor in relation to fulfilling the request must satisfy the Fees Exception (§ 171.302), and § 171.301(b)(3), under which any license of interoperability elements granted by the actor in relation to fulfilling the request satisfy the Licensing Exception (§ 171.303).

We also welcome comment on whether revisions to the wording of § 171.204(a)(4)(ii) would help ensure an actor can only claim to a requestor that fulfilling the request is “infeasible” under the *manner exception exhausted* condition when the actor has exhausted the Manner Exception, as we intend. We welcome comment on whether any such revisions could also discourage actors from attempting to abuse the condition. We also propose to incorporate language into the regulation text consistent with the preamble of the HTI–1 Final Rule, as discussed above, to emphasize a distinction between the Manner Exception (§ 171.301) and the *manner exception exhausted* condition (§ 171.204(a)(4)): satisfying the *manner exception exhausted* condition does not require that the requestor identify the alternative manner or agree to it, which

is required for actors to be able to fully meet the Manner Exception.

In § 171.204(a)(4)(iii), we propose three revisions. First, we proposed to replace “same” with “analogous” as it refers to the access, exchange, or use of EHI. We discussed in the HTI–1 Final Rule how “same” meant the same requested access, exchange, or use, including the “same” manners of EHI access, exchange, or use, as provided to others. We still intend to include the concept of “the same” access, exchange, or use of EHI in consideration of whether the provision is met, but we believe the more expansive term “analogous” is more appropriate. We believe using “analogous” access, exchange, or use in comparison to what the actor provides to other individual(s) or entity(ies) is a basis less subject to manipulation than “same,” which some actors may argue equates to “identical” access, exchange, or use of EHI. We do not intend for “same” to be interpreted in a way that could be limiting and potentially manipulated to deny access, exchange, or use. For example, this condition would not be available to an actor when a requestor requests API access with certain features, such as “write” capabilities or filtering functionality, that the actor provides to other entities. Assuming for the sake of this example that the actor is not prohibited by applicable law from providing the requested access, exchange, or use of the requested EHI to the requestor,⁷⁴ the request is not infeasible under any other condition in § 171.204 (e.g., § 171.204(a)(1) *uncontrollable events*) and that no other exception in subpart B of part 171 (e.g., the Privacy Exception) applies to the particular facts and circumstances, we would expect such access would be provided to the requestor without unnecessary delay. In providing such access, exchange, or use, an actor who seeks certainty that their practices in fulfilling the requested access, exchange, or use of EHI via the API with certain features will not be considered information blocking can align their

⁷⁴ Where applicable law prohibits an actor from fulfilling a requestor’s requested access, exchange, or use of requested EHI, the actor need not satisfy an exception to have certainty that complying with the law to which they are subject will not be considered “information blocking.” Where applicable law, such as the HIPAA Privacy Rule, permits use or disclosure (access, exchange, or use) of the requested EHI *only* when certain requirements (“preconditions”) are met, the Precondition Not Satisfied (45 CFR 171.202(b)) sub-exception of the Privacy Exception outlines a framework for actors to follow so that the actors’ practices of not fulfilling requests to access, exchange, or use EHI would not constitute information blocking when a precondition of applicable law has not been satisfied.

practices with other relevant exception(s), such as the Fees Exception and, as necessary, the Licensing Exception.⁷⁵

Similarly, the *manner exception exhausted* condition (as § 171.204(a)(4) is currently codified or as we propose in this proposed rule to modify it) would not be available to an actor if the actor makes an API available to entities or individuals and a requestor attempts to access the API through automated means (such as robotic process automation and agentic AI).⁷⁶ In such cases, the access achieved by automated means would be the same and analogous to an entity or individual accessing the API using more manual means. Accordingly, we believe replacing “the same” with “analogous” is a better basis for comparing the request with what the actor provides to other individuals or entities, including those who may use different automated means, or may use manual means. We believe this revision aligns more with the intent of the statutory information blocking definition (PHSA section 3022(a)(1)), which focuses on practices “likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information” without any specification of, or limitation to, access, exchange, or use of EHI through particular mechanisms, technologies, or workflows.

Second and third, we propose: changing the “substantial number” element to “any,” by which we mean at least one individual or entity; and removing consideration of whether such individual or entity is similarly situated to the requestor. The proposed revisions to § 171.204(a)(4)(iii) would explicitly exclude from application of the condition any situation where the actor offers at least one individual or entity the requested access, exchange, or use. These revisions would alleviate concerns that the terms “substantial” and “similarly situated” are being manipulated to deny access, exchange, or use. Further, we do not believe that removal of the terms would undermine the stated overall objective of the condition when it was proposed, which was to provide certainty to actors when they were faced with situations where the request would involve building “one off” access, exchange, or use interfaces. Rather, the condition could still be met if the actor does not provide analogous

⁷⁵ “Interoperability element” is defined in § 171.102. Additional information about this definition is available in the preamble of the Cures Act Final Rule at 85 FR 25806 through 25808.

⁷⁶ Please see section IV.A of this preamble, above, for descriptions of robotic process automation and agentic AI.

access, exchange, or use of the requested EHI to any other individual or entity.

If we finalize the proposal to retain the § 171.204(a)(4) condition with removal of the “similarly situated” element from § 171.204(a)(4)(iii), instead of our alternative proposal (below) to remove § 171.204(a)(4) in its entirety, we also propose to remove § 171.204(a)(4)(iv). Specifying bases an actor shall not use in determining whether a requestor is “similarly situated” under § 171.204(a)(4)(iii) would be moot upon removal of “substantially similar” from § 171.204(a)(4)(iii).

In the alternative to our proposed revisions to the condition above, we propose to remove the § 171.204(a)(4) *manner exception exhausted* condition entirely if public comments we receive on this proposed rule indicate that our proposed revisions would not be sufficient to eliminate or substantially mitigate the misuse or abuse of the condition. We seek comments on this alternative approach.

If we were to finalize the alternative proposal to remove the § 171.204(a)(4) *manner exception exhausted* condition, we would reserve subparagraph (4) within § 171.204(a) to preserve accuracy of references in existing information blocking education materials to specific conditions of the Infeasibility Exception by CFR citation. We are not proposing at this time to redesignate any of the conditions currently codified within § 171.204(a) that would remain in the event we finalize the alternative proposal to remove subparagraph (4), the proposal discussed in section IV.A.1 of this preamble to remove subparagraph (3) of § 171.204(a), or both.

C. Manner Exception

In the Cures Act Final Rule, we established the Manner Exception (then referred to as the “Content and Manner” Exception) in § 171.301 (85 FR 25959, *see also* 85 FR 25875 through 25879). In finalizing the exception, we stated our belief that it addressed comments received regarding the breadth of the EHI definition and flexibility in the manner an actor fulfills a request to access, exchange, or use EHI, while providing market participants the ability to reach and maintain market negotiated terms (85 FR 25876). As finalized in the Cures Act Final Rule (85 FR 25642) and the Cures Act Interim Final Rule (85 FR 70085), the information blocking definition (§ 171.103) and the Content and Manner Exception (§ 171.301) were limited for a period of time to a subset of EHI that was narrower than the EHI definition finalized in the Cures Act

Final Rule in § 171.102. The narrower subset included only the EHI identified by the data elements represented in USCDI version 1 for the first 18 months (until May 2, 2022) after the applicability date for 45 CFR part 171 (November 2, 2020) (85 FR 25792). The Cures Act Interim Final Rule extended the applicability date of 45 CFR part 171 to April 5, 2021 (85 FR 70069). This extension moved the end of the first 18 months of applicability of 45 CFR part 171 to October 5, 2022 (85 FR 70069).

In the HTI-1 Final Rule (effective April 8, 2024), we revised § 171.301 to remove reference to the *content* condition, which had been moot as of October 6, 2022 (89 FR 1372). We also accordingly renumbered the remaining provisions in § 171.301 and simplified the name to the “Manner” Exception (89 FR 1372).

Based on comments received in response to the CMS-ASTP/ONC RFI, questions received through the ASTP/ONC Health IT Feedback and Inquiry Portal,⁷⁷ and other stakeholder feedback, we are concerned that some actors may be attempting to abuse the exception, and that all participants in the health information ecosystem would benefit from greater certainty that the *manner requested* condition does not apply to any contracts, agreements, or licenses that are for the purposes of accomplishing access, exchange, or use of EHI in the manner requested, but that: (1) are not at “market” rate (85 FR 25877); (2) are contracts of adhesion; or (3) contain unconscionable terms (as defined below). Specifically, we are concerned that some actors may be incorrectly citing the *manner requested* condition to persuade requestors that the exception applies to agreements and terms to which it has never applied.

In both the Cures Act Proposed Rule and the Cures Act Final Rule, we recognized the inherent power inequity between EHR developers and various types of requestors (*see* 84 FR 7520, noting that EHR developers are in a unique position to block access to EHI for use in competing systems or applications). We also specifically address this concept of inequity and how it could impact terms of contracts in the Cures Act Final Rule (85 FR 25812). Foremost, we stated that a contract may implicate the information blocking provision if it included unconscionable terms for the access, exchange, or use of EHI or licensing of an interoperability element, which could include, but not be limited to, requiring a software company that produced a patient access application to

relinquish all IP rights to the actor or agreeing to indemnify the actor for acts beyond standard practice, such as gross negligence on the part of the actor. Further, we noted that such terms may be problematic with regard to information blocking in situations involving unequal bargaining power related to accessing, exchanging, and using EHI (85 FR 25812).

As currently codified, the Manner Exception’s *manner requested* condition (§ 171.301(a)) applies when an actor fulfills a request for EHI in any manner requested that the actor is technically able to fulfill and for which the actor is able to reach agreeable terms with the requestor. As set forth in the Cures Act Final Rule, if the actor fulfills a request to access, exchange, or use EHI in any manner requested, the fees or licensing agreements associated with fulfilling such requests will not be limited by the conditions in the Fees Exception (§ 171.302) or Licensing Exception (§ 171.303). Our rationale was that actors would first attempt to negotiate agreements in any manner requested with terms the actor chooses at the “market” rate—which supports innovation and competition (85 FR 25877). If the actor could not reach agreeable terms by negotiation at the market rate, actors could still fulfill the request in an alternative manner (85 FR 25877). Given the language in the Cures Act Final Rule, we understood “agreeable terms” were those terms agreed upon by actors through arms-length negotiation at market rate (85 FR 25877). Agreeable terms did not incorporate contracts of adhesion or contracts with unconscionable terms. These types of agreements, by their very nature, are either not agreed upon through arm’s length negotiation or at market rate.

Further, the *manner requested* condition allows the negotiation of market rates and terms for the *manner* of access, exchange, or use only—that is, the requested combination of content and transport standard(s),⁷⁸ ability to use an API or portal, or any other requested health IT functionality or technological mechanism that otherwise achieves the requested access, exchange, or use of the requested EHI.⁷⁹ The

⁷⁸ In the Cures Act Final Rule preamble discussion of alternative manners using content and transport standards specified by the requestor under what is now codified at § 171.301(b)(1)(ii), such an alternative “manner” includes two distinct components: (1) content standard; and (2) transport standard (85 FR 25878).

⁷⁹ Manners of access, exchange, and use would include, without limitation and where applicable, *modification* use of EHI that may be maintained by the actor (for example, where an actor maintains

⁷⁷ <https://healthit.gov/feedback>.

Manner Exception does not apply to an actor's practices in negotiating any aspect of a contract with a requestor *other than* the manner in which access, exchange, or use of requested EHI is achieved and, *if* the request is fulfilled in the *manner requested*, to market fees for items and services provided and market terms for any licensing of interoperability elements needed to fulfill the requested access, exchange, and use of EHI in that manner.

We reiterate the plain language of the Manner Exception, and particularly the *manner requested* condition, in that the Manner Exception only covers the technical manner of exchange of the requested EHI, and not any other term(s) in any contract or agreement entered or reached between the actor and requestor. Further, such contracts or agreements for access, exchange, and use of EHI cannot be contracts of adhesion or contracts containing unconscionable terms. These types of contracts are not covered by the Manner Exception even if these agreements were styled as, or in fact were, achieving access, exchange, or use of the requested EHI in the requested manner. These types of contracts would also likely constitute an interference (85 FR 25813) under the information blocking regulations.

To further explicate the applicability of the Manner Exception where the actor has the technical capability and is able to reach agreement with the requestor to fulfill access, exchange, or use of requested EHI in a manner requested by the requestor, we offer two proposals. First, we propose to revise § 171.301(a)(2) to add a new subparagraph (iii) to incorporate in regulation text and explicitly state that any contract or agreement related to the access, exchange, or use of EHI: (1) must be at market rate; (2) must not be a contract of adhesion; and (3) must not contain unconscionable terms. As stated in the Cures Act Final Rule, agreements must be negotiated at market rate (85 FR 25877). We propose to define, in § 171.102, "market rate" using paragraph (1) of the definition of "fair market value" found in the Stark Law regulations at 42 CFR 411.351: "(1) *General*. The value in an arm's-length transaction, consistent with the general market value of the subject transaction" (42 CFR 411.351). We propose to define, in § 171.102, "contract of adhesion" as a contract provided on a standardized form, or on a "take it or leave it basis"

without a realistic opportunity to bargain where the desired product, services, access, use, or exchange cannot be provided except by acquiescing to the form contract. We propose to incorporate the Merriam Webster dictionary's definition of "unconscionable" to define, in § 171.102, "unconscionable terms" as those terms that are excessive, unreasonable, or shockingly unfair or unjust. We further explain unconscionable terms by way of examples in this preamble as well as by the examples found in the preamble to the Cures Act Final Rule (85 FR 25811 through 25812). Examples of unconscionable terms related to the access, exchange, or use of EHI would include indemnification waivers, waivers of rights to file claims of wrongdoing with state or Federal authorities, terms that specify unreasonable revenue sharing beyond fair market value (as already prohibited by the Fees Exception), or terms that require surrendering intellectual property rights without fair compensation.

An actor's practice that meets the *manner requested* condition of the Manner Exception does not currently, and would not under the first proposed revision, have to also satisfy the Fees Exception (§ 171.302) or the Licensing Exception (§ 171.303) in order for the actor to have certainty the actor's practice specific to charging a fee or licensing interoperability elements for fulfilling the requested EHI access, exchange, or use in the *manner requested* would not be considered information blocking.

This proposed approach offers both benefits and some potential challenges. We believe this proposal to define new terms and emphasize the parameters of the condition would offer more certainty to responding actors and to requestors⁸⁰ about what types, terms, or provisions of agreements could be covered by the Manner Exception under the *manner requested* condition (§ 171.301(a)). However, we also recognize that actors would not have the same degree of certainty that any fees and licensing terms the actor may seek to institute are covered by an exception under the proposed revision of § 171.301(a) as they would have under the Fees Exception and the Licensing

⁸⁰ Any individual or entity can be a requestor, including without limitation an individual or entity that happens to meet the § 171.102 "actor" definition. For example, a health care provider is often also a requestor seeking access, exchange, or use of EHI from health IT developers of certified health IT, HIN/HIEs, and other health care providers.

Exception. Similarly, a requestor would not have the clarity and certainty provided by the Fees Exception's (§ 171.302) specifications for the fees it covers, including its exclusion of certain bases for fees (e.g., § 171.302(b)(3) and (4)), or the requirements in the Licensing Exception (§ 171.303) for an actor's practices in licensing interoperability elements in relation to fulfilling access, exchange, or use of requested EHI in the manner requested. Therefore, we offer another proposal discussed in more detail below. As to this proposal, we seek comments on the proposed provision and proposed definitions, suggestions for alternative definitions, and any missing components that would more explicitly describe excluded contractual terms. For example, should we instead, or in addition, include the definition of "general market value" at 42 CFR 411.351—"with respect to the purchase of an asset, the price that an asset would bring on the date of acquisition of the asset as the result of bona fide bargaining between a well-informed buyer and seller that are not otherwise in a position to generate business for each other."?

We recognize the first proposed approach of adding explicit language to § 171.301(a) to ensure fair market rates and exclude certain types of contracts and contractual terms may not fully address all concerns about the misuse of the Manner Exception and may add complexity or ambiguity with new terms. Therefore, we also propose in the alternative to remove paragraph (a)(2) from the *manner requested* condition of the Manner Exception, and explicitly apply the conditions of both the Fees Exception (§ 171.302) and the Licensing Exception (§ 171.303) to any agreement an actor makes with a requestor related to fulfilling the request for access, exchange, or use of EHI in any manner requested. Paragraph (a)(2) is where the *manner requested* condition currently states that if an actor fulfills a request for EHI in any manner requested, any fees charged by the actor in relation to fulfilling the request are not required to satisfy the Fees Exception (subparagraph (i) of paragraph (a)(2)), and any license of interoperability elements granted by the actor in relation to fulfilling the request are not required to satisfy the Licensing Exception (subparagraph (ii) of paragraph (a)(2)). Under this alternative proposal, we propose that the agreement would need to satisfy the Fees Exception and the Licensing Exception, even when fulfilling the request in any manner requested. This approach would mean

EHI on behalf of a health care provider and the health care provider wants to use a third-party app or service to add or update data points in various data classes or elements).

that, while the actor and requestor retain flexibility to reach mutually agreeable terms for the actor to fulfill access, exchange, or use of the requested EHI in the manner requested, any fees charged by the actor and any licensing terms for interoperability elements from the actor to the requestor related to fulfilling the request must meet all of the requirements of the Fees Exception and the Licensing Exception for the actor to have certainty that their practice of charging fees or licensing interoperability elements would not constitute information blocking. In addition to simplifying the Manner Exception, this alternative proposal to revise the Manner Exception could promote greater consistency in actors' practices specific to fees and licensing terms for fulfilling EHI access, exchange, and use requests by following specified provisions of regulatory exceptions.

Removing paragraph (2) from § 171.301(a) and applying the Fees and Licensing Exceptions also specifically addresses the concerns related to indemnification terms in contracts, as well as revenue-sharing agreements. Under this alternative proposal, the actor and requestor would retain the flexibility to negotiate and execute specific details related to the requested manner of access, exchange, or use of the requested EHI. This proposal also ensures there is no mistaken belief that the Manner Exception would apply to any other practice of the actor related to fulfilling the request, including any contract or agreement on fees, licensing terms, or any matter other than the specific technical details of what EHI is requested, and how the request to access, exchange, or use the requested EHI will be fulfilled. As noted above, we have heard that actors may be abusing the *manner requested* conditions to convince requestors to accept disagreeable terms that would be considered an interference and likely information blocking. Removing paragraph (2) from § 171.301(a) and applying the Fees Exception and Licensing Exception would address these issues.

We welcome comments on our proposed revisions to the Manner Exception, including each of our proposals.

D. Removal of Subpart D Exception and Other Provisions Specific to TEFCA

In the HTI-1 Final Rule, we finalized a new TEFCA Manner Exception in 45 CFR 171.403, explaining that an actor's practice of limiting the manner in which it fulfills a request for access, exchange, or use of EHI to providing such access,

exchange, or use only via TEFCA would not be considered information blocking when the practice follows certain conditions (89 FR 1387). The conditions include that the actor and requestor are both part of TEFCA, that the requestor is capable of such access, exchange, or use of the requested EHI from the actor via TEFCA, that the request is not made via the standards adopted in 45 CFR 170.215 or version approved pursuant to 45 CFR 170.405(b)(8), and that any fees charged by the actor and the terms for any license of interoperability elements granted by the actor in relation to fulfilling the request satisfy, respectively, the Fees Exception (45 CFR 171.302) and the Licensing Exception (§ 171.303) (89 FR 1388).

In the HTI-2 Proposed Rule, we requested further comment on the TEFCA Manner Exception. We noted that the finalized exception differed in two ways from the proposal in the HTI-1 Proposed Rule: by applying the Fees Exception and the Licensing Exception to the TEFCA Manner Exception, and by including the limitation that carves out requests made for access, exchange, or use of EHI via FHIR API standards (89 FR 63643). We also solicited comment on the "FHIR" carve out, specifically for options for revising or sunseting the condition (89 FR 63643). Having considered comments received, we finalized the exception without changes in the HTI-2 Final Rule (89 FR 101778 through 80). We also proposed in the HTI-2 Proposed Rule (89 FR 63642) and finalized in the HTI-2 Final Rule (89 FR 101777 through 78) the addition of a definitions section (§ 171.401) to Subpart D of part 171: "Exceptions That Involve Practices Related to Actors' Participation in The Trusted Exchange Framework and Common Agreement (TEFCA™)".

We now propose to remove the TEFCA Manner Exception (§ 171.403) from 45 CFR part 171. Based on TEFCA's continued implementation and maturation and public comments received, including those received in response to the CMS-ASTP/ONC Request for Information; Health Technology Ecosystem (90 FR 21034) (CMS-ASTP/ONC RFI), the removal of the TEFCA Manner Exception (§ 171.403) is appropriate for multiple reasons.

The exception was intended to incentivize participation in TEFCA. However, many of the Qualified Health Information Networks (QHINs)—who already participate in TEFCA—were critical of the exception when it was proposed and presumably did not find the exception to be an incentive. Further, we have observed that there is

significant private sector investment being made toward TEFCA participation in the health information ecosystem. In comments on the CMS-ASTP RFI, stakeholders representing health care providers, technology innovators, and other perspectives, in addition to QHINs, advocated for continued use and advancement of TEFCA. We therefore believe that it is unnecessary to sustain the TEFCA Manner Exception to incentivize participation in TEFCA.

We also believe the TEFCA Exception may be negatively impacting participants in the health information ecosystem due to some entities' potential misunderstanding regarding its purpose and applicability. For example, although we stated when we finalized the exception that an actor responding to a request from an individual (e.g., a patient or the patient's personal representative) would not be able to make use of this exception, we have observed some ongoing misunderstanding of this exception as shielding actors who are part of TEFCA from information blocking penalties for practices that interfere with individual-access use cases.

The exception is also now unnecessary because it describes activities that are, given the robust TEFCA participation we are seeing, still covered by the Manner Exception (§ 171.301) or Infeasibility Exception (§ 171.204). The Manner Exception encourages active negotiation between a requestor and actor toward getting requestors the EHI access, exchange, and use they seek in a manner to which the requestor agrees. Conversely, the TEFCA Manner Exception allows for responding actors to limit a requestor who also participates in TEFCA to receiving EHI only via TEFCA when certain conditions are met by the actor, potentially slowing adoption of more innovative manners of access, exchange, or use than may be generally supported by TEFCA participants at any given point in time. Further, if an actor is unable to provide access, exchange, or use of EHI in the manner requested, the actor may find the Infeasibility Exception applicable to their circumstances, including the "*manner exception exhausted*" condition.

With consideration of comments received in response to the CMS-ASTP/ONC RFI and other RFIs, such as the Federal Trade Commission's Request for Public Comment Regarding Reducing Anti-Competitive Regulatory Barriers (FTC-2025-0028), we have become concerned that the narrow TEFCA Manner Exception (applicable only to certain types of exchange) may create an

unintended ceiling on future growth of TEFCA by discouraging participation by new entrants for whom other manners of access, exchange, or use of EHI will more efficiently support their innovative products and services. Instead, TEFCA's future growth will be supported by competition-oriented policies, compliance with applicable laws, and the continual advancement of efficient, interoperable manners of EHI access, exchange, and use of EHI that TEFCA supports.

We note that removing the TEFCA Manner Exception would not remove any obligations an actor may have as a QHIN, Participant, or Sub-participant in TEFCA to fulfill TEFCA requirements. The TEFCA Manner Exception does not create, reduce, or otherwise affect any obligations any actor may have as a QHIN, Participant, or Sub-participant in TEFCA to fulfill TEFCA requirements.

Finally, we remind readers that removing this exception would *not* mean that a practice that would have been covered by the TEFCA Manner Exception would automatically be considered information blocking. As always, for any practice to be considered information blocking, it must be examined on a case-by-case basis in order to assess the specific facts and circumstances and determine whether the practice meets the information blocking definition (*see* § 171.103, *see also* IB.FAQ46.1.2022FEB: How would any claim or report of information blocking be evaluated).⁸¹

Because the TEFCA Manner Exception (§ 171.403) is the only exception codified in subpart D of part 171, we also propose to remove the entire subpart (subpart D). As currently codified, subpart D includes only three sections: § 171.400; § 171.401; and § 171.403. The removal of § 171.403 would render the remaining two sections unnecessary. Section 171.400, "Availability and effect of exceptions," mirrors §§ 171.200 and 171.300, stating that a practice shall not be treated as information blocking if the actor satisfies an exception to the information blocking provision as set forth in subpart D by meeting all applicable requirements and conditions of the exception at all relevant times (89 FR 1388). Without any exceptions specific to practices related to an actor's participation in TEFCA, § 171.400 would serve no purpose. Similarly, § 171.401 would serve no purpose because it only includes definitions for the subpart via cross-reference to the

TEFCA definitions included 45 CFR part 172, "Trusted Exchange Framework and Common Agreement."

We welcome comments on these proposals.

V. Incorporation by Reference

The Office of the Federal Register has established requirements for materials (e.g., standards and implementation specifications) that agencies propose to incorporate by reference in the Code of Federal Regulations (79 FR 66267; 1 CFR 51.5). Specifically, 1 CFR 51.5(a) requires agencies to discuss, in the preamble of a proposed rule, the ways that the materials they propose to incorporate by reference are reasonably available to interested parties and how interested parties can obtain the materials, and to summarize, in the preamble of the proposed rule, the material it proposes to incorporate by reference.

To make the material we intend to incorporate by reference reasonably available, we provide a uniform resource locator (URL) for the standard. This standard is directly accessible through the URL provided. As an alternative, a copy of the standard may be viewed for free at the U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, 330 C Street SW, Washington, DC 20201. Please call (202) 690-7171 in advance to arrange inspection.

The NTTAA and the OMB Circular A-119 require the use of, wherever practical, technical standards that are developed or adopted by voluntary consensus standards bodies to carry out policy objectives or activities, with certain exceptions. The NTTAA and OMB Circular A-119 provide exceptions to selecting only standards developed or adopted by voluntary consensus standards bodies, namely when doing so would be inconsistent with applicable law or otherwise impractical. As discussed in section III.B.1.a of this preamble, we have followed the NTTAA and OMB Circular A-119 in proposing a standard for adoption, including describing any exceptions in the adoption of the standard.

As required by 1 CFR 51.5(a), we provide a summary of the standard we propose to adopt and subsequently incorporate by reference in the CFR. We also provide relevant information about the standard throughout the preamble.

United States Core Data for Interoperability—45 CFR 170.213

- *United States Core Data for Interoperability (USCDI), June 2025, Version 3.1 (v3.1)* URL: https://www.healthit.gov/isp/sites/isp/files/USCDI-Version-3-1_2025_508.pdf. This is a direct access link.

Summary: USCDI establishes a minimum set of data classes that are required to be interoperable nationwide and is designed to be expanded in an iterative and predictable way over time.

The following standards appear in the amendatory text of this document and have already been approved for the locations in which they appear:

- HL7 Messaging Standard Version 2.5.1,
- HL7 Clinical Document Architecture (CDA), Release 2.0, Normative Edition,
- HL7 CDA® Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1; DSTU Release 1.1, Volume 1—Introductory Material and Volume 2—Templates and Supporting Material,
- HL7 Implementation Guide for CDA® Release 2: National Health Care Surveys (NHCS), Release 1—US Realm, HL7 Draft Standard for Trial Use, Volume 1—Introductory Material and Volume 2—Templates and Supporting Material,
- HL7® FHIR® Implementation Guide: Electronic Case Reporting (eCR)—US Realm 2.1.0—STU 2 US (HL7 FHIR eCR IG),
- HL7 CDA® R2 Implementation Guide: Public Health Case Report—the Electronic Initial Case Report (eICR) Release 2, STU Release 3.1—US Realm (HL7 CDA eICR IG),
- HL7® CDA® R2 Implementation Guide: Reportability Response, Release 1, STU Release 1.1—US Realm (HL7 CDA RR IG), and
- Reportable Conditions Trigger Codes Value Set for Electronic Case Reporting.

No changes are proposed to the IBR material.

VI. Response to Comments

Because of the large number of public comments normally received in response to **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and when we proceed with a subsequent document, we will respond to the comments in the preamble of that document.

⁸¹ <https://www.healthit.gov/faq/how-would-any-claim-or-report-information-blocking-be-evaluated>.

VII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), codified as amended at 44 U.S.C. 3501 *et seq.*, agencies are required to provide notice in the **Federal Register** and solicit public comment on a proposed collection of information before it is submitted to the Office of Management and Budget for review and approval. In order to fairly evaluate whether an information collection should be approved by the OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

1. Whether the information collection is necessary and useful to carry out the proper functions of the agency;
2. The accuracy of the agency's estimate of the information collection burden;
3. The quality, utility, and clarity of the information to be collected; and
4. Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Under the PRA, the time, effort, and financial resources necessary to meet the information collection requirements referenced in this section are to be considered. We explicitly seek, and will consider, public comment on our assumptions as they relate to the PRA requirements summarized in this section.

A. *ONC-ACBs*

We propose to descope the “Real World Testing” Condition and Maintenance of Certification requirements in § 170.405 with deregulatory actions related to real world testing plans, results, and the use of the standards version advancement process (SVAP). Consistent with these proposals to descope the Real World Testing Condition and Maintenance of Certification requirements, we propose to make conforming edits in § 170.523(p) to remove the ONC-ACB review and confirmation process for real world testing plans in § 170.523(p)(1), and the submission of real world testing plans in § 170.523(p)(3) which requires ONC-ACBs to collect and report certain information to ONC related to real world testing plans (e.g., verify that the health IT developer submits an annual, publicly available real world testing plan and perform a completeness check). Our proposals in this proposed rule would not add any new collection of information burden and would instead reduce reporting burden associated with the proposed deregulatory actions.

In the 2015 Edition proposed rule (80 FR 16894), we estimated fewer than ten annual respondents for all of the regulatory “collection of information” requirements that apply to the ONC-Approved Accreditor (ONC-AA) and ONC-ACBs, including those previously approved by OMB. In the 2015 Edition Final Rule (80 FR 62733), we concluded that the regulatory “collection of information” requirements for the ONC-AA and the ONC-ACBs were not subject to the PRA under 5 CFR 1320.3(c). We continue to estimate less than ten annual respondents for all of the proposed regulatory “collection of information” requirements for ONC-ACBs under part 170 of title 45, including those previously approved by OMB and proposed in this proposed rule. Accordingly, the regulatory “collection of information” requirements under the Program described in this section are not subject to the PRA under 5 CFR 1320.3(c). We welcome comments on these conclusions and the supporting rationale on which they are based. For the cost and burden reduction estimates related to these proposed deregulatory actions, we refer readers to section VIII (Regulatory Impact Analysis) of this proposed rule.

B. *Health IT Developers*

The “Insights” Condition and Maintenance of Certification requirements in § 170.407 include seven measures that health IT developers under the ONC Health IT Certification Program must annually report on consistent with specified regulatory compliance timelines. In the HTI-1 Final Rule (89 FR 1399), we estimated the total crude upper bound burden to be 1,767,692 hours. In this proposed rule, we propose to remove and descope measures associated in § 170.407 to limit reporting requirements only to the “use of FHIR in apps through certified health IT” measure, which would reduce reporting burden for health IT developers reporting under the Certification Program. In other words, we propose to reduce reporting burden associated with the Insights Condition and Maintenance of Certification requirements, and do not propose any new requirements that would add information collection burden. For more detailed discussion of burden reduction estimates of these deregulatory actions associated with the Insights Condition and Maintenance of Certification, we refer readers to section VIII (Regulatory Impact Analysis) of this proposed rule.

VIII. Regulatory Impact Analysis

A. *Statement of Need*

E.O. 14192 on Unleashing Prosperity Through Deregulation, issued January 31, 2025, sets the policy to “to significantly reduce the private expenditures required to comply with Federal regulations to secure America’s economic prosperity and national security and the highest possible quality of life for each citizen.”⁸² To that end, E.O. 14192 requires that “any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.”⁸³ This proposed rule, if finalized as proposed, is expected to be an E.O. 14192 deregulatory action and includes regulations and policies ASTP/ONC proposes to remove and revise to unleash prosperity. We believe the proposed changes will reduce burden on developers of certified health IT, returning time and effort to them, and in turn, enhancing competition, entrepreneurship, and innovation. These proposed deregulatory actions will reduce barriers to entry for novel technologies and digital health solutions, give time back to developers of certified health IT to focus on the needs and requests of their customers, and, overall, advance progress toward nationwide interoperability and universal patient access to their electronic health information.

B. *Overall Impact*

We have examined the impacts of this proposed rule as required by E.O. 12866, “Regulatory Planning and Review”; E.O. 13132, “Federalism”; E.O. 13563, “Improving Regulation and Regulatory Review”; E.O. 14192, “Unleashing Prosperity Through Deregulation”; section 202 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532); and the Regulatory Flexibility Act (RFA) (Pub. L. 96–354).

1. *Regulatory Planning and Review Analysis*

This proposed rule implements relevant policy priorities outlined in E.O.s 12866, 13563, and 14192. E.O. 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety

⁸² <https://www.federalregister.gov/d/2025-02345/p-2>.

⁸³ <https://www.federalregister.gov/d/2025-02345/p-6>.

effects, and distributive impacts). E.O. 14192 directs agencies to repeal ten existing regulations for each new regulation issued in 2025 and thereafter and to account for cost savings associated with deregulatory actions. This proposed rulemaking, if finalized as proposed, is expected to be an E.O. 14192 deregulatory action, and we have therefore prepared an RIA that to the best of our ability presents the expected significant cost savings to regulated entities generated by the proposed actions.

a. Costs and Benefits

These proposed deregulatory actions provide substantial relief for developers of certified health IT and significant cost savings realized from the revision and removal of certain program requirements. For the purpose of estimating the cost savings of this proposed rulemaking, we have determined that these policies would continue absent this regulatory action. The cost savings have been estimated using the best available data and modeled on the costs estimated and finalized in prior ASTP/ONC rulemakings. As articulated in the preamble, these proposed deregulatory actions reduce the effort of developers of certified health IT to meet ongoing program requirements and reduce barriers to entry for new program participants. The proposed actions, importantly, return effort back to developers of certified health IT to innovate their technology and focus on the needs of their clients and end users.

Employee Assumptions and Hourly Wage

We have made employee assumptions about the level of expertise needed to complete the requirements that are affected by this proposed rule. Unless indicated otherwise, for wage calculations for Federal employees and ONC-ACBs, we have correlated the employee's expertise with the corresponding grade and step of an employee classified under the General Schedule (GS) Federal Salary Classification, relying on the associated employee hourly rates for the Washington, DC, locality pay area as published by the OPM for 2025.⁸⁴ We have assumed that other indirect costs (including benefits) are equal to 100% of pre-tax wages. Therefore, we have doubled the employee's hourly wage to account for other indirect costs. We have concluded that a 100% expenditure on benefits and overhead is

an appropriate estimate based on research conducted by HHS.⁸⁵

Unless otherwise noted, we have consistently used the May 2024 National Occupational Employment and Wage Estimates reported by the U.S. Bureau of Labor Statistics (BLS) to calculate private sector employee wage estimates (*e.g.*, health IT developers, health care providers, HINs, attorneys, etc.), as we believe BLS provides the most accurate and comprehensive wage data for private sector positions.⁸⁶ These wage estimates are a national average and we do not consider regional wage variation in our estimates. We also do not consider possible variation in the average wages for software developers in health care IT positions versus IT positions, more generally, which the BLS wage estimate is based upon. Just as with the General Schedule Federal Salary Classification calculations, we have assumed that other indirect costs (including benefits) are equal to 100% of pre-tax wages. We welcome comments on our methodology for estimating labor costs, including the effects of any regional or IT sector wage variation on our estimates.

According to the May 2024 BLS occupational employment statistics, the mean hourly wage for a "Software Developer" is \$69.50. As noted previously, we have assumed that other indirect costs (including benefits) are equal to 100% of pre-tax wages, so the hourly wage including other indirect costs for Software Developers is \$139.00.

Quantifying the Estimated Number of Health IT Developers and Products

Given the wide range of proposed deregulatory actions, we have not adopted a single, over-arching approach to calculate the number of health IT developers and products affected by this rulemaking. We believe, however, that each current developer of certified health IT and participant in the Certification Program will be affected by these proposed actions, but that impact will vary, given the breadth and scope of each developer's participation in the Certification Program. For each set of proposed actions, we describe our methodology for calculating the current number of health IT developers and products affected, and, where applicable, model estimated future

counts of developers and products affected.

Number of End Users That Might Be Impacted by ASTP/ONC's Proposed Regulations

The breadth and scope of the proposed deregulatory actions create immediate and significant cost savings for developers of certified health IT. As we have finalized in prior ASTP/ONC rulemakings—Cures Act Final Rule (85 FR 25642) and HTI-1 Final Rule (89 FR 1192)—we assume the regulatory costs imposed by those rules on developers may be passed on to end users of their technology in the form of increased fees and other costs. These deregulatory actions, though scoped to provide immediate relief and reduce ongoing burden on developers of certified health IT, may have downstream impacts on technology end users who may benefit from lower marginal costs to license and update their software; focused developers efforts on emerging end user needs; and other forms of innovation that may lead to unquantified benefits and savings for end users. We assume developers of certified health IT will use the cost savings to invest in innovation and emerging technology, rather than directly reduce costs on their end users, but, overall, believe the cost savings will create a net benefit to end users, if not directly as an immediate financial savings.

Costs

We do not expect costs to be associated with the deregulatory action proposals. We do, however, estimate the costs to review the rule.

All entities affected by this proposed rule, if finalized, would spend time to read and understand the final rule, resulting in a one-time cost. The current Preamble and proposed regulatory text together contain approximately 64,727 words; we use this as a proxy for the length of the final rule. Consistent with HHS guidelines, we assume that industry reviewers read at the average adult reading speed of approximately 288 (64,727/225) words per minute, so the time to read and understand the regulation would be about 4 hours per person (288*60=17,280) (64,727/17,280=3.75). We estimate the total number of reviewers by taking the number of estimated developers and adding an estimated number of medical associations that represent health care providers and health information networks, etc. The counts of developers included in Table R-1 were calculated using publicly available Certification Program data available through the

⁸⁴ <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2025/general-schedule/>.

⁸⁵ See U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation (ASPE), Guidelines for Regulatory Impact Analysis, at 28–30 (2016), available at <https://aspe.hhs.gov/reports/guidelines-regulatory-impact-analysis>.

⁸⁶ <https://data.bls.gov/oes/#/industry/000000>.

CHPL.⁸⁷ We took the estimated number of developers from Table R–1, which is 444 developers and estimated 200 medical associations.⁸⁸ We then determined that there would likely be 644 individuals to review the proposed rule. As mentioned above, we used the May 2024 National Occupational Employment and Wage Estimates reported by the BLS to calculate private sector employee wage estimates.⁸⁹ We identified the “Management Analyst” position as comparable to a position that would review the rule. According to the May 2024 BLS occupational employment statistics, the mean hourly wage for a “Management Analyst” is \$55.15. As noted previously, we have assumed that other indirect costs (including benefits) are equal to 100% of pre-tax wages, so the hourly wage including other indirect costs for a Management Analyst is \$110.30. We estimate it will take four hours to review the proposed rule. Therefore, the total cost to review the rule for one reviewer would be \$441.20 (\$110.30*4). We took the estimated number of individuals to review the rule which is 644 and then multiplied that by \$441.20 and calculated the estimated total cost to review the rule to be \$284,132 (\$441.20*644).

Benefits

We expect the proposed deregulatory actions to result in significant benefits for health IT developers, providers, ONC–ACBs, ONC–ATLs, and ASTP/ONC. These expected benefits are detailed below. Generally, these benefits are in the form of cost and time savings and reductions in administrative burden to comply with Certification Program requirements. The proposed actions reduce the scope and breadth of program requirements. The proposed program revisions provide direct cost savings (quantified, below) to developers of certified health IT and their users (i.e., providers) through fewer program requirements and lower

regulatory barriers, freeing up time for more innovation and meeting customer needs. In turn, the revised program requirements may reduce the implementation effort on ONC–ACBs, ONC–ATLs, and ASTP/ONC, who works with ACBs and ATLs to implement program requirements. These savings in time and effort to ONC–ACBs, ONC–ATLs, and ASTP/ONC can be used toward remaining program improvement and implementation efforts, enhancing the operation and management of the program.

1. Removal

1.1 Removal of Certification Criteria

We propose to remove 34 certification criteria. Of these, we propose to remove 24 criteria as of the effective date of any final rule and the remaining ten criteria as of January 1, 2027. We developed a common model for estimating cost savings associated with the removal of all but one certification criterion, described below. For all criteria we assume that the cost savings from these criteria would begin January 1, 2027.

Table R–1, below, provides criterion-level results of our model for 32 of the proposed criteria removals. For each certification criterion we identified the original costs to certify to the functionality from prior rules (the lower and upper bounds of “Total Hours” in Table R–1.)^{90 91 92} We then assumed that the annual cost to maintain certification was a small fraction of the initial costs. We are not aware of any published evidence that would directly inform this calculation, and, therefore, developed a novel approach using various information sources. We defined this fraction (“Final Effort Multiplier” in Table R–1) based on five factors: (1)

“Test”: the criterion’s certification conformance method, assuming that criteria with a test procedure had additional maintenance costs while those with a conformance method of attestation had no additional cost beyond what was initially incurred; (2) “Stakeholder feedback”: stakeholder feedback received by ASTP/ONC through meetings, informal conversations, and letters from impacted parties on effort involved in certifying and updating the specific certification criterion; (3) “Complexity of standard”: whether the criterion referenced a standard and an assessment of the complexity involved in maintaining and updating conformance to that standard over time, including through future regulatory requirements to update criteria to support new versions of the USCDI; (4) “Complexity of test procedure”: an assessment of the complexity of the test procedure or evaluative work to support attestation when it was necessary to undertake the certification process; and (5) “General complexity”: an overall assessment of the complexity of maintaining the certification criterion and underlying functionality.

The “Final Effort Multiplier” is a sum of the five factors listed in the table and described above. We then used this multiplier to determine the annual costs of meeting and maintaining the individual criteria by taking the product of the lower and upper bound “Total Hours”, described above, and this multiplier. We then estimated the lower and upper bounds of “Hours saved” by multiplying the “Annual” hours by the number of products that certify each criterion. The counts of developers and products included in Table R–1 are current as of May 1, 2025. The counts were calculated using publicly available Certification Program data available through the CHPL.⁹³ Although we primarily use the count of products to estimate “Hours saved”, the count of developers is included for reference and comparison.

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⁹³ <https://chpl.healthit.gov>.

⁹⁰ <https://www.federalregister.gov/documents/2015/10/16/2015-25597/2015-edition-health-information-technology-health-it-certification-criteria-2015-edition-base#p-185>.

⁹¹ <https://www.federalregister.gov/documents/2024/01/09/2023-28857/health-data-technology-and-interoperability-certification-program-updates-algorithm-transparency-and>.

⁹² <https://www.federalregister.gov/documents/2020/05/01/2020-07419/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification>.

⁸⁷ <https://chpl.healthit.gov>.

⁸⁸ https://www.ama-assn.org/house-delegates/hod-organization/member-organizations-ama-house-delegates?utm_source=chatgpt.com.

⁸⁹ <https://data.bls.gov/oes/#/industry/000000>.

Table R-1: Panel A – Estimates of Annual Labor Hours Saved for the Removal of Certification Criteria

Criterion	Adjustments					Final Effort Multiplier	Total hours		Annual		Developers certified	Products certified	Hours saved	
	Test	Stakeholder feedback	Complexity of standard	Complexity of test procedure	General complexity		LB	UB	LB	UB			LB	UB
§ 170.315(a)(12)	0%	2%	5%	2%	2%	11%	50	100	5.5	11	262	325	1,788	3,575
§ 170.315(a)(14)	0%	2%	0%	2%	2%	6%	700	2,000	42	120	266	327	13,734	39,240
§ 170.315(b)(2)	2%	4%	10%	6%	6%	28%	500	600	140	168	225	267	37,380	44,856
§ 170.315(b)(7)	2%	0%	10%	2%	4%	18%	800	1,300	144	234	31	32	4,608	7,488
§ 170.315(b)(8)	2%	0%	10%	2%	4%	18%	800	1,300	144	234	30	31	4,464	7,254
§ 170.315(b)(9)	0%	2%	5%	2%	4%	13%	700	1,000	91	130	38	45	4,095	5,850
§ 170.315(c)(4)	2%	0%	5%	2%	0%	9%	1,000	1,500	90	135	59	67	6,030	9,045
§ 170.315(d)(1)	0%	0%	0%	2%	6%	8%	50	100	4	8	426	567	2,268	4,536
§ 170.315(d)(2)	0%	0%	5%	2%	2%	9%	50	100	4.5	9	408	546	2,457	4,914
§ 170.315(d)(3)	0%	0%	10%	2%	2%	14%	50	100	7	14	411	552	3,864	7,728
§ 170.315(d)(4)	0%	0%	0%	2%	6%	8%	50	100	4	8	319	393	1,572	3,144
§ 170.315(d)(5)	0%	0%	0%	2%	0%	2%	50	100	1	2	391	503	503	1,006
§ 170.315(d)(6)	0%	0%	0%	2%	2%	4%	50	100	2	4	340	426	852	1,704
§ 170.315(d)(7)	0%	0%	5%	2%	4%	11%	50	100	5.5	11	380	502	2,761	5,522
§ 170.315(d)(8)	0%	0%	5%	2%	4%	11%	50	100	5.5	11	310	389	2,140	4,279
§ 170.315(d)(9)	0%	0%	10%	2%	4%	16%	100	200	16	32	323	411	6,576	13,152
§ 170.315(d)(10)	0%	2%	10%	2%	4%	18%	50	100	9	18	42	45	405	810
§ 170.315(d)(11)	0%	0%	0%	2%	0%	2%	400	600	8	12	84	113	904	1,356
§ 170.315(d)(12)	0%	2%	5%	2%	2%	11%	50	100	5.5	11	439	581	3,196	6,391
§ 170.315(d)(13)	0%	2%	0%	2%	2%	6%	50	100	3	6	439	581	1,743	3,486
§ 170.315(e)(3)	0%	2%	0%	2%	2%	6%	500	800	30	48	218	279	8,370	13,392
§ 170.315(f)(4)	0%	0%	5%	2%	4%	11%	800	1,000	88	110	39	44	3,872	4,840
§ 170.315(f)(7)	0%	0%	5%	2%	2%	9%	1,000	1,400	90	126	48	56	5,040	7,056
§ 170.315(g)(1)	2%	6%	0%	4%	4%	16%	800	1,200	128	192	21	26	3,328	4,992
§ 170.315(g)(2)	2%	6%	0%	4%	4%	16%	1,000	1,600	160	256	216	275	44,000	70,400
§ 170.315(g)(4)	2%	2%	0%	4%	2%	10%	50	160	5	16	444	589	2,945	9,424
§ 170.315(g)(5)	2%	0%	0%	4%	4%	10%	50	100	5	10	444	589	2,945	5,890
§ 170.315(g)(6)	2%	4%	10%	2%	4%	22%	400	900	88	198	282	360	31,680	712,80
§ 170.315(g)(7)	0%	0%	0%	4%	4%	8%	300	400	24	32	248	303	7,272	9,696
§ 170.315(g)(9)	2%	4%	10%	4%	4%	24%	300	400	72	96	243	296	21,312	28,416
§ 170.315(h)(1)	2%	4%	10%	2%	4%	22%	800	1,100	176	242	176	209	36,784	50,578
§ 170.315(h)(2)	2%	4%	15%	2%	4%	27%	800	1,100	216	297	16	16	3,456	4,752
All Criteria	--	--	--	--	--	--	--	--	--	--	444	589	272,344	456,052

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TABLE R-1—PANEL B—ANNUAL UNDISCOUNTED COST SAVINGS ESTIMATES FOR THE REMOVAL OF CERTIFICATION CRITERIA

Criterion	Name	Lower bound	Upper bound
§ 170.315(a)(12)	Family health history	\$248,463	\$496,925
§ 170.315(a)(14)	Implantable device list	1,909,026	5,454,360
§ 170.315(b)(2)	Clinical information reconciliation and incorporation	5,195,820	6,234,984
§ 170.315(b)(7)	Security tags—summary of care—send	640,512	1,040,832

TABLE R-1—PANEL B—ANNUAL UNDISCOUNTED COST SAVINGS ESTIMATES FOR THE REMOVAL OF CERTIFICATION CRITERIA—Continued

Criterion	Name	Lower bound	Upper bound
§ 170.315(b)(8)	Security tags—summary of care—receive	620,496	1,008,306
§ 170.315(b)(9)	Care plan	569,205	813,150
§ 170.315(c)(4)	Clinical quality measures (CQMs)—filter	838,170	1,257,255
§ 170.315(d)(1)	Authentication, access control, authorization	315,252	630,504
§ 170.315(d)(2)	Auditable events and tamper-resistance	341,523	683,046
§ 170.315(d)(3)	Audit report(s)	537,096	1,074,192
§ 170.315(d)(4)	Amendments	218,508	437,016
§ 170.315(d)(5)	Automatic access time-out	69,917	139,834
§ 170.315(d)(6)	Emergency access	118,428	236,856
§ 170.315(d)(7)	End-user device encryption	383,779	767,558
§ 170.315(d)(8)	Integrity	297,391	594,781
§ 170.315(d)(9)	Trusted connection	914,064	1,828,128
§ 170.315(d)(10)	Auditing actions on health information	56,295	112,590
§ 170.315(d)(11)	Accounting of disclosures	125,656	188,484
§ 170.315(d)(12)	Encrypt authentication credentials	444,175	888,349
§ 170.315(d)(13)	Multi-factor authentication	242,277	484,554
§ 170.315(e)(3)	Patient health information capture	1,163,430	1,861,488
§ 170.315(f)(4)	Transmission to Cancer Registries	538,208	672,760
§ 170.315(f)(7)	Transmission to PHAs—Health Care Surveys	700,560	980,784
§ 170.315(g)(1)	Automated numerator recording	462,592	693,888
§ 170.315(g)(2)	Automated measure calculation	6,116,000	9,785,600
§ 170.315(g)(4)	Quality management system	409,355	1,309,936
§ 170.315(g)(5)	Accessibility-centered design	409,355	818,710
§ 170.315(g)(6)	Consolidated CDA creation performance	4,403,520	9,907,920
§ 170.315(g)(7)	Application access—patient selection	1,010,808	1,347,744
§ 170.315(g)(9)	Application access—all data request	2,962,368	3,949,824
§ 170.315(h)(1)	Direct Project	5,112,976	7,030,342
§ 170.315(h)(2)	Direct Project, Edge Protocol, and XDR/XDM	480,384	660,528
Total Cost Savings		37,855,816	63,391,228

* The lower and upper bound cost savings estimates use the hourly wage (\$139.00) we describe above in “Employee Assumptions and Hourly Wage”.

For the 32 certification criteria proposed for removal in Table R-1, we estimate the total annual hours saved to range from 272,344 to 456,052, among 444 developers of certified health IT and 589 certified products (Table R-1). Using the hourly labor rate (\$139), described above, we estimate the total undiscounted annual cost savings to range from \$37,855,816 to \$63,391,228. We welcome comments on the proposed methodology and the accuracy and validity of the model’s estimates.

1.2 Removal of Safety-Enhanced Design

Cost savings from the proposed removal of § 170.315(g)(3) safety-enhanced design (SED) is estimated separately from non-SED removed criteria. In the 2015 Edition Final Rule, we estimated that developers would spend 300 to 400 hours implementing the SED criterion at a cost of \$63 per hour and that 266 developers would certify to SED. This resulted in a final cost estimate ranging from \$5,027,400 to \$6,703,200 in 2014 dollars. Since the finalization of that policy, we have received substantial input from

developers of certified health IT that the cost estimates specified in that rule were an under-estimate of the initial and recurring costs associated with the SED certification criterion. In contrast to those estimates, we understand that individual developers of certified health IT incur recurring costs greater than \$200,000 to recruit participants and conduct testing specified by the SED certification criterion. In response to input from the impacted community, we have revised our estimates of the costs of SED and potential cost savings that can be realized from the proposed removal of the SED certification criterion in this proposed rule.

The SED certification criterion is required for all developers seeking certification to § 170.315(a)(1) through (5), (9) (until the certification criterion’s expiration date), (a)(14), (b)(2), (b)(3) or (b)(11). Developers must recruit at least ten participants, conduct testing, and submit metrics for each of the criterion for which they seek certification that is referenced within § 170.315(g)(3). Thus, we believe cost savings from the removal of SED are incremental per the number of dependent criteria certified

because there are additional costs per product associated with SED testing and data reporting. Based on stakeholder input and because developers can certify multiple products each with up to ten criteria that requires SED, we believe an estimated annual cost of between \$8,000 and \$12,000 per product per certification criterion that requires SED testing is appropriate. This estimate represents the effort to design tests, recruit participants, conduct testing, document that testing, and report results to the ONC-ACB in the required format.

To estimate the total costs of SED, we estimated the number of products that will be certified to SED and the number of SED criteria each product will certify. We report those costs in Table R-2. The count of products that are certified to SED and number of SED criteria each product certifies in the table are current as of May 1, 2025. The counts were calculated using publicly available Certification Program data available through the CHPL.⁹⁴

⁹⁴ <https://chpl.healthit.gov>.

TABLE R-2—ANNUAL COST SAVINGS ESTIMATES FOR REMOVAL OF § 170.315(g)(3)

Number of SED criteria certified	Number of products	Lower bound cost per product (hours)	Upper bound cost per product (hours)	Total lower bound cost (\$)	Total upper bound cost (\$)
1	17	8,000	12,000	136,000	204,000
2	4	8,000	12,000	64,000	96,000
3	7	8,000	12,000	168,000	252,000
4	19	8,000	12,000	608,000	912,000
5	21	8,000	12,000	840,000	1,260,000
6	28	8,000	12,000	1,344,000	2,016,000
7	33	8,000	12,000	1,848,000	2,772,000
8	62	8,000	12,000	3,968,000	5,952,000
9	182	8,000	12,000	13,104,000	19,656,000
	373			22,080,000	33,120,000

Note: The lower and upper bound cost estimates use the hourly wage (\$139.00) we describe above in “Employee Assumptions and Hourly Wage”.

In total, 373 products are certified to SED and at least one SED certification criterion. Based on Table R-2, we estimate the total undiscounted annual cost savings from removing the SED certification criteria to be between \$22,080,000 and \$33,120,000. We welcome comments on the proposed methodology and the accuracy and validity of the estimates.

2. Revisions

2.1 Revision of Certification Criteria

We propose to revise seven certification criteria. For each revised certification criterion, we have estimated the annual savings generated by the proposed revisions.

2.1.1 § 170.315(a)(5) Patient Demographics and Observations

We propose to codify certification guidance for the Certification Program exercising our enforcement discretion—specifically, for the “patient demographics and observations” certification criterion in § 170.315(a)(5).⁹⁵ We expect this proposed revision to reduce the effort associated with meeting the requirements in § 170.315(a)(5) in the form of reduced maintenance costs. Using the approach described for removed criteria, we estimate that the removal of these requirements will reduce the annual effort of maintaining certification by 5% of the projected development costs estimated in the HTI-1 Final Rule. We note that 288 developers have certified 352 products to § 170.315(a)(5) and that the initial developer hours estimated to implement updates to the criterion in the HTI-1 Final Rule had a lower bound of 720 hours and an upper bound of 1,860

hours. We therefore estimate that the revision of this criterion will reduce effort by between 36 and 93 hours per product and 12,672 to 32,736 hours across all products. We estimate the total undiscounted annual cost savings for reduced maintenance to range from \$1,761,408 to \$4,550,304.

2.1.2 § 170.315(b)(1) Transitions of Care

We propose to revise the certification criterion in § 170.315(b)(1) to reduce burden on developers of health IT by removing the “send and receive via edge protocol” C-CDA requirement and “create” C-CDA requirement in the criterion and by simplifying the remaining criterion requirements to focus solely on validating receipt of C-CDA documents. We believe that these revisions remove a substantial proportion of the ongoing effort required to maintain and update the functional requirement of the certification criterion, but we acknowledge that it does not remove requirements to support the C-CDA standard or to update functionality to receive C-CDA documents. We assume that this reduces the overall ongoing cost for this criterion by 60%. Following the methodology described for removed criterion, we considered annual maintenance of § 170.315(b)(1) to represent high complexity equivalent to 15% of the initial development costs annually. We note from an analysis of current Certification Program data that 256 developers have certified 300 products to § 170.315(b)(1) and that the initial developer hours estimated to implement the criterion had a lower bound of 3,000 hours and an upper bound of 4,000 hours in the 2015 Edition Final Rule (80 FR 62602).⁹⁶ We

therefore estimate that the revision of this criterion will reduce effort to maintain the criterion annually by 9% annually or between 270 and 360 hours per product and 81,000 to 108,000 hours across all products. We estimate the total undiscounted annual cost savings to range from \$11,259,000 to \$15,012,000.

2.1.3 § 170.315(b)(11) Decision Support Interventions

We propose to remove all requirements related to source attributes, their access, and modification and requirements to manage risks related to the development of predictive DSIs.

In the HTI-1 Final Rule, we indicated that the costs to implement § 170.315(b)(11) ranged from 2,200 hours to 4,600 hours, that updating source attribute information annually would cost an additional 0 to 1085 hours annually, depending on the number of DSIs the developer supplied, and that engaging in risk management and updating information would result in an additional 0 to 285 hours annually. Without this revision, we estimate that annual maintenance costs for this criterion would represent 12% of initial development costs. We believe these changes reduce these costs by 80% and would eliminate annual costs to update information for source attributes and risk management.

In total, we estimate that the revision will reduce maintenance costs by 211 to 1,812 hours per product. We note that 232 products developed by 183 developers were certified to § 170.315(b)(11) resulting in an annual reduction of 48,952 to 420,384 labor hours. We estimate the total undiscounted annual cost savings to range from \$6,804,328 to \$58,433,376.

⁹⁵ <https://www.healthit.gov/topic/uscdi-v3-data-elements-enforcement-discretion-notice>.

⁹⁶ <https://www.federalregister.gov/d/2015-25597/p-1773>.

2.1.4 § 170.315(c)(3) Clinical Quality Measures (CQMs)—Report

We propose revisions to § 170.315(c)(3) to remove expired standards references. These proposed revisions are considered de minimis and do not create net new cost savings.

2.1.5 § 170.315(e)(1) View, Download and Transmit to a 3rd Party

We propose to revise § 170.315(e)(1) to remove the standards referenced in § 170.315(e)(1)(i), Web Content Accessibility Guidelines (WCAG) 2.0, and § 170.315(e)(1)(ii), Network Time Protocol (NTP) standard. We believe that the requirement to demonstrate conformance to the WCAG standard creates substantial burden for developers. We received feedback from developers that licensing a tool for WCAG assessments costs thousands of dollars annually. We acknowledge that the current referenced standards are old and do not easily work with newer versions of both the standard itself as well as testing tools to determine compliance. Thus, we expect these changes will reduce unnecessary burden associated with maintaining current conformance requirements as part of certification. In total, we estimate that the annual maintenance burden associated with the WCAG standard represented 2% of the initial development costs of the VDT criterion. We note that 215 developers have certified 255 products to § 170.315(e)(1) and that the initial developer hours estimated to implement the criterion had a lower bound of 1,300 hours and an upper bound of 2,000 hours in the 2015 Edition Final Rule which included the updated WCAG requirement. We therefore estimate that the revision of this criterion will reduce effort to maintain the criterion annually by 2% annually or between 26 and 40 hours per product and 6,630 to 10,200 hours across all products. We estimate the total undiscounted annual cost savings to range from \$921,570 to \$1,417,800.

2.1.6 § 170.315(f)(5) Transmission to Public Health Agencies—Electronic Case Reporting

We propose to codify certification guidance for the Certification Program

exercising our enforcement discretion for—specifically, the “Transmission to public health agencies—electronic case reporting” certification criterion in § 170.315(f)(5).⁹⁷ We expect this proposed revision to reduce the burden associated with meeting the requirements in the eCR certification criterion in the form of reduced maintenance costs. Following the methodology described for removed criterion, we considered annual maintenance of § 170.315(f)(5), as finalized in the HTI–1 Final Rule and becoming effective on December 31, 2025, to represent high complexity equivalent to 27% of the initial development costs annually. We estimate that removal of standards-based requirements will reduce annual maintenance costs to 10% of initial development costs, a 63% reduction in effort.

Currently, 94 developers and 127 products are certified to § 170.315(f)(5). Eighty-six developers and 112 products are certified to the “functional” requirements in § 170.315(f)(5)(i) alone, while 10 developers and 15 products are certified to the standards-based requirements in § 170.315(f)(5)(ii). The initial developer hours estimated to implement the criterion had a lower bound of 0 hours and an upper bound of 2,160 in the HTI–1 Final Rule. We therefore estimate that the revision of this criterion will reduce annual effort to maintain the criterion by between 0 and 367 labor hours per product and 0 to 46,609 labor hours across all 127 products. We estimate the total undiscounted annual cost savings for reduced maintenance to range from \$0 to \$6,478,651.

2.1.7 § 170.315(f)(6) Transmission to Public Health Agencies—Antimicrobial Use and Resistance Reporting

We propose to remove the standards-based requirements in § 170.315(f)(6) that were adopted in the 2015 Edition Final Rule and revise this criterion to be a functional requirement. We received stakeholder feedback that the CDA-

based standards cited in this criterion are not required for users to submit antimicrobial use and resistance (AUR) data to the CDC’s National Healthcare Safety Network (NHSN), creating a disconnect between the criterion and what is used in practice. We expect the removal of standards-based requirements to better align with the NHSN’s goals for reporting and reduce the burden on developers to meet this requirement. Following the methodology described for removed criteria, we considered annual maintenance of § 170.315(f)(6) to represent medium complexity equivalent to 20% of the initial development costs annually. We estimate that removal of standards-based requirements will reduce annual maintenance costs to 6% of initial development costs, resulting in a 70% reduction in effort.

Currently, 28 developers and 47 products are certified to § 170.315(f)(6). The initial developer hours estimated to implement the criterion had a lower bound of 1,000 hours and an upper bound of 1,400 hours in the 2015 Edition. We therefore estimate that the revision of this criterion will reduce effort to maintain the criterion annually by 14% or between 140 to 196 hours per product and 6,580 to 9,212 hours across all products. We estimate the total undiscounted annual cost savings to range from \$914,620 to \$1,280,468.

In Table R–3, we estimate the total annual hours saved from the proposed criteria revisions to range from 155,834 to 627,141 among 328 developers of certified health IT and 418 certified products. Using the labor rate of \$139, described above, we estimate the total undiscounted annual cost savings to range from \$21,660,9326 to \$87,172,599. We welcome comments on the proposed methodology and the accuracy and validity of the estimates.

⁹⁷ <http://healthit.gov/topic/electronic-case-reporting-certification-criterion-enforcement-discretion-notice>.

TABLE R-3—PANEL A—ESTIMATES OF LABOR HOURS SAVED FOR THE REVISIONS OF CERTIFICATION CRITERIA

Criterion citation	Total hours		Annual hours		Percent effort saved	Developers certified	Products certified	Hours saved	
	LB	UB	LB	UB				LB	UB
§ 170.315(a)(5)	720	1,860	36	93	100%	288	352	12,672	32,736
§ 170.315(b)(1)	3,000	4,000	450	600	60%	256	300	81,000	108,000
§ 170.315(b)(11) Task 1. Annual Maintenance	2,200	4,600	264	552	80%	183	232	48,952	102,544
§ 170.315(b)(11) Task 2. Information Updates	0	1,370	0	1,370	100%	183	232	0	317,840
§ 170.315(e)(1)	1300	2000	8	24	20%	215	255	6,630	10,200
§ 170.315(f)(5)	0	2,160	0	216	63%	94	127	0	46,609
§ 170.315(f)(6)	1,000	1,400	60	84	70%	28	47	6,580	9,212
All criteria						328	418	155,834	627,141

TABLE R-3—PANEL B—ANNUAL COST SAVINGS ESTIMATES FOR REVISIONS OF CERTIFICATION CRITERIA

Criterion citation	Annual cost savings	
	LB	UB
§ 170.315(a)(5)	\$1,761,408	\$4,550,304
§ 170.315(b)(1)	11,259,000	15,012,000
§ 170.315(b)(11)	6,804,328	58,433,376
§ 170.315(e)(1)	921,570	1,417,800
§ 170.315(f)(5)	0	6,478,651
§ 170.315(f)(6)	914,620	1,280,468
Total Annual Cost Savings	21,660,926	87,172,599

Note: The lower and upper bound cost estimates use the hourly wage (\$139.00) we describe above in “Employee Assumptions and Hourly Wage”.

2.2 Revisions to Standards and Implementation Specifications for Health Information Technology

2.2.1 Revisions to the United States Core Data for Interoperability (USCDI) v3

We propose to codify certification guidance for the Certification Program exercising our enforcement discretion—specifically, for the United States Core Data for Interoperability (USCDI) v3 standard.⁹⁸ The action removed or revised data elements from USCDI v3, as finalized in the HTI-1 Final Rule (89 FR 1192).

As finalized in the HTI-1 Final Rule, developers of certified health IT were required to update and certify their Health IT Modules to adopt USCDI v3 by January 1, 2026. This proposal reduces the effort for developers of certified health IT to adopt the USCDI v3 via the removal or revision of two data elements: sexual orientation and gender identity. We do not estimate reduced effort from ongoing maintenance of these requirements, as the effort is considered part of activities that occurred prior to the effective date of any final rule. We request comments on this approach.

2.3 Revisions to the ONC Health IT Certification Program Administration

Unless noted differently, proposed revisions to Certification Program administration conform to revisions proposed elsewhere related to Certification Program requirements. We do not assess net new cost savings or costs to program administration for these conforming revisions. We welcome comments on whether these conforming revisions create net new cost savings or costs.

2.3.1 Principles of Proper Conduct for ONC-ACBs

Under the principles of proper conduct for ONC-ACBs, we propose to revise the “certified product listing” principle in § 170.523(f)(1)(viii) to remove requirements on ONC-ACBs to include the test data version used and whether any test data was altered for the certification criterion or criteria to which the Health IT Module has been certified. This proposed revision is meant to reduce the overall effort for ONC-ACBs for this principle, as our analysis shows that these data elements for the “certified product listing” are low value. We determined that the cost savings to ONC-ACBs are de minimis, and welcome comments on this analysis. In addition, we propose conforming revisions to the principles of proper conduct for ONC-ACBs. These conforming revisions do not create net new cost savings to developers of certified health IT, ASTP/ONC, or ONC-ACBs. These conform to revisions made elsewhere to Certification Program requirements, and cost savings, if applicable, are assessed elsewhere in this impact analysis.

2.3.2 Principles of Proper Conduct for ONC-ATLs

We propose conforming revisions to the principles of proper conduct for ONC-ATLs. These conforming revisions do not create net new cost savings to developers of certified health IT, ASTP/ONC, or ONC-ATLs. These conform to revisions made elsewhere to Certification Program requirements, and cost savings, if applicable, are assessed elsewhere in this impact analysis.

2.3.3 Health IT Module Certification

We propose conforming revisions to Health IT Module certification. These conforming revisions do not create net new cost savings to developers of certified health IT, ASTP/ONC, or ONC-ACBs. These conform to revisions made elsewhere to Certification Program

requirements, and cost savings, if applicable, are assessed elsewhere in this impact analysis.

2.3.4 Certification to Newer Versions of Certain Standards

We propose conforming revisions to certification to newer versions of certain standards. These conforming revisions do not create net new cost savings to developers of certified health IT, ASTP/ONC, or ONC-ACBs. These conform to revisions made elsewhere to Certification Program requirements, and cost savings, if applicable, are assessed elsewhere in this impact analysis.

2.3.5 Effect of Revocation on the Certifications Issued to Health IT Module(s)

We propose conforming revisions that do not create net new cost savings.

2.4 Revisions to Conditions and Maintenance of Certification Requirements for Health IT Developers (Subpart D)

2.4.1 Assurances Condition of Certification

We propose updates to the Code of Federal Regulations (CFR) that do not create net new cost savings.

2.4.2 Application Programming Interfaces Condition of Certification

We propose updates to the CFR that do not create net new cost savings.

2.4.3 Real World Testing Condition of Certification

We propose revisions to the Real World Testing Condition of Certification that de-scope reporting requirements and codify certification guidance for the Certification Program exercising our enforcement discretion for the Condition of Certification.⁹⁹ As finalized in the Cures Act Final Rule (85 FR 25642), real world testing would be

⁹⁸ <https://www.healthit.gov/topic/uscdi-v3-data-elements-enforcement-discretion-notice>.

⁹⁹ <https://www.healthit.gov/topic/real-world-testing-condition-and-maintenance-certification-requirements-enforcement>.

applicable for specific criteria—at the time of finalization, 23 criteria in all. This deregulatory action revises the Real World Testing Condition of Certification to apply reporting to only the API criteria adopted by the Certification Program. This revision creates cost savings to developers of certified health IT, as developers would no longer be required to plan, collect, and report on real world testing results for the full originally finalized set of criteria. We explain below the rationale and methodology that informed the cost savings for these proposed revisions to real world testing.

The proposed revisions to real world testing would take effect beginning in 2027. Cost savings to developers for ongoing compliance are, therefore, estimated beginning in 2027. Any costs for 2024 and 2025 are considered sunk. Beginning in the 2026 reporting year, as permitted in the real world testing enforcement discretion, only developers of certified APIs would be required to report for real world testing, specifically developers who certify to the standardized API for patient and population services certification criterion, § 170.315(g)(10).¹⁰⁰ Cost savings calculations beginning in 2027 reflect the decreased burden on developers of certified health IT to comply with the condition of certification minus requirements that remain in place for developers who certify to the applicable API-based criteria.

As of the end of 2024, using publicly available Certification Program data, we calculated that 336 developers had submitted real world testing plans for 2025 collection and 2026 reporting.¹⁰¹ That is 93 fewer developers required to report for real world testing than estimated in the Cures Act Final Rule—a decrease of about 19 developers per year.¹⁰² Calculating developer exits during this time period, after the Cures Act Final Rule took effect and prior to this proposed rule's effective date, is important to assess the estimated number of developers expected to comply with the remaining real world testing requirements, as proposed.

Beginning in 2026, we calculated an expected count of developers who we estimated would be required to report for real world testing in 2026 and beyond. This count assumes attrition

from the original count of developers required to report for real world testing as finalized in the Cures Act Final Rule, as we described above for years prior to 2026. But given the changed program dynamics, in that real world testing would be required only for developers of certified APIs, the attrition rate beyond 2026 is harder to estimate. Given that current requirements are applicable for over 20 criteria adopted in the Certification Program and our attrition rate is based on participant exits from the Certification Program (for developers who certify for any of these criteria), we assume that attrition rate is likely more profound than exits for developers of certified APIs alone. We therefore estimate a new rate of developers who would be required to report for real world testing in total ($n=320$), beginning in 2026.

In our RIA for the HTI-4 Final Rule (included in the FY2026 IPPS/LTHC PPS Final Rule (90 FR 36536) as an ancillary provision), we estimated that beginning in 2027, approximately 189 developers would certify an electronic prior authorization API. The 189 count is a proxy measure, representing our estimation of the number of developers that would certify the § 170.315(g)(10) certification criterion in 2027.

Given that the revised Real World Testing Condition of Certification would only be associated with developers of certified APIs, we estimate beginning in 2026 that approximately 189 developers would be subject to the revised real world testing requirements. We used this count (189) to determine the net number of developers who would have been required to report for real world testing under the original requirements (inclusive of those who would have reported § 170.315(g)(10) testing results under the original requirements.)

At the end of 2024, of the 336 developers required to report for real world testing, 198 developers certified to the § 170.315(g)(10) certification criterion or 59% of all developers. Using this rate, we estimate that beginning in 2026, approximately 320 developers would be subject to real world testing requirements, as finalized by the Cures Act Final Rule.¹⁰³ In 2026, however, only 189 developers would be subject to revised real world testing requirements—our estimate of the number of developers who would be subject to revised real world testing requirements (API only.) This considers some attrition but at a different rate than used for years prior to 2026, as explained above.

¹⁰³ Formula: $189/(1 - 0.41) = 320$.

Total savings beginning in 2027 are considered consistent and do not decrease due to future unknown attrition; however, we consider these cost savings to be realized by developers when the revised requirements take effect. If they were to exit the program in a year beyond 2027, these are still cost savings to be realized today from requirements they do not need to meet in all future years.

Beginning in 2027, cost savings are calculated by totaling the cost to all developers who certify real world testing applicable criteria to meet current real world testing requirements as finalized in the Cures Act Final Rule and revised in subsequent rulemakings (the HTI-1 Final Rule and the HTI-4 Final Rule) and subtracting the remaining cost for developers of certified APIs to comply with revised real world testing requirements. We estimate that, per developer, the cost of collecting and reporting real world testing data on § 170.315(g)(10) would be on average \$4,400 annually. We estimate this by calculating the average cost per criterion to meet real world testing requirements as finalized by the Cures Act Final Rule ($\$109,557/23 = \$4,763$) and decrease that by the proposed eliminated effort to submit annual testing plans (estimated to be 8% of total annual testing effort.)¹⁰⁴ This is congruent with our methodology finalized in the HTI-4 Final Rule about the average per criterion cost to plan, collect, and report for real world testing.¹⁰⁵ The total cost of the remaining requirement to test for § 170.315(g)(10) would be subtracted from the total original program cost, as finalized by the Cures Act Final Rule, to estimate this deregulatory action's annual cost savings.

Beginning in 2027, we also assume that developers of certified APIs would need to meet requirements for § 170.315(g)(10), as well as for § 170.315(g)(31), (g)(32), and (g)(33), as finalized in the HTI-4 Final Rule.¹⁰⁶ Real world testing requirements for the certification criteria adopted in § 170.315(g)(31), (g)(32), and (g)(33) were finalized in the HTI-4 Final Rule and would be a net new cost minus revisions to real world testing for developers not to submit annual testing plans. Furthermore, we also updated real world testing requirements in the HTI-4 Final Rule to include the new

¹⁰⁴ Formula: $\$4,763 \times (1 - 0.08) = \$4,382$.

¹⁰⁵ <https://www.federalregister.gov/d/2025-14681/p-7025>.

¹⁰⁶ <https://www.federalregister.gov/documents/2025/08/04/2025-14681/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-ipp-and>.

¹⁰⁰ <https://www.healthit.gov/topic/real-world-testing-condition-and-maintenance-certification-requirements-enforcement>.

¹⁰¹ <https://chpl.healthit.gov/>.

¹⁰² <https://www.federalregister.gov/documents/2020/05/01/2020-07419/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification>.

§ 170.315(b)(4) certification criterion, which created net new costs to developers for real world testing. This deregulatory action now removes the § 170.315(b)(4) real world testing requirement and so we also assess the cost savings from that revision beginning in 2027 as well.

We estimate cost savings for reduced upfront effort in 2027 to be (original real world testing costs + § 170.315(b)(4) planning costs) minus (§ 170.315(g)(10) revised costs), which equal \$35.1 million in undiscounted cost savings for 2026. For costs savings, beginning in 2027 and in perpetuity, we estimate that together, (original real world testing costs + § 170.315(b)(4) costs) minus ((g)(10)+(g)(31)+(g)(32)+(g)(33) revised costs) equal the estimated annual undiscounted cost savings of \$33.6 million.

2.4.4 Attestations

We propose updates to the CFR that do not create net new cost savings.

2.4.5 Insights Condition of Certification

In the HTI–1 Final Rule (89 FR 1192), we finalized requirements for developers to report on the Insights Condition of Certification, a set of uniform measures collected and reported by developers of certified health IT about the performance of their certified technology.¹⁰⁷ Applicable developers would be required to begin data collection January 1, 2026, for “Year 1” measures, with results reported in July 2027 and with “Year 2” measures set to begin collection January 1, 2027. Effort to plan and develop capabilities for these finalized measures was estimated to begin after the effective date of the HTI–1 Final Rule in January

2024. Effort to plan and develop the measurement capabilities for measures required to be collected in 2026 (“Year 1”) would be completed by January 1, 2026, and effort to plan and develop the measurement capabilities for measures required to be collected for the first time in 2027 (“Year 2”) would be completed by January 1, 2027, etc. We estimated developers would face annual data collection and reporting costs beginning in 2026 and in perpetuity. As we finalized in the HTI–1 Final Rule, the large majority of costs to developers of certified health IT would be costs to plan and develop for initial data collection of the finalized measures (effort largely expended from 2024–2026 in our original analysis).

ASTP/ONC issued enforcement discretion in April 2025 that effectively de-scoped Insights requirements on developers to a single measure—“Use of FHIR”—a “Year 1” measure.¹⁰⁸ The enforcement discretion effectively paused development and planning efforts to collect all Insights measures but one (“Use of FHIR”), reducing sunk costs and creating cost savings to developers by reducing the upfront effort to plan and report for Insights. We propose to codify certification guidance for the Certification Program exercising our enforcement discretion for the Insights Condition of Certification. We explain below the rationale and methodology that informed the cost savings for these proposed revisions to Insights.

To calculate cost savings associated with the proposed revisions to the Insights Condition of Certification, we subtracted the estimated amount for developers to report for the remaining Insights measure (“Use of FHIR”) from the estimated cost for developers to

meet the Insights Condition of Certification, as finalized in the HTI–1 Final Rule. In Table 35 of the HTI–1 Final Rule, we estimated that the upper bound cost for all developers to report on the “Use of FHIR” measure over a ten-year period was \$36.3 million.¹⁰⁹ The total upper bound cost to report on all measures for all developers over a ten-year period was \$218.7 million. Therefore, we estimate the “Use of FHIR” measure to be 17% of all estimated Insights costs.

In Table R–4 we show the undiscounted revised costs for the Insights Condition of Certification. We estimated, on average, that the HTI–1 Final Rule costs for Insights would be \$137.9 million. We estimated that the cost for developers to begin implementing Insights in 2024 (toward effort to collect and report on measures in 2026 and 2027) would on average, total \$46.4 million. This included initial planning and development costs for all measures with more assumed effort toward completing work to prepare for “Year 1” measures set to begin collection January 1, 2026. We consider these costs as sunk. The Insights enforcement discretion, however, reduced effort for ongoing planning and development work for 2025 and after. We consider this reduced effort in 2025 and 2026 and reduced effort to meet this requirements in years 2027 and after to be a net cost savings to developers, as Table R–4 shows.

Cost savings in 2027 and thereafter are considered tied to the reduced effort associated with ongoing planning and reporting for the proposed revised requirements. The total undiscounted cost savings for this reduced ongoing effort, beginning in 2027, are \$12.7 million (Table R–4).

TABLE R–4—REVISED INSIGHTS UNDISCOUNTED COST SAVINGS

Year	Upfront effort	Ongoing effort	Total
2024	\$0	\$0	\$0
2025	38,513,661	0	38,513,661
2026	24,814,672	0	24,814,672
2027	0	8,601,676	8,601,676
2028	0	680,593	680,593
Total—Undiscounted	63,328,333	12,685,234	76,013,568

b. Accounting Statement and Table

This proposed rule, if finalized as proposed, is expected to be an E.O. 14192 deregulatory action. The

proposals remove or reduce requirements on developers of certified health IT. No proposals create net new requirements or additional burden to

comply with existing requirements. However, we do estimate some costs for reviewers who review this proposed rule. We estimate those costs to be

¹⁰⁷ <https://www.federalregister.gov/documents/2024/01/09/2023-28857/health-data-technology-and-interoperability-certification-program-updates-algorithm-transparency-and>.

¹⁰⁸ <https://www.healthit.gov/topic/insights-condition-and-maintenance-certification-enforcement-discretion>.

¹⁰⁹ <https://www.federalregister.gov/d/2023-28857/p-2641>.

\$284,132 in total for an estimated 644 reviewers, which include developers and medical associations. As articulated in the preamble, these proposed deregulatory actions reduce the effort of developers of certified health IT to meet ongoing program requirements and reduce barriers to entry for new program participants, generating benefits to developers of certified health IT in the form of time back to them to innovate their technology and focus on the needs of their clients and end users. We do not, however, quantify these benefits, and instead rely on our calculation of cost savings to developers of certified health IT to quantify in dollars the time

and effort developers would have expended had these requirements remained in effect in perpetuity. We estimate that these proposals do generate significant cost savings for developers of certified health IT. To calculate the cost savings associated with this proposed rulemaking, we replicate the analysis of prior finalized rulemakings and align those with current data, adopting, where necessary, novel methodologies and models to assess the current costs to developers of certified health IT of the proposed revisions to the Certification Program. As shown in Table R–5, we present the undiscounted cost savings

over ten years and in Table R–6 we present the discounted cost savings associated with these proposals. In Table R–6, we adopt a 3% and 7% discount rate consistent with Circular A–4 (2003).¹¹⁰ Cost savings for this proposed rulemaking include savings from reduced ongoing effort to comply with finalized requirements, as shown in Tables R–5 and R–6. In total, this proposed rulemaking would result in a present value of cost savings of \$1.53 billion in 2024 dollars and discounted at a rate of 7%, beginning in 2027 and in perpetuity, consistent with analytic guidance on E.O. 14192, as shown in Table R–7.¹¹¹

TABLE R–5—E.O. 12866 SUMMARY TABLE NON-DISCOUNTED FLOWS
[2024 Dollars]

	Year 1	Year 2	Year 3	Year 4	Year 5
Costs	\$284,132				
Cost Savings	174,843,873.10	\$166,922,790.67	\$166,922,790.67	\$166,922,790.67	\$166,922,790.67
	Year 6	Year 7	Year 8	Year 9	Year 10
Costs					
Cost Savings	166,922,790.67	166,922,790.67	166,922,790.67	166,922,790.67	166,922,790.67

TABLE R–6—E.O. 12866 SUMMARY TABLE
[2024 Dollars]

	Primary (3%)	Primary (7%)
Present Value of Quantified Costs	\$275,856.31	\$265,543.93
Present Value of Quantified Cost Savings	2,491,079,993.12	1,775,785,303.03
Present Value of Net Cost Savings	2,490,804,136.81	1,775,519,759.11
Annualized Quantified Costs	18,541.88	25,065.47
Annualized Quantified Cost Savings	167,439,704.42	167,621,570.24
Annualized Net Quantified Cost Savings	167,421,162.54	167,596,504.78

TABLE R–7—E.O. 14192 SUMMARY TABLE
[2024 Dollars]

	Primary (7%)
Present Value of Quantified Costs	\$265,543.93
Present Value of Quantified Cost Savings	1,525,278,264.39
Present Value of Net Cost Savings	1,525,012,720.46
Annualized Quantified Costs	25,065.47
Annualized Quantified Cost Savings	143,975,477.95
Annualized Net Quantified Cost Savings	143,950,412.48

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. The Small Business Administration

(SBA) establishes the size of small businesses for Federal Government programs based on average annual receipts or the average employment of a firm.¹¹²

The entities that are likely to be directly affected by the requirements in

this proposed rule are health IT developers. We note that the reasonable and necessary activities identified by the Secretary as not constituting information blocking are themselves exceptions to compliance with the information blocking definition and

¹¹⁰ <https://trumpwhitehouse.archives.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf>.
¹¹¹ <https://www.whitehouse.gov/wp-content/uploads/2025/02/M-25-20-Guidance-Implementing->

Section-3-of-Executive-Order-14192-Titled-Unleashing-Prosperity-Through-Deregulation.pdf.
¹¹² The SBA references that annual receipts mean “total income” (or in the case of a sole

proprietorship, “gross income”) plus “cost of goods sold” as these terms are defined and reported on Internal Revenue Service tax return forms.

provide relief for those entities subject to the information blocking regulations. We refer readers to section IV for our information blocking-related proposals and welcome comments on their impacts on small entities.

While health IT developers that pursue certification of their health IT under the Certification Program represent a small segment of the overall information technology industry, we believe that many health IT developers impacted by the requirements proposed in this proposed rule most likely fall under the North American Industry Classification System (NAICS) code 541511 “Custom Computer Programming Services.”

OMB advised that the Federal statistical establishment data published for reference years beginning on or after January 1, 2022, should be published using the 2022 NAICS United States codes.¹¹³ The SBA size standard associated with this NAICS code is set at \$34 million annual receipts or less. There is enough data generally available to establish that between 75% and 90% of entities that are categorized under the NAICS code 541511 are under the SBA size standard. We also note that with the exception of aggregate business information available through the U.S. Census Bureau and the SBA related to NAICS code 541511, it appears that many health IT developers that pursue certification of their health IT under the Certification Program are privately held or owned and do not regularly, if at all, make their specific annual receipts publicly available. As a result, it is difficult to locate empirical data related to many of these health IT developers to correlate to the SBA size standard. However, although not perfectly correlated to the size standard for NAICS code 541511, we do have information indicating that over 60% of health IT developers that have had Complete EHRs and/or Health IT Modules certified to the 2011 Edition have less than 51 employees.

With the exception of rule review costs, this proposed rulemaking is deregulatory and does not create new requirements on developers of certified health IT, including small businesses. We believe the proposed deregulatory actions will create net cost savings for developers and would not create a significant economic impact on a substantial number of small entities. Additionally, the Secretary proposes to certify that this proposed rule would not have a significant economic impact on a substantial number of small entities.

However, we request comments on whether: there are (and how many) small entities that currently pursue certification of health IT under the Certification Program; what products they certify; whether there are any negative or unintended costs for small entities from the proposals included in this proposed rule; and whether small entities will significantly benefit from the proposals include in this proposed rule.

D. Executive Order 13132—Federalism

E.O. 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Nothing in this proposed rule imposes substantial direct compliance costs on State and local governments, preempts State law, or otherwise has federalism implications. We are not aware of any State laws or regulations that are contradicted or impeded by any of the proposals in this proposed rule. We welcome comments on this assessment.

E. Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule that imposes unfunded mandates on State, local, and Tribal governments or the private sector requiring spending in any one year of \$100 million in 1995 dollars, updated annually for inflation. The current inflation-adjusted statutory threshold is approximately \$187 million in 2025. This proposed rule is deregulatory, and, therefore, the estimated potential cost effects of this proposed rule do not reach the statutory threshold. This proposed rule does not impose unfunded mandates on State, local, and Tribal governments, or the private sector. We welcome comments on these conclusions.

List of Subjects

45 CFR Part 170

Computer technology, Electronic health record, Electronic information system, Electronic transactions, Health, Healthcare, Health information technology, Health insurance, Health records, Hospitals, Incorporation by reference, Laboratories, Medicaid, Medicare, Privacy, Reporting and record keeping requirements, Public health, Security.

45 CFR Part 171

Computer technology, Electronic health record, Electronic information system, Electronic transactions, Health, Healthcare, Health care provider, Health information exchange, Health information technology, Health information network, Health insurance, Health records, Hospitals, Privacy, Public health, Reporting and record keeping requirements, Security.

For the reasons set forth in the preamble, HHS proposes to amend 45 CFR subtitle A, subchapter D, as follows:

PART 170—HEALTH INFORMATION TECHNOLOGY STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA AND CERTIFICATION PROGRAMS FOR HEALTH INFORMATION TECHNOLOGY

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

Authority: 42 U.S.C. 300jj–11; 42 U.S.C. 300jj–14; 5 U.S.C. 552

■ 2. Amend § 170.102 by:

■ a. In the definition of “Base EHR”:

■ i. Revising paragraph (3)(i); and

■ ii. Removing and reserving paragraphs (3)(ii) and (iii); and

■ b. Removing definitions for “Common Clinical Data Set,” “Global Unique Device Identification Database (GUDID),” and “Production Identifier.”

The revision reads as follows:

§ 170.102 Definitions.

* * * * *

Base EHR * * *

(3) * * *

(i) Section 170.315(a)(1), (2), or (3), (a)(5), (b)(1) and (11), (c)(1), and (g)(10).

* * * * *

■ 3. Revising and republishing § 170.202 to read as follows:

§ 170.202 Transport standards and other protocols.

The Secretary adopts the following transport standard: ONC Applicability Statement for Secure Health Transport, Version 1.2 (incorporated by reference in § 170.299).

§ 170.204 [Removed and Reserved]

■ 4. Removing and reserving § 170.204.

■ 5. Amend § 170.205 by:

■ a. Removing and reserving paragraphs (a)(3) and (5);

■ b. Revising paragraphs (d)(2) and (i)(2);

■ c. Removing and reserving paragraphs (k)(1) and (2) and (r)(1); and

■ d. Revising paragraphs (s)(1) and (t)(1) through (4).

The revisions read as follows:

¹¹³ <https://www.sba.gov/article/2022/feb/01/guidance-using-naics-2022-procurement>.

§ 170.205 Content exchange standards and implementation specifications for exchanging electronic health information.

* * * *

(d) * * *

(2) *Standard.* HL7 Messaging Standard Version 2.5.1 (incorporated by reference in § 170.299).

* * * *

(i) * * *

(2) *Standard.* HL7 Clinical Document Architecture (CDA), Release 2.0, Normative Edition (incorporated by reference in § 170.299). Implementation specifications. HL7 CDA® Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1; DSTU Release 1.1, Volume 1—Introductory Material and HL7 CDA® Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1; DSTU Release 1.1 (US Realm), Volume 2—Templates and Supporting Material (incorporated by reference in § 170.299). The adoption of this standard expires on January 1, 2027.

* * * *

(s) * * *

(1) *Standard.* HL7 Implementation Guide for CDA® Release 2: National Health Care Surveys (NHCS), Release 1—US Realm, HL7 Draft Standard for Trial Use, Volume 1—Introductory Material and HL7 Implementation Guide for CDA® Release 2: National Health Care Surveys (NHCS), Release 1—US Realm, HL7 Draft Standard for Trial Use, Volume 2—Templates and Supporting Material (incorporated by reference in § 170.299). The adoption of this standard expires on January 1, 2027.

* * * *

(t) * * *

(1) *Standard.* HL7® FHIR® Implementation Guide: Electronic Case Reporting (eCR)—US Realm 2.1.0—STU 2 US (HL7 FHIR eCR IG) (incorporated by reference, see § 170.299). The adoption of this standard expires on January 1, 2027.

(2) *Standard.* HL7 CDA® R2 Implementation Guide: Public Health Case Report—the Electronic Initial Case Report (eICR) Release 2, STU Release 3.1—US Realm (HL7 CDA eICR IG) (incorporated by reference, see § 170.299). The adoption of this standard expires on January 1, 2027.

(3) *Standard.* HL7® CDA® R2 Implementation Guide: Reportability Response, Release 1, STU Release 1.1—US Realm (HL7 CDA RR IG) (incorporated by reference, see § 170.299). The adoption of this standard expires on January 1, 2027.

(4) *Standard.* Reportable Conditions Trigger Codes Value Set for Electronic Case Reporting. (incorporated by reference, see § 170.299). The adoption of this standard expires on January 1, 2027.

* * * *

§ 170.207 [Amended]

■ 6. Amend § 170.207 by:

■ a. Removing paragraphs (a)(4) and

(c)(3);

■ b. Removing and reserving paragraphs (d)(1)(ii) and (iii);

■ c. Removing paragraphs (e)(3) and (4);

■ d. Removing and reserving paragraphs (f)(2), (m)(1), (n)(1) and (3), and (o); and

■ e. Removing paragraphs (r) and (s).

§ 170.210 [Removed and Reserved]

■ 7. Removing and reserving § 170.210.

■ 8. Revising § 170.213 to read as follows:

§ 170.213 United States Core Data for Interoperability.

The Secretary adopts the following versions of the United States Core Data for Interoperability standard:

(a) *Standard.* United States Core Data for Interoperability Version 3.1 (USCDI v3.1) (incorporated by reference, see § 170.299).

(b) [Reserved]

§ 170.215 [Amended]

■ 9. Amend § 170.215 by removing and reserving paragraphs (b)(1)(i) and (c)(1).

■ 10. Revising and republishing § 170.299 to read as follows:

§ 170.299 Incorporation by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(b) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at the U.S. Department of Health and Human Services (HHS) and at the National Archives and Records Administration (NARA). Contact HHS at: U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, 330 C Street SW, Washington, DC 20201; call ahead to arrange for inspection at 202–690–7151. For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov. The material may be obtained from the sources in the following paragraphs of this section.

(b) Centers for Disease Control and Prevention, 2500 Century Parkway, Mailstop E–78, Atlanta, GA 30333; phone: (800) 232–4636; website: www.cdc.gov/cdc-info/index.html.

(1)–(3) [Reserved]

(4) HL7 2.5.1 Implementation Guide for Immunization Messaging Release 1.0, May 1, 2010, IBR approved for § 170.205.

(5) PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data, ADT Messages A01, A03, A04, and A08, HL7 Version 2.5.1 (Version 2.3.1 Compatible), Release 1.1, August 2012, IBR approved for § 170.205.

(6) Conformance Clarification for EHR Certification of Electronic Syndromic Surveillance, ADT MESSAGES A01, A03, A04, and A08, HL7 Version 2.5.1, Addendum to PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data (Release 1.1), August 2012, IBR approved for § 170.205.

(7)–(8) [Reserved]

(9) ELR 2.5.1 Clarification Document for EHR Technology Certification, July 16, 2012, IBR approved for § 170.205.

(10) PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings, Release 2.0, April 21, 2015, IBR approved for § 170.205(d).

(11) Erratum to the CDC PHIN 2.0 Implementation Guide, August 2015; Erratum to the CDC PHIN 2.0 Messaging Guide, April 2015 Release for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings, IBR approved for § 170.205(d).

(12) HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5, October 1, 2014, IBR approved for § 170.205(e).

(13) HL7 Version 2.5.1 Implementation Guide for Immunization Messaging (Release 1.5)—Addendum, July 2015, IBR approved for § 170.205(e).

(14)–(16) [Reserved]

(17) HL7® Standard Code Set CVX—Vaccines Administered, dated June 15, 2022; IBR approved for § 170.207(e).

(18) National Drug Code Directory (NDC)—Vaccine NDC Linker, dated July 19, 2022; IBR approved for § 170.207(e).

(19) CDC Race and Ethnicity Code Set version 1.2 (July 08, 2021); IBR approved for § 170.207(f).

(c) Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, 7500 Security Boulevard, Baltimore, Maryland 21244; phone: (410) 786–3000; website: www.cms.gov.

(1) CMS PQRI 2009 Registry XML Specifications, IBR approved for § 170.205.

(2) 2009 Physician Quality Reporting Initiative Measure Specifications Manual for Claims and Registry, Version

3.0, December 8, 2008 IBR approved for § 170.205.

(3) [Reserved]

(4) CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting Implementation Guide for 2020; published December 3, 2019, IBR approved for § 170.205(h).

(5) CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs Implementation Guide for 2020; published April 30, 2020, IBR approved for § 170.205(k).

(d) Council of State and Territorial Epidemiologists, 2635 Century Parkway NE, Suite 700, Atlanta, GA 30345; phone: (770) 458–3811; website: www.cste.org/.

(1) Reportable Conditions Trigger Codes Value Set for Electronic Case Reporting. RCTC OID: 2.16.840.1.114222.4.11.7508, Release March 29, 2022; IBR approved for § 170.205(t).

(2) [Reserved]

(e) Health Level Seven, 3300 Washtenaw Avenue, Suite 227, Ann Arbor, MI 48104; phone: (734) 677–7777; website: www.hl7.org/.

(1) [Reserved]

(2) Health Level Seven Messaging Standard Version 2.5.1 (HL7 2.5.1), An Application Protocol for Electronic Data Exchange in Healthcare Environments, February 21, 2007, IBR approved for § 170.205.

(3) [Reserved]

(4) HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) HL7 Version 2.5.1: ORU–R01, HL7 Informative Document, February, 2010, IBR approved for § 170.205.

(5)–(8) [Reserved]

(9) HL7 Clinical Document Architecture, Release 2.0, Normative Edition, May 2005, IBR approved for § 170.205.

(10)–(11) [Reserved]

(12) HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture, DSTU Release 2 (Universal Realm), Draft Standard for Trial Use, July 2012, IBR approved for § 170.205.

(13) HL7 v2.5.1 IG: Electronic Laboratory Reporting to Public Health (US Realm), Release 1 Errata and Clarifications, September, 29, 2011, IBR approved for § 170.205.

(14)–(17) [Reserved]

(18) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Volume 1—Introductory Material,

Release 2.1, August 2015, IBR approved for § 170.205(a).

(19) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Volume 2—Templates and Supporting Material, Release 2.1, August 2015, IBR approved for § 170.205(a).

(20) HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture—Category I (QRDA I); Release 1, DSTU Release 3 (US Realm), Volume 1—Introductory Material, June 2015, IBR approved for § 170.205(h).

(21) HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture—Category I (QRDA I); Release 1, DSTU Release 3 (US Realm), Volume 2—Templates and Supporting Material, June 2015, IBR approved for § 170.205(h).

(22)–(24) [Reserved]

(25) HL7 Version 3 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1, Part 1: CDA R2 and Privacy Metadata Reusable Content Profile, May 16, 2014, IBR approved for § 170.205(o).

(26) [Reserved]

(27) HL7 Implementation Guide for CDA® Release 2: National Health Care Surveys (NHCS), Release 1—US Realm, HL7 Draft Standard for Trial Use, Volume 1—Introductory Material, December 2014, IBR approved for § 170.205(s).

(28) HL7 Implementation Guide for CDA® Release 2: National Health Care Surveys (NHCS), Release 1—US Realm, HL7 Draft Standard for Trial Use, Volume 2—Templates and Supporting Material, December 2014, IBR approved for § 170.205(s).

(29)–(30) [Reserved]

(31) HL7 FHIR® Bulk Data Access (Flat FHIR®) (v1.0.0: STU 1), August 22, 2019, IBR approved for § 170.215(a).

(32) HL7 FHIR SMART Application Launch Framework Implementation Guide Release 1.0.0, November 13, 2018, IBR approved for § 170.215(a).

(33) HL7 Fast Healthcare Interoperability Resources Specification (FHIR®) Release 4, Version 4.0.1: R4, October 30, 2019, including Technical Correction #1, November 1, 2019, IBR approved for § 170.215(a).

(34) HL7 FHIR® US Core Implementation Guide STU3 Release 3.1.1, August 28, 2020, IBR approved for § 170.215(a).

(35) HL7 CDA® R2 Implementation Guide: C—CDA Templates for Clinical Notes STU Companion Guide, Release 4.1 (US Realm) Standard for Trial Use, Specification Version: 4.1.1, June 2023 (including appendices A and B); IBR approved for § 170.205(a).

(36) HL7 FHIR® Implementation Guide: Electronic Case Reporting (eCR)—US Realm, Version 2.1.0—STU 2 US (HL7 FHIR eCR IG), August 31, 2022; IBR approved for § 170.205(t).

(37) HL7 CDA® R2 Implementation Guide: Public Health Case Report—the Electronic Initial Case Report (eICR) Release 2, STU Release 3.1—US Realm (HL7 CDA eICR IG), July 2022, volumes 1 and 2; IBR approved for § 170.205(t).

(38) HL7 CDA® R2 Implementation Guide: Reportability Response, Release 1, STU Release 1.1—US Realm (HL7 CDA RR IG), July 2022, volumes 1 through 4; IBR approved for § 170.205(t).

(39) HL7 FHIR US Core Implementation Guide Version 6.1.0—STU 6, June 19, 2023; IBR approved for § 170.215(b).

(40) HL7 FHIR® SMART App Launch [Implementation Guide], 2.0.0—Standard for Trial Use, November 26, 2021; IBR approved for § 170.215(c).

(41) HL7 FHIR® Da Vinci—Coverage Requirements Discovery (CRD) Implementation Guide, Version 2.0.1—STU 2, January 8, 2024, IBR approved for § 170.215(j).

(42) HL7 FHIR® Da Vinci—Documentation Templates and Rules (DTR) Implementation Guide, Version 2.0.1—STU 2, January 11, 2024, IBR approved for § 170.215(j).

(43) HL7 FHIR® Da Vinci Prior Authorization Support (PAS) FHIR Implementation Guide, Version 2.0.1—STU 2, December 1, 2023, IBR approved for § 170.215(j).

(44) HL7 FHIR® CARIN Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) Implementation Guide, Version 2.0.0—STU 2 US, November 28, 2022, IBR approved for § 170.215(k).

(45) HL7 FHIR® Da Vinci Payer Data Exchange (PDex) Implementation Guide, Version 2.1.0—STU 2.1, June 18, 2025, IBR approved for § 170.215(k).

(46) HL7 FHIR® Da Vinci Payer Data Exchange (PDex) US Drug Formulary Implementation Guide, Version 2.0.1—STU 2, December 1, 2023, IBR approved for § 170.215(m).

(47) HL7 FHIR® Da Vinci Payer Data Exchange (PDex) Plan Net Implementation Guide, Version 1.1.0—STU 1.1 US, April 4, 2022, IBR approved for § 170.215(n).

(48) HL7 FHIR® Subscriptions R5 Backport Implementation Guide, Version 1.1.0—Standard for Trial Use, draft as of January 11, 2023, IBR approved for § 170.215(h).

(49) HL7 FHIR® CDS Hooks Implementation Guide, Version 2.0.1—ci-build, March 12, 2025, IBR approved for § 170.215(f).

(f) Integrating the Healthcare Enterprise (IHE), 820 Jorie Boulevard, Oak Brook, IL Telephone (630) 481-1004, <http://www.ihe.net/>.

(1) IHE IT Infrastructure Technical Framework Volume 2b (ITI TF-2b), Transactions Part B—Sections 3.29—2.43, Revision 7.0, August 10, 2010, IBR approved for § 170.205(p).

(2) [Reserved]

(g) Internet Engineering Task Force (IETF) Secretariat, c/o Association Management Solutions, LLC (AMS), 48377 Fremont Blvd., Suite 117, Fremont, CA 94538, Telephone (510) 492-4080, <http://www.ietf.org/rfc.html>.

(1)–(2) [Reserved]

(3) Request for Comment (RFC) 5646, “Tags for Identifying Languages, September 2009,” copyright 2009, IBR approved for § 170.207(g).

(h) International Telecommunication Union (ITU), Place des Nations, 1211 Geneva 20 Switzerland, Telephone (41) 22 730 511, <http://www.itu.int/en/pages/default.aspx>.

(1) ITU-T E.123, Series E: Overall Network Operation, Telephone Service, Service Operation and Human Factors, International operation—General provisions concerning users: Notation for national and international telephone numbers, email addresses and web addresses, February 2001, IBR approved for § 170.207(q).

(2) ITU-T E.164, Series E: Overall Network Operation, Telephone Service, Service Operation and Human Factors, International operation—Numbering plan of the international telephone service, The international public telecommunication numbering plan, November 2010, IBR approved for § 170.207(q).

(i) National Council for Prescription Drug Programs (NCPDP), Incorporated, 9240 E Raintree Drive, Scottsdale, AZ 85260-7518; phone (480) 477-1000; fax: (480) 767-1042; website: www.ncdp.org.

(1) NCPDP SCRIPT Standard, Implementation Guide, Version 2017071, ANSI-approved July 28, 2017; IBR approved for § 170.205(b).

(2) NCPDP SCRIPT Standard, Implementation Guide, Version 2023011, ANSI-approved January 17, 2023; IBR approved for § 170.205(b).

(3) NCPDP Real-Time Prescription Benefit Standard, Implementation Guide, Version 13, ANSI-approved May 19, 2022; IBR approved for § 170.205(c).

(4) NCPDP Formulary and Benefit Standard, Implementation Guide, Version 60, ANSI-approved April 12, 2023; IBR approved for § 170.205(u).

(j) Office of the National Coordinator for Health Information Technology (ONC), 330 C Street SW, Washington,

DC 20201; phone: (202) 690-7151; website: <https://healthit.gov>.

(1) United States Core Data for Interoperability (USCDI), Version 3.1 (v3.1), June 2025, IBR approved for § 170.213.

(2) [Reserved]

(k) Public Health Data Standards Consortium, 111 South Calvert Street, Suite 2700, Baltimore, MD 21202; phone: (801) 532-2299; website: www.nahdo.org/sopt.

(1) Public Health Data Standards Consortium Source of Payment Typology Code Set Version 5.0 (October 2011), IBR approved for § 170.207(s).

(2) Users Guide for Source of Payment Typology, Version 9.2, December 2020; IBR approved for § 170.207(s).

(l) Regenstrief Institute, Inc., LOINC® c/o Regenstrief Center for Biomedical Informatics, Inc., 410 West 10th Street, Suite 2000, Indianapolis, IN 46202-3012; phone: (317) 274-9000; website: <https://loinc.org/> and <https://ucum.org/ucum>.

(1) Logical Observation Identifiers Names and Codes (LOINC®) Database Version 2.72, February 2022; IBR approved for § 170.207(c).

(2) The Unified Code for Units of Measure, Version 2.1, November 21, 2017; IBR approved for § 170.207(m).

(m) U.S. National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20894; phone (301) 594-5983; website: www.nlm.nih.gov/.

(1) SNOMED CT® [SNOMED Clinical Terms] U.S. Edition, March 2022 Release; IBR approved for § 170.207(a).

(2) RxNorm, Full Update Release, July 5, 2022; IBR approved for § 170.207(d).

(3) RxNorm, December 4, 2023, Full Update Release, IBR approved for § 170.207(d).

■ 11. Amend § 170.315 by:

■ a. Revising and republishing paragraph (a)(5);

■ b. Removing and reserving paragraphs (a)(9), (12), and (14);

■ c. Revising paragraph (b)(1);

■ d. Removing and reserving paragraphs (b)(2) and (7) through (9);

■ e. Removing paragraph (b)(11)(ii)(B);

■ f. Redesignating paragraph (b)(11)(ii)(C) as paragraph (b)(11)(ii)(B);

■ g. Revising paragraph (b)(11)(iii) introductory text and paragraph (b)(11)(iii)(B);

■ h. Removing and reserving paragraphs (b)(11)(iv) through (vi);

■ i. Revising paragraph (c)(3);

■ j. Removing and reserving paragraphs (c)(4) and (d);

■ k. Revising and republishing paragraph (e)(1);

■ l. Removing and reserving paragraphs (e)(3) and (f)(4);

■ m. Revising paragraph (f)(5) introductory text;

■ n. Removing and reserving paragraph (f)(5)(ii);

■ o. Revising paragraph (f)(6);

■ p. Removing paragraph (f)(7);

■ q. Removing and reserving paragraphs (g)(1) through (7) and (9); and

■ r. Removing and reserving paragraph (h).

The revisions and republication read as follows:

§ 170.315 ONC certification criteria for Health IT.

* * * * *

(a) * * *

(5) *Patient demographics.* (i) Enable a user to record, change, and access patient demographic data including race, ethnicity, preferred language, sex, and date of birth.

(A) *Race and ethnicity.* (1) Enable each one of a patient's races to be recorded in accordance with, at a minimum, the standard specified in § 170.207(f)(3) and whether a patient declines to specify race.

(2) Enable each one of a patient's ethnicities to be recorded in accordance with, at a minimum, the standard specified in § 170.207(f)(3) and whether a patient declines to specify ethnicity.

(3) Aggregate each one of the patient's races and ethnicities recorded in accordance with paragraphs (a)(5)(i)(A)(1) and (2) of this section to the categories in the standard specified in § 170.207(f)(1).

(B) *Preferred language.* Enable preferred language to be recorded in accordance with the standard specified in § 170.207(g)(2) and whether a patient declines to specify a preferred language.

(C) *Sex.* Enable sex to be recorded in accordance with the standard specified in § 170.207(n)(2).

(ii) Inpatient setting only. Enable a user to record, change, and access the preliminary cause of death and date of death in the event of mortality.

* * * * *

(b) * * *

(1) *Transitions of care—receive and validate—(i) Validate C-CDA conformance—system performance.*

Demonstrate the ability to detect valid and invalid transition of care/referral summaries received and formatted in accordance with the standard specified in § 170.205(a)(6) for the Continuity of Care Document, Referral Note, and (inpatient setting only) Discharge Summary document templates. This includes the ability to:

(A) Parse each of the document types.

(B) Detect errors in corresponding “document-templates,” “section-templates,” and “entry-templates,” including invalid vocabulary standards and codes not specified in the standard adopted in § 170.205(a)(6).

(C) Identify valid document-templates and process the data elements required in the corresponding section-templates and entry-templates from the standard adopted in § 170.205(a)(6).

(D) Correctly interpret empty sections and null combinations.

(E) Record errors encountered and allow a user through at least one of the following ways to:

- (1) Be notified of the errors produced.
- (2) Review the errors produced.
- (ii) [Reserved]

* * * *

(11) * * *

(iii) *Decision support intervention selection.* Enable a limited set of identified users to select (*i.e.*, activate) electronic decision support interventions that are:

* * * *

(B) Predictive Decision Support Interventions and use any data in paragraph (b)(11)(iii)(A) of this section as well as Clinical Notes and Assessment and Plan of Treatment expressed in the standards for this data in § 170.213.

* * * *

(c) * * *

(3) *Clinical quality measures—report.* Enable a user to electronically create a data file for transmission of clinical quality measurement data in accordance with the applicable implementation specifications specified by the CMS implementation guides for Quality Reporting Document Architecture (QRDA), category I, for inpatient measures in § 170.205(h)(3) and CMS implementation guide for QRDA, category III for ambulatory measures in § 170.205(k)(3).

* * * *

(e) * * *

(1) *View, download, and transmit to 3rd party—(i) General.* Patients (and their authorized representatives) must be able to use internet-based technology to view, download, and transmit their health information to a 3rd party in the manner specified in this paragraph (e)(1)(i).

(A) *View.* Patients (and their authorized representatives) must be able to use health IT to view, at a minimum, the following data:

(1) [Reserved]

(2) The data classes expressed in the standards in § 170.213 (which should be in their English (*i.e.*, non-coded) representation if they associate with a vocabulary/code set), and in accordance with § 170.205(a)(4) and (6), and paragraphs (e)(1)(i)(A)(3)(i) through (iii) of this section.

(3) The following data classes:

(i) *Assessment and plan of treatment.* In accordance with the “Assessment

and Plan Section (V2)” of the standard specified in § 170.205(a)(4); or in accordance with the “Assessment Section (V2)” and “Plan of Treatment Section (V2)” of the standard specified in § 170.205(a)(4).

(ii) *Goals.* In accordance with the “Goals Section” of the standard specified in § 170.205(a)(4).

(iii) *Health concerns.* In accordance with the “Health Concerns Section” of the standard specified in § 170.205(a)(4).

(iv) *Unique device identifier(s) for a patient’s implantable device(s).* In accordance with the “Product Instance” in the “Procedure Activity Procedure Section” of the standards specified in § 170.205(a)(4).

(4) *Ambulatory setting only.* Provider’s name and office contact information.

(5) *Inpatient setting only.* Admission and discharge dates and locations; discharge instructions; and reason(s) for hospitalization.

(6) *Laboratory test report(s).*

Laboratory test report(s), including:

(i) The information for a test report as specified all the data specified in 42 CFR 493.1291(c)(1) through (7);

(ii) The information related to reference intervals or normal values as specified in 42 CFR 493.1291(d); and

(iii) The information for corrected reports as specified in 42 CFR 493.1291(k)(2).

(7) *Diagnostic image report(s).*

(B) *Download.* (1) Patients (and their authorized representatives) must be able to use technology to download an ambulatory summary or inpatient summary (as applicable to the health IT setting for which certification is requested) in the following formats:

(i) Human readable format; and

(ii) The format specified in accordance with the standard specified in § 170.205(a)(4) and (6) and following the CCD document template.

(2) When downloaded according to the standard specified in § 170.205(a)(4) and (6) following the CCD document template, the ambulatory summary or inpatient summary must include, at a minimum, the following data (which, for the human readable version, should be in their English representation if they associate with a vocabulary/code set):

(i) *Ambulatory setting only.* All of the data specified in paragraph (e)(1)(i)(A)(1), (2), (4), and (5) of this section.

(ii) *Inpatient setting only.* All of the data specified in paragraphs (e)(1)(i)(A)(1) and (3) through (5) of this section.

(3) *Inpatient setting only.* Patients (and their authorized representatives) must be able to download transition of

care/referral summaries that were created as a result of a transition of care (pursuant to the capability expressed in the certification criterion specified in paragraph (b)(1) of this section).

(C) *Transmit to third party.* Patients (and their authorized representatives) must be able to:

(1) Transmit the ambulatory summary or inpatient summary (as applicable to the health IT setting for which certification is requested) created in paragraph (e)(1)(i)(B)(2) of this section in accordance with both of the following ways:

(i) Email transmission to any email address; and

(ii) An encrypted method of electronic transmission.

(2) *Inpatient setting only.* Transmit transition of care/referral summaries (as a result of a transition of care/referral as referenced by paragraph (e)(1)(i)(B)(3) of this section) of this section selected by the patient (or their authorized representative) in both of the ways referenced in paragraphs (e)(1)(i)(C)(1)(i) and (ii) of this section).

(D) *Timeframe selection.* With respect to the data available to view, download, and transmit as referenced paragraphs (e)(1)(i)(A) through (C) of this section, patients (and their authorized representatives) must be able to:

(1) Select data associated with a specific date (to be viewed, downloaded, or transmitted); and

(2) Select data within an identified date range (to be viewed, downloaded, or transmitted).

(ii) *Activity history log.* (A) When any of the capabilities included in paragraphs (e)(1)(i)(A) through (C) of this section are used, the following information must be recorded and made accessible to the patient (or his/her authorized representative):

(1) The action(s) (*i.e.*, view, download, transmission) that occurred;

(2) The date and time each action occurred;

(3) The user who took the action; and

(4) Where applicable, the addressee to whom an ambulatory summary or inpatient summary was transmitted.

(B) [Reserved]

(iii) *Request for restrictions.* Patients (and their authorized representatives) must be able to use an internet-based method to request a restriction to be applied for any data expressed in the standards in § 170.213. Conformance with this paragraph is required by January 1, 2026.

* * * *

(f) * * *

(5) *Transmission to public health agencies—electronic case reporting.*

Enable a user to create a case report for electronic transmission meeting the requirements described in paragraph (f)(5)(i) of this section.

* * * * *

(6) *Transmission to public health agencies—antimicrobial use and resistance reporting.* Create antimicrobial use and resistance reporting information for electronic transmission.

* * * * *

- 12. Amend § 170.402 by
- a. Revising paragraph (b)(2); and
- b. Removing paragraph (b)(4).

The revision reads as follows:

§ 170.402 Assurances.

* * * * *

(b) * * *

(2) A health IT developer that must comply with the requirements of paragraph (a)(4) of this section must provide all of its customers of certified health IT with the health IT certified to the certification criterion in § 170.315(b)(10).

* * * * *

- 13. Amend § 170.404 by:
- a. Revising the introductory text and paragraph (b)(2) introductory text;
- b. Removing paragraphs (b)(3) and (4); and
- c. Revising the definition for “Certified API technology” in paragraph (c).

The revisions read as follows:

§ 170.404 Application programming interfaces.

The following Condition and Maintenance of Certification requirements apply to developers of Health IT Modules certified to any of the certification criteria adopted in § 170.315(g)(10) and (31) through (33) unless otherwise specified in this section.

* * * * *

(b) * * *

(2) *Service base URL publication.* For all Health IT Modules certified to § 170.315(g)(10), a Certified API Developer must publish, at no charge, the service base URLs and related organization details that can be used by patients to access their electronic health information. This includes all customers regardless of whether the Health IT Modules certified to § 170.315(g)(10) are centrally managed by the Certified API Developer or locally deployed by an API Information Source. These service base URLs and organization details must conform to the following:

* * * * *

(c) * * *

Certified API Technology means the capabilities of Health IT Modules that

are certified to any of the API-focused certification criteria adopted in § 170.315(g)(10), (31), (32), and (33).

■ 14. Amend § 170.405 by:

- a. Revising paragraph (a);
- b. Removing and reserving paragraph (b)(1);
- c. Revising and republishing paragraph (b)(2); and
- d. Revising paragraph (b)(8) introductory text.

The revisions and republication read as follows:

§ 170.405 Real world testing.

(a) *Condition of Certification requirement.* A health IT developer with one or more Health IT Module(s) certified to any one or more of the Certification Criteria for Health IT in § 170.315(b), (c), (e), (f), (g), and (j) must, on an annual basis, successfully test the real world use of those Health IT Module(s) for interoperability (as defined in 42 U.S.C. 300jj(9) and § 170.102) in the type of setting in which such Health IT Module(s) would be/is marketed.

(b) * * *

(2) *Real world testing results reporting.* (i) If in the course of conducting real world testing the developer discovers one or more non-conformities with the full scope of any certification criterion under the Program, the developer must report that non-conformity to the ONC-ACB within 30 days.

(ii) For real world testing activities conducted during the immediately preceding calendar year, a health IT developer must submit to its ONC-ACB an annual real world testing results report that:

(A) Addresses each of its certified Health IT Modules that were certified to, including through Inherited Certified Status, the § 170.315(g) certification criteria referenced in paragraph (a) in the year preceding the real world testing calendar year reporting period.

(B) Includes the newer versions of certified Health IT Modules that include the § 170.315(g) certification criteria referenced in paragraph (a) of this section that were updated using Inherited Certified Status during the real world testing reporting period; and

(C) Is submitted by a date determined by the ONC-ACB that enables the ONC-ACB to publish a publicly available hyperlink to the results report on the CHPL no later than March 15 of each calendar year, beginning in 2023.

(iii) The real world testing results must report the following for each of the § 170.315(g) certification criteria identified in paragraph (a) of this section that are included in the Health IT Module's scope of certification:

(A) The method(s) that was used to demonstrate real world interoperability;

(B) The care setting(s) that was tested for real world interoperability;

(C) The voluntary updates to standards and implementation specifications that the National Coordinator has approved through the Standards Version Advancement Process;

(D) A list of the key milestones met during real world testing;

(E) The outcomes of real world testing including a description of any challenges encountered during real world testing; and

(F) At least one measurement/metric associated with the real world testing.

(iv) For each Health IT Module certified to any certification criterion specified in paragraph (a) of this section, other than the § 170.315(g) certification criteria (see paragraph (b)(2)(iii) for requirements), identify the voluntary updates to standards and implementation specifications that the National Coordinator has approved through the Standards Version Advancement Process.

* * * * *

(8) *Standards Version Advancement Process—voluntary updates of certified health IT to newer versions of standards and implementation specifications.* A health IT developer of certified health IT subject to paragraph (a) of this section is permitted to update Health IT Module(s) certified to any one or more of the certification criteria referenced in paragraph (a) of this section to a newer version of any adopted standard or implementation specification included in the criterion, provided that newer version is approved by the National Coordinator for use in certifications issued under the ONC Health IT Certification Program. A developer that pursues such updates to its certified Health IT Module(s) must:

* * * * *

- 15. Amend § 170.406 by revising paragraphs (a)(4) and (5) to read as follows:

§ 170.406 Attestations.

(a) * * *

(4) Section 170.404 if the health IT developer has a Health IT Module(s) certified to any of the certification criteria adopted in § 170.315(g); and such health IT developer must also ensure that health IT allows for health information to be exchanged, accessed, and used, in the manner described in § 170.404; and

(5) Section 170.405 if a health IT developer has a Health IT Module(s) certified to any one or more ONC

Certification Criteria for Health IT set forth in § 170.405(a).

* * * * *

■ 16. Amend § 170.407 by:

■ a. Revising the section heading and paragraphs (a)(1)(ii)(B) and (C) and (a)(3); and

■ b. Revising and republishing paragraph (b).

The revisions and republication read as follows:

§ 170.407 Insights.

(a) * * *

(1) * * *

(ii) * * *

(B) Have health IT certified to the certification criteria specified in each measure in paragraph (a)(3) of this section; or

(C) Have any users using the certified health IT specified in each measure in paragraphs (a)(3) of this section during the reporting period.

* * * * *

(3) *Measures*—(i) *Use of FHIR in apps through certified health IT*. If a health IT developer has a Health IT Module certified to § 170.315(g)(10), then the health IT developer must submit responses on the number of requests made to distinct certified health IT deployments that returned FHIR resources, number of distinct certified health IT deployments active at any time, the number of distinct deployments active at any time that returned FHIR resources in response to API calls from apps connected to certified health IT, including stratifying responses by the following:

(A) User type;

(B) FHIR resource; and

(C) US Core Implementation Guide version.

(ii) [Reserved]

(b) *Maintenance of Certification*. (1) A health IT developer must provide responses to the Insights Condition of Certification specified in paragraph (a) of this section annually for any Health IT Module that has or has had an active certification as of January 1 for each reporting period under the ONC Health IT Certification Program:

(i) A health IT developer must provide responses for measures specified in:

(A) Paragraphs (a)(3)(i)(A) and (B) of this section beginning July 2027.

(B) Paragraphs (a)(3)(i)(C) of this section beginning July 2028.

(2) [Reserved]

■ 17. Amend § 170.523 by:

■ a. Revising paragraph (f)(1)(viii);

■ b. Removing and reserving paragraphs (f)(1)(ix) through (xi), (xix), and (xxi) and (p)(1); and

■ c. Revising paragraph (p)(3).

The revisions read as follows.

§ 170.523 Principles of proper conduct for ONC-ACBs.

* * * * *

(f) * * *

(1) * * *

(viii) The certification criterion or criteria to which the Health IT Module has been certified, including the test procedure and test tool version used;

* * * * *

(p) * * *

(3) Submit real world testing results by March 15 of each calendar year to ONC for public availability.

* * * * *

■ 18. Amend § 170.550 by:

■ a. Revising paragraph (e);

■ b. Revising and republishing paragraph (g); and

■ c. Removing and reserving paragraphs (h) and (j).

The revisions and republication read as follows:

§ 170.550 Health IT Module certification.

* * * * *

(e) *Standards updates*. ONC-ACBs must provide an option for certification of Health IT Modules consistent with § 170.405(b)(7) or (8) to any one or more of the criteria referenced in § 170.405(a) based on newer versions of standards included in the criteria which have been approved by the National Coordinator for use in certification.

* * * * *

(g) *Health IT Module dependent criteria*. When certifying a Health IT Module to the ONC Certification Criteria for Health IT, an ONC-ACB must certify the Health IT Module in accordance with the certification criteria at:

(1) Section 170.315(b)(10) when a health IT developer presents a Health IT Module for certification that can store electronic health information at the time of certification by the product, of which the Health IT Module is a part.

(2) Section 170.315(b)(4) if the Health IT Module is presented for certification to the certification criteria in § 170.315(b)(3).

* * * * *

■ 19. Amend § 170.555 by revising and republishing paragraph (b)(2) to read as follows:

§ 170.555 Certification to newer versions of certain standards.

* * * * *

(b) * * *

(2) A certified Health IT Module may be upgraded to comply with newer versions of standards identified as minimum standards in subpart B of this part without adversely affecting its

certification status, unless the Secretary prohibits the use of a newer version for certification.

■ 20. Amend § 170.570 by revising the section heading to read as follows:

§ 170.570 Effect of revocation on the certifications issued to Health IT Module(s).

* * * * *

PART 171—INFORMATION BLOCKING

■ 21. The authority citation for part 171 continues to read as follows:

Authority: 42 U.S.C. 300jj–52; 5 U.S.C. 552.

■ 22. Amend § 171.102 by:

■ a. Revising definitions of “Access” and “Use”; and

■ b. Adding, in alphabetical order, the definitions of “Contract of adhesion”, “Market rate”, and “Unconscionable terms”.

The revisions and additions read as follows:

§ 171.102 Definitions.

* * * * *

Access means the ability or means necessary to make electronic health information available for exchange or use, including, without limitation, by automation technologies (e.g., robotic process automation, agentic artificial intelligence).

* * * * *

Contract of adhesion means a contract provided on a standardized form, or on a “take it or leave it basis” without a realistic opportunity to bargain where the desired product, services, access, use, or exchange cannot be provided except by acquiescing to the form contract.

* * * * *

Market rate means the value in an arm’s-length transaction, consistent with the general market value of the subject transaction.

* * * * *

Unconscionable terms means contractual terms that are excessive, unreasonable, or shockingly unfair or unjust.

* * * * *

Use means the ability for electronic health information, once accessed or exchanged through automation technologies or otherwise, to be understood and acted upon, including, without limitation, by automation technologies (e.g., robotic process automation, autonomous artificial intelligence systems).

■ 23. Amend § 171.204 by:

■ a. Removing and reserving paragraph (a)(3);

■ b. Revising and republishing paragraphs (a)(4)(ii) and (iii); and

■ c. Removing and reserving paragraph (a)(4)(iv).

The revisions and republication read as follows:

§ 171.204 Infeasibility exception—When will an actor’s practice of not fulfilling a request to access, exchange, or use electronic health information due to the infeasibility of the request not be considered information blocking?

* * * * *

- (a) * * *
- (4) * * *

(ii) The actor offered all alternative manners that are set forth in § 171.301(b) in accordance with § 171.301(b), regardless of whether the requestor specified the manner or agreed to it.

(iii) The actor does not provide analogous access, exchange, or use of the requested electronic health

information to any other individual or entity.

* * * * *

■ 24. Amend § 171.301 by:

- a. Removing the word “and” at the end of paragraph (a)(2)(i);
- b. Removing the period at the end of paragraph (a)(2)(ii) and adding “; and” in its place; and
- c. Adding paragraph (a)(2)(iii).

The addition reads as follows:

§ 171.301 Manner exception—When will an actor’s practice of limiting the manner in which it fulfills a request to access, exchange, or use electronic health information not be considered information blocking?

* * * * *

- (a) * * *
- (2) * * *

(iii) Any contract or agreement under which the actor and requestor agree to

fulfill a request for access, exchange, or use of EHI, and any license from the actor of interoperability elements used in fulfilling the request in the manner requested:

- (A) must be at market rate,
- (B) must not be a contract of adhesion, and
- (C) must not contain unconscionable terms.

* * * * *

Subpart D [Removed and Reserved]

■ 25. Remove and reserve subpart D, consisting of §§ 171.400 through 171.403.

Robert F. Kennedy, Jr.,
Secretary, Department of Health and Human Services.
[FR Doc. 2025–23896 Filed 12–22–25; 4:15 pm]
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